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FOOD AND AGRICULTURE  
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**Agenda Item 7**

**CX/FH 09/41/7**

**July 2009**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX COMMITTEE ON FOOD HYGIENE**

**Forty first Session**

**The Coronado Hotel, San Diego, United States of America**

#### **PROPOSED DRAFT ANNEX ON THE CONTROL MEASURES FOR *VIBRIO* *PARAHAEMOLYTICUS* AND *VIBRIO VULNIFICUS* IN MOLLUSCSAN SHELFISH AT STEP 3**

**Prepared by the physical working group led by Japan**

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Annex at Step 3 (see Appendix II) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, Seventeenth Edition*) to: Ms Barbara McNiff, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4870, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-690-4719, or email [Barbara.McNiff@fsis.usda.gov](mailto:Barbara.McNiff@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 email [codex@fao.org](mailto:codex@fao.org) or fax: +39-06-5705-4593 **by 30 September 2009.**

#### **REPORT OF THE PHYSICAL WORKING GROUP ON THE DEVELOPMENT OF THE PROPOSED DRAFT ANNEX ON CONTROL MEASURES FOR *VIBRIO PARAHAEMOLYTICUS* AND *VIBRIO VULNIFICUS* IN MOLLUSCAN SHELLFISH (STEP 3)**

##### **Background**

1. The Codex Committee on Food Hygiene (CCFH) held in December 2008 had agreed with the proposal to develop an annex on control measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in molluscan shellfish to the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio species in Seafood*.
2. The Committee had agreed to reconvene the physical working group led by Japan, open to all interested parties and working in English only to develop this annex for circulation at Step 3 for comments and consideration by the next session of the Committee (ALINORM 09/32/13 para.146).

##### **Report of the physical working group**

3. The physical working group led by Japan met on 26 – 29 May 2009 in Kyoto, Japan with attendance of delegates from Brazil, China, European Community, France, Japan, Thailand, and the United States of America. The Representatives from ICMSF and FAO also participated in the meeting.
4. The physical working group took into account written comments submitted by Argentina, Australia, Canada, France, Mexico, New Zealand, Norway and FAO and comments raised during the meeting. The

proposed draft annex is presented in **Appendix II** and a complete list of participants is included as **Appendix I** to this document.

5. The key points brought forward in the discussion of the physical working group are summarized as follows:

Title of annex

6. The physical working group agreed that the annex should address only bivalve molluscs but not all molluscan shellfish. Bivalve molluscs are harvested, handled and consumed differently than most other seafood products and are inherently riskier than other seafood due to their filter feeding activity that concentrates pathogens present in the water. The title was changed to read as follows: “proposed draft annex on the control of *Vibrio parahaemolyticus* and *Vibrio vulnificus* in bivalve molluscs”.

Food categories

7. There are the following four different states of bivalve molluscs: (i)“live”; (ii)“raw”; (iii)“partially treated”; and (iv)“thoroughly treated” as designated in the *Proposed Draft Guidelines on the Control of Pathogenic Vibrio spp. in Seafood* (ALINORM 09/32/13 Appendix IV) (herein after referred to as “the main document”). The physical working group agreed that:
- (i)“live” and (ii) “raw” bivalve molluscs including those destined for receiving “post harvest processing”, which are not treated before consumption, should be covered by Part I of the annex;
  - (iii) bivalve molluscs in a “partially treated” state, which are destined to be partially treated before consumption or to be directly consumed with no further treatment, should be addressed in Part II of the annex.
  - (iv) bivalve molluscs in a “thoroughly treated” state that are destined for direct consumption, such as canned foods and other sterilized foods, should not be addressed in the annex because they could be adequately covered by the main document and other existing document (i.e. the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1- 1969)).
8. Table below summarizes the characteristics of the food categories as agreed by the physical working group.

Status at consumption and control characteristics of two food categories, Part I and Part II, designated for Sections III – X in Annex

Characteristics of control by:	Part I			Part II	
	Status of food at consumption:			Status of food at consumption:	
	Live	Raw	Raw after post- harvest processing	Partially treated <sup>1</sup> primarily by consumer	Partially treated <sup>1</sup> primarily by business operator
<b>Producer</b>					
Primary production control <sup>2</sup>	+	+	+	+	+
<b>Business operators<sup>3</sup></b>					
Post-harvest processing <sup>4</sup>	–	–	+	–	–
Time and temperature control	+	+	+	+	+
Adequate partial treatment before consumption <sup>5</sup> [Proportional time/temperature control] <sup>6</sup>	–	–	–	+/–	+
<b>Consumer</b>					
Additional partial treatment before consumption	–	–	–	+	–

+: conducted, –: not conducted, +/-: conducted or not conducted.

<sup>1</sup> Any treatment intended to significantly reduce or limit but not completely eliminate *Vibrio* spp. in seafood. As a result of partial treatment, the raw sensory characteristics are lost.

<sup>2</sup> Time and temperature control at primary production for live and raw (without post harvest processing) categories are more stringent than other categories to the left.

<sup>3</sup> Establishment including distributors, restaurants, caterers, etc. <sup>4</sup> For example, quick frozen, high-pressured or mild heat treated oysters, which are retaining sensory characteristic of live oysters.

<sup>5</sup> Conducted due to preference of consumers and wide variations of cooking. Post-harvest processing is excluded.

<sup>6</sup> Equivalent Level of Protection to live and raw categories should be achieved.

Definition of “post- harvest processing” (paragraph 6 of annex)

9. The physical working group defined the term “post-harvest processing” as this processing was often applied in harvesting and distributing bivalve molluscs. For example, quick frozen, high-pressured and/or mild heat treatments are applied in order to reduce levels of *V. parahaemolyticus* and/or *V. vulnificus*, but not to eliminate them completely. After the application of such the treatments, sensory characteristics of live bivalve molluscs are essentially retained in the bivalve molluscs, despite that they are not alive any more. The definition was prepared in principle in line with the detailed explanatory note that was already available in Section 7.7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

Vibrio species to be addressed by Annex

10. The physical working group considered as to whether *Vibrio* species other than *V. parahaemolyticus* and *V. vulnificus* also be covered in the proposed draft annex. It was recognized that there were some case reports of infections caused by other *Vibrio* species (e.g. *Vibrio cholera* non O1 / non O139, *Vibrio alginolyticus*) in certain regions and countries. The physical working group, however, due to lack of data for other *Vibrio* species and availability of their risk assessments results, agreed that the proposed draft annex should address *V. parahaemolyticus* and *V. vulnificus* only. It was noted that countries might wish to apply the proposed draft annex in controlling other *Vibrio* spp., where applicable.

Predictive models

11. In relation to paragraphs 10 and 11, the physical working group considered how the predictive models using the data in Table 1 in the proposed draft annex could be applied in different situations of controlling *Vibrio* spp, in shellfish. The physical working group elaborated texts of footnotes stating that the data and information on growth rates and doubling time of *V. parahaemolyticus* and *V. vulnificus* was obtained by the methods described in the FAO/WHO risk assessment, therefore countries might consider using local data on the growth rate and doubling time of the *Vibrio* spp. in using the models for control of risk associated with these pathogens.
12. The physical working group expressed its wishes that the CCFH, during its 41<sup>st</sup> Session, would allow the delegation of the United States of America to present an example of a risk calculator, for the sake of better understanding among member countries on the use of the predictive models.
13. Given the fact that lack of data on growth rate of *V. parahaemolyticus* and *V. vulnificus* in different shellfish species, lack of epidemiological data on illness associated with *Vibrio* spp., and variation of their virulence made it difficult to predict human health risks associated with *Vibrio* spp. at national and regional level, the working group agreed to **recommend** that the CCFH should request FAO and WHO for convening a future expert consultation to conduct validation of the models developed based on the FAO/WHO risk assessments, with a view to constructing more applicable models for wide use among member countries.
14. Further, in order to ensure the proper application of the predictive tools to control *Vibrio* spp. in partially treated products, the physical working group agreed to **recommend** that a research should be initiated to generate data on log reduction of growth of *Vibrio* spp., which were not available at the moment.

Methods to monitor pathogenic and total *V. parahaemolyticus* and *V. vulnificus*.

15. On paragraphs 12 -15, the physical working group considered detection methods which were used in monitoring total *V. vulnificus* and total and pathogenic *V. parahaemolyticus* in bivalve molluscs and sea water at harvest, including a way of validating these methods for inter laboratory calibration, in view of the regional and seasonal variation. There was a common view that, unlike other methods that were used to determine the levels of pathogens in food and examine the compliance of standards, the detection methods used in monitoring levels of total and pathogenic *V. parahaemolyticus* and a level of *V. vulnificus* in bivalve molluscs at harvest should not be necessarily approved by competent authorities and that, however, at least these methods should be scientifically validated.
16. Recognizing the different situations, in regions and countries, on the contaminations of *V. parahaemolyticus* and *V. vulnificus*, and the importance of evaluating the performance of the methods applied in monitoring *V. parahaemolyticus* and *V. vulnificus*, the physical working group agreed to

**recommend** that the CCFH, at its forthcoming 41<sup>st</sup> Session, should encourage FAO and WHO to provide member countries with relevant technical assistance, possibly through an existing mechanism (i.e. WHO Global Foodborne Infections Network), with a view to improving capacity of laboratories or institutes in detecting and enumerating virulent *Vibrio* spp. at national and regional level.

#### Impact of ballast discharge (paragraph 13)

17. The working group discussed the impact of ballast discharge in or around the harvesting area and water and agreed that adequate measures be taken to evaluate impact on areas in close proximity to international shipping in relation to ballast discharge. It was noted that ballast water was a source of spreading *V. parahaemolyticus*, but not *V. vulnificus*, which was not found in water at a high salinity (e.g. 35g/l (ppt: parts per thousand)).

#### Temperature and time control in handling, storage and transportation

18. The working group carefully drafted the text in 3<sup>rd</sup> bullet point in paragraph 18 of Section 3.3 to describe time and temperature control applied in handling, storage and transportation, to be consistent with Section 7.3 of the *Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)*, which was required for maintaining quality of live or raw bivalve molluscs.

#### Time and temperature controls (paragraph 24, section 5.2.1 of Part I)

19. Some delegations were of the opinion that temperature control to the point that *Vibrio* spp. did not grow should be applied in the entire food chain from farm to consumption. Other delegation was of the different view that this section 5.2.1 should apply only in processing /operation undertaken by food business operators, and should not include treatments/practices followed by consumer. As there was no consensus reached on this matter, relevant texts in this section were bracketed for further discussion at the forthcoming 41<sup>st</sup> Session of the CCFH.

#### The term “undercooked”

20. The physical working group did not accept a proposal to use the term “undercooked” rather than “partially treated” throughout the whole text, following the decision of the last CCFH to replace the term “undercooked” with “partially treated” (see paragraph 110 of ALINORM 09/32/13). It was noted that processing other than heating (e.g. acid treatment) also was effective to reduce *V. parahaemolyticus*.

#### Combination of measures to control *Vibrio* spp. in bivalve molluscs consumed in partially treated state

21. The physical working group considered combination of control measures in Part II applied for the primary production of bivalve molluscs destined for partial treatment, in view of preventing cross-contamination and ensuring sufficient risk reduction throughout the entire food chain. The physical working group agreed that the combination of measures of the treatment and those described in Section III of Part II should achieve at least an equivalent level of protection to the level of protection applied for raw or live bivalve mollusks. The physical working group further agreed that bivalve molluscs destined for partial treatment should be handled separately from those to be consumed live, untreated raw or after post-harvest processing.
22. The physical working group noted that partial treatment was to reduce the level of vibrios, but was not to eliminate them completely, unlike sterilization, and therefore, elaborated some texts under relevant sections including section 3.3. It was highlighted that any measure or practice to reduce or limit, but not to eliminate *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs should be adequately validated to ensure that the control measures were effective and such validated control measures should be implemented under an HACCP system.

#### Labelling (section 9.3 of part II)

23. The physical working group discussed labeling requirements that should provide information on specific safe handling practices and storage recommendations (e.g. heating time and temperature, storage temperature). It is important to avoid insufficient treatments at the point of consumption as it is essential to ensure adequate reduction of the level of, and/or control of the growth of *Vibrio* spp. in partially treated bivalve molluscs till the end of entire food chain.
24. Some delegations were of the view that competent authorities should examine the food preparation

habits of their population and determine appropriate control measures that could achieve an equivalent level of protection. In this connection, the same delegations proposed to add a text stating that, for the preparation of labeling, food business operators should validate such food treatment practices performed by consumer in order to ensure prevention of health risks associated with consumption of partially treated products. There was no agreement reached on this matter during the meeting.

#### Amendments to the main document

25. Although the terms of reference of the physical working group did not include amendment to the main document, the physical working group agreed to **recommend** that:

- in the context of partially treated, including post harvest processing, the definition of “partially treated” currently available in the main document (paragraph 25 of ALINORM 09/32/13) should be amended as follows:

**Partially treated:** Any treatment intended to significantly reduce or limit but not completely eliminate *Vibrio* spp. in seafood. As a result of partial treatment, the raw sensory characteristics are lost.

and

- the texts in paragraphs 29, 30 and 31 of the main documents should be moved to the proposed draft annex as these paragraphs were addressing bivalve molluscs only.

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## APPENDIX II

**PROPOSED DRAFT ANNEX ON THE CONTROL MEASURES FOR *VIBRIO* *PARAHAEMOLYTICUS* AND *VIBRIO* *VULNIFICUS* IN BIVALVE MOLLUSCS<sup>1</sup>****INTRODUCTION**

1. Bivalve molluscs are an important food source in international trade and are a well documented vehicle for transmission of illnesses caused by *Vibrio* spp., especially *Vibrio parahaemolyticus* and *Vibrio vulnificus*. Bivalve molluscs are unique in that they are harvested, handled and consumed differently than most other seafood products and therefore present unique risks and control options. They are inherently riskier than other seafoods because of their filter feeding activity that concentrates pathogens present in the water and also they may be consumed whole and raw or after insufficient cooking. Unlike most other aquatic species that are slaughtered at harvest, bivalve molluscs may be able to survive out of the water for days after harvest at temperatures that permit the growth of *V. parahaemolyticus* and *V. vulnificus* with little loss of quality. In many countries, bivalve molluscs are often held at ambient temperatures for extended periods resulting in post-harvest growth of these pathogens and that contributes heavily to their risk, according to recently completed FAO/WHO risk assessments for both of these pathogens<sup>2</sup>.

**SECTION I – OBJECTIVES**

2. The purpose of this Annex is to provide guidance on control measures that minimize the risk arising from the presence of pathogenic *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs, especially minimizing and/or preventing the introduction/contamination and/or the growth of these pathogens, and adequate partial treatment<sup>3</sup> of bivalve molluscs before consumption. Controls for these pathogens are similar but differ to the extent that characteristics of growth and survival differ. The controls outlined in this Annex will reflect these differences, where they exist. This Annex also provides information that will be of interest to regulatory authorities, the food industry, consumers, and other interested parties.

**SECTION II – SCOPE, DEFINITION AND USE OF THE DOCUMENT****2.1 SCOPE**

3. This Annex covers bivalve molluscs that are intended for consumption in a live, raw, or partially treated state. The target microbiological hazards of this Annex are pathogenic *V. parahaemolyticus* and *V. vulnificus*.
4. This Annex highlights the key control measures that influence the introduction/contamination of and minimize levels of *V. parahaemolyticus* and *V. vulnificus* and thus the risk of foodborne diseases caused by these pathogens.
5. This Annex is applicable throughout the food chain, from primary production through to final consumption. Additionally, guidance is provided on post-harvest processing. Controls in Part I apply to live and raw bivalve molluscs (including those that receive post-harvest processing), while those in Part II apply to bivalve molluscs consumed after partial treatment.<sup>4</sup>

**2.2 DEFINITIONS**

6. For the purpose of this annex, the following definitions apply:

Definitions contained in the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3); and

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<sup>1</sup> Phylum Mollusca: Class Bivalvia

<sup>2</sup> FAO/WHO has developed and published Risk assessments of *Vibrio vulnificus* in raw oysters (2005), *V. parahaemolyticus* in bloody clams and *V. parahaemolyticus* in raw oysters (in Press). This Annex is based on key findings and outcomes derived from these risk assessments and other relevant epidemiological evaluations.

<sup>3</sup> Including cooking.

<sup>4</sup> Risk assessment of *V. parahaemolyticus* in bloody clams

live and raw bivalve molluscs production definitions defined in the *Codex Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008).

**Post-harvest processing:** processes (e.g. freezing, high pressure and mild heating) intended to significantly reduce or limit but not completely eliminate *V. parahaemolyticus* and *V. vulnificus* while essentially retaining the sensory characteristics of live bivalve molluscs (Section 7.7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003)).

## 2.3 USE OF THE DOCUMENT

7. This Annex is supplemental to and should be used in conjunction with the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969), the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003), Hygiene section of the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008) and the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3). The use of this Annex may require modifications and amendments that take into account such factors as regional differences in the prevalence of pathogenic strains of *V. parahaemolyticus* and *V. vulnificus* and the epidemiological data, including the susceptibility of the population.
8. In many instances, the control measures are articulated in a general manner in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) as part of the general strategy for the control of foodborne pathogens in all foods. In providing this Annex, it is assumed that the *General Principles of Food Hygiene* is being implemented.

## **PART I: Bivalve molluscs consumed live and raw**

### **SECTION III - PRIMARY PRODUCTION**

#### **3.1 ENVIRONMENTAL HYGIENE**

9. Refer to Section 3.1 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products*, (CAC/RCP 52-2003) and Section 3.1 of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).
10. The controls described in this section generally apply to pre-harvest environmental conditions and practices during and immediately following harvest, typically while under the control of the harvester. Effective control measures for *V. parahaemolyticus* and *V. vulnificus* will typically require an evaluation in terms of the risk associated with environmental factors in the harvesting area and harvesting practices based on epidemiology and environmental conditions (i.e. water temperature and salinity, air temperature). An important element in estimating risk is understanding that *V. parahaemolyticus* grows faster and at colder temperatures than *V. vulnificus* (growth rates for *V. parahaemolyticus* and *V. vulnificus* are provided in Table 1). Predictive tools<sup>5</sup> using these environmental monitoring parameters and growth rates as inputs have been developed based on the FAO/WHO risk assessments and are available to estimate corresponding *V. parahaemolyticus* and *V. vulnificus* levels and risk.
11. In cases where predictive models are used to estimate the concentration and risk of pathogenic *Vibrio* spp. in seawater and/or bivalve molluscs based on air and water temperatures and/or salinity, their accuracy would be enhanced by incorporating local data on levels of total and pathogenic *V. parahaemolyticus* and *V. vulnificus* and growth in local bivalve spp. Factors such as hydrodynamic effects (currents, tides, hurricanes, rainfall, etc.) and sunlight will influence the levels of *Vibrio* spp. The dose response model used in the predictive tool may need modifications based on epidemiology, for example, attack rate relative to exposure to *V. parahaemolyticus* strains that occur in those areas.
12. Monitoring of bivalve molluscs at harvest for the levels of total *V. vulnificus* and total and pathogenic *V. parahaemolyticus* should be conducted to determine the regional and seasonal variation. Prevalence of pathogenic strains of *V. parahaemolyticus* and *V. vulnificus* and the epidemiological data, including the

<sup>5</sup> Predictive tools (construction is in progress) using *V. parahaemolyticus* / *V. vulnificus* Risk Calculation worksheets, undertaken by the United States were reviewed by the physical working group meeting in Kyoto.

susceptibility of the population, should be considered.<sup>6</sup> This information, and some factors articulated in para. 15, are useful for model inputs and evaluation of model outputs and application of appropriate controls.

13. Additionally, there are some indications that *Vibrio* spp. can be introduced into a harvest area through the release of ballast water. Therefore, the impact of ballast discharge in or around the harvesting area should be controlled regarding the presence of *Vibrio* spp., especially in areas that are in close proximity to international shipping lanes.
14. Factors to be considered in determining the need for controls in a given harvest area include:
  - The number of sporadic illnesses and outbreaks of *V. parahaemolyticus* and *V. vulnificus* associated with bivalve molluscs harvested from a distinct hydrographic area, and whether these illnesses are indicative of an annual reoccurrence;
  - Water temperatures representative of harvesting conditions. Water temperatures below 15°C<sup>7</sup> for *V. parahaemolyticus* and below 20°C for *V. vulnificus* have generally not been historically associated with illnesses;
  - Time period to first refrigeration and post-harvest air temperatures above the minimum growth temperatures for *V. parahaemolyticus* (10°C) and *V. vulnificus* (13°C), which may increase risk regardless of harvest water temperature;
  - Harvest practices that allow radiant solar heating to raise temperatures of bivalve molluscs to temperatures above ambient air temperatures prior to harvest (i.e. intertidal harvest) and exposure time;
  - Salinity ranges and optima are different for *V. parahaemolyticus* and *V. vulnificus*. Environmental and epidemiological data indicate low *V. parahaemolyticus* and *V. vulnificus* levels and few cases of illnesses are associated with bivalve molluscs when salinity exceeds 35 ppt (g/l) and 30 ppt (g/l), respectively.
15. The competent authority should inform the food operator to implement control measures contained in Sections 3.2 (HYGIENIC PRODUCTION OF FOOD SOURCES), 3.3 (HANDLING STORAGE AND TRANSPORT) and 5.1 (CONTROL OF FOOD HAZARDS) and 5.2 (KEY ASPECTS OF HYGIENE CONTROL SYSTEMS) of this Annex when at least:
  - Levels of *V. parahaemolyticus* and/or *V. vulnificus*, or environmental parameters exceed testing/monitoring criteria that are based on risk assessment, if applicable.
  - An unusual increase of *Vibrio* spp. illnesses is reported.
16. The activities described in this section should be applied in cooperation with the regulatory authority having jurisdiction.

### 3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

17. Pre-harvest and harvest measures should be applied as necessary based upon the factors identified in Section 3.1 above, such as:
  - Restrict harvest or otherwise prevent use of product for raw consumption (e.g. close area to harvest or divert product for further processing).
  - Where possible, sink bivalve molluscs below the thermocline where the growth of pathogenic *Vibrio* spp. will not occur

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<sup>6</sup> As an example, pandemic *V. parahaemolyticus* may require more stringent controls than other strains of pathogenic *V. parahaemolyticus* because epidemiological evidence indicates higher attack rates.

<sup>7</sup> J. B. McLaughlin, A. DePaola, C. A. Bopp, K. A. Martinek, N. P. Napolilli, C. G. Allison, S. L. Murray, E. C. Thompson, M. M. Bird, and J. P. Middaugh. Outbreak of *Vibrio parahaemolyticus* gastroenteritis associated with Alaskan oysters. *N Engl J Med* 14:1463-1470, 2005.

- Relay bivalve molluscs to areas where risk is sufficiently reduced (e.g. relay bivalve molluscs with *V. vulnificus* to high salinity offshore waters)

### 3.3 HANDLING, STORAGE AND TRANSPORT

18. The following control measures during handling, storage and transport of harvested bivalve molluscs should be applied as necessary based upon the factors identified in Section 3.1. It is important that any control for *V. parahaemolyticus* and/or *V. vulnificus* is not less than that required for the control of any other pathogenic organisms in bivalve molluscs.
  - Limit time from harvest or first exposure to ambient air temperature, to initial refrigeration based on modeling and sampling to achieve the appropriate level of protection.
  - Minimize time and temperature conditions that would allow the growth of *V. parahaemolyticus* and *V. vulnificus* during wet storage of bivalve molluscs.
  - Bivalve molluscs are to be transported at the lowest temperature tolerable for the *Vibrio* spp. The time between refrigeration and reaching a temperature that does not support growth of *V. parahaemolyticus* and *V. vulnificus* should be minimized when the temperature of the bivalve molluscs exceeds the minimum growth temperature for pathogenic vibrios, and the time between harvest and raw consumption should be limited appropriately or the product should undergo additional treatment to reduce *Vibrio* levels. Special attention should be paid to maintaining the characteristics of bivalve molluscs to be consumed live following Section 7.3 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).
  - It may be useful to survey levels periodically of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs at various points in the distribution chain to verify effectiveness of recommended controls.
  - Anyone involved in the handling, storage or transport of bivalve molluscs should be educated regarding the relationship between temperature control and growth of pathogenic *V. parahaemolyticus* and *V. vulnificus* and trained regarding proper handling, storage and transport.
19. Bivalve molluscs destined to be consumed live or untreated raw should be handled separately from those destined for post-harvest processing or other treatment.

## SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

20. Refer to Section IV of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section IV of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).

## SECTION V - CONTROL OF OPERATION

### 5.1 CONTROL OF FOOD HAZARDS

21. Refer to Section 5.1 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003), the *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008) and Section 5.1 of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).
22. The controls described in this section generally apply to post-harvest handling and processing. Control of *V. parahaemolyticus* and *V. vulnificus* will typically require the stringent application of Good Hygienic Practices and other supportive programs. These prerequisite programs, together with HACCP, can provide a sound framework for the control of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.
23. Any measure or practice selected to reduce or limit but not completely eliminate *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs (e.g. freezing, high pressure, mild heating, etc.), should be adequately validated to ensure that the control measure is effective and approved by the competent authority. Such validated control measures/practices should be implemented under the HACCP system. *V. parahaemolyticus* is generally more resistant than *V. vulnificus* to any given treatment. Therefore, a

process that is effective for *V. vulnificus* may not be as effective for *V. parahaemolyticus*.

## 5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

### 5.2.1 Time and temperature control

24. Refer to Section 4.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003). Temperature control to reduce the temperature to the point that *V. parahaemolyticus* and *V. vulnificus* do not grow should be used and maintained during processing [operation] [and subsequently until consumption] [during the entire food chain] [during the entire food production/preparation chain].

### 5.2.2 Specific process steps

25. Bivalve molluscs destined to be consumed live or untreated raw should be distributed separately from those destined for post-harvest processing or other treatment.

## SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

26. Refer to Section VI of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section VI of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).

## SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

27. Refer to Section VII of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section VII of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).

## SECTION VIII – TRANSPORTATION

28. Refer to Section VIII of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).

## SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

29. Refer to Section IX of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).
30. In addition, programs for consumer information should be directed at consumers with increased susceptibility to contracting vibriosis (see para. 106 of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3)) to help consumers make informed choices about purchase, storage, shelf-life labelling and appropriate consumption of a live and raw bivalve molluscs, taking into consideration the specific regional conditions and consumption habits.

### 9.3 Labelling

31. Refer to Section 9.3 (Labelling) of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3) and Section I-7 and II-7 of the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008).

### 9.4 Consumer education

32. Refer to Section 9.4 (Consumer education) of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).
33. Since each country has specific consumption habits, communication programs pertaining to *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs are most effective when established by individual governments.
34. Programs for consumer information should increase awareness of consumers to follow the instructions

on handling and preparation of bivalve mollusks aimed at avoiding food safety risk associated with *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.

## SECTION X - TRAINING

35. Refer to Section X of the *Recommended International Code of Practice-General Principles of Food Hygiene*, (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products*, (CAC/RCP 52-2003) and Section X of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).

## **PART II. BIVALVE MOLLUSCS CONSUMED IN PARTIALLY TREATED STATE<sup>8</sup>**

### SECTION III - PRIMARY PRODUCTION

#### 3.1 ENVIRONMENTAL HYGIENE

36. Refer to Section 3.1 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section 3.1 of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).
37. The controls described in Section III (PRIMARY PRODUCTION) of PART I should be implemented. The combination of measures of the treatment and those described in Section III of this part should achieve at least an equivalent level of protection to the level of protection provided for raw or live bivalve molluscs in Section III of PART I.
38. If data on log reduction achieved by partial treatment is available, predictive tools in PART I could be applicable.

#### 3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

39. Refer to Section 3.2 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section 3.2 of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).
- The controls described in Section III (PRIMARY PRODUCTION) of PART I should be implemented. The combination of measures of the treatment and those described in Section III of this part should achieve at least an equivalent level of protection to the level of protection provided for bivalve molluscs in Section III of PART I. Bivalve molluscs destined for partial treatment should be handled separately from those to be consumed live, untreated raw or after post-harvest processing.

#### 3.3 HANDLING, STORAGE AND TRANSPORT

40. Refer to Section 3.3 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section 3.3 of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).
41. The controls described in Section III (PRIMARY PRODUCTION) of PART I should be implemented. The combination of measures of the treatment and those described in Section III of this part should achieve at least an equivalent level of protection to the level of protection provided for bivalve molluscs in Section III of PART I. Bivalve molluscs destined for partial treatment should be handled and distributed separately from those to be consumed live, untreated raw or after post-harvest processing.:

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<sup>8</sup> PART II applies only to products which are partially treated, excluding post-harvest processing. For products in thoroughly treated state, refer to relevant parts of the Good Hygienic Practices as specified in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969), *Code of Practice for fish and fishery products* (CAC/RCP 52-2003) and other applicable Codex documents as those are generally suitable to control *V. parahaemolyticus* and *V. vulnificus* in fully cooked bivalve molluscs.

## SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

42. Refer to Section IV of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).

## SECTION V - CONTROL OF OPERATION

### 5.1 CONTROL OF FOOD HAZARDS

43. Refer to Section 5.1 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003), the *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008) and Section 5.1 of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3). Competent authorities should ensure that partial treatment and additional control measures assure the safety of the product.
44. The controls described in this section generally apply to post-harvest handling and processing. Control of *V. parahaemolyticus* and *V. vulnificus* will typically require the stringent application of Good Hygienic Practices and other supportive programs. These prerequisite programs, together with HACCP, can provide a sound framework for the control of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.
45. *V. parahaemolyticus* is generally more resistant than *V. vulnificus* to any given treatment. Therefore, a process that is effective for *V. vulnificus* may not be as effective for *V. parahaemolyticus*. Any measure or practice to reduce or limit but not eliminate *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs should be adequately validated to assure that the control measures are effective and such validated control measures as practiced should be implemented under an HACCP system.

### 5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

#### 5.2.1 Time and temperature control

46. Refer to Section 4.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003). The partial heat treatment of bivalve molluscs should ensure the internal temperature of the bivalve molluscs reaches the temperature to ensure a reduction of *V. parahaemolyticus* and *V. vulnificus*. Achievement of the validated time and temperature treatment should be ensured. After partial heat treatment, growth of *V. parahaemolyticus* and *V. vulnificus* should be controlled

#### 5.2.2 Specific process steps

47. The partial treatment other than heat of bivalve molluscs should be validated to ensure the intended reduction of *V. parahaemolyticus* and *V. vulnificus*. The parameters (e.g. target pH, salt concentration, water activity) should be controlled, monitored and verified.

#### 5.2.4 Microbiological cross contamination

48. Control measures should be in place to avoid cross contamination between bivalve molluscs before partial treatment and after partial treatment. Refer to para. 85 of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).

## SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

49. Refer to Section VI of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section VI of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).

## SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

50. Refer to Section VII of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section VII of Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).



## SECTION VIII – TRANSPORTATION

51. Refer to Section VIII of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section VIII of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).

## SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

52. Refer to Section 9.1 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section 9.1 of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).

### 9.3 Labelling

53. Refer to the *General Standard for the Labelling of Prepackaged Foods* (CODEX STANDARD 1-1985) and Section II-7 Labelling in the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008). Where appropriate, product labels should include information on safe handling practices and storage recommendations.
54. In addition, where appropriate, labelling for bivalve molluscs should include advice on specific safe handling practices (e.g. time, temperature) and consumption. Further it should also indicate that bivalve molluscs are exclusively for further treatment (e.g. indicated appropriate cooking before consumption).

### 9.4 CONSUMER EDUCATION

55. Since each country has regional specific differences in the prevalence of pathogenic vibrios as well as variations in consumption habits, communication programs pertaining to *V.parahaemolyticus* and *V.vulnificus* in bivalve molluscs are most effective when established by individual governments.
56. Programs for consumer information should increase awareness of consumer to follow the instructions on handling and preparation of bivalve mollusks aimed at avoiding food safety risk associated with *V.parahaemolyticus* and *V.vulnificus* in bivalve molluscs.

## SECTION X - TRAINING

57. Refer to Section X of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section X of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3).

**Table 1. Predicted<sup>9</sup> temperature-specific *V. parahaemolyticus* and *V. vulnificus* growth rates and doubling times in oysters for calculating cumulative growth based on hourly temperature observations.**

Oyster Temperature (°C)	<i>V. parahaemolyticus</i>		<i>V. vulnificus</i>	
	Growth rate <sup>10</sup> (logs/hr)	Doubling time (hrs)	Growth rate <sup>11</sup> (logs/hr)	Doubling time (hrs)
10	0.008	35.8	0	
11	0.013	24.0	0	
12	0.017	17.3	0	
13	0.023	13.0	0	
14	0.030	10.1	0.011	27.4
15	0.037	8.11	0.022	13.7
16	0.045	6.64	0.033	9.12
17	0.054	5.54	0.044	6.84
18	0.064	4.69	0.055	5.47
19	0.075	4.02	0.066	4.56
20	0.086	3.49	0.077	3.91
21	0.099	3.06	0.088	3.42
22	0.112	2.70	0.099	3.04
23	0.126	2.40	0.110	2.74
24	0.140	2.15	0.121	2.49
25	0.156	1.93	0.132	2.28
26	0.172	1.75	0.143	2.11
27	0.189	1.59	0.154	1.95
28	0.207	1.45	0.165	1.82
29	0.226	1.33	0.176	1.71
30	0.246	1.23	0.187	1.61
31	0.266	1.13	0.198	1.52
32	0.287	1.05	0.209	1.44
33	0.309	0.97	0.220	1.37
34	0.332	0.91	0.231	1.30
35	0.356	0.85	0.242	1.24

<sup>9</sup> These values are derived from the FAO/WHO Risk Assessments of *V. parahaemolyticus* and *V. vulnificus* in Raw Oysters.

<sup>10</sup> Square root of growth rate (in logs/hr) =  $0.0202 \times \text{Temperature} - 0.1103$ , if Temperature > 10°C

<sup>11</sup> Growth rate (in logs/hr) =  $0.011 \times (\text{Temperature} - 13)$  if Temperature > 13°C The information in this table is based on growth rates of natural *V. parahaemolyticus* and *V. vulnificus* populations in *Crassostrea virginica* as described in the *V. parahaemolyticus* and *V. vulnificus* Risk Assessments and is based on environmental conditions in *Vibrio* populations occurring in the US. These growth rates may be different in other species of bivalve molluscs, and countries should consider using local species to confirm growth rates.