

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
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Agenda Item 9

CX/FH 07/39/09  
August 2007

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

Thirty-ninth Session

Hyatt Regency, New Delhi, India

### PROPOSALS FOR NEW WORK AND/OR REVISION OF EXISTING STANDARDS

Prepared by India

Governments and interested international organizations are invited to submit comments on the document below, especially on the section containing recommendations, and should do so in writing to: Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or e-mail to [syed.ali@fsis.usda.gov](mailto:syed.ali@fsis.usda.gov) with a copy to: Secretary, Codex Alimentarius Commission, Joint WHO / FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, by e-mail to [codex@fao.org](mailto:codex@fao.org) or fax: +39-06-5705-4593 **by 1 October 2007.**

#### Introduction

The 37<sup>th</sup> Session of the Codex Committee on Food Hygiene agreed to follow its newly established process by which it would consider possible future work proposals of member countries and developed a text titled, "Process by which the Codex Committee on Food Hygiene will undertake its Work". This process was sent to Codex Committee General Principles Committee (CCGP) for endorsement, which suggested certain changes to the text. The Committee, at its 38<sup>th</sup> Session, amended the text and also incorporated the suggestions made by CCGP and adopted the revised text (ALINORM 07/30/13, Appendix V). The first meeting of the *Ad hoc* Working Group was held in conjunction with the 38<sup>th</sup> Session of the Committee. The member countries present at the *Ad hoc* Working Group presented the following four items for new work :

Sweden: *Guidelines for the Application of the General Principles of Food Hygiene to the Risk-based Control of Salmonella spp. in Broiler Chickens*

New Zealand: *Guidelines for Risk Management Options for Campylobacter in Broiler Chickens*

United States: *Vibrio spp. in seafood*

The Netherlands: *Viruses in Food*

Prior to the meeting of the *Ad hoc* Working Group, the delegation of United States suggested that their proposal for new work on “Guidelines for the Application of the General Principles of Food Hygiene to the Risk-based Control of Enterohaemorrhagic *E coli* in Ground Beef and Fermented Sausages” would be delayed for one year.

The *Ad hoc* Working Group made the following recommendations to the Committee:

- That the two proposals for the development of *Guidelines for the Control of Campylobacter* as well as for *Salmonella spp. in Broiler (young bird) Chicken and Chicken Meat* be consolidated into a single proposal and that this work be given the highest priority for new work to be undertaken by the Committee.
- That second priority be given to the development of a *Draft Code of Hygienic Practice for Management of Pathogenic Vibrio parahaemolyticus in Seafood*;
- That new work on *Guidelines for the Control of Norovirus in Bivalve Molluscan Shellfish* be not undertaken at this time but that an FAO/WHO Joint Expert Consultation on “Foodborne Viruses” be undertaken in 2007 with a view to further investigating the source attribution of the norovirus in food so that the proposal could be refined for consideration by the Working Group.

### **Committee’s Action at its 38<sup>th</sup> Session on the Recommendations of the *Ad hoc* Working Group and Status of Decisions**

The Committee, at its 38<sup>th</sup> Session, noting the recommendations and prioritisation of the proposed new work by the Working Group and the recommendation of the Chairperson to undertake only one new work item (ALINORM 07/30/13, paragraph 202), agreed to combine the two proposals to develop “Guidelines for the control of *Campylobacter* and *Salmonella spp.* in Broiler (young bird) Chicken and Chicken Meat and to initiate new work on the text. The CCFH also agreed to establish a Working Group led by New Zealand and Sweden to develop a discussion paper. Subsequently, the Executive Committee of the CAC, at its 59<sup>th</sup> Session, noting that CCFH was proposing to develop the document, recommended to the Commission to expand the scope of work to cover chicken meat in general by removing the reference to “*broiler (young bird)*” and invited CCFH to consider re-scoping the document, as appropriate, taking into account all relevant factors including the availability of risk assessments (ALINORM 07/30/3, paras 44-45). The new work proposal along with the project document was forwarded to the 30<sup>th</sup> Session of the Codex Alimentarius Commission for approval. The CAC agreed to the recommendation of the Executive Committee.

With regard to the development of a Draft Code of Hygienic Practice for Management of Pathogenic *Vibrio spp. in Seafood*, some delegations indicated the importance of proceeding with this work as soon as possible taking into account the workload of the Committee.

In relation to last year’s proposal by The Netherlands for new work on the control of norovirus in bivalve molluscan shellfish, the Committee noted the recommendation of the Working Group and agreed to request the FAO and WHO to implement an Expert Consultation on Foodborne Viruses in 2007 (ALINORM 07/30/13, para 209-210). Meeting of the Joint FAO/WHO Expert Consultation was hosted by The Netherlands in May 2007 and, at the time of submission of this agenda item, the final version of the expert consultation report had not been received.

The Committee also agreed to re-establish the *Ad hoc* Working Group for Establishment of CCFH Work Priorities that would meet the day prior to the 39<sup>th</sup> Session and accepted the offer of India to Chair the Working Group (ALINORM 07/30/13, para 207).

### **Response to the request for new work**

Vide CL 2007/7 – FH of March 2007, the Codex Secretariat requested member countries to submit proposals for new work by 1<sup>st</sup> May 2007. In response, two proposals for new work have been received.

These are:

- Code of Hygienic Practice for *Vibrio spp.* in Seafood submitted by the United States, with the assistance of Denmark, Japan, Malaysia, Mozambique and Thailand (*Attachment 1*)
- Commodity - specific annexes to the Code of Hygienic Practices for Fresh Fruits and Vegetables submitted by the United States (*Attachment 2*)

#### Criteria for considering proposals for new work

The criteria for considering proposals for new work have been established using the guidance provided in the Codex Procedural Manual<sup>1</sup> and from the document; “Process by which the Codex Committee on Food Hygiene will undertake its Work” (ALINORM 07/30/13, Appendix V, *Attachment 3*). To facilitate the examination of new work proposals, the criteria are given in the following table :

Criteria	Reference
<ul style="list-style-type: none"> <li>• Include a risk profile, as appropriate;</li> <li>• Indicate specific nature or outcome of the new work being proposed.</li> </ul>	ALINORM 07/30/13, Appendix V, Paragraph 5
<ul style="list-style-type: none"> <li>• Typically address a food hygiene issue of public health significance;</li> <li>• Describe in as much detail as possible the scope and impact of the issue;</li> <li>• Describe the extent to which it impacts on international trade.</li> </ul>	ALINORM 07/30/13, Appendix V, Paragraph 6
<p>Where appropriate:</p> <ul style="list-style-type: none"> <li>• Address an issue that affects progress within CCFH or by another committees, provided it is consistent with the mandate of CCFH;</li> <li>• Facilitate risk analysis activities;</li> <li>• Establish or revise general principles or guidance. The need to revise existing CCFH texts may be to reflect current knowledge and / or improve consistency with the <i>Recommended International Code of Practice: General Principles of Food Hygiene</i>.</li> </ul>	ALINORM 07/30/13, Appendix V, Paragraph 7
<p>Proposals are to be presented as a project document and should include:</p> <ul style="list-style-type: none"> <li>• Purpose and scope of the proposed standard (work);</li> <li>• Relevance and timeliness;</li> <li>• Main aspects to be covered;</li> <li>• Assessment against the criteria for the establishment of work priorities;</li> <li>• Relevance to Codex strategic objectives;</li> <li>• Information on the relation between the proposal and other existing Codex documents;</li> </ul>	Codex Procedural Manual, 16 <sup>th</sup> Edition, Page 21

<sup>1</sup> Codex Procedural Manual, 16<sup>th</sup> Edition (2006)

<ul style="list-style-type: none"> <li>• Identification of any requirement for and availability of expert scientific advice;</li> <li>• Identification of any need for technical input to the standard from external bodies so that this can be planned for;</li> <li>• The proposed timeline for completion (not normally to exceed 5 years).</li> </ul>	
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Further, the 59<sup>th</sup> Session of the Executive Committee of the CAC, while reviewing the project documents noted that the information contained therein varied significantly in terms of quantity and quality, though the overall format as set out in the Procedural Manual was respected. Thus, the Executive Committee encouraged the Codex Committees to prepare future project documents following the format prescribed in the current revision of the Procedural Manual and provide sufficiently detailed relevant information, particularly evidence-based assessment in respect of all the Criteria for the Establishment of Work Priorities (ALINORM 07/30/3, para 46). The Codex Alimentarius Commission noted this at its 30<sup>th</sup> Session held in 2007.

### **Preliminary assessment of new work proposals against criteria**

It is our opinion the proposals submitted for new work broadly meet the criteria set by Codex Alimentarius Commission and the Codex Committee on Food Hygiene. Sponsors of the proposals are requested to summarise their proposals at the meeting of the *Ad hoc* Working Group.

### **Committee's Assignment to the *Ad hoc* Working Group**

The CCFH, at its 38<sup>th</sup> Session, referred the proposal for work on development of the CCFH risk analysis policies document to the CCFH Working Group on Priorities for consideration (ALINORM 07/30/13, para 17).

It is for information that the CCFH, while reviewing the amendments suggested by the CCGP to the text on the "Process by which the Codex Committee on Food Hygiene will Undertake its Work", noted the recommendation of the CCGP to develop a document on the application of risk analysis policies to be applied by the CCFH and that this process might include an iterative process between the Hygiene Committee and FAO/WHO for possible inclusion in the Codex Procedural Manual. The iterative process (**Annex I**) was originally proposed in the above document but was deleted by the CCFH from the text with the understanding that the wording proposed in the annex would be considered for incorporation in the risk analysis policies document. While considering the proposal for work on developing the document, members might wish to take note of the following background:

- The 26<sup>th</sup> Session of the CAC held in 2003 (ALINORM 03/41, para 147), while considering the risk analysis policies of the Codex Alimentarius Commission, took note of the recommendations in the Action Plan adopted by the 22<sup>nd</sup> Session of the Commission held in 1997 (ALINORM 97/37, paras 160-167) and requested all Codex Committees to develop or complete specific guidelines on risk analysis in their respective areas for inclusion in the Procedural Manual. The Commission also noted that these texts would be submitted to the CCGP in order to ensure coordination of work and consistency with overarching Working Principles.
- The 27<sup>th</sup> Session of the Commission held in 2004 (ALINORM 04/27/41, para 124), while considering the strategic plan for the Codex Alimentarius Commission, decided to :
  - (a) request each relevant Committee, when developing or completing specific guidelines on risk analysis, to review and document the mechanism it uses to identify and prioritise proposals for new work, particularly, in light of the need for and availability of scientific advice;
  - (b) request the CCGP, when examining specific guidelines submitted by other Committees, to ensure as much consistency as possible between the guideline texts.

- The 36th Session of the CCFH held in March/April 2004, while considering the Principles and Guidelines for the Conduct of Microbiological Risk Management, noted that the Committee should not wait until the CCGP finalized the document on Working Principles for Risk Analysis for Application by governments and suggested to proceed with the elaboration of the Principles and Guidelines for the Conduct of Microbiological Risk Management applicable to both governments and Codex, as this guidance was urgently needed (ALINORM 04/27/13, paras 63-74). The Committee also noted the request of the 26<sup>th</sup> Session of the CAC that relevant Committees develop or complete specific guidelines on risk analysis in their respective areas, for inclusion in the Procedural Manual. The Committee also reported the steps taken by it to the Commission and sought their advice whether these were consistent with the Commission's expectations.
- The 27<sup>th</sup> Session of the Commission (ALINORM 04/27/41, para 140) endorsed the view of the 54<sup>th</sup> Session of the Executive Committee (ALINORM 04/27/4, para 63) that the past and ongoing work by the CCFH on the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL-30, 1999) and the proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management addressing issues relevant to both member governments and to Codex was consistent with the Commission's expectations.
- While considering the draft risk analysis principles to be applied by CCFAC, the 21<sup>st</sup> (Extraordinary) Session of the CCGP (ALINORM 05/28/33, para 12) noted that the Secretariat recalled that the mandate given by the Commission was to ensure as much consistency as possible between the guideline texts, particularly, between the texts developed by the Codex Committees and the *Working Principles for Risk Analysis for application in the Framework of the Codex Alimentarius* (16<sup>th</sup> Edition of the Codex Procedural Manual, page103).
- Discussions at the 24<sup>th</sup> Session of the CCGP held in April 2007, wherein draft risk analysis policy/principles to be applied by CCPR (ALINORM 07/30/33, Appendix II), CCRVDF (ALINORM 07/30/33, Appendix III & IV) and governments (ALINORM 07/30/33, Appendix VIII) were considered. These documents were forwarded to the 30<sup>th</sup> Session of the Codex Alimentarius Commission for adoption and these were adopted.

### Issues Arising from the Previous Discussions

- (a) The *Ad hoc* Working Group under the Chairpersonship of Australia while presenting their report to the CCFH at its 38<sup>th</sup> Session held in 2006 (CRD - 1) presented a list of Codes for possible future work by the CCFH. This list, in the order of priority, is placed as **Attachment 4**. The Working Group noted that out of these, the following codes have been adopted or are currently underway :
- The Code of Hygienic Practice for Egg and Egg Products (adopted)
  - The Revised Code of Practice for Foods for Infants and Young Children, renamed as “The Code of Practice for Powdered Formulae for Infants and Young Children” (Step 2/3)
  - The Revised Code of practice for the Processing and Handling of Quick Frozen Foods, which is to be undertaken by the Inter-governmental *Ad hoc* Codex Task Force on the Processing and Handling of Quick Frozen Foods.

The remaining codes for possible revisions are not on the formal work plan of the CCFH but are proposed to be retained as a historical resource to assist in decisions regarding future work by the Committee. Proposals for new work in these cases could be initiated by identification of a project sponsor and would need to follow the established process using the guidance provided in the Codex Procedural Manual and from the document; “Process by which the Codex Committee on Food Hygiene will undertake its Work” (ALINORM 07/30/13, Appendix V).

- (b) Prior to the meeting of the *Ad hoc* Working Group at the 38<sup>th</sup> Session of the CCFH, the delegation of United States indicated that their proposal for new work on “Guidelines for the Application of the General Principles of Food Hygiene to the Risk-based Control of Enterohaemorrhagic *E coli* in Ground Beef and Fermented Sausages” would be delayed for one year. In the absence of a new work proposal, this item is also proposed to be retained as a resource to assist in decisions regarding future work by the Committee. In this context, the Working Group might wish to consider the concern being noted in Codex discussions about various microbial pathogens associated with fresh fruits & vegetables, meat, etc. and the priority it would propose to give.
- (c) In the absence of the final version of the report of FAO/WHO Joint Expert Consultation on “Foodborne Viruses” held in May 2007 on the proposal by The Netherlands for new work on the control of norovirus in bivalve molluscan shellfish, this item is also retained as a resource to assist in decisions regarding future work by the Committee.

### **Provisional Agenda for the *Ad hoc* Working Group Meeting**

The Provisional Agenda for the *Ad hoc* Working Group meeting to be held a day prior (29<sup>th</sup> October 2007) to the 39<sup>th</sup> Session of the CCFH is placed as *Attachment 5*.

### **Recommendations**

- (a) *The member countries may take note of the provisional agenda for the meeting of the Ad hoc Working Group;*
- (b) *Members may review the two proposals for new work with regard to their completeness and prioritise them;*
- (c) *The members may take note of the Committee’s assignment to the Ad hoc Working Group to consider development of a document on the CCFH risk analysis policies. The process might address the priority to be attached to this work, determination of a sponsoring member country in the event of an early priority, in which case the possibility of development of a draft outline for a new work proposal;*
- (d) *Members may consider development of a list of new work priorities in light of the discussions during the 38<sup>th</sup> Session of the CCFH.*

**ANNEX I****ITERATIVE PROCESS BETWEEN THE CODEX COMMITTEE ON FOOD HYGIENE AND FAO/WHO FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT**

[The Codex Committee on Food Hygiene recognizes that an iterative process between risk managers and risk assessors is essential for the adequate undertaking of any microbiological risk assessment and the development of any microbiological risk management guidance document or other CCFH document(s). In particular, dialogue between the Committee and FAO/WHO is desirable to thoroughly assess the feasibility of the risk assessment, to assure that risk assessment policy are clear, and to ensure that the risk management questions posed by the Committee are appropriate.] If FAO/WHO agrees that the requested risk assessment proposed in the Risk Profile is feasible and will be undertaken, a series of planned interactions between the FAO/WHO JEMRA and the Committee should be scheduled to assure effective interaction. In certain instances when the subject matter would benefit from additional interaction with other Codex Committees or other FAO/WHO risk assessment bodies, these committees should be included into the iterative process.

[It is essential that communications between these entities are timely and effective.]

[The Committee is likely to receive questions from FAO/WHO or the designated risk assessment body (e.g., JEMRA) relating to the requested microbiological risk assessment(s). The questions may include those needed to clarify the scope and application of the risk assessment, the nature of the risk management control options to be considered, key assumptions to be made regarding the risk assessment, and the analytical strategy to be employed in the absence of key data needed to perform the risk assessment. Likewise, the Committee may pose questions to FAO/WHO or their designation (JEMRA) to clarify, expand, or adjust the risk assessment to better address the risk management questions posed or to develop and/or understand the risk management control options selected. Timely, appropriate responses are needed for these interactions.]

The Committee may elect to discontinue or modify work on a risk assessment if the iterative process demonstrates that: 1) completion of an adequate risk assessment is not feasible; or 2) it is not possible to provide appropriate risk management options. However, FAO/WHO may decide to continue the work if it is considered necessary to meet the needs of their member countries.

**ATTACHMENT 1****CODE OF HYGIENIC PRACTICE****FOR *VIBRIO* SPP. IN SEAFOOD*****Proposal To Undertake New Work***

*(Prepared by the United States, with the assistance of Denmark, Japan, Malaysia, Mozambique and Thailand)*

**Purpose and Scope of the New Work**

At the 37<sup>th</sup> Session of the Codex Committee for Food Hygiene (CCFH), the committee agreed to use the newly established process to consider further work on the Discussion Paper on Risk Management Strategies for *Vibrio* spp. in seafood (attached), and identified the United States to prepare the written proposal (ALINORM 5/28/13 para 167; 168).

The Codex Committee for Fish and Fishery Products (CCFFP) agreed that further work on risk management of *Vibrio* spp. in seafood was essential and encouraged CCFH to proceed with its work in this area.

The CCFFP requested that CCFH continue to work on *Vibrio* spp. risk management with emphasis on bivalve mollusks. In particular, to a) assess the outcome of the Risk Assessments on *Vibrio* spp. in seafood and make recommendations on how this should be transformed into Good Hygienic Practices and risk management strategies and b) address the four areas put forward by the CCFFP related to the risk profile for *Vibrio* spp. (see Alinorm 4/27/18, para 128), specifically, (i) the identification of effective of control measures; (ii) the establishment of appropriate microbiological criteria including identification of relevant testing methods; (iii) the need for risk managers to establish tolerances, and (iv) the consideration of source of seafood as a risk factor impacting the control of pathogenic *Vibrio* spp..

Although the codes and standards developed by CCFFP provide some information on hygienic practices for seafood products, the level of guidance is not sufficiently detailed in relation to the information needed for a code of hygienic practice that can be used to develop food safety systems based on effective implementation of GHP and HACCP programs. Accordingly, the purpose of the proposed new work is the development of a “Draft Code of Hygienic Practice for the Control of *Vibrio* spp in Fish and Shellfish.” The purpose of the proposed new work is to provide to member countries and industry, within the framework of a code of hygienic practice, guidance on control of pathogenic *Vibrio* spp in raw seafood. The scope of the document will include finfish, crustaceans, and bivalve molluscan shellfish that are marketed in an uncooked state. The new work is envisioned to encompass a base document for the control of all pathogenic *Vibrio* spp., with annexes developed for individual *Vibrio* species or seafood products if CCFH finds that they are necessary to provide more specific guidance. It is anticipated that this new work would be undertaken in close collaboration with CCFFP.

**Relevance and Timeliness**

During the past several years there has been an increase in reported outbreaks and cases of foodborne disease attributed to pathogenic *Vibrio* species. For example, the United States CDC reported a 75% increase *Vibrio* cases reported through their FoodNet system over the past 5 years. This increased concern has been particularly evident with *V. parahaemolyticus* where there has been a series of pandemic outbreaks due to consumption of raw seafood, its emergence in regions of the world previously thought to be unaffected by this pathogen, and the emergence of strains with increased pathogenicity (i.e., serotype O3K6). The number of *Vibrio* species recognized as being potential human pathogens continues to increase.



## **Main Aspects to be covered**

The proposed new work will focus on the development of risk management guidance for the control of pathogenic *Vibrio* species using the framework of code of hygienic practice. This focus on a core risk management document will include all general components of food safety systems that would be needed to control these pathogens in finfish, crustaceans, and bivalve shellfish. The general format outlined in the Codex Alimentarius General Requirements (Food Hygiene) will be followed, with a focus on identifying those components that are unique to this group of product/pathogen pairs that will require guidance in greater detail than outlined in the general text. The document will address each of the ten sections within the general international code of practice for food hygiene, spanning the continuum from primary production through consumer use.

It is anticipated that one or more annexes may need to be developed to cover in more detail specific guidance needed to adequately manage the food safety risk associated with specific *Vibrio* species/product combinations. An additional annex may be needed to provide the scientific rationale and details for any microbiological criteria or other risk management metrics recommended for development after consultation with CCFFP. The identification of how to assess and validate the effectiveness of food safety systems will be particularly important with these classes of product where guidance must be flexible due to the anticipated development of new control measures and risk management strategies.

## **Assessment against the Criteria for the Establishment of Work Priorities**

*Vibrio parahaemolyticus*, *V. vulnificus*, and choleraogenic *V. cholerae* O1 and O139 are important bacterial seafood-borne pathogens worldwide. Choleraogenic *V. cholerae* is an important pathogen in many developing countries, causing significant public health and economic burdens. While a relatively rare disease, foodborne *Vibrio vulnificus* has the highest case-mortality rates of any foodborne illness in the United States, and has emerged as a food safety issue in several regions around the world. The incidence of *Vibrio parahaemolyticus* gastroenteritis has been increasing worldwide, causing both sporadic cases and large national and pandemic outbreaks. There have been several instances in the last few years where concerns about the presence of pathogenic *Vibrio* species in seafood have led to a disruption in international trade, impacting in particular developing countries. The food safety concerns associated with these microorganisms and the concomitant need to provide scientifically sound risk management guidance warrant the attention of the Committee.

As mentioned previously, CCFFP has encouraged CCFH to continue its work on risk management of *Vibrio* spp. It is also timely for CCFH to focus on this issue because FAO/WHO has conducted and, by fall of 2007, will have completed five risk assessments on various pathogenic *Vibrio*/product pairs (described later).

## **Relevance to the Codex strategic objectives**

The work proposed fall under all six Codex strategic objectives :

### Objective 1. Promotion of Sound National Food Control and Regulatory Systems from Farm to Table.

The results of this work will assist in promoting sound national food control infrastructure and promote safety of foods entering domestic and international trade by using scientific knowledge and risk assessments to develop risk-based guidance that provides foci and options for prevention and mitigation strategies to control pathogenic *Vibrio* species in seafood.

Objective 2. Promotion of the Widest Application of Risk Analysis. This work will establish risk management options and strategies for the control of pathogenic *Vibrio* species based on risk assessment and supporting scientific analyses. It will serve as a positive example of how risk analysis can be effectively used within a code of hygienic practice framework, including providing flexibility in achieving public health goals.

Objective 3. Promotion of Seamless Linkages between Codex and Other Multilateral Bodies. This work is based on a close coordination between FAO, WHO, and CODEX and will additionally rely of ongoing close collaboration with CCFFP.

Objective 4. Increased Efficiency and Stronger Management Oversight of Codex Work. By establishing a general framework for the management of food safety risks associated with seafood, CCFH will provide a general document that can be referenced by CCFFP and thereby eliminating the need for that committee to develop a detailed series of hygienic codes as they develop standards for fish and fish products.

Objective 5. Full Participation by Codex Members and Interested Parties. Due to the international nature of this problem, this work will support and embrace all aspects of this objective by requiring participation of both developed and developing countries to conduct the work.

### **Relation Between Proposal and Other Existing Codex documents**

The proposed new work may require review and possible modification of several existing Codex documents from different Codex committees, particularly documents from the Codex Committee for Fish and Fishery Products.

### **Requirement for and Availability of Expert Advice**

Substantial scientific advice has already been obtained or is pending, and additional scientific advice is not likely to be necessary for completion of the proposed new work. The FAO/WHO conducted five risk assessments on *Vibrio* spp. in seafood to address the following pathogen/commodity combinations (see ALINORM 05/28/18, para 20 and 21):

- *Vibrio vulnificus* in oysters;
- Choleraogenic *Vibrio cholerae* in warm waters shrimp in international trade;
- *Vibrio parahaemolyticus* in bloody clams;
- *Vibrio parahaemolyticus* in finfish; and
- *Vibrio parahaemolyticus* in oysters.

Of these five risk assessment, FAO/WHO has completed the risk assessments on *V. vulnificus* in oysters and choleraogenic *Vibrio cholerae* in warm waters shrimp in international trade have been completed, and the other risk assessments related to *Vibrio parahemolyticus* in finfish and shellfish are being combined into a single report which is expected to be published during the fall of 2007.

In addition, the United States delegation led a CCFH working group that developed a risk profile in 2002 for CCFH that reviewed existing Codex guidance on codes of hygiene for the control of *Vibrio* in fish and shellfish. A copy of that risk profile is attached.

Additional risk assessments and risk profiles developed by individual member nations are also available.

### **Proposed Timeline for Completion of the New Work**

It should be feasible to produce the core code of hygienic practice within five years. Additional product or *Vibrio* species annexes should be feasible within the same time frame unless identified late in the process of developing the core document.

*VIBRIO PARAHAEMOLYTICUS* RISK PROFILE

This risk profile section is a comprehensive description of the food safety problem involving *V. parahaemolyticus*, the commodities and public health impact, including economic impact. It is divided into 6 parts, four risk profile elements, a section on risk assessment needs and questions for the risk assessors, and a section on available information and major knowledge gaps. References are found in Annex 1. Tables and figures are found in Annex 2.

**1. Pathogen-food commodity combination(s) of concern****1.1 Pathogen of concern**

*Vibrio parahaemolyticus*

**1.2 Description of the food or food product and/or condition of its use with which problems (foodborne illness, trade restrictions) due to this pathogen have been associated.**

Foods associated with illnesses due to consumption of *V. parahaemolyticus* include crayfish, lobster, shrimp, fish-balls, boiled surf clams, jack-knife clams, fried mackerel, mussel, tuna, seafood salad, raw oysters, steamed/boiled crabmeat, scallops, squid, sea urchin, mycids, and sardines (4, 7, 8, 13, 18, 31, 38, 39, 41) (Table 7; Figure 1). These products include both raw or undercooked seafood products and cooked products that have been substantially recontaminated.

**2. Description of the public health problem****2.1 Description of the pathogen including key attributes that are the focus of its public health impact (e.g., virulence characteristics, thermal resistance, antimicrobial resistance).**

*V. parahaemolyticus* is a Gram-negative, halophilic marine bacterium that occurs naturally in estuaries and is, therefore, commonly found in seafood. It was first identified as a foodborne pathogen in Japan in the 1950s (16). By the late 1960s and early 1970s, *V. parahaemolyticus* was recognized as a cause of diarrheal disease worldwide.

- Virulence Characteristics

Some strains or types of *V. parahaemolyticus* are pathogenic, and can cause illness in people who eat fish or shellfish containing these strains. Several different virulence traits have been associated with the pathogenesis of *V. parahaemolyticus* strains. These include their ability to produce a thermostable direct hemolysin (TDH), once the organism has entered the gut and colonized the intestinal cell wall (27); produce a thermostable direct hemolysin related toxin (TRH) (32); invade enterocytes (2); produce an enterotoxin (19); and, d) produce urease (1). Because the latter two characteristics have only recently been investigated, the only trait known to reliably distinguish pathogenic from non-pathogenic strains of *V. parahaemolyticus* is the production of TDH, a thermostable direct hemolysin. The vast majority of strains isolated from patients with diarrhea are TDH positive (26, 27, 37). It has therefore been considered that pathogenic strains possess a *tdh* gene and produce TDH, and non-pathogenic strains lack the gene and the trait (26). Additionally, based on the discussion of the expert consultation for *Vibrio* and *Campylobacter* risk assessments held in Geneva, Switzerland in July 2002, it has been suggested that strains that produce TRH should also be regarded as pathogenic.

- Serotypes

More than a dozen different serotypes have been associated with outbreaks from different countries. These include: O3:K6, O4:K12, O4:K8, O4:K68, O4:K10, O4:K11, O4:K4, O3:K29, O1:K56, O4:K55, O5:K17, O1:K32, O5:K15, O2:K28. Note that, since 1996, serotype transition from O4:K8 to O3:K6 has been noticed in Japan. The transition was observed in both environmental and patient

isolates. The O3:K6 strains that have been detected in the United States, Southeast Asia, and Japan resemble each other and are suspected to have a common source. Recent increases in O4:K68-caused infections have also been observed in Southeast Asia, India and Japan.

- Thermal Resistance

*V. parahaemolyticus* is not thermal resistant. Mild heat treatment (5 min at 50 °C) of oysters, which causes at least a 4.5 log decrease in the number of viable *V. parahaemolyticus* in oysters, practically eliminates the likelihood of illness occurring (15).

- Susceptibility to antimicrobial agents

*Vibrio parahaemolyticus* strains are sensitive to most common antibiotics used for treatment. (Tables 2&3) (28, 33).

## 2.2 Characteristics of the disease, including:

- Susceptible populations

Epidemiological data indicate that the whole population is susceptible to infection by *V. parahaemolyticus*. However, immunocompromised consumers are at special risk for septicemia and other more severe sequelae associated with *V. parahaemolyticus* infections.

- Annual incidence rate in humans including, if possible, any differences between age and sex and any differences according to regional and seasonal variations

As noted above, epidemiological data indicate that all age groups are susceptible to infection by *V. parahaemolyticus*, and males and females are equally susceptible to infection (Table 4) (20). Additionally, the number of illnesses varies with season (Table 5): illness rates are higher during the warmer months periods, then during the colder months (45). Regional differences exist not only from country to country, but also among different regions within one country (Table 5). In countries in which *V. parahaemolyticus* is endemic, illnesses due to this organism peaked in the late 1990s, but are still reported with a high frequency (Table 8).

- Outcome of exposure

Infection usually causes mild gastroenteritis, with an incubation time ranging from 4-96 hours after exposure (5, 6, 22).

- Severity of clinical manifestation

Symptoms include explosive watery diarrhea, nausea, vomiting, abdominal cramps and, less frequently, headache, fever and chills (Table 6). Most cases are self-limiting; however, severe cases of gastroenteritis requiring hospitalization have been reported. On rare occasions, septicemia, an illness characterized by fever or hypotension and the isolation of the microorganism from the blood, can occur. In these cases, subsequent symptoms can include swollen, painful extremities with hemorrhagic bullae (18, 22).

- Case fatality rate

In the United States, the annual incidence of fatal raw oyster-associated infections from any *Vibrio* species was estimated to be 1.6/1,000,000 oyster-consuming adults (95% CI: 1.3-1.9).

- Nature and frequency of long-term complications

Most persons recover after 3 days and suffer no long-term consequences. However, subsequent symptoms including swollen, painful extremities with hemorrhagic bullae (18, 22), as well as reactive arthritis (40) can last months or longer.

- Availability and nature of treatment

In most cases of gastroenteritis antibiotic treatment is contraindicated unless symptoms are severe and prolonged. Where treatment is indicated, prompt treatment with antibiotics and oral rehydration solutions (ORS) on IV fluid is available for patients in almost all hospitals.

- Percentage of annual cases attributable to foodborne transmission

In some countries such as Japan and Thailand, almost 100% of annual cases are considered to be foodborne. In the United States about 65% of *V. parahaemolyticus* cases are estimated to be foodborne.

### 2.3 Characteristics of the foodborne transmission

- Epidemiology and etiology of foodborne transmission, including characteristics of the food or its use and handling that influence foodborne transmission of the pathogen

*V. parahaemolyticus* is naturally present in many types of seafood (Table 1). Worldwide, incidents of illnesses have been traced to caterers, manufacturers, households, cafeterias, food stores, restaurants, and street vendors. Outbreaks have involved incidents of cross contamination by raw seafood or processing equipment, improper hygienic practices, inadequate temperature control, and insufficient heating (21, 40). In Japan, incidents attributable to catering and packed-meal manufacturers and households have been increasing since 1996.

- Foods implicated

Foods implicated include molluscan shellfish (especially raw oysters), crustaceans (crab, crayfish, lobster, shrimp), scallops, squid, sea urchins, sardines, mycids, and fish (fish-balls) (Tables 1-2, 7) (4, 7, 8, 13, 18, 31, 38, 39, 40). Recently, sampling studies in the Adriatic Sea demonstrated the presence of *V. parahaemolyticus* in fish, mussels and clams, (4). Studies in the U.S. demonstrated the presence of *V. parahaemolyticus* in oysters at retail, including restaurants or oyster bars, and wholesale and retail seafood markets (44); in this study, although levels did not exceed 100 organisms/g in the majority of lots tested, the study demonstrated that levels can exceed 10,000 organisms/g in certain regions.

- Frequency and characteristics of foodborne outbreaks The frequencies and characteristics of foodborne outbreaks vary widely from region-to-region. In the United States, the first confirmed outbreak occurred in 1971, and between 1973 and 1998, forty more outbreaks were reported to the Centers for Disease Control and Prevention (CDC) from 15 states and territories ranging from 2 to >100 cases per outbreak (13, 14). All involve either the consumption of raw or undercooked seafood or cross-contamination of cooked seafood, and the peak numbers of cases occur during warm weather months. Though sporadic cases caused by *V. parahaemolyticus* are common, outbreaks (see below) occur far less frequently. In Japan, outbreaks caused by *V. parahaemolyticus* usually involve fewer than 10 cases. From 1996-1998, 496 outbreaks were reported, and the peak occurrence for these was August (Figure 2). In Thailand far fewer outbreaks caused by *V. parahaemolyticus* have been reported, no more than 5 per year and most outbreaks affected less than 100 patients (30, 36). From the Epidemiological Surveillance Report, during 1995-2001 there were 15 incidents with 1650 patients, and no fatalities (3, 36).

- Frequency and characteristics of foodborne sporadic cases

Sporadic cases caused by *V. parahaemolyticus* infections are commonly reported. Most cases present clinically as gastroenteritis, and are rarely fatal. Life threatening septicemia can occur, especially in patients with underlying medical conditions. Sporadic cases occur throughout the year, with peak occurrence in September to October. Many published case reports outline clinical presentations and outcomes of patients with *V. parahaemolyticus*. For example, one report describes a 35-year-old woman who sought medical attention for abdominal pain after she had consumed raw fish (40). *V. parahaemolyticus* was isolated from the stool culture. She was diagnosed as having reactive arthritis induced by *V. parahaemolyticus* infection. Another clinical case report describes a 31-year-old female with a history of alcohol abuse, Hepatitis C virus infection, and cirrhosis, who ingested raw oysters and steamed shrimp 72 hours prior to admission (17). She presented with diarrhea, weakness, leg pain, and urine retention. She developed cardiac arrest and died six days after presentation. *V. parahaemolyticus* was isolated from blood samples.

- Epidemiological data from outbreak investigations

In the United States during 1971, 3 outbreaks caused by *V. parahaemolyticus* occurred in Maryland (13). Steamed crabs were implicated in two of the outbreaks after cross-contamination with live crabs. The third outbreak was associated with crabmeat that had become contaminated before and during canning. In 1972, an estimated 600 of 1,200 persons who attended a shrimp feast in Louisiana became ill with *V. parahaemolyticus* gastroenteritis (25). In 1974 and 1975 outbreaks were reported aboard two Caribbean cruise ships, most likely caused by contamination of cooked seafood with seawater from the ships' seawater fire systems (24). In Japan, restaurants account for 48% of outbreaks, hotels 18%, catering and packed-meal sales 12%, and households 12%. Retailers account for only 4%. In some incidents, mass meal preparation facilities and manufacturers also have been implicated as sources (Figure 3). In Thailand, school and college cafeterias account for the highest numbers of outbreaks, and meal preparation manufacturers also have been implicated in some incidents (21, 41).

## 2.4 Economic impact or burden of the disease

- Medical, hospital costs

In the U.S. estimated costs per case of *V. parahaemolyticus* by severity (Table 9), and the estimated total cost of *V. parahaemolyticus* by severity (Table 10) demonstrate that the cost increases with severity of the illness (43).

In Japan, the number of foodborne outbreaks between 1991 and 1997, number of patients involved in each outbreak and the compensation for each case in every incidence that was considered as either bacterial or viral (SRSV) as a causative organism was evaluated (46). Table 11 demonstrates the cost of illness due to *V. parahaemolyticus* relative to other foodborne illnesses such as *Salmonella* spp. and pathogenic *E. coli* (46).

- Working days lost due to illness, etc

Normally 1-3 days are lost due to illness.

- Damage to seafood markets

The economic effects of illnesses reverberate throughout the seafood supply industry causing loss of consumer confidence and concomitant loss of sales. Consequently, a slowing affect for seafood sales overall occurs, which can represent a short-term serious economic loss. In general, the various reports of seafood related illnesses also appear to combine to affect the entire seafood supply in a cumulative fashion, which can lead to long term depressed sales.

### **3. Food Production, processing, distribution and consumption**

#### **3.1 Characteristics of the commodity (commodities) that are involved and that may impact on risk management**

Today, processed products comprise the majority of seafood consumed, and processing with mild heat or by freezing can effectively eliminate or reduce the threat from *V. parahaemolyticus* in raw seafood. Even so, raw oysters and clams continue to be extensively consumed and other raw seafood such as Sashimi and Sushi, long popular in Japan (39) (Table 7), are becoming increasingly popular in other countries as well. The consumption of raw seafood is an important factor in the transmission of *V. parahaemolyticus* illnesses. However, improper cooking and/or re-contamination after cooking also are important factors (11).

#### **3.2 Description of the farm to table continuum including factors which may impact the microbiological safety of the commodity (i.e., primary production, processing, transport, storage, consumer handling practices).**

- **Pre-harvest and harvest**

*V. parahaemolyticus* occurs naturally in estuarine environments and on many types of seafood. Its densities are influenced by water temperature and salinity (29), air temperature (34), tide (23), and plankton (10, 35). The United States *V. parahaemolyticus* risk assessment, found that water and air temperatures at time of harvest are the major factors influencing the initial levels of this pathogen in oysters (15). Temperature control of seafood post-harvest also is important for controlling levels of *V. parahaemolyticus*. Temperature control onboard harvest vessels may be influencing the levels of *V. parahaemolyticus* in seafood if air temperatures are warm and the time between harvest and chilling after landing is extended.

- **Post-harvest handling and processing**

Post-harvest handling and processing factors that affect product safety include the following:

- Quality of water used in washing and processing after harvest;
- Type and adequacy of sanitation measures;
- Proper temperatures during processing, distribution and storage including refrigeration temperatures and, as appropriate, hot-holding temperatures.
- Avoiding cross-contamination. Ensuring all surfaces, baskets, shucking knives, etc., which may have been in contact with raw seafood, are cleaned before use with any additional raw or cooked food/seafood.
- Appropriate labeling to inform product handlers and users.

Several post-harvest treatments, such as mild heat and freezing, have been shown to be effective in reducing *V. parahaemolyticus* levels in oysters (12).

- **What is currently known about the risk, how it arises with respect to the commodity's production, processing, transport and consumer handling practices, and who it affects.**

Major causes of foodborne *V. parahaemolyticus* infections include:

- 1) Uptake of the pathogen by raw fish/shellfish from environmental waters

2) Multiplication of *V. parahaemolyticus* and other bacteria under inadequate temperature control after harvest and during distribution.

3) Improper handling practices after harvest, including:

- Lack of knowledge by food handlers at restaurants serving raw seafood.
  - Cross contamination and non-sanitary practices by processors, food preparers, and street food vendors.
- Summary of the extent and effectiveness of current risk management practices including food safety production/processing control measures, educational programs, and public health intervention programs (e.g., vaccines).

Factors considered as possible influences on the levels of pathogenic *V. parahaemolyticus* at consumption include:

- Levels of *V. parahaemolyticus* at harvest.
- Ambient air temperatures at times of harvest.
- Length of exposure to ambient temperatures from harvest to refrigeration.
- Time required to cool raw, product once refrigerated after harvest.
- For cooked products; recontamination and conditions of time/temperature favoring growth in the interim between recontamination and consumption.
- Post harvest treatments, such as mild heat treatment, freezing, hydrostatic pressure, depuration, and relaying<sup>2</sup>, to reduce the densities and the risks posed by *V. parahaemolyticus* (15).

Several countries use different strategies and programs to manage the risks associated with various factors. The United States follows the National Shellfish Sanitation Program (NSSP) time/temperature matrix for control of *V. vulnificus* (42), and measures at harvest also have been established to prevent oyster-borne outbreaks caused by pathogenic *V. parahaemolyticus*. In 1999 the Interstate Shellfish Sanitation Conference (ISSC) adopted an Interim Control Plan for *V. parahaemolyticus*, which was then revised in 2001, based on monitoring when and where historical episodes indicate. Detection of pathogenic *V. parahaemolyticus* (*tdh+*) results in closure of waters to harvesting shellfish until monitoring indicates the pathogen is no longer detectable or until environmental temperatures becomes unfavorable for the proliferation of this organism. This plan includes monitoring for total *V. parahaemolyticus* levels. When levels greater than 5,000 total *V. parahaemolyticus* cells/g oyster tissue are found, additional oyster samples are promptly examined for pathogenic *V. parahaemolyticus*.

Japan also monitors for total *V. parahaemolyticus* strains, and new standards for seafood consumed raw include the following:

- 1) Fewer than 100 *V. parahaemolyticus* MPN/g in seafood for raw consumption.
- 2) Temperature of seafood is maintained below 10°C throughout distribution and storage.

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<sup>2</sup> Process of moving shellfish from contaminated to non-contaminated growing areas for the purpose of removing contaminants.



3) After harvest and during food preparation fish/shellfish are washed with disinfected seawater or potable water.

Also in Japan, some local governments release warnings, based on conditions such as water temperature, to make the public more aware of the possible risk associated with eating raw seafood taken from waters during these conditions.

**ATTACHMENT 2****COMMODITY-SPECIFIC ANNEXES FOR  
CODE OF HYGIENIC PRACTICES FOR FRESH FRUITS AND VEGETABLES****Proposal to Undertake New Work**

*(Prepared by the United States)*

**Purpose and scope of work**

In 2003, the Codex Committee for Food Hygiene (CCFH) elaborated a “Code of Hygienic Practice for Fresh Fruits and Vegetables” (the Code) to address Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) to help control microbial hazards associated with all stages of the production of fresh fruits and vegetables from primary production to packing. The Code provides a general framework of recommendations to allow uniform adoption by this sector, regardless of the diverse environmental conditions encountered or the commodities to which it might be applied.

Since the Code was established, experience in produce safety has grown dramatically. In implementing current GAP and GMP recommendations, it has become apparent that public health would benefit from the availability of more detailed, commodity-specific guidance. This need is being met, in part, through industry efforts. For example, several U.S. industry groups have developed commodity-specific supply chain guidance documents. However, the global nature of produce production, processing, and marketing requires an international perspective, and both public health and international trade in produce could be enhanced by the systematic development and elaboration of a series of commodity-specific annexes to the Code.

At the 38<sup>th</sup> Session of the CCFH, the Delegation of the United States indicated that it intended to propose new work at the next session to develop commodity-specific guidelines which would be annexes to the Code (ALINORM 07/30/13 para 229). It was noted that in originally developing that document, it was envisaged that over time, a series of commodity specific annexes, which follow the General Principles – Food Hygiene but address in more detail aspects related to the control of specific hazards of concern in specific products, would be added.

An intra-session *ad hoc* working group drafted terms of reference for an FAO/WHO expert consultation to support the development of commodity-specific annexes for the Code. There was broad support among CCFH delegates for this proposal within the working group and commodities of interest were identified. The FAO/WHO has responded positively to this request, and has acquired supplemental funding for the project from at least two countries. Initial activities associated with the consultation are scheduled to commence in the summer of 2007.

The *ad hoc* working group acknowledged that selection of commodities should be based on their public health impact and should focus on the most significant pathogens associated with the commodity. An initial evaluation of available epidemiological data suggests that the commodities of primary concern would likely include leafy green vegetables, tomatoes, melons, green onions, sprouted seeds, herbs and berries and root vegetables. At this time, the United States is proposing that CCFH begin the process for developing commodity-specific annexes for all the commodities described above using leafy green vegetables as the basis for a model, with documents on tomatoes and carrots to follow soon after as part of this proposed work.

**Relevance and timeliness**

Outbreaks of foodborne illness due to contamination of fresh fruits and vegetables have been reported world-wide with increasing regularity. The global nature of produce production, processing, and marketing requires an international perspective in addressing this problem.

The United States has begun to take steps with its neighbors, Mexico and Canada, to improve the safety of fresh produce. The three have implemented a Food Safety Task Force under the agenda of the Security and Prosperity Partnership of North America (SPP) and agreed that risk management approaches for the safe production of fresh fruits and vegetables should be an initial priority.

With respect to leafy green vegetables, over the past decade in the United States, there have been at least two dozen outbreaks associated with fresh leafy green vegetables, especially lettuce and spinach. In several instances where a source was identified, the outbreak was the result of sources from outside of the U.S. The international public health literature has documented outbreaks linked leafy green vegetables in several other countries.

With respect to tomatoes, over the past decade in the U.S., there have been at least a dozen *Salmonella* outbreaks associated with fresh tomatoes with hundreds of cases of illness reported, especially in more recent years. Tomato-associated *Salmonella* outbreaks reported to the U.S. Centers for Disease Control and Prevention (CDC) have increased in frequency and magnitude in recent years and caused 1,616 reported illnesses in nine outbreaks during 1990 to 2004, representing approximately 60,000 illnesses when accounting for the estimated proportion (97.5%) of unreported illness.<sup>3</sup> Tomatoes are associated with 16 percent of all produce-related food-borne illness outbreaks. At the same time, per capita consumption data reveal that tomatoes are the third most commonly consumed fresh vegetable in the U.S. and that consumption of fresh tomatoes has increased by 20 percent in the past 20 years. Again, the international public health literature indicates that the association of foodborne disease is not limited to the United States

With respect to carrots, outbreaks have not been frequent historically. However, fresh carrots have been the medium for an emerging pathogen, *Yersinia pseudotuberculosis*, including a recent outbreak in Finland which involved an estimated 558 patients of whom 111 were confirmed cases, mostly children in day-care centers or schools.<sup>4</sup> Additionally, carrot juice has been recently associated with an international outbreak of *Clostridium botulinum* neurotoxin intoxication.

While global tomato production may be more economically prominent and the frequency and scope of *Salmonella* outbreaks associated with tomatoes very great, it is proposed that leafy green vegetables be the initial focus of an additional annex to the Code. The CDC recently reported that 40% of foodborne outbreaks associated with produce from 1998-2004 implicated leafy greens as the source, compared with 10% for tomatoes. In addition, the severity of illness from infection by the typical pathogen observed in leafy green vegetables during an outbreak, *E. coli* O157:H7, is much greater and frequently includes the life-threatening development of hemolytic uremic syndrome (HUS), characterized by renal failure and hemolytic anemia. In a 2006 *E. coli* O157:H7 outbreak in the United States that was associated with fresh spinach, 26 states were involved with 204 cases of illness due to *E. coli* O157:H7 infection that included 31 cases involving HUS, 104 hospitalizations, and three deaths.

### **Main aspects to be covered**

1. Review the advice from expert consultations conducted by FAO/WHO regarding the safety of agricultural and manufacturing practices for fresh produce.
2. Develop a draft annex to the current *Code of Hygienic Practice for Fresh Fruits and Vegetables* for leafy green vegetables, tomatoes and carrots (each).
3. Consider the development of additional annexes for other vegetables and fruits.

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<sup>3</sup> Voetsch AC, Van Gilder TJ, Angulo FJ, et al. FoodNet estimate of the burden of illness caused by nontyphoidal *Salmonella* infections in the United States. Clin Infect Dis (2004); 38(Suppl 3):S127-34.

<sup>4</sup> Jalava K, Hakkinen M, Valkonen M, Nakari UM, Palo T, Hallanvuo S, Ollgren J, Siitonen A, Nuorti JP. An outbreak of gastrointestinal illness and erythema nodosum from grated carrots contaminated with *Yersinia pseudotuberculosis*. J Infect Dis. 2006 Nov 1;194(9):1191-3.

### **Assessment against the *Criteria for the Establishment of Work Priorities***

Fresh produce, such as leafy green vegetables, has a complex distribution pattern that can include substantial international trade. Many products cross international borders and outbreaks cross borders with them. Improved international guidelines for agricultural and manufacturing practices for fresh produce will result in reduce microbiological hazards associated with these products. In addition, such measures will lead to improved consumer confidence in fresh produce and will aid in encouraging consumers to adopt and maintain a diet rich in fresh fruits and vegetables.

According to FAO statistics, the global production of leafy green vegetables exceeds 35 million metric tons and \$12 billion, and global trade is on the order of \$2-3 billion per year. China accounts for over 60% of production, the U.S. for over 15%, and Spain, Italy and India being the next three largest producers. There are at least 18 other countries that have production exceeding \$30 million per year.

According to FAO statistics, the global production of tomatoes exceeds 100 million metric tons and \$24 billion per year and global trade of tomatoes exceeds four million metric tons and \$4 billion per year. China accounts for over 30% of production. The U.S., Turkey, Italy, India, Egypt and Spain all have production greater than \$1 billion per year and another ten countries have production greater than \$250 million per year.

According to FAO statistics, the global production of carrots exceeds 20 million metric tons and \$3.5 billion per year and global trade of carrots is about 1.5 million metric tons and \$500 million per year. China accounts for over 40% of production. The Russian Federation and U.S. have production greater than \$250 million per year and 15 other countries have production greater than \$50 million per year.

### **Relevance to the Codex strategic objectives**

The Codex Alimentarius Commission (CAC) has six strategic objectives and priorities.

#### Objective 1: Promoting Sound Regulatory Framework

The results of this work will assist in promoting sound national food control infrastructure and promote the safety of foods entering domestic and international trade by expanding Good Agricultural Practices and Good Manufacturing Practices to help control microbial hazards associated with various produce commodities.

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

This work will establish sound working principles for the analysis and identification of microbial hazards associated with various agricultural and manufacturing practices in the production of fresh produce. By understanding the relative risk of various practices, the most effective mitigation strategies (i.e., those that reduce the greatest risks the most) can be implemented to insure the greatest public health benefit.

#### Objective 3: Promoting Linkages/ between Codex and other Multilateral Regulatory Instruments and Conventions

FAO and WHO will provide expert consultations for the development of the commodity-specific annexes. The involvement of FAO and WHO in CODEX activities has already formed a close link. Their involvement in this effort will continue to support this linkage.

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

By taking on this work and expanding its expertise with specific commodities, Codex will enhance its capacity and will be able to respond to new issues on a commodity-specific level. Furthermore, having

commodity-specific expertise will permit Codex to respond more quickly and effectively to targeted food safety issues.

#### Objective 5: Promoting Maximum Membership and Participation

By developing commodity-specific annexes to the Code, there is an opportunity for the CAC to reach out to member countries that may have an interest in a particular commodity for participation where they might not typically be involved.

#### Objective 6: Promoting Maximum Application of Codex Standards

Developing annexes to the Code which incorporate commodity-specific recommendations and the most up to date science currently available will make the document more relevant to potential users thus expanding the application of these Codex standards.

#### **Relation between proposal and other existing Codex documents**

The proposed work would directly modify the *Code of Hygienic Practice for Fresh Fruits and Vegetables*. In addition, other codes of practice would likely be impacted including *Recommended International Code of Practice - General Principles of Food Hygiene*.

#### **Requirement for and availability of expert advice**

The United States has made an initial commitment of \$100,000 towards FAO/WHO expert consultations on international produce safety for the Codex Committee on Food Hygiene. Japan has recently made a similar commitment. The scope of these consultations includes evaluation of pathogen-specific hazards associated with produce and the role of various agricultural and manufacturing practices in enhancing or mitigating these hazards towards consumers. FAO/WHO is empanelling appropriate experts worldwide to focus on the identification, impact, and practical application of GAPs and GMPs on the safety of produce. The consultation will consider the entire farm to table continuum including processing and marketing and with a focus on the factors at primary production that contribute to the risk of foodborne disease, especially environmental hygiene, water for primary production and packing, and personnel health, personnel hygiene and sanitary facilities. The identification of experts on produce production in developing countries is a priority area priority component of the consultations. While the greatest information needs are associated with primary production, the expert consultation will also consider packing establishments, field packing operations, and other post-harvest handling facilities, particularly key aspects of hygiene control systems such as post-harvest water use, worker health and hygiene, cleaning/sanitizing of equipment and facilities, and the maintenance of the cold chain.

#### **Proposed timeline for completion of the new work**

A five-year timeline is proposed for the completion of the three proposed annexes. There is a 12-to-18 month timeframe for completion of the expert consultation from its initiation in the spring of 2007. An additional 12-18 months beyond that would be needed to complete the first proposed annex on leafy green vegetables; however, work by the CCFH could begin immediately once the new work is accepted. Work on the additional annexes will commence for tomatoes and carrots once the general template developed for the annex on leafy green vegetables has been agreed upon by CCFH.

#### **Inclusion of a risk profile, as appropriate, with proposal for new work**

This new work involves the addition of annexes to an existing Code of Practice, which established the presence of hazards from fruits and vegetables and the associated public health problem. Therefore, it is not necessary to develop individual risk profiles for the commodities for which annexes will be developed. In addition, it is possible that the FAO/WHO expert consultation will prioritize commodities other than the three listed above as posing the greatest risk.

**ATTACHMENT 3****PROCESS BY WHICH THE CODEX COMMITTEE ON FOOD HYGIENE WILL UNDERTAKE ITS WORK (ALINORM 07/30/13, Appendix V)**

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**Purpose**

1. The following guidelines are established to assist the CCFH to:
  - Identify, prioritize and efficiently carry out its work; and
  - Interact with FAO/WHO and their scientific bodies as the need arises.

**Scope**

2. These guidelines apply to all work undertaken by the CCFH and encompass: guidelines and procedures for proposing new work; criteria and procedures for considering the priorities for proposed and existing work; procedures for implementing new work; and a process by which CCFH will obtain scientific advice from FAO/WHO.

**Process for Considering Proposals for New Work**

3. To facilitate the process of managing the work of the Committee, CCFH may establish an *ad hoc* Working Group for the Establishment of CCFH Work Priorities (“*ad hoc* Working Group”) at each Session, in accordance with the Guidelines on Physical Working Groups.
4. The Codex Committee on Food Hygiene will, normally, employ the following process for undertaking new work
  - i. A request for proposals for new work and/or revision of an existing standard will be issued in the form of a Codex Circular Letter, if required.
  - ii. Proposals for new work received in response to the Codex Circular Letter will be transmitted to the Host of the *ad hoc* Working Group as well as the CCFH Host government and Codex Secretariats.
  - iii. The Host of the *ad hoc* Working Group will collate the proposals for new work in a document that will be distributed by the Codex Secretariat to Codex members and observers for review and comment within a specified time frame.
  - iv. The *ad hoc* Working Group will meet as decided by the Committee, normally on the day prior to the plenary session of CCFH to develop recommendations for consideration by the Committee during the CCFH session. The *ad hoc* Working Group will review the proposals for new work along with comments submitted. It will verify the completeness and compliance with the prioritization criteria of the proposals for new work and make recommendations to the Committee on whether the proposals for new work should be accepted, denied, or returned for additional information.

If accepted, a recommendation will be provided on the priority of the proposal for new work compared to pre-established priorities. The priority of the proposals for new work will be established using the guidelines outlined below, taking into account the ‘Criteria for the Establishment of Work Priorities’<sup>1</sup>. Proposals for new work of lower priority may be delayed if resources are limiting. Proposals for new work of lower priority not recommended may be reconsidered at the next CCFH session. If the *ad hoc* Working Group recommends that a proposal for new work be “denied” or “returned for revision,” a justification for this recommendation will be provided.

- v. At the CCFH session, the *ad hoc* Working Group Chair will introduce the recommendations of the *ad hoc* Working Group to the Committee. The CCFH will decide whether a proposal for new work and / or revision of an existing standard is accepted, returned for revision, or denied. If accepted, a project document<sup>5</sup>, which may include amendments agreed upon by the Committee, will be prepared by the CCFH and submitted to the Codex Alimentarius Commission (CAC) with a request for approval of the proposed new work.

### Proposals for New Work

5 In addition to the provisions applying to proposals for new work in the Procedural Manual, the proposals for new work should include a Risk Profile<sup>6</sup>, as appropriate. The proposals for new work should indicate the specific nature or outcome of the new work being proposed (e.g., new or revised code of hygienic practice, risk management guidance document).

6. The proposals for new work will typically address a food hygiene issue of public health significance. It should describe in as much detail as possible, the scope and impact of the issue and the extent to which it impacts on international trade.

7. The proposal for new work may also:

- address an issue that affects progress within CCFH or by other committees, provided it is consistent with the mandate of CCFH;
- facilitate risk analysis activities; or
- establish or revise general principles or guidance. The need to revise existing CCFH texts may be to reflect current knowledge and/or improve consistency with the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

### Prioritization of Proposals for New Work

8. The Committee will prioritize its proposals for new work at each CCFH meeting, if required. This will be carried out by the Committee after consideration of the recommendations from the *ad hoc* Working Group. The *ad hoc* Working Group will consider the priority of proposals for new work taking into account the current workload of the Committee, and in accordance with the “Criteria for the Establishment of Work Priorities” and if necessary, additional criteria to be prepared by the Committee. If CCFH resources are limited, proposals for new work or existing work may need to be delayed in order to advance higher priority work. A higher priority should be given to proposals for new work needed to control an urgent public health problem.

### Obtaining Scientific Advice

9. There are instances where progress on the work of the Committee will require an international risk assessment or other expert scientific advice. This advice will be typically be sought through FAO/WHO (e.g. through JEMRA, *ad hoc* expert consultations), though in certain instances such advice may be requested from other specialized international scientific bodies (e.g. ICMSF). When undertaking such work, the Committee should follow the structured approach given in the *Codex Principles and Guidelines for the Conduct of Microbiological Risk Management* (under development and the *Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*<sup>7</sup>.

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<sup>5</sup> The elements of a project document are described in the Codex Alimentarius Commission, *Procedural Manual*, 16<sup>th</sup> Edition.

<sup>6</sup> Definition of a risk profile is “the description of the food safety problem and its context” (Codex Alimentarius Commission, *Procedural Manual*, 16<sup>th</sup> Edition). The elements of a risk profile are provided in the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

<sup>7</sup> Codex Alimentarius Commission, *Procedural Manual*, 16<sup>th</sup> edition.

10. In seeking an international risk assessment to be conducted by FAO/WHO (e.g., through JEMRA), CCFH should consider and seek advice on whether:

- i. Sufficient scientific knowledge and data to conduct the needed risk assessment are available or obtainable in a timely manner. (An initial evaluation of available knowledge and data will typically be provided within the Risk Profile.)
- ii. There is a reasonable expectation that a risk assessment will provide results that can assist in reaching risk management decisions related to control of the microbiological hazard without unduly delaying the adoption of the needed microbiological risk management guidance.
- iii. Risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment are available.

11. If the Committee decides to request that a microbiological risk assessment or other scientific advice be developed, the Committee will forward a specific request to FAO/WHO, the risk profile document, a clear statement of the purpose and scope of the work to be undertaken, any time constraints facing the Committee that could impact the work, and the case of a risk assessment, the specific risk management questions to be addressed by the risk assessors. The Committee will, as appropriate, also provide FAO/WHO with information relating to the risk assessment policy for the specific risk assessment work to be undertaken. FAO/WHO will evaluate the request according to their criteria and subsequently inform the Committee of its decision on whether or not to carry out such work together with a scope of work to be undertaken. If FAO/WHO respond favorably, the Committee will encourage its members to submit their relevant scientific data. If a decision is made by FAO/WHO not to perform the requested risk assessment, FAO/WHO will inform the Committee of this fact and the reasons for not undertaking the work (e.g., lack of data, lack of financial resources).

12. The Committee recognizes that an iterative process between risk managers and risk assessors is essential throughout the process described above and for the adequate undertaking of any microbiological risk assessment and the development of any microbiological risk management guidance document or other CCFH document(s).

13. The FAO/WHO will provide the results of the microbiological risk assessment(s) to the Committee in a format and fashion to be determined jointly by the Committee and FAO/WHO. As needed, the FAO/WHO will provide scientific expertise to the Committee, as feasible, to provide guidance on the appropriate interpretation of the risk assessment.

14. Microbiological risk assessments carried out by FAO/WHO (JEMRA) will operate under the framework contained in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/RCP 020-1999).



**ATTACHMENT 4****Priority proposed for Revision of Codes**

<b>Code</b>	<b>Priority</b>
Egg products	1
Foods for Infants and Children	2
Tree nuts and Groundnuts with a view to combining these two codes into a single code of practice for nuts	3
All codes of hygienic practice for fruits and vegetables, with a view to combining all existing codes of hygienic practices for fruit, vegetables and products thereof into a single code of practice for fruits and vegetables	4
Desiccated Coconut, with a view to combining this code with the code for fruits and vegetable <b>or</b> the code for nuts if considered to be more appropriate	5
Quick Frozen Foods, ensuring that all general requirements for frozen foods from the fruit and vegetables and fish codes are adequately addressed;	6
Spices and Aromatic Plants	7
Low-Acid and Acidified Low-Acid Canned Foods and Aseptically Processed and Packaged Low-Acid Canned Foods, with consideration being given to whether these codes can be combine and incorporated as appendices to the General Principles of Foods Hygiene	8
Natural Mineral Waters	9
Recommended International Code of Hygienic Practice for The Processing of Frog Legs	10
Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering	11
Code of Hygienic Practice for the Preparation and Sale of Street-vended Foods	As required

**ATTACHMENT 5****MANAGEMENT OF THE WORK OF THE CODEX COMMITTEE ON FOOD HYGIENE*****Ad hoc* Working Group for the Establishment of CCFH Work Priorities**

**Hotel Hyatt Regency, Bhikaji Cama Place, New Delhi, India  
(29th October 2007 : 0930 - 1700 hrs. )**

**Provisional Agenda**

1. Welcome and introduction by Chairperson - India.
2. Consideration of new work proposals (*Attachments 1 and 2*).
3. Consideration of the Committee's assignment to the *Ad hoc* Working Group to consider the proposal for work on development of the CCFH risk analysis policies document.
4. Review the list of new work priorities of the Committee (*Attachment 4, US proposal on E. coli and the Dutch proposal on Norovirus*).
5. Recommendations to the CCFH.
6. Arrangements for the next Chair of the *Ad hoc* Working Group.

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