



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEx COMMITTEE ON FOOD HYGIENE

#### Fifty-fourth Session

#### Nairobi, Kenya

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### PROPOSED DRAFT REVISION ON THE *GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF PATHOGENIC VIBRIO SPECIES IN SEAFOOD (CXG 73-2010)*

(Prepared by the Electronic Working Group chaired by Japan and co-chaired by Chile<sup>1</sup>)

Codex Members and Observers wishing to submit comments on the discussion paper should do so as instructed in CL 2024/09/FH available on the Codex webpage/Circular Letters 2024: <https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/pt/>

#### Background

1. At the 53<sup>rd</sup> Session of the Codex Committee on Food Hygiene (CCFH53),<sup>2</sup> Japan and New Zealand introduced a discussion paper and project document on revising the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood (CXG 73-2010)* aiming to provide updated risk management options based on the latest scientific advice provided by FAO/WHO since their adoption in 2010.
2. CCFH53 agreed to start this new work taking into consideration the factors relevant to the control of *V. parahaemolyticus* and *V. vulnificus* in seafood such as:
  - microbiological monitoring methods, particularly molecular-based approaches;
  - recently available scientific data, in particular information on new pathogenic strains and their geographical spread and clinical incidence;
  - methods for the detection and characterization of vibrios;
  - remote sensing-based techniques to measure variables such as temperature and salinity, climate change; and
  - practical interventions that can be used to reduce vibriosis risks associated with the consumption of seafood, including preharvest intervention e.g. relaying, interventions at harvest (such as reduced cooling times), and post-harvest treatments, e.g., high pressure processing, freezing and pasteurization etc.
3. CCFH53 also agreed to establish an electronic working group (EWG) and hold a potential virtual meeting of the EWG, chaired by Japan and co-chaired by Chile, working in English, to prepare, subject to approval of the Commission, the proposed draft revised guidelines for circulation for comments at Step 3 and consideration at CCFH54.

<sup>1</sup> Members of the EWG included Argentina, Australia, Brazil, Canada, Denmark, France, Iran, Republic of Korea, Japan, Mexico, Morocco, Norway, Saudi Arabia, Singapore, Spain, Thailand, the United Kingdom, the United States of America and Uruguay

<sup>2</sup> REP23/FH, paras. 132 and 147

4. The new work was approved by the 46<sup>th</sup> Session of the Codex Alimentarius Commission (27 November-2 December 2023).<sup>3</sup>

### Electronic working group

5. An invitation was sent to all Codex Members and Observers to participate in the EWG. Nineteen Codex Members and FAO registered for the EWG<sup>1</sup>. The EWG work was conducted using the Codex online platform.

6. The Chair and co-Chair (referred to as the Chairs) prepared the draft of the revised Guidelines based on the discussion before and during CCFH53<sup>4</sup> as well as some specific questions asking for further inputs from EWG members, e.g., *Vibrio* species to be covered, major pathogenic *Vibrio* spp., examples of relevant seafood, etc. The draft Guidelines were posted on the Codex online platform for comments (12 June-10 August 2023), and written comments were received from seventeen members.

7. The draft was generally well received and there were few points of conflict. The Chairs have redrafted the Guidelines (Appendix I) taking into account to the extent possible the comments from EWG members and added explanatory notes on Chairs' proposals. The main points of discussion were as follows:

- Most members considered that nine *Vibrio* species, which could cause food-borne illness, should be covered in this document, of the eleven species that the Chairs proposed as pathogenic to humans. Some members suggested adding *V. mimicus* as it also causes food-borne illness. The chairs have proposed inclusion of ten *Vibrio* spp. based on the comments received. (Paragraph 2 of Appendix I).
- Most members agreed to maintain the statement that the pathogenic mechanisms of *V. vulnificus* have not been clearly explained. Some members suggested that all strains of *V. vulnificus* should be considered "potentially virulent". This statement regarding *V. vulnificus* has therefore been retained with the addition of a recommendation that all strains of *V. vulnificus* be considered potentially virulent and the risk managed accordingly. (Paragraph 4 of Appendix I).
- Most members agreed to maintain reference to *V. parahaemolyticus*, *V. vulnificus* and *V. cholerae* as the "major pathogenic" *Vibrio* species. Some members proposed to include an explanation of what is meant by "major pathogenic", and some explanatory text has been added accordingly. (Paragraph 6 of Appendix I).
- Most members agreed to still include examples of seafood associated with *V. parahaemolyticus* illness. Some members proposed the modification of the list of seafood. The examples have been retained but have been categorized into finfish, bivalve molluscs, crustaceans, cephalopods, echinoderms and seaweed. (Paragraph 12 of Appendix I).
- Based on information provided by members and from the literature, additional text has been added on *V. cholera* highlighting the association observed between continuous changes in environmental and climate-related factors, particularly water temperature and salinity, and cholera infections. (Paragraph 16 of Appendix I),
- Some members suggested that for detailed information on the virulence of *V. vulnificus* there should simply be a reference to the JEMRA report. Some additional clarity has been provided on the virulence of *V. vulnificus* with reference to the JEMRA report for more details. (Paragraph 17 of Appendix I).
- Some members agreed to keep the section on the FAO/WHO risk assessments. Other members suggested that the risk assessment should be referenced, but information should be simplified and could be included in the "Scope" as part of the alignment with the *General Principles of Food Hygiene* (GPFH), revised in 2022. (Paragraph 21 and 22 of Appendix I). It has been retained unchanged for now pending the discussions on alignment with CXG1-1969.
- Additional information has been provided on food processing practices to minimize the growth and reduce the level of *Vibrio* spp. in seafood. (Paragraph 72 and 73 of Appendix I).
- Some members supported retaining the three subsections for water, other members suggested they can be combined into one section with reference to Section 13.3 of the GPFH and Annex II on Fishery Products of the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG100-2023).

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<sup>3</sup> REP23/CAC, para. 32ii

<sup>4</sup> CX/FH 22/53/7, CX/FH 22/53/7 Add.1, CCFH53/CRD10, REP23/FH Appendix VI

Some members suggested waiting until Annex II on Fishery Products has been further elaborated. The three sub-sections have been retained for now. (Paragraph 83-86 of Appendix I.)

- A new section on laboratory analysis criteria for detection and enumeration of *Vibrio* spp. has been added.
  - The annexes have also been updated based on the information provided in the JEMRA reports.
8. With regard to the alignment with CXC 1-1969<sup>5</sup>, the Chairs decided to simply update the references to GPFH (section numbers) in accordance with the latest version of GPFH until the report of the working group on alignment would be made available.

### **Recommendations**

9. It is recommended that CCFH54 consider the Proposed Draft Revised Guidelines on the *Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* as presented in Appendix I with a view to progress it through the Codex Step Process.

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<sup>5</sup> REP23/FH, para. 150

## Appendix I

**PROPOSED DRAFT REVISION TO GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF PATHOGENIC *VIBRIO* SPECIES IN SEAFOOD (CXG 73-2010)**

**(Deleted text is in strikethrough and proposed text is underlined)**

**1. INTRODUCTION**

1. ~~During the last few years~~ There has been an increase in reported outbreaks in some areas and cases of foodborne disease attributed to pathogenic *Vibrio* species. As a result, there have been several instances where the presence of pathogenic *Vibrio* spp. in seafood has led to a disruption in international trade. This has been particularly evident with *Vibrio parahaemolyticus* where there has been a series of pandemic outbreaks due to the consumption of seafood, and its emergence has been observed in regions of the world where it was previously unreported. A number of *Vibrio* species are increasingly being recognized as potential human pathogens. The food safety concerns associated with these microorganisms have led to the need for specific guidance on potential risk management strategies for their control. These risk management strategies need to be developed and implemented based on the specific harvest area site characteristics such as water and ambient temperatures, salinity and water sources flowing into a harvest area. The ingestion of a large number of viable cells was previously thought to be needed for pathogenic *Vibrio* spp. to survive the acidic environment of the stomach and establish an infection in the gastrointestinal tract. With the emergence of highly pathogenic strains, there is now recognition that the dose-response may be much lower depending on the individual strains and virulence profiles.

**General Characteristics of Pathogenic *Vibrio* spp. associated with foodborne illness**

**Question to EWG members 1:**

Chairs consider at least eleven species pathogenic to humans, i.e., 1) *Vibrio alginolyticus*, 2) *Vibrio cholerae* O1, 3) *Vibrio cholerae* non O1, 4) *Vibrio fluvialis*, 5) *Vibrio furnissii*, 6) *Vibrio hollisae*, 7) *Vibrio metschnikovii*, 8) *Vibrio parahaemolyticus*, 9) *Vibrio vulnificus*, 10) *Vibrio carchariae*, 11) *Vibrio cincinnatiensis*. Nine of which can cause food-borne illness. We consider that, among the list above, 10) *Vibrio carchariae*, and 11) *Vibrio cincinnatiensis* do not cause GI infection, therefore they do not cause foodborne illness and should not be included in the new draft. Is it ok to just include *Vibrio* species from number 1 to 9?

Most members agreed to include nine *Vibrio* species that cause food-borne illness in this guideline. Some members suggested they should be listed in the order with the three major pathogenic species first. One member suggested that *Vibrio cholerae* could be defined as meaning the cholerae and non-cholerae strains that cause foodborne illness in the context of this document. Some members suggested that *V. mimicus* should be added or that *V. carchariae* and *V. cincinnatiensis* could be indicated as a cause of GI infection.

Chairs proposed ten *Vibrio* species, including *V. mimicus* that could also cause food-borne illness, to be listed with the three major pathogenic species first.

**Question to EWG members 2:**

With regards to the second sentence of para 4, even though number of studies have been carried out to investigate the pathogenic mechanisms of *V. vulnificus*, Chairs consider the statement of the 2nd sentence is still valid and therefore all strains should be considered virulent. Do you agree to maintain the second statement as it is proposed by the Chairs? If not, please provide new suggestion with supporting data or reference in support.

Most members agreed to maintain the second statement of paragraph 4. One member has concerns about major virulence factors of *V. parahaemolyticus*. Some members suggested that all strain of *V. vulnificus* should be considered "potentially virulent".

Chairs proposed to maintain the statement that the pathogenic mechanisms of *V. vulnificus* have not been clearly explained. Chairs also proposed that it should be recommended to implement measures to mitigate the risk assuming that all strains of *V. vulnificus* are potentially virulent.

**Question to EWG members 3:**

In this draft, Chairs believe that *V. parahaemolyticus*, *V. vulnificus*, and *V. cholerae* are the major pathogenic species of *Vibrio*. Do you agree to maintain calling these 3 species as the “major pathogenic” in the new draft?

Most members agreed to maintain reference to above 3 species as the “major pathogenic”. Some members proposed the explanations for “major pathogenic”.

Chairs proposed to maintain the statement that *V. parahaemolyticus*, *V. vulnificus* and *V. cholerae* are the “major pathogenic” strains, since these three species are recognized as the major pathogen of the *Vibrio* spp. and cause either the most illness and/or the severe health outcomes.

2. The genus *Vibrio* contains at least ~~eleven~~twelve species pathogenic to humans, ~~nineteen~~ of which can cause food-borne illness. The majority of food-borne illness is caused by *V. parahaemolyticus*, choleraogenic *Vibrio cholerae* (O1, O139), or *Vibrio vulnificus*. *V. parahaemolyticus* and *V. cholerae* are mainly isolated from gastroenteritis cases that are attributable to the consumption of contaminated food (both species) or from the intake of contaminated water (*V. cholerae*). In contrast, *V. vulnificus* is primarily reported from extraintestinal infections (e.g. septicaemia, wounds, etc.) and primary septicaemia due to *V. vulnificus* infection is often associated with consumption of seafood. *V. alginolyticus*, non-choleraogenic *V. cholerae*, *V. fluvialis*, *V. furnissii*, *V. hollisae* (re-classified as *Grimontia hollisae*), *V. metschnikovii* and *V. mimicus* can also cause food-borne illness.
3. In tropical and temperate regions, these species of *Vibrio* occur naturally in marine, coastal and estuarine (brackish) environments and are most abundant in estuaries. Pathogenic *Vibrio* spp., in particular *V. cholerae*, can also be recovered from freshwater reaches of estuaries, where it can ~~also~~ be introduced by faecal contamination. *V. cholerae*, unlike most other *Vibrio* species, can survive in freshwater environments.
4. It is now possible to differentiate environmental strains of *V. cholerae* and *V. parahaemolyticus* between virulent and avirulent strains based on their ability to produce ~~their~~ major virulence factors. The pathogenic mechanisms of *V. vulnificus* have not been clearly ~~elucidated~~ explained, and its virulence appears to be multi-factorial and is not well understood, and therefore ~~all strains are considered virulent~~ it is recommended to implement measures to mitigate the risk assuming that all strains are potentially virulent.
5. The following are important characteristics common to all *Vibrio* spp. *Vibrio* spp. are sensitive to low pH but can grow well at higher pHs, and thus infections caused by *Vibrio* spp. are frequently associated with low-acid foods. ~~In addition, it was previously thought that the ingestion of a large number of viable cells is needed for pathogenic *Vibrio* spp. to survive the acidic environment of transition through the stomach and establish an infection. Cooking of food products readily inactivates *Vibrio* spp. even in highly contaminated products. Hygienic practices used with all food-borne pathogens will in general control the growth of pathogenic *Vibrio* spp. However, new and highly pathogenic strains have emerged with a significantly lower infectious dose with 50% probability (ID<sub>50</sub>). These strains also exhibited different growth characteristics compared to the *V. parahaemolyticus* strains used in the previous risk assessments<sup>1</sup>.~~
6. There are, however, characteristics specific to each of the three major pathogenic species of *Vibrio* responsible for the majority of human infections, and therefore of country's highest public health interest, that require attention as described below.

*Vibrio parahaemolyticus***Question to EWG members 4:**

Chairs want to ask views of EWG members whether examples of seafood which are associated with *V. parahaemolyticus* illness should be included in the para 12?

Most members agreed to include examples of seafood associated with *V. parahaemolyticus* illness. Some members proposed the modification for the list of seafood.

Chairs proposed that the examples of seafood associated with *V. parahaemolyticus* illness are still included with categorical modification.

7. *V. parahaemolyticus* is considered to be part of the autochthonous microflora in the estuarine and coastal environments in tropical to temperate zones. Seawater temperature has been reported as one of the principal

<sup>1</sup> FAO and WHO, 2020, Advances in science and risk assessment tools for *Vibrio parahaemolyticus* and *V. vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 35) (Section 3.2).

environmental factors increasing the abundance of *V. parahaemolyticus* in many areas of the world. The positive effect of warming seawater temperature in spring and summer of temperate zone on the abundance of *V. parahaemolyticus* has been observed in temperate regions with low and moderate temperatures. It is also found that positive correlation for temperature to *Vibrio* levels in tropical areas where there are high fluctuations, such as macro-tidal harbours and near tidal creeks. While *V. parahaemolyticus* typically is undetectable in seawater at 10°C or lower, it can be cultured from sediments throughout the year at temperatures as low as 1°C. In temperate zones, the life cycle consists of a phase of survival in winter in sediments and a phase of release with the zooplankton when the temperature of the water increases up to 14 - 19 °C. *V. parahaemolyticus* is characterized by its rapid growth in the water under favourable conditions<sup>2</sup>.

8. The vast majority of strains isolated from patients with diarrhoea produce a thermostable direct hemolysin (TDH). 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. Additionally, strains that produce a TDH-related hemolysin (TRH) encoded by the *trh* gene should also be regarded as pathogenic. Although detection of *tdh*- *trh*- strains among clinical strains has been the source of debate on the pathogenic roles of *tdh* and *trh* genes, and the mode of pathogenicity is not fully understood, these genes are still the most well defined markers of pathogenicity.

8-9. Symptoms of *V. parahaemolyticus* infections include explosive watery diarrhoea (sometimes watery and bloody), nausea, vomiting, abdominal cramps and, less frequently, headache, fever and chills. Most cases are self-limiting, however, severe cases of gastroenteritis requiring hospitalization have been reported. Virulent strains are seldom detected in the environment or in foods. A low proportion of environmental or food strains, including seafoods, contain known virulence markers, while virulent strains are detected as major strains from faeces of infected patients. Given this limitation in testing, non detection of virulent strains in the environment or in food does not mean there is no risk to the consumer.

9-10. *V. parahaemolyticus* was first identified as a foodborne pathogen in Japan in the 1950s. By the late 1960s and early 1970s *V. parahaemolyticus* was recognized as a cause of diarrhoeal disease worldwide. A new *V. parahaemolyticus* clone of O3:K6 serotype emerged in Calcutta in 1996. This clone, including its sero-variants, has spread throughout Asia and to the USA, elevating the status of the spread of *V. parahaemolyticus* infection to pandemic. In Asia, *V. parahaemolyticus* is a common cause of foodborne disease. In general, the outbreaks are small in scale, involving fewer than 10 cases, but can occur frequently especially in the months with high water temperature. This pandemic *V. parahaemolyticus* has now spread to at least 5 continents. There is a suggestion that ballast discharge may be a major mechanism for global spread of pandemic *V. parahaemolyticus*, but a possibility of export/import seafood-mediated international spread cannot be ruled out. While the pandemic clone ST3 has now spread, other pandemic variants have emerged, such as ST36, ST43 and ST636 and have spread rapidly and globally. In addition, most countries have seen an increase in *V. parahaemolyticus* cases associated with a large genetic diversity of *V. parahaemolyticus* strains. Some genetic modifications noted in the pandemic strains include altered nucleotide bases in the *toxR* gene an open reading frame (ORF8) in a lysogenic filamentous phage and gene sequences in 16-kb or 23-kb chromosomal inserts specific to the pandemic clone<sup>3</sup>.

10-11. From the point of controlling seafood-borne *V. parahaemolyticus* illnesses, harvest is probably the most critical stage, since it is from this point onwards that individuals can actually implement measures to control *V. parahaemolyticus* can be implemented. Additionally, the pre-harvest control for aquaculture is also important for managing the risks. It is also important to consider control measures at post-harvest, during processing, wet storage and associated transport and packaging operations, and during retail, in particular setting appropriate time-temperature requirements of these control measures, especially time-temperature controls on post-harvest refrigeration<sup>4</sup>.

11-12. Foods associated with illnesses due to consumption of *V. parahaemolyticus* include for example crayfish, lobster, shrimp, fish-balls, boiled surf clams, jack-knife clams, fried mackerel, mussel, tuna, seafood salad, raw oysters, clams, steamed/boiled crabmeat, scallops, squid, sea urchin, mysids, and sardines finfish (such as mackerel, tuna), crustaceans (such as prawns, crabmeat), bivalve molluscs (such as oysters, scallops), cephalopods (such as squid), echinoderms (such as sea urchin) and seaweed (such as sea grapes). These

<sup>2</sup> FAO and WHO, 2020, Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20) (Section 3.1).

<sup>3</sup> FAO and WHO, 2020, Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20) (Section 2.1).

<sup>4</sup> FAO and WHO, 2016, Selection and application of methods for the detection and enumeration of human-pathogenic halophilic *Vibrio* spp. in seafood (Microbiological Risk Assessment series, No. 22) (Section 2.2).

products include both raw and partially treated<sup>5</sup> and ~~thoroughly~~-treated seafood products that have been substantially recontaminated through contaminated utensils, water and ice, hands, coming into contact with uncooked contaminated seafood, etc.

#### *Vibrio cholerae*

~~42-13.~~ *V. cholerae* is indigenous to fresh and brackish water environments in tropical, subtropical and temperate areas worldwide. Over 200 O serogroups have been ~~established~~ identified for *V. cholerae*. Strains belonging to O1 and O139 serotypes generally possess the *ctx* gene, and produce which encodes the cholera toxin (CT) and are responsible for epidemic cholera. Epidemic cholera is confined mainly to developing countries with warm climates. ~~Cholera is exclusively a human disease and human faeces from infected individuals are the primary source of infection in cholera epidemics.~~ Contamination of food production environments (including aquaculture ponds) by human faeces can indirectly introduce choleraogenic *V. cholerae* into foods. The concentration of free-living choleraogenic *V. cholerae* in the natural aquatic environment is low, but *V. cholerae* is known to attach and multiply on zooplankton such as copepods.

~~43-14.~~ Seven pandemics of cholera have been recorded since 1823. The first six pandemics were caused by the classical biotype strains, whereas the seventh pandemic that started in 1961 and has lasted until now, is due to *V. cholerae* O1 biotype El Tor strains. Epidemic cholera can be ~~introduced from abroad~~ spread by infected travelers, imported foods and through the ballast water of cargo ships. Detection frequencies of choleraogenic strains of *V. cholerae* from legally imported foods ~~were are~~ very low and ~~they~~ have seldom been implicated in cholera outbreaks. *V. cholerae* O139 has been responsible for the outbreaks of cholera ~~in the Bengal area~~ since 1992, and this bacterium has spread to other parts of the world ~~through travellers~~. The choleraogenic strains of *V. cholerae* ~~that spread to different parts of the world~~ may persist, and some factors may trigger an epidemic in the newly established environment.

~~44-15.~~ Some strains belonging to the O serogroups other than O1 and O139 (referred as non-O1/non-O139) can cause food-borne diarrhoea that is milder than cholera. Recent years have seen an increase in infections associated with these particular strains, with the first outbreak reported in 2018 from the consumption of herring roe.

~~45-16.~~ Outbreaks of food-borne cholera have been noted quite often in the past 30 years; seafood, including bivalve molluscs, crustaceans, and finfish, and surface water contact and seafood handling are most often incriminated in linked to food-borne cholera cases in many countries. While shrimp has historically been a concern for transmission of choleraogenic *V. cholerae* in international trade, it has not been linked to outbreaks and it is rarely found in shrimp in international trade. A strong association has been observed between continuous changes in environmental and climate-related factors, particularly water temperature and salinity, and cholera infections. However, there are several complex and multifaceted epidemiological factors that are often associated with these factors.

#### *Vibrio vulnificus*

##### **Question to EWG members 5:**

After reviewing three JEMRA reports, Chairs could not determine the needs of revision of the 2<sup>nd</sup> sentence of paragraph 17 (underlined). If any members have additional information which should be revised/added in this sentence, please provide any suggestions with supporting data/reference. Chairs added the 4-6 sentences based on JEMRA report 35 and 20. If any members have additional information which should be revised/added in these sentences, please provide any suggestions of change with supporting data/reference.

Some members suggested that detailed information on the virulence of *V. vulnificus* should simply be referred to the JEMRA report. One member provided recent studies of virulence factors.

*Chairs proposed to modify the statement relating to the virulence factors of *V. vulnificus*, but detailed information on the virulence factor of *V. vulnificus* should not be included, just refer to the JEMRA report.*

##### **Question to EWG members 6:**

After reviewing three JEMRA reports, Chairs could not find any relevant additional information on *V. cholerae*. If any members have additional information which should be added in these paragraphs, please provide any

<sup>5</sup> "treated" means any vibriocidal treatment (e.g., heat treatment, high pressure.). Refer to Section 2.3 (definition for "partially treated").

suggestions of change with supporting data/reference.

Some members provided relevant additional information on *V. cholerae*.

It has been reported that there is a correlation between changes in water temperature and salinity, which are closely related to climate change, and an increase in cholera related illness. Chairs propose that the following sentences be added to paragraph 16:

“A strong association has been observed between continuous changes in environmental and climate-related factors, particularly water temperature and salinity, and cholera infections. However, there are several complex and multifaceted epidemiological factors that are often associated with these factors.”

~~16-17.~~ *V. vulnificus* can occasionally cause mild gastroenteritis in healthy individuals, but it can cause primary septicaemia in individuals with chronic pre-existing conditions, especially liver disease or alcoholism, diabetes, haemochromatosis and HIV/AIDS, following consumption of raw or partially cooked bivalve molluscs and other seafood. This is a serious, often fatal, disease with one of the highest fatality rates of any known foodborne bacterial pathogen. ~~The ability to acquire iron is considered essential for virulence expression of *V. vulnificus*, but a virulence determinant has not been established and, therefore, it is not clear whether only a particular group of the strains are virulent.~~ The host factor (underlying chronic diseases) appears to be the primary determinant for *V. vulnificus* infection. The dose response for humans is not known. Incubation period ranges from 7 hours to several days, with the average being ~~26~~ 24 hours. ~~The dose response for humans is not known.~~ Some virulence factors have been identified, however definitive virulence determinants have not yet been established, therefore, it is not clear whether all strains are capable of causing disease. The ability to acquire iron is considered essential for virulence expression of *V. vulnificus*, and other relevant virulence factors include the capsule and the MARTX toxin (Multi Functional Autoprocessing Repeat in Toxin), also known as RtxA1 toxin, the virulence correlated gene (*vcg*) and the pilus-type IV- related gene (*pilF*)<sup>6,7</sup>.

17. — Of the three biotypes of *V. vulnificus*, biotype 1 is generally considered to be responsible for most seafood-associated human infection and thus the term *V. vulnificus* refers to biotype 1 in this Code.

18. Foodborne illness from *V. vulnificus* is characterized by sporadic cases ~~and an outbreak has never been reported.~~ However, outbreaks have occurred. *V. vulnificus* has been isolated from oysters, other bivalve molluscs, and other seafood worldwide.

19. Seawater temperature has been reported as one of the principal environmental factors increasing the abundance of *V. vulnificus* in many areas of the world. Studies in 2008 have involved inoculation of live oysters with *V. vulnificus* and have shown that growth is possible in oysters at least in the temperature range 13-30°C.

~~19-20.~~ The densities of *V. vulnificus* are high in oysters at harvest when water temperatures exceed 20°C in areas where *V. vulnificus* is endemic; *V. vulnificus* multiplies in oysters at a temperature higher than 13°C. The salinity optimum for *V. vulnificus* appears to vary considerably from area to area, but highest numbers are usually found at intermediate salinities of 5 to 25 g/l (ppt: parts per thousand). Relaying oysters to high salinity waters (>32 g/l (ppt: parts per thousand) was shown to reduce *V. vulnificus* numbers by 3–4 logs (<10 per g) within 2 weeks. According to the data available, the salinity in the coastal environment has played an important role in *V. vulnificus* incidence and population levels. Evidence shows that salinity is negatively correlated with *V. vulnificus* concentrations<sup>8</sup>. *V. vulnificus* is affected by salinity, where levels lower than 1 ppt (parts per thousand) or higher than 30 ppt will not allow its growth. Flow-through depuration with higher salinity levels (>30 ppt) may be used to reduce or eliminate *V. vulnificus* in oysters. High-salinity field or high salinity recirculating aquaculture (>30 ppt) may effectively reduce *V. vulnificus* within 21 to 30 days, although reductions vary.

FAO/WHO Risk Assessments

**Question to EWG members 7:**

Should we keep this section (FAO/WHO risk assessments) in this document?

Some members agreed to keep FAO/WHO risk assessments section. Some members suggested that risk

<sup>6</sup> FAO and WHO, 2020, Advances in science and risk assessment tools for *Vibrio parahaemolyticus* and *V. vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 35) (Section 1.3).

<sup>7</sup> FAO and WHO, 2020, Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20) (Section 2.2).

<sup>8</sup> S.M. Rasz et. al. *Vibrio parahaemolyticus* and *Vibrio vulnificus* in South America: water, seafood and human infections. *Journal of Applied Microbiology* 121, 1201-1222, 2016



assessment should be referenced, but information should be simplified and could be included in 'Scope' when aligning with the latest version of CXC1-1969.

Chairs proposed that the structure of this section remain unchanged at this time and to await the UK's proposals for structural alignment with the latest version of CXC1-1969.

~~20-21.~~ A number of FAO/WHO risk assessments have been conducted. The first ones were on *Vibrio vulnificus* in raw oysters and choleraogenic *Vibrio cholerae* O1 and O139 in warm water shrimp in international trade ~~have been which were~~ published in (2005)<sup>9,10</sup>. Additional risk assessments on *Vibrio parahaemolyticus* in raw oysters, in raw and undercooked finfish and in *Anadara granosa* (bloody clams) have been completed and published in 2011<sup>11</sup>. ~~These risk assessments constitute the basis of this Code.~~ Finally, the FAO/WHO convened an Expert Meeting on 13-17 September 2010, and a meeting report has been recently published in 2020<sup>12</sup>.

22. FAO/WHO convened an Expert Meeting in 2011 that produced a Guidance document on methods for detection and enumeration of *V. parahaemolyticus* and *V. vulnificus*, including performance characteristics of the methods and the application of these methods for different end uses, ranging from harvest area monitoring, postharvest process verification, end product testing, outbreak investigation and growth studies<sup>13</sup>. The experts reviewed and updated the existing risk assessment models/tools on *V. parahaemolyticus* and *V. vulnificus* that could be used to inform a range of risk management questions in a number of geographical different regions. Experts agreed that the basic information of pathogenicity (including virulence markers), major factors relevant to the survival of *V. parahaemolyticus* and *V. vulnificus* (water temperature and salinity) and other main components used in the original models have not been changed; however, there are several new models and methods that have become available in the last decade. These risk assessments constitute the basis of this Code.

## 2. SECTION I – OBJECTIVES

24-23. These Guidelines provide guidance on control of pathogenic *Vibrio* spp. in seafood, with a view towards protecting the health of consumers and ensuring fair practices in food trade. The primary purpose of these Guidelines is to highlight the key control measures that can be used to minimize the likelihood of illness arising from the presence of pathogenic *Vibrio* spp. in seafood. These Guidelines ~~also~~ provide information that will be of interest to the food industry, consumers, regulators and other interested parties.

## 3. SECTION II – SCOPE, USE AND DEFINITION

### 2.1 Scope

~~22-24.~~ These Guidelines cover seafood that is marketed and may be consumed in a live, raw, chilled/frozen, partially treated, or thoroughly treated state. It is applicable ~~to~~ across the whole food chain from primary production to ~~final~~ consumption. Bivalve molluscs are covered more thoroughly in the Annex, which is supplemental to these Guidelines.

~~23-25.~~ As major causative agents of foodborne bacterial illnesses associated with seafood, the target microbiological hazards of these Guidelines are three pathogenic *Vibrio* spp. (*V. parahaemolyticus*, *V. vulnificus* and ~~choleraogenic~~ *V. cholerae*). The control measures described in these Guidelines may be applicable to other pathogenic *Vibrio* spp.

### 2.2 Use of the document

24-26. These Guidelines are supplemental to, and should be used in conjunction with, the *General Principles of Food Hygiene* (CXC 1-1969) and the *Code of Practice for Fish and Fishery Products* (CXC 52-2003). The application of these Guidelines by countries may require modifications and amendments, taking into account regional differences such as the prevalence of pathogenic *Vibrio* spp., water temperatures and salinity.

<sup>9</sup> FAO and WHO, 2005, Risk assessment of *Vibrio vulnificus* in raw oysters (Microbiological Risk Assessment Series, No.8).

<sup>10</sup> FAO and WHO, 2005, Risk assessment of choleraogenic *Vibrio cholerae* O1 and O139 in warm-water shrimp in international trade (Microbiological Risk Assessment Series, No.9).

<sup>11</sup> FAO and WHO, 2011, Risk assessment of *Vibrio parahaemolyticus* in seafood (Microbiological Risk Assessment Series, No.16).

<sup>12</sup> FAO and WHO, 2020, Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20).

<sup>13</sup> FAO and WHO, 2016, Selection and application of methods for the detection and enumeration of human-pathogenic halophilic *Vibrio* spp. in seafood (Microbiological Risk Assessment series, No. 22).

## 2.3 Definition

~~25-27.~~ For the purpose of these Guidelines, the following definitions apply:

Definitions of the *General Principles of Food Hygiene* (CXC 1-1969) and the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

Refrigeration: The lowering of product temperature to limit microbial activity.

Seafood: Fish, shellfish and other aquatic invertebrates from marine and fresh water sources and their products which are intended for human consumption.

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 sensory characteristics of the raw product are lost.~~

Thoroughly treated: Any treatment intended to eliminate *Vibrio* spp. in seafood.

Clean water: ~~means w~~Water that does not meet the criteria for potable water but from any source where harmful microbiological contamination, substances and/or toxic plankton are not present in such quantities that may affect the safety of fish, shellfish and their products intended for human consumption.

*NOTE: The definition of "Clean water" was modified with reference to the definition in the CXC 52-2003.*

## 4. SECTION III - PRIMARY PRODUCTION

### 3.1 ~~Environmental hygiene control~~

~~26-28.~~ Refer to Section ~~3.48.1~~ of the *General Principles of Food Hygiene* (CXC 1-1969). In addition:

~~27-29.~~ Generally, pre-harvest controls are more applicable to bivalve molluscs than to other seafood (e.g. open-sea harvested fish). Where relevant to other seafood, pre-harvest controls should be considered for areas where the likelihood of introduction of pathogenic *Vibrio* spp. is significant and can be controlled.

~~28-30.~~ Temperature, time and salinity should be considered for controlling pathogenic *Vibrio* spp. in seafood. Where applicable, specific temperature or salinity levels that can be used as control measures should be identified based on epidemiological and exposure studies as well as monitoring of pre-harvest pathogenic *Vibrio* levels.

~~29-31.~~ For monitoring bivalve molluscs, at harvest, refer to the Annex to ~~this~~ these Guideline.

~~30-32.~~ For seafood grown in coastal localities, especially in cholera-endemic areas, care should be taken to avoid contamination harvest of seafood contaminated with faecal cholerae *V. cholerae*. This includes contamination caused by significant environmental impacts such as flooding, unregulated discharges from sewage spills.

### 3.2 Hygienic production of seafood sources

~~34-33.~~ Refer to Section ~~3.28.2~~ of the *General Principles of Food Hygiene* (CXC 1-1969).

#### 3.2 Handling, storage and transport

~~32-34.~~ For the storage and handling of seafood aboard fishing vessels, portable or clean water should be used for seafood intended to be eaten raw or partially treated, and for preparing ~~ice for such use~~. The use of sea water taken from near the seashore or from a drainage outlet or river contaminated with sewage should be avoided. Seafood should be held at temperatures that minimize and/or prevent the growth of pathogenic *Vibrio* spp. after harvest, for example, in an ice-water slurry, ice or refrigeration on fishing vessels and at harvest sites. The delay between harvest and refrigeration should be as short as ~~possible~~ practicable.

~~33-35.~~ For on-boat cooked (boiled, blanched) seafood products, ice and/or refrigeration should be used to facilitate the rapid cooling. Ice made from clean water should be used to minimize cross-contamination.

~~34-36.~~ For the storage of live seafood products, clean water should be used to minimize ~~initial cross~~ contamination from the water.

~~35-37.~~ When the product is required to be washed, whether onboard the boat or at port, clean water should be used.

~~36-38.~~ During on-land transportation from the landing port to the on-shore market and/or processing establishments, in order to minimize and/or prevent the growth of pathogenic *Vibrio* spp. in seafood, the time elapsed between harvest and refrigeration or freezing is critical and should be minimized. Ice can be used efficiently to keep seafood ~~under refrigeration~~ chilled during transportation and sale. Live fish and shellfish should

be transported at the lowest temperature tolerable for the species. Covered containers should be used for transport to prevent contamination.

### 3.4 Cleaning, maintenance and personnel hygiene at primary production

~~37-39.~~ Refer to Section ~~3.48.4~~ of the *General Principles of Food Hygiene* (CXC 1-1969) and the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023).

~~38-40.~~ Refer to Section ~~7.112.1~~ of the *General Principles of Food Hygiene* (CXC 1-1969). A carrier who is excreting ~~cholerae~~ *V. cholerae* should not handle seafood or ice for the storage of seafood, which may result in the contamination of the seafood with cholerae *V. cholerae*.

## 5. **SECTION IV - ESTABLISHMENT: DESIGN ~~AND~~ OF FACILITIES ~~AND~~ EQUIPMENT**

### Objectives

~~39-41.~~ Equipment and facilities should be designed, constructed and laid out to minimize the potential for cross-contamination and recontamination of seafood with pathogenic *Vibrio* spp.

#### 4.1 Location and structure

~~40-42.~~ Refer to Section ~~3.19.1~~ of the *General Principles of Food Hygiene* (CXC 1-1969).

##### 4.1.1 Location of Establishments

~~41-43.~~ Refer to Section ~~3.1.19.1.1~~ of the *General Principles of Food Hygiene* (CXC 1-1969).

##### 4.1.2 Equipment Design and layout of food establishment

~~42-44.~~ Refer to Section ~~4.1.29.1.2~~ of the *General Principles of Food Hygiene* (CXC 1-1969).

#### 4.2 Premises and rooms

##### 4.2.1 Design and layout

~~43-45.~~ Refer to Section ~~4.2.19.1.2~~ of the *General Principles of Food Hygiene* (CXC 1-1969).

~~44-46.~~ Whenever feasible, premises and rooms should be designed to keep raw material areas separated from finished seafood product areas. This can be accomplished in a number of ways, including linear product flow (raw materials to finished products) or physical partitions.

~~45-47.~~ Where feasible, the washing room for food handling equipment used ~~in the~~ for finished product manufacturing should be physically segregated from the finished product processing area.

##### 4.2.2 Internal structures and fittings

~~46-48.~~ Refer to Section ~~4.2.29.1.3~~ of the *General Principles of Food Hygiene* (CXC 1-1969).

##### 4.2.3 Temporary/mobile premises and vending machines

~~47-49.~~ Refer to Section ~~4.2.39.1.4~~ of the *General Principles of Food Hygiene* (CXC 1-1969).

#### 4.3 Equipment

##### 4.3.1 General

~~48-50.~~ Refer to Section ~~3.39.3.1~~ of the *General Principles of Food Hygiene* (CXC 1-1969).

##### 4.3.2 Food control and monitoring equipment

~~49-51.~~ Refer to Section ~~3.3.29.3.2~~ of the *General Principles of Food Hygiene* (CXC 1-1969).

~~50-52.~~ The chill room should be equipped with a calibrated thermometer.

##### ~~4.3.3 Containers for waste and inedible substances~~

~~51.~~ Refer to Section ~~4.3.3~~ of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

#### 4.4 Facilities

##### 4.4.1 General

~~52-53.~~ Refer to Section ~~3-29.2~~ of the *General Principles of Food Hygiene* (CXC 1-1969).

~~53-54.~~ Adequate facilities should be provided for the handling and washing of products.

~~54-55.~~ Suitable and adequate facilities should be provided for storage and/or production of ice.

#### 4.4.1 Water supply

~~55.~~ An adequate supply of clean water and/or potable water should be available for handling and washing of seafood to limit the load of pathogenic *Vibrio* spp.

#### 4.4.2 Drainage and waste disposal

~~56.~~ Refer to Section 9.2.1 of the *General Principles of Food Hygiene* (CXC 1-1969).

~~56-57.~~ All drainage and waste lines should be capable of coping with peak demands.

~~57-58.~~ Accumulation of solid, semi-solid or liquid wastes should be minimized to prevent contamination, because pathogenic *Vibrio* spp. may grow rapidly in these wastes under certain ~~circumstances~~ conditions.

~~58-59.~~ Separate and adequate facilities should be provided to prevent contamination by offal and waste material.

#### 4.4.3 Cleaning facilities

~~59-60.~~ Refer to Section ~~3-2-29.2.2~~ of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.2.1 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

#### 4.4.4 Personnel hygiene facilities and toilets

~~60-61.~~ Refer to Section ~~3-2-39.2.3~~ of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.5.1 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

#### 4.4.5 Temperature control

~~61-62.~~ Refer to Section ~~3-2-49.2.4~~ of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 4.1 of *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

~~62-63.~~ The *Code of Practice for Fish and Fishery Products* indicates maintaining the product at temperature as close to 0°C as possible. For pathogenic *Vibrio* spp., a temperature of ~~40~~ 5°C or lower is adequate to limit growth. In this Code, ~~40~~ 5°C is used as the target temperature to prevent/minimize growth of *Vibrio* spp. However, pathogenic bacteria species such as *Listeria monocytogenes*, *Clostridium botulinum* and histamine formers may also be hazards in addition to *Vibrio* spp. If this is the case, more strict temperature control, as close to 0°C as possible, should be implemented. In the case of bivalve molluscs, a different temperature control specified in the Annex would be required. The facility should be capable of controlling ambient temperature to ensure that product temperature during processing of raw seafood is maintained at a temperature of ~~40~~ 5°C or lower.

**NOTE: If there are no objections from other members, it is better to control the temperature at "5°C or lower" to limit the growth of pathogenic *Vibrio* spp.**

#### 4.4.6 Air quality and ventilation

~~63-64.~~ Refer to Section ~~3-2-59.2.5~~ of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.2.2 of *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

#### 4.4.7 Lighting

~~64-65.~~ Refer to Section ~~3-2-69.2.6~~ of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.2.3 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

#### 4.4.8 Storage

~~65-66.~~ Refer to Section ~~3-2-79.2.7~~ of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.2.2 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

## 6. SECTION V - CONTROL OF OPERATION

### 5.1 ~~Control of food hazards~~ Description of products and process

~~66-67.~~ Refer to Section ~~7-413.1~~ of the *General Principles of Food Hygiene* (CXC 1-1969).

### 5.2 ~~Key aspects of hygiene control systems~~ GHPs

### 5.2.1 Time and temperature control

~~67-68.~~ Refer to Section 4.1 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003). Time and temperature are the most important factors affecting the rate of growth of pathogenic *Vibrio* spp. in seafood. At each step in processing the temperature of the product should be controlled and monitored via calibrated thermometer.

### 5.2.2 Specific process steps

#### 5.2.2.1 Washing and processing

~~68-69.~~ Clean water at low temperature should be used for washing and processing seafood ~~at processing establishments.~~ However, the eviscerated cavity of fish and other edible parts of seafood intended for raw consumption (e.g., preparation of sashimi) should be thoroughly washed with potable cold running water.

#### 5.2.2.2 Cooking

~~69-70.~~ Time and temperature should be determined for each cooking operation to ensure the inactivation and elimination of pathogenic *Vibrio* spp.

~~70-71.~~ After cooking and blanching, potable water should be used for cooling.

#### 5.2.2.3 Food processing practices

##### **Question to EWG members 8:**

After reviewing three JEMRA reports, Chairs updated this paragraph based on JEMRA report 35 and 20. If any members have additional information which should be revised/added in these sentences, please provide any suggestions of change with supporting data/reference.

Some members suggested the modification of above sentences and the need for additional references.

Chairs proposed that these practices be described separately into “minimizing the growth” and “reducing the level” depending on their effectiveness.

~~71-72.~~ Food processing practices (e.g., acidification to pH below 4.8, salting to a sodium chloride concentration of more than 10% for *V. parahaemolyticus*, food preservatives and/or water activity less than 0.94) ~~can be used to minimise the growth and possibly reduce the levels of pathogenic *Vibrio* spp. in seafood.~~ should be used to minimize the growth or reduce the level of the pathogenic *Vibrio* spp. in seafood. Food business operators can choose some of these interventions depending on their actual situation. Examples of these interventions are:

- Minimizing the growth
  - acidification to pH below 4.8;
  - adding food preservatives which have efficacy in reducing or preventing the growth of *Vibrio* spp.
- Reducing the level
  - salting to a sodium chloride concentration of more than 10% for *V. parahaemolyticus*;
  - exposing oysters or other seafood to ionising energy, e.g., gamma rays, machine-generated electrons or X-rays.
  - hydrostatic compression in the range of 14,500 to 145,000 pound per square inch (100 to 1,000 megapascal (MPa));
  - depuration under optimal conditions, e.g., at a temperature of 12.5°C and stocking density of two oysters/L of artificial seawater for 5 days, and/or water activity less than 0.94 and high salinity (30 ppt); and
  - cryogenic individual quick freezing (IQF) involving the use of cryogenic or blast freezing technology to rapidly lower the product temperature below freezing.

The use and approval of these technologies should be done in accordance with the regulations/standards of the country where the products would be sold

~~72-73.~~ When Freezing could be is used to reduce the level or prevent the growth of pathogenic *Vibrio* spp. in seafood, consideration should be given to the sensitivity of pathogens to freezing. For example, *V. parahaemolyticus* and *V. vulnificus* are especially sensitive to colder temperatures. To reduce

*V. parahaemolyticus* and/or *V. vulnificus* to nondetectable levels, the IQF process should be followed by a period of frozen storage, which may vary depending on organism. It is needed to consider the freezing temperature, length of the time, initial load, and rate of temperature decreasing while freezing<sup>14,15</sup>.

~~73. Several possible technologies such as high pressure, mild heating, freezing and extended storage, have been reported to inactivate *Vibrio* spp.<sup>5</sup>. The use of these technologies should be done in accordance with the legislation of the country of retail sale.~~

74. Any practice or combination of practices selected to reduce/inactivate pathogenic *Vibrio* spp. in seafood or control/minimize the growth of pathogenic *Vibrio* spp. should be adequately validated to ensure that the process is effective. Such validation should be performed according to the Guidelines for the Validation of the Food Safety Control Measures (CXG 69-2008).

75. The food processing practices should be closely monitored and verified to ensure that pathogenic *Vibrio* spp. are controlled and/or reduced as intended.

#### 5.2.2.4 Storage

76. Seafood intended for raw consumption should be stored in shallow layers and surrounded by sufficient quantities of finely crushed ice or with a mixture of ice and potable or clean water. Live fish and shellfish should be stored at the lowest temperature tolerable for the species (Refer to Section 9 of the *Code of Practice for Fish and Fisher Products* (CXC 52-2003)).

77. Over-stacking and/or over-filling of containers should be avoided to allow cold air to circulate adequately.

#### 5.2.3 Microbiological ~~and other~~ specifications

78. Refer to Section ~~7.2.3~~13.2.3 of the *General Principles of Food Hygiene* (CXC 1-1969) and the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXG 21-1997).

#### 5.2.4 Microbiological ~~cross~~-contamination

79. Refer to Section ~~7.2.4~~13.2.4 of the *General Principles of Food Hygiene* (CXC 1-1969) and Sections 3.2.2 and 3.3.2 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

#### 5.2.5 Physical and chemical contamination

80. Refer to Section ~~7.2.5~~13.2.5 and 13.2.6 the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.2.2 and 3.3.2 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

### 5.3 Incoming material requirements

81. Refer to Section ~~7.2.8~~13.2.8 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section ~~8.5.19~~5.1 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

### 5.4 Packaging

82. Refer to Section ~~7.2.9~~13.2.9 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section ~~8.5.29~~5.2 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

## 5.5 Water

### Question to EWG members 9:

Do we need to separate water section into subsections i) water in contact with food, ii) water as an ingredient, and iii) ice and steam? How should we integrate section 7.3 (water) of the *General Principles of Food Hygiene* and *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing*, Annexes II Fishery Products (under develop) in this document? If any members have any idea, please provide any suggestions of change with supporting data/reference.

Some members supported retaining the three subsections for water, some members suggested they can be combined into one section with reference to Section 13.3 of CXG 1-1969 and Annex II on Fishery Products of *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing*. Some members suggested

<sup>14</sup> FAO and WHO, 2020, Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20) (See section 3.5)

<sup>15</sup> FAO and WHO, 2020, Advances in science and risk assessment tools for *Vibrio parahaemolyticus* and *V. vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 35) (Section 3.4).

waiting until Annex II on Fishery Products has been further elaborated.

Chairs proposed maintaining these three subsections for water and awaiting the discussion on the alignment with CXG 1-1969 and the development of Annex II on Fishery Products of *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing*.

#### 5.5.1 In contact with food

83. Refer to Section ~~7-3~~13.3 of the *General Principles of Food Hygiene* (CXC 1-1969) and *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023) except cases specified within this Code where clean water could be used.

84. Coastal seawaters used at landing docks and at markets have been shown to be occasionally contaminated with high level of pathogenic *V. parahaemolyticus*. Therefore, only clean/potable waters should be used in the post-harvest stage.

#### 5.5.2 As an ingredient

85. Refer to Section ~~7-3~~13.3 of the *General Principles of Food Hygiene* (CXC 1-1969) and *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023).

#### 5.5.3 Ice and steam

86. Refer to Section ~~7-3~~13.3 of the *General Principles of Food Hygiene* (CXC 1-1969) and *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023).

### 5.6 Management and supervision

~~87. Refer to Section 5.6 of the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969).~~

### 5.7. Documentation and records

~~88-87.~~ Refer to Section ~~7-4~~13.4 of the *General Principles of Food Hygiene* (CXC 1-1969).

88. Records should show information regarding the control measures monitoring, for example temperature, at key process steps for mitigation of pathogenic *Vibrio*.

### 5.8 Recall procedures – removal from the market of unsafe food

89. Refer to Section ~~7-5~~13.5 of the *General Principles of Food Hygiene* (CXC 1-1969).

## SECTION VI - ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL

90. Refer to Section ~~5~~11 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.4 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

## SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

91. Refer to Section ~~6~~12 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.5 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

## SECTION VIII – TRANSPORTATION

92. Refer to Section ~~8~~15 of the *General Principles of Food Hygiene* (CXC 1-1969) and Sections 3.6 and ~~4~~721 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

93. Transportation is an integral step in the food chain and temperature during this period should be as low as possible and should be controlled, monitored and recorded where appropriate.

## SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

### 9.1 Lot identification and traceability

94. Refer to Section ~~8-4~~14.1 of the *General Principles of Food Hygiene* (CXC 1-1969).

### 9.2 Product information

95. Refer to Section ~~8-2~~14.2 of the *General Principles of Food Hygiene* (CXC 1-1969).

### 9.3 Product Labelling

96. Refer to the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985). Where appropriate, product labels should include information on safe handling practices and storage recommendations.

97. In addition, countries should give consideration to labelling of unpackaged live or raw seafood, so that consumers are adequately informed with respect to the safety and true nature (alive or not alive) of these products. In particular, seafood that is at a high risk of being contaminated with pathogenic *Vibrio* spp., should be labelled to alert at-risk consumers to avoid or cook these products, in line with the legislation in the countries where these products are retailed or sold. Any treatment (e.g., heat treatment) and storage condition, that is applied to the product should be mentioned in the labelling if consumers would be misled by its omission.

### 9.4 Consumer education

98. Since each country has specific food habits, communication and education programs pertaining to pathogenic *Vibrio* spp. are most effective when established by individual governments.

99. Programs should be directed at consumers:

- To educate them on household practices and behaviours as indicated in Five Keys to Safer Food (WHO) “that would specifically keep the numbers of pathogenic *Vibrio* spp. that may be present in foods, to as low a level as possible and minimize the potential of cross-contamination from seafood, ~~to hands of~~ via food handlers, ~~and then from hands to other foods, or from seafood to utensils (e.g., cutting board), and then from utensils to other foods~~ by:

- keeping seafood cold to minimize and/or prevent the growth of pathogenic *Vibrio* spp.;
- keeping refrigerator temperatures as low as practical;
- using thermometers inside home refrigerators, ice chests or other storage containers;
- preparing, cooking and/or consuming seafood immediately after removing them from the refrigerator;
- promptly refrigerating leftover seafood in shallow containers that encourage rapid and even cooling;
- washing and disinfecting hands, utensils and equipments whenever raw seafood is handled; and
- using separateing utensils and equipment used for raw and cooked seafood, ~~from those use for finished product~~, where appropriate.

- To help them make informed choices about the purchase, storage, shelf-life labelling and appropriate consumption of certain raw seafood that have been identified in relevant risk assessment and other studies, taking into consideration the specific regional conditions and consumption habits.

#### 9.4.1 Special attention to susceptible subpopulations

100. Liver disease is a prominent risk factor for human infection with pathogenic *Vibrio* spp., especially *V. vulnificus*. Additional risk factors include diabetes, haemochromatosis and HIV/AIDS<sup>16</sup> Subpopulations with increased susceptibility should follow the advice below:

- Avoid the consumption of raw or partially treated seafood; ~~and~~
- Cook seafood thoroughly before consumption.
- Handle shellfish safely to avoid injury from knives and shell.

*NOTE: The 3<sup>rd</sup> practice is against *V. vulnificus* infection through open wounds, not relating to foodborne illness. Further discussion may be necessary as to whether it should be included in the consumer education part of this guideline.*

## **SECTION X – TRAINING AND COMPETENCE**

### **10.1 Awareness and responsibilities**

101. Refer to Section 4.410.1 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.8 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

<sup>16</sup> FAO and WHO, 2005, Risk assessment of *Vibrio vulnificus* in raw oysters (Microbiological Risk Assessment Series, No.8).



102. Industry (fishermen, primary producers, manufacturers, distributors, retailers and food service/institutional establishments) and trade associations play an important role in providing specific instructions and/or training to employees for the control of pathogenic *Vibrio* spp. Special consideration should be given to possible differences in prevalence of pathogenic *Vibrio* spp. in the harvesting areas and various fishing techniques.

## 10.2 Training programmes

103. Personnel involved in the primary production, harvesting, processing and handling of seafood should have appropriate training for the tasks they are performing. This may include:

- The nature of pathogenic *Vibrio* spp., namely *V. parahaemolyticus*, ~~cholerae~~ *V. cholerae* and *V. vulnificus*, their harbourage sites, and their resistance to various environmental conditions to be able to conduct a suitable hazard analysis for their products;
- Control measures for reducing the risk of pathogenic *Vibrio* spp. associated with seafood during harvesting, processing, distribution, marketing, use and storage, for preventing cross-contamination and minimizing the growth of pathogenic *Vibrio* spp.; and
- The means for verifying effectiveness of control programs, including sampling and analytical techniques.

## 10.3 Instruction and supervision

104. Refer to Section 10.3 of the *General Principles of Food Hygiene* (CXC 1-1969).

## 10.4 Refresher training

105. Refer to Section 10.4 of the *General Principles of Food Hygiene* (CXC 1-1969) and Section 3.8 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

## **SECTION XI – LABORATORY ANALYSIS CRITERIA FOR DETECTION AND ENUMERATION OF PATHOGENIC VIBRIO SPP.**

106. The choice of analytical method should reflect both the type of sample to be tested and the purpose for which the data collected will be used. The purpose of analysis for bacterial foodborne pathogens, including pathogenic *Vibrio* spp., can be divided into the following categories:

- harvest area monitoring;
- post-harvest process verification and end-product monitoring;
- public health investigations

107. The target of analysis for pathogenic *Vibrio* spp. are seafood and environmental samples (water, soil, sewage) from habitats or harvest area, etc.

108. Although it differs depending on the end uses, the purpose of the analysis is to determine whether the product conforms to the standards of the country or region, to demonstrate the reduction of pathogenic *Vibrio* spp. using post-harvest process, to continuously investigate the environment, and to conduct risk assessment at the national, regional, or global level.

109. The analysis methods include direct plating, selective enrichment, most probable number (MPN) assay, robe-hybridization on plate assay, conventional PCR, quantitative PCR, Loop mediated isothermal amplification assay, etc. Useful guidance has been provided for the selection of appropriate analytical method depending on the potential end use of the obtained data<sup>13</sup>.

110. It is possible to genetically analyze the characteristics of bacterial strains between food and clinical isolates, and investigate the possibility that the strains are the same.

111. Research on the virulence factors and virulence related genes of *V. parahaemolyticus*, *V. vulnificus*, and *V. cholerae* is ongoing, and these genes can be used as PCR targets to assess the pathogenicity of the bacteria strains.

## ANNEX ON THE CONTROL MEASURES FOR *VIBRIO PARAHAEMOLYTICUS* AND *VIBRIO VULNIFICUS* IN BIVALVE MOLLUSCS<sup>17</sup>

### INTRODUCTION

1. Bivalve molluscs 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 from most other seafood products and therefore present unique risks and control options. They are inherently riskier than other seafood because of their filter feeding activity that concentrates pathogens present in the water. They are often consumed live and raw or after insufficient cooking. According to FAO/WHO risk assessments for both of these pathogens in many countries, bivalve molluscs are often kept alive out of water for days after harvest at ambient temperatures which allows the growth of *V. parahaemolyticus* and *V. vulnificus*.

### 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. It deals with the means to minimize and/or prevent the introduction/contamination and/or the growth of these pathogens, and adequate partial treatment<sup>18</sup> of bivalve molluscs before consumption. Control measures required for these pathogens are similar but not the same to the extent that they have different characteristics on the growth and survival. The control measures outlined in this Annex reflects these differences, where they exist. This Annex further provides information that may 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. Bivalve molluscs (e.g., clams, mussels and oysters) consumed after a vibriocidal treatment are not covered in this Annex, noting that the control measures presented in the main documents are sufficient to control the safety of these products. The target microbiological hazards of this Annex are only 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* in bivalve molluscs and thus the risk of foodborne diseases caused by these pathogens.

5. This Annex provides guidance applicable throughout the food chain, from primary production through to final consumption of bivalve molluscs and particular guidance on post-harvest processing. Controls measures presented 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>19</sup>.

#### 2.2 Definitions

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

Definitions contained in the *General Principles of Food Hygiene* (CXC 1-1969), the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*; and live and raw bivalve molluscs production definitions defined in the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008).

**Post-harvest processing:** processes (e.g., high pressure and mild heating) or treatments (e.g., freezing) intended to significantly reduce or limit but not necessarily 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* (CXC 52-2003)).

#### 2.3 Use of the document

7. This Annex is supplemental to and should be used in conjunction with the *General Principles of Food*

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<sup>17</sup> Phylum Mollusca: Class Bivalvia

<sup>18</sup> Including cooking.

<sup>19</sup> Risk assessment of *V. parahaemolyticus* in *Anadara granosa* (bloody clams)

*Hygiene* (CXC 1-1969), the *Code of Practice for Fish and Fishery Products* (CXC 52-2003), Hygiene section of the *Standard for Live and Raw Bivalve Molluscs* (CXSODEX-STAN 292-2008) and the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*. This Annex may require modifications and amendments in use, taking 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.

## PART I: BIVALVE MOLLUSCS CONSUMED LIVE AND RAW

### SECTION III - PRIMARY PRODUCTION

#### 3.1 Environmental hygiene

8. Refer to Section 3.48.1 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section 3.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

9. The control measures 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., air and water temperature and salinity). An important element in estimating risk is that *V. parahaemolyticus* grows faster and at colder temperatures than *V. vulnificus*. Predictive tools using these environmental monitoring parameters and growth rates as inputs have been elaborated based on the FAO/WHO risk assessments and, when validated, may be used to estimate corresponding *V. parahaemolyticus* and *V. vulnificus* levels and risk. The predictive ability can be improved by incorporating local data and considering additional factors such as hydrodynamic effects (occurrence of tidal waves, rainfall) and sunlight. In addition to seawater temperature and salinity, some additional abiotic and biotic factors have been identified modulating the presence and abundance of *V. vulnificus* and *V. parahaemolyticus* in coastal water around the world. However, the effects of these variables are not conclusive and, in some cases, have been reported in a particular study affecting a specific area. In addition, the presence of chlorophyll, turbidity, high water temperature, and the bacteriophages are known to be related to *Vibrio* abundance<sup>20</sup>.

10. In cases where predictive models are used to estimate the concentration and risks 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 species. Factors such as hydrodynamic effects (e.g., currents, tides, hurricanes and rainfall) and sunlight influence the levels of *Vibrio* spp. ~~JEMRA20 4.5.1.2 states that the *V. parahaemolyticus* prediction model as it currently exists is a linear model and therefore may be useful to estimate relative change in risk (percent reduction in risk) for different countries with more virulent strains, provided that the ranges of doses in that country are much less than the range of virulent strains. in risk (percent reduction in risk) for different countries with more virulent strains, provided that the ranges of doses in that country are much less than the ID50 for the more virulent strain (i.e., in the linear range of the dose response relationship). For *V. vulnificus*, the FAO/WHO *V. vulnificus* calculation tool is unlikely to be applicable to a wider area outside the U.S. because of different environmental, fishing, and post-harvest parameters. More importantly, however, the basis for the dose-response relationship is derived from rice epidemiological data coupled with estimated exposure levels. It has also been shown that certain shellfish species may influence risk estimates. The dose response model used in the predictive tool may need modifications based on epidemiology, as regional differences exist in the prevalence of pathogenic strains of *V. parahaemolyticus* and *V. vulnificus* including attack rate relative to exposure to *V. parahaemolyticus* strains occurred in those areas concerned<sup>21</sup>.~~

11. Monitoring of bivalve molluscs ~~at harvest~~ for the levels of total *V. vulnificus* and total and pathogenic *V. parahaemolyticus* should be conducted for lengthy period to determine the regional and seasonal variation. Prevalence of pathogenic strains of *V. parahaemolyticus* and *V. vulnificus* and the epidemiological data, including the susceptibility of the population, should be considered<sup>22</sup>. This information and some factors articulated in paragraph 15 are useful for model inputs and evaluation of model outputs and application of appropriate controls.

12. ~~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 due to potential for contamination by a range of hazards, including the presence of *Vibrio* spp., especially in areas that are in close proximity to international shipping lanes.

<sup>20</sup> FAO and WHO, 2020, the Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20) (Section 3.5).

<sup>21</sup> FAO and WHO, 2020, the Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20) (Section 4.5.1.2).

<sup>22</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.

13. 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 or an unusual increase of *Vibrio* spp. illnesses is reported;
  - Water temperatures representative of harvesting conditions. Water temperatures below 15°C<sup>23</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. The effects of salinity and temperature on abundance of *Vibrio* differ depending on the range of fluctuations in water temperature and salinity throughout the year<sup>24</sup>.
14. The competent authority should inform food business operators of the control measures contained in Sections 3.2 (Hygienic production of food sources), 3.3 (Handling, storage and transportation) and 5.1 (~~Control of food hazards~~ Description of products and process) and 5.2 (~~Key aspects of hygiene control systems~~ GHPs) 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.
  - Environmental conditions on harvesting areas could represent a risk for *V. parahaemolyticus* and/or *V. vulnificus*, for example seawater average temperature.
  - An unusual increase of *Vibrio* spp. illnesses is reported.
15. The activities described in this section should be implemented by producers in cooperation with the regulatory authority having jurisdiction.
- 3.2 Hygienic production of food sources
16. 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~~ avoid harvesting from a specified lease/harvest area or divert product for further processing).
  - Where possible, sink bivalve molluscs below the thermocline where the growth of pathogenic *Vibrio* spp. should not occur
  - Restrict the time to refrigeration
  - 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
17. Bivalve molluscs destined to be consumed live or untreated raw should be handled separately from those harvested in other area destined for post-harvest processing or other treatment to avoid cross contamination.

<sup>23</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.

<sup>24</sup> FAO and WHO, 2020, the Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20) (Section 3.6).

18. During handling, storage and transport of harvested bivalve molluscs, the following control measures 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 that may be present in bivalve molluscs.

- Limit time from harvest or first exposure to ambient air temperature to initial refrigeration based on modelling and sampling.
- 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 that minimizes growth of *V. parahaemolyticus* and *V. vulnificus*. 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 *Vibrio* spp., and the time between harvest and raw consumption should be limited appropriately or the product should undergo additional treatment to reduce pathogenic *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* (CXC 52-2003).
- It may be useful to periodically survey levels of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs at various points in the distribution chain to verify effectiveness of recommended control measures.
- Anyone involved in the handling, storage or transport of bivalve molluscs should be educated in the relationship between temperature control and growth of *V. parahaemolyticus* and *V. vulnificus* and trained in proper handling, storage and transport.

#### **SECTION IV - ESTABLISHMENT: DESIGN AND OF FACILITIES AND EQUIPMENT**

19. Refer to Section 4.9 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section IV of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

#### **SECTION V - CONTROL OF OPERATION**

##### **5.1 Control of Food Hazards** Description of products and process

20. Refer to Section 7.4.13.1 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003), the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008) and Section 5.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

21. The control measures described in this section generally apply to post-harvest handling and processing. Control of *V. parahaemolyticus* and *V. vulnificus* typically requires 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.

22. Any control measures or practice selected to significantly reduce or limit but not necessarily completely eliminate *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs (e.g., freezing, high pressure and mild heating), should be adequately validated to ensure that the control measure is effective. They should also be 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~~ GHPs**

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

23. Refer to Section 4.1 of the *Code of Practice for Fish and Fishery Products* (CXC 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.

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

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

### 5.2.3. Microbiological ~~cross~~ contamination

25. Control measures should be in place to avoid cross contamination between bivalve molluscs destined to be consumed live or untreated raw and those harvested in other area destined for post-harvest processing or other treatment.

## **SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION, CLEANING AND DISINFECTION, AND PEST CONTROL**

26. Refer to Section ~~V~~11 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section VI of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

## **SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE**

27. Refer to Section ~~V~~12 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section VII of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

## **SECTION VIII – TRANSPORTATION**

28. Refer to Section ~~X~~15 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and the Section VIII of Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood.

## **SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS**

29. Refer to Section ~~VI~~14 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section IX of the Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood.

30. In addition, programs for consumer information should be directed at consumers with increased susceptibility to contracting vibriosis (see para. 100 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*) to help consumers make informed choices about purchase, storage, shelf-life labelling and appropriate food preparation and consumption of live and raw bivalve molluscs, taking into consideration the specific regional conditions and consumption habits.

### 9.3 Product Labelling

31. Refer to Section 9.3 (Product Labelling) of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* and Section ~~1~~1-7 and ~~2~~2-7 of the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008).

#### 9.4.1 Consumer education

32. Refer to Section 9.4 (Consumer education) of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

33. Programs for consumer education should inform consumers of safe consumption practice and handling and preparation of bivalve molluscs aimed at avoiding food safety risks associated with *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.

## **SECTION X - TRAINING AND COMPETENCE**

34. Refer to Section ~~V~~10 of the *General Principles of Food Hygiene*, (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products*, (CXC 52-2003) and Section X of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

## **PART II. BIVALVE MOLLUSCS CONSUMED IN PARTIALLY TREATED STATE<sup>25</sup>**

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

#### **3.1 Environmental hygiene**

35. Refer to Section ~~3.18.1~~ of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section 3.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

36. 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.

37. 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**

38. Refer to Section ~~3.28.2~~ of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section 3.2 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

- The control measures described in Section III (Primary production) of Part I should be implemented to achieve at least an equivalent level of protection for bivalve molluscs to be consumed live or raw ~~despite the fact that~~ that even though these bivalve molluscs are to be consumed after partial treatment.

#### **3.3 Handling, storage and transport**

39. Refer to Section ~~3.38.3~~ of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section 3.3 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

40. The control measures described in Section III (Primary production) of Part I should be implemented to achieve at least an equivalent level of protection for bivalve molluscs to be consumed live or raw despite the fact that these bivalve molluscs are to be consumed after partial treatment.

### **SECTION IV - ESTABLISHMENT: DESIGN AND OF FACILITIES AND EQUIPMENT**

41. Refer to Section IVIII of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and the Section IV of the Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood.

### **SECTION V - CONTROL OF OPERATION**

#### **5.1 ~~Control of food hazards~~ Description of products and process**

42. Refer to Section ~~7.113.1~~ of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003), the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008) and Section 5.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*. Competent authorities should ensure that the food business operator is able to verify the delivery of any partial treatment and additional control measures necessary to assure the safety of the product.

43. 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.

44. *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

<sup>25</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 *General Principles of Food Hygiene* (CXC 1-1969), *Code of Practice for fish and fishery products* (CXC 52-2003) and other applicable Codex documents as those are generally suitable to control *V. parahaemolyticus* and *V. vulnificus* in fully cooked bivalve molluscs.



to significantly reduce or limit but not necessarily completely 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~~ GHPs

### 5.2.1 Time and temperature control

45. Refer to Section ~~4.1~~13.2 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003). The partial heat treatment of bivalve molluscs should ensure that the internal temperature of the bivalve molluscs reaches the temperature to ~~ensure secure~~ a reduction of *V. parahaemolyticus* and *V. vulnificus*. Achievement of the validated time and temperature treatment should be ~~ensured~~ guaranteed. After partial heat treatment, growth of *V. parahaemolyticus* and *V. vulnificus* should be controlled.

### 5.2.2 Specific process steps

46. The partial treatment of bivalve molluscs ~~by means other than heat~~ 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.

### 5.2.3 Microbiological ~~cross~~-contamination

47. Control measures should be in place to avoid cross contamination between bivalve molluscs before partial treatment and after partial treatment.]

## **SECTION VI – ESTABLISHMENT MAINTENANCE AND SANITATION, CLEANING AND DISINFECTION, AND PEST CONTROL**

48. Refer to Section ~~V~~11 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section VI of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

## **SECTION VII - ESTABLISHMENT- PERSONAL HYGIENE**

49. Refer to Section ~~V~~12 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section VII of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

## **SECTION VIII – TRANSPORTATION**

50. Refer to Section ~~VIII~~14 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section 9.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

## **SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS**

51. Refer to Section ~~VIII~~14 of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section 9.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

### **9.1 Product Labelling**

52. Refer to the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and Section ~~H~~2-7 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.

53. In addition, where appropriate, labelling for bivalve molluscs should include advice on specific safe handling practices (e.g., time, temperature) and consumption.

### **9.2 Consumer education**

54. Refer to Section 9.4 (Consumer education) of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

55. Programs for consumer education should inform consumers of safe consumption practice and handling and preparation of bivalve molluscs aimed at avoiding food safety risk associated with *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.

**SECTION X - TRAINING AND COMPETENCE**

56. Refer to Section ~~10~~ of the *General Principles of Food Hygiene* (CXC 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and Section X of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.