CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda item 5

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CODEX COMMITTEE ON FOOD HYGIENE

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REVISION OF 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 Honduras, Morocco and New Zealand)

This version was prepared by the EWG chair and co-chairs taking into consideration the comments received in response to CL 2026/68-FH. All additional changes compared to the working document (CX/FH 26/56/5) are marked as tracked changes in colour. This document will be used as the basis for discussion at the PWG on Sunday 15th November.

1. INTRODUCTION

1. 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 a series of pandemic outbreaks occurred 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~~ spp. 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. It was previously thought that the ingestion of a large number of viable cells was 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 a recognition that the dose-response may be much lower depending on the individual strains and virulence profiles.

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

2. Most species of the genus *Vibrio* that are pathogenic to humans can cause ~~food borne~~**foodborne** illness. The majority of ~~food borne~~**foodborne** illness is caused by *V. parahaemolyticus*, choleragenic *V. cholerae* (O1, O139), or *V. vulnificus*[1]. *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, infected wounds, etc.) and primary septicaemia due to *V. vulnificus* infection is often associated with consumption of seafood.

3. Non-foodborne routes of infection of *V. vulnificus* is outside the scope of these ~~g~~**G**uidelines, but special attention to the susceptible subpopulations handling shellfish will be needed to prevent *V. vulnificus* infections associated with injuries from knives or shells.

[1] Other *Vibrio* species that have been reported to cause foodborne illness include, but **are** not ~~be~~ limited to, *V. alginolyticus*, **ctx-positive** ~~non-choleragenic *V. cholerae* (~~non-O1/non-O139 ***V. cholera***e (non-choleragenic)~~ strains possessing the ctx gene for cholera toxin)~~, *V. fluvialis*, *V. furnissii*, *V. hollisae* (re-classified as *Grimontia hollisae*), *V. metoecus*, *V. metschnikovii*, *V. mimicus*, *V. paracholerae*, *V. ponticus* and ~~*d*~~*V tarriae*.

4. 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 the freshwater ~~reaches~~ parts of estuaries, where ~~it~~**they** can be introduced by faecal contamination. *V. cholerae*, unlike most other *Vibrio* species, can survive in freshwater environments. The abundance of *Vibrio* spp. in marine and estuarine environments is primarily influenced by water temperature and salinity, which may vary geographically and seasonally. Additional factors that may influence *Vibrio* concentrations include chlorophyll *a* concentration, turbidity, bacteriophage abundance and other ecological conditions.

5. It is now possible to differentiate between virulent and avirulent strains of *V. cholerae* and *V. parahaemolyticus* based on their ability to produce major virulence factors. **In contrast,** ~~T~~**t**he pathogenic mechanisms of *V. vulnificus* have not been clearly explained, and its virulence appears to be multi-factorial and is not well understood**.**~~, and t~~**T**herefore it ~~is recommended~~**remains necessary** to ~~implement measures to mitigate the risk~~ assume~~ing~~ that all strains **of *V. vulnificus* may** ~~need to~~ be ~~handled as~~ pathogenic **when implementing measures to mitigate the risk**.

6. The following are important characteristics common to all *Vibrio* spp. *Vibrio* spp. are sensitive to low pH but can grow at higher pHs, and thus infections caused by *Vibrio* spp. are frequently associated with low-acid foods. It was previously thought that the ingestion of a large number of cells was needed for pathogenic *Vibrio* spp. to transition through the stomach and establish an infection. However, new and highly pathogenic strains of *Vibrio* spp. have emerged with a significantly lower infectious dose than previous strains. These new strains also exhibited different growth characteristics compared to the *V. parahaemolyticus* strains used in the previous risk assessments[2].

7. There are, however, characteristics specific to each of the three major pathogenic ***Vibrio*** ~~species~~ spp. ~~of *Vibrio*~~ responsible for the majority of human foodborne infections, and therefore of ~~country's~~ public health concern **in many countries**, that require attention as described below.

1.2 *Vibrio parahaemolyticus*

8. *V. parahaemolyticus* is considered to be part of the naturally occurring microbiota in the estuarine and coastal environments in tropical to temperate zones. Seawater temperature has been reported as one of the principal environmental factors increasing the abundance of *V. parahaemolyticus* in many areas of the world. Increased levels of *V. parahaemolyticus* are correlated with warming seawater temperatures in spring and summer for temperate regions and are observed in macro-tidal harbours and creeks with high fluctuation temperatures for tropical regions. While *V. parahaemolyticus* is typically 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[3].

9. While the mode of pathogenicity is not fully understood, t~~T~~he vast majority of strains isolated from patients with diarrhoea produce a thermostable direct hemolysin (TDH) encoded by the *tdh* gene. Additionally, strains that produce a TDH-related hemolysin (TRH) encoded by the *trh* gene should also be regarded as pathogenic, as should those that produce a less virulent thermolabile hemolysin (TLH) encoded by the *tlh* gene. While the *tdh* and *trh* genes are still the most well-defined markers of virulence, uncertainty around the pathogenic roles of *tdh* and *trh* genes due to ~~Although~~ detection of *tdh*- and *trh*- strains among clinical strains ~~has been~~remains ~~the~~ a 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 virulence.~~

10. Virulent strains are seldom detected in the environment or foods. In contrast to strains from clinical cases that will nearly always possess these virulence ~~factors~~ markers, the probability of detection of environmental or food strains, including seafood~~s~~, which possess virulence markers will be ~~very~~ low as most do not contain known virulence markers and their distribution within seafood and across growing areas is not homogeneous. In addition, current selective media cannot distinguish colonies of virulent strains from those of avirulent strains. Given this limitation, failure to detect virulent strains in the environment or in foods does not mean there is no risk to consumers.

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[2] FAO and WHO, ~~2020~~2021, Advances in science and risk assessment tools for *Vibrio parahaemolyticus* and *V. vulnificus* associated with seafood (Microbiological Risk Assessment ~~series~~Series, No. 35). (Section 3.2).

[3] FAO and WHO, 2020, Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment ~~series~~Series, No. 20). (Section 3.1).

11. In general, but not always, the outbreaks are small in scale, involving fewer than 10 cases, but can occur frequently, especially in the months with high water temperature.

12. In relation to seafood-borne *V. parahaemolyticus* illnesses, harvest and post-harvest are the most critical stage**s** since it is from this point onwards that most measures to control *V. parahaemolyticus* ~~should~~ 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. Setting appropriate time-temperature requirements of these control measures is important, especially time-temperature controls on post-harvest refrigeration[4].

13. Foods associated with illnesses due to consumption of *V. parahaemolyticus* include for example finfish (such as mackerel, tuna), crustaceans (such as prawns, crab~~meat~~), bivalve molluscs (such as oysters, mussels, scallops), cephalopods (such as squid), and echinoderms (such as sea urchin). These products include raw~~, partially treated~~ and ~~treated~~**undercooked seafood products as well as cooked** seafood products that have been cross-contaminated, for example through utensils, water and ice, hands, **and contact with** uncooked contaminated seafood, etc.

1.3 *Vibrio cholerae*

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

15. Epidemic cholera can be spread by factors such as: infected travel**l**ers and the food trade. These factors, ~~but also~~as well as climate change, may increase the probability of an epidemic in the newly established environments. Detection frequencies of choleragenic strains of *V. cholerae* from legal food trade are very low and have seldom been implicated in cholera outbreaks.

16. Some strains belonging to the O serogroups other than O1 and O139 (referred as non-O1/non-O139) can cause ~~food-borne~~**foodborne** diarrhoea that is milder than cholera. Recent years have seen an increase in infections associated with these particular strains.

17. Outbreaks of ~~food-borne~~**foodborne** cholera have been noted in some parts of the world in the past 30 years~~;~~. ~~seafood~~Seafood, including bivalve molluscs, crustaceans, and finfish, as well as contact with surface water and seafood handling are most often linked to ~~food-borne~~**foodborne** cholera cases in many countries. 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.

1.4 *Vibrio vulnificus*

18. *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 treated~~**undercooked** bivalve molluscs and other seafood. This is a serious disease with one of the highest fatality rates of any known foodborne bacterial pathogen. The ~~dose~~ dose-response for humans is still unclear and more data are necessary. Incubation period ranges from 7 hours to several days, with the average being 24 hours. 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*.

19. Most of the foodborne illnesses associated with *V. vulnificus* are sporadic cases although some outbreaks have been reported. *V. vulnificus* has been isolated from oysters and other seafood worldwide.

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[4] 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~~Series, No. 22). (Section 2.2).

20. Seawater temperature has been reported as one of the principal environmental factors increasing the abundance of *V. vulnificus* in many areas of the world. *V. vulnificus* can grow in oysters in the temperature range of 13-30 °C.

21. According to the available data, the coastal environmental salinity plays an important role in *V. vulnificus* incidence and population levels. Evidence shows that salinity is negatively correlated with *V. vulnificus* concentrations. Salinity levels lower than 1 ppt (parts per thousand) or higher than 30 ppt will not allow *V. vulnificus* growth.

2. OBJECTIVES

22. 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 provide information that will be of interest to the food business operators (FBOs), consumers, competent authorities and other interested parties.

3. SCOPE

23. These Guidelines cover seafood that is marketed and may be consumed in a live, raw, chilled/frozen, ~~partially treated~~**undercooked**, or ~~in a treated~~**cooked** state. ~~It is~~**These Guidelines are** applicable across the whole food chain from primary production to final consumption. Bivalve molluscs are covered more thoroughly in ~~the~~ Annex **I**, which is supplemental to these Guidelines. ~~**Guidance on the selection and application of analytical methods for the detection and enumeration of pathogenic *Vibrio* spp. is provided in Annex II.**~~

24. 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 *V. cholerae*). The control measures described in these Guidelines may be applicable to other pathogenic *Vibrio* spp.

4. USE

25. 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) and the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023)**, in particular Annex II Fish and Fishery Products. The term "water fit-for-purpose" is used broadly in these Guidelines and includes potable water, clean water, and other sources of water deemed suitable for their specific use through an in-depth water fit-for-purpose assessment. Section 6 of Annex II of the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023) provides more specific guidelines on which types of water are appropriate for specific uses and their application.** The application of these Guidelines by countries may require modification~~s~~ and amendment~~s~~, taking into account regional differences such as the prevalence of pathogenic *Vibrio* spp., air and water temperatures and salinity.

~~**4.1 Roles of competent authorities, food business operators, and consumers**~~

~~26. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).~~

5. GENERAL PRINCIPLES

27. Refer to **Section 5 of** the *General Principles of Food Hygiene* (CXC 1-1969).

~~**5.1 Management commitment to food safety**~~

~~28. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).~~

6. DEFINITIONS

29. 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) **and the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023)**.

Refrigeration: The lowering and maintaining 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.

Partial~~ly~~ treat**ment**~~ed~~: Any treatment intended to reduce or limit, but not eliminate, *Vibrio* spp. in seafood (e.g.~~,~~ freezing, high pressure and mild heating such as steaming, boiling and blanching).

Treat**ment**~~ed~~: Any treatment intended to eliminate *Vibrio* spp. in seafood.

~~[~~Clean water: Water that does not meet the criteria for potable water but does not compromise the safety of the food in the context of its use.

Potable water: Water fit for human consumption.

Water ~~fit~~ fit ~~for~~ for-purpose: Water that is determined to be safe for an intended purpose through the identification, evaluation, and understanding of potential microbiological hazards and other relevant factors (e.g. history of use, the intended use of the food, etc.), including the application of control measures such as treatment options and their efficacy to ensure effective elimination or mitigation of such hazards.~~]~~

PART ~~1~~I GOOD HYGIENE PRACTICES

7. INTRODUCTION AND CONTROL OF FOOD HAZARDS

30. Refer to **Section 7 of** the *General Principles of Food Hygiene* (CXC 1-1969).

8. PRIMARY PRODUCTION

30bis. Refer to Section 8 of the *General Principles of Food Hygiene* (CXC 1-1969), together with the following:

8.1 Environmental control

~~31. Refer to Section 8.1 of the *General Principles of Food Hygiene* (CXC 1-1969). In addition:~~

32. Generally, pre-harvest controls are more applicable to farmed bivalve molluscs and fish 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.

33. Environmental parameters such as wate t~~T~~emperature and salinity should be considered, together with data from ~~for controlling pathogenic *Vibrio* spp. in seafood. Where applicable, specific water 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~~ and pre-harvest monitoring of pathogenic *Vibrio* spp. levels, when selecting growing areas and establishing/implementing pre-harvest control measures, as appropriate.

34. For monitoring bivalve molluscs, at harvest, refer to ~~the~~ Annex ~~of these Guidelines~~**I of these Guidelines. Where analytical testing for pathogenic *Vibrio* spp. is undertaken as part of harvest area monitoring programmes, the selection and application of analytical methods should be consistent with Annex II**.

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

~~8.2 Hygiene production~~

~~36. Refer to Section 8.2 of the *General Principles of Food Hygiene* (CXC 1-1969).~~

8.3 Handling, storage and transport

37. Refer to ~~Section 8.3~~**Annex II** of the ~~*General Principles of Food Hygiene* (CXC 1-1969)~~***Guidelines for the Safe Use and Reuse of Water in Food Production and Processing*** **(CXG 100-2023), together with the following:**.

~~38. For the storage and handling of seafood aboard fishing vessels, [water fit for purpose (in this case, at least clean water)] should be used for seafood intended to be eaten raw or partially treated, and for preparing ice. The use of sea water taken from near 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.~~

~~39. For on board cooked (boiled, blanched) seafood products, ice and/or refrigeration should be used to facilitate the rapid cooling. Ice made from [water fit for purpose (in this case, at least clean water)] should be used to minimize cross-contamination.~~

~~40. For the storage of live seafood products, [clean water] should be used to minimize contamination from the water.~~

~~41. When the product is required to be washed, whether onboard the boat or at port, [clean water] should be used.~~

Chair's note: During the development of these Guidelines, different views were expressed regarding how provisions related to water use should be presented. One approach is to rely primarily on the concept of water fit-for-purpose, while specifying particular water types (e.g. potable water) and applications only where necessary. Another approach is to reproduce relevant provisions from CXG 100-2023 Annex II within these Guidelines in order to provide additional clarity.

As consensus was not reached on the preferred drafting approach, the Chairs invite the Committee to consider the following options and provide their views:

Option 1: Refer to and apply the provisions of CXG 100-2023 Annex II, specifying particular water types (e.g. potable water) and applications only where necessary.

Option 2: Reproduce and adapt, as appropriate, relevant provisions from CXG 100-2023 Annex II within these Guidelines to ensure a clear understanding of the water to be used according to its source

[Option 1]

38. Water fit-for-purpose should generally be used when storing and handling seafood on board fishing vessels or at port. However, potable water should be used for final washing and preparation of seafood intended to be eaten raw or without further cooking or treatment as well as on processing contact surfaces and/or ice used for refrigeration.

39. Clean seawater, when used, should be taken from offshore areas that are sufficiently distant from known pollution sources (e.g. sewage outflow) and the water sources should be assessed based on recent relevant microbiological data, if available, to ensure that the water is of suitable quality. The use of seawater from near a coastline should be subject to an in-depth fit-for-purpose assessment.

40. Seafood should be rapidly cooled and 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. Live fish and shellfish should be cooled at a rate, and to the lowest temperature, tolerable for the species. The time elapsed between harvest and refrigeration or freezing should be as short as possible.

41. Ice and/or refrigeration should be used when rapid cooling of seafood products is required following cooking and partial treatment (e.g. boiled, blanched) on board ~~fishing~~ vessels. Water fit-for-purpose should generally be used for preparing ice to minimize cross-contamination. However, potable water should be used when the product is unpackaged and intended to be eaten without further cooking or treatment (i.e. ready-to-eat products).

42. For the wet storage of live seafood products, water fit-for-purpose should be used to minimize their contamination from the water.

[Option 2]

38bis. Water fit-for-purpose should generally be used when storing and handling seafood on board fishing vessels or at port as follows:

a) clean water for all uses as well as on processing contact surfaces and/or ice used for refrigeration, except as an ingredient and for washing at the final stage of the preparation of filleted fishery products eaten raw or without further cooking or treatment;

b) potable water should be used for final washing and preparation of filleted seafood intended to be eaten raw or without further cooking or treatment as well as on processing contact surfaces and/or ice used for refrigeration; and

c) other sources of water can be used but only after an in-depth water fit-for-purpose assessment to specify what use it is suitable for.

39bis. Clean seawater, when used, should be taken from offshore areas that are sufficiently distant from known pollution sources (e.g. sewage outflow) and the water sources should be assessed based on recent relevant microbiological data, if available, to ensure that the water is of suitable quality. The use of seawater from near a coastline should be subject to an in-depth fit-for-purpose assessment.

40bis. Seafood should be rapidly cooled and 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. Live fish and shellfish should be cooled at a rate, and to the lowest temperature, tolerable for the species. The time elapsed between harvest and refrigeration or freezing should be as short as possible.

40ter. For ice making, storage and transport of fish and fishery products intended to be potentially eaten raw or undercooked, clean (sea)water or potable water is used. If other sources of water are used, an in-depth water fit-for-purpose assessment should be conducted to demonstrate that it is fit for the intended purpose.

41bis. Ice and/or refrigeration should be used when rapid cooling of seafood products is required following cooking and partial treatment (e.g. boiled, blanched) on board ~~fishing~~ vessels. Clean (sea)water or potable water is used for preparing ice to minimize cross-contamination. If other sources of water are used, an in-depth water fit-for-purpose assessment should be conducted to demonstrate that it is fit for the intended purpose.

42bis. For the wet storage of live seafood products, clean (sea)water or other water fit-for-purpose should be used to minimize their contamination from the water.

42. During transportation from harvest to the on-shore market and/or processing establishments, 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 to keep seafood 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.

8.4 Cleaning, maintenance and personnel hygiene

~~43. Refer to Section 8.4 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).~~

44. Refer to Section 12.1 of the *General Principles of Food Hygiene* (CXC 1-1969)~~.~~**, together with the following:**

44bis. A carrier who is excreting *V. cholerae* should not handle seafood, water, or ice for the storage of seafood, which may result in the contamination of the seafood with choleragenic *V. cholerae*.

Alternative proposal of 44bis. Food handlers should pay particular attention to personal hygiene practices, especially in cholera-endemic areas, recognizing that infected individuals may shed choleragenic *V. cholerae* even in the absence of symptoms.

9. ESTABLISHMENT - DESIGN OF FACILITIES AND EQUIPMENT

44ter. Refer to Section 9 of the *General Principles of Food Hygiene* (CXC 1-1969), together with the following:

45. 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.

~~**9.1 Location and structure**~~

~~46. Refer to Section 9.1 of the *General Principles of Food Hygiene* (CXC 1-1969).~~

~~**9.1.1 Location of establishments**~~

~~47. Refer to Section 9.1.1 of the *General Principles of Food Hygiene* (CXC 1-1969).~~

9.1.2 Design and layout of food establishment

~~48. Refer to Section 9.1.2 of the *General Principles of Food Hygiene* (CXC 1-1969).~~

~~49. 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.~~

50. The washing room for food handling equipment used for finished product manufacturing should be physically segregated from the finished product processing area.

~~9.1.3 Internal structures and fittings~~

~~51. Refer to Section 9.1.3 of the *General Principles of Food Hygiene* (CXC 1-1969).~~

~~9.1.4 Temporary/mobile premises and vending machines~~

~~52. Refer to Section 9.1.4 of the *General Principles of Food Hygiene* (CXC 1-1969).~~

9.2 Facilities

~~53. Refer to Section 9.2 of the *General Principles of Food Hygiene* (CXC 1-1969).~~

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

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

9.2.1 Drainage and waste disposal facilities

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

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

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

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

9.2.2 Cleaning facilities

60. Refer to ~~Section 9.2.2 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).

9.2.3 Personnel hygiene facilities and toilets

61. Refer to ~~Section 9.2.3 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).

9.2.4 Temperature

62. Refer to ~~Section 9.2.4 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)~~.~~**, together with the following:**

63. ~~The *Code of Practice for Fish and Fishery Products* **(CXC 52-2003)** indicates maintaining the product at temperature as close to 0ºC as possible.~~ For pathogenic *Vibrio* spp., a temperature of 10 ºC or lower is adequate to limit growth. However, other ~~pathogenic bacteria species~~microbiological hazards such as *Listeria monocytogenes*, *Clostridium botulinum* and histamine formers may also be ~~hazards~~ associated with seafood in addition to *Vibrio* spp. Therefore, t~~T~~emperature control, as close to 0 ºC 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 product temperature during processing of raw seafood at a temperature of 10 ºC or lower. In the case of bivalve molluscs, a different temperature control specified in ~~the~~ Annex I would be required.

9.2.5 Air quality and ventilation

64. Refer to ~~Section 9.2.5 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).

9.2.6 Lighting

65. Refer to ~~Section 9.2.6 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).

9.2.7 Storage

66. Refer to ~~Section 9.2.7 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).

9.3 Equipment

~~**9.3.1 General**~~

~~67. Refer to Section 9.3.1 of the *General Principles of Food Hygiene* (CXC 1-1969).~~

9.3.2 Food control and monitoring equipment

~~68. Refer to Section 9.3.2 of the *General Principles of Food Hygiene* (CXC 1-1969).~~

69. Areas where refrigeration is necessary should be equipped with a calibrated thermometer.

10. TRAINING AND COMPETENCE

69bis. Refer to Section 10 of the *General Principles of Food Hygiene* (CXC 1-1969), together with the following:

10.1 Awareness and responsibilities

70. Refer to ~~Section 10.1 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) ~~in addition to~~**, together with** the following~~.~~**:**

71. FBOs (fishermen, primary producers, manufacturers, distributors, retailers and food service) and trade associations play an important role in providing specific instructions and/or training to employees for the control of pathogenic *Vibrio* spp. Consideration should be given to possible differences in prevalence of pathogenic *Vibrio* spp. in the harvesting areas.

10.2 Training programmes

72. Refer to ~~Section 10.2 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) ~~in addition to~~**, together with** the following~~:~~:

73. 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*, *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;
- Prevention and 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**~~

~~74. Refer to Section 10.3 of the *General Principles of Food Hygiene* (CXC 1-1969).~~

10.4 Refresher training

75. 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).

11. ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL

76. Refer to Section 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).

12. PERSONAL HYGIENE

77. Refer to Section 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).

13. CONTROL OF OPERATION

~~**13.1 Description of products and process**~~

78. Refer to Section 13~~.1~~ of the *General Principles of Food Hygiene* (CXC 1-1969)~~.~~**, together with the following:**

13.2 Key aspects of ~~Good Hygiene Practices (~~GHPs~~)~~

13.2.1 Time and temperature control

79. Refer to Section 4.1 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003)~~.~~**, together with the following:**

79bis. Time and temperature are the most important factors affecting the rate of growth of pathogenic *Vibrio* spp. in seafood. During each processing step, the temperature of the product should be controlled and monitored via calibrated thermometers.

13.2.2 Specific process steps

13.2.2.1 Washing and processing

~~80. [Water fit for purpose (in this case, at least clean water)] at low temperature should be used for washing and processing whole seafood.~~

[Option 1]

80. Seafood should generally be washed and processed using water fit-for-purpose that is at an appropriate temperature. However, potable water should be used for final washing and processing of products intended to be eaten raw or without further cooking or treatment.

[Option 2]

80bis. Seafood should be washed and processed using water fit-for-purpose, especially clean water or potable water, that is at an appropriate temperature. Other sources of water can be used but only after an in-depth water fit-for-purpose assessment. However, potable water should be used for final washing and processing of filleted or other fishery products intended to be eaten raw or without further cooking or treatment.

13.2.2.2 Cooking

81. Time and temperature should be determined for each cooking operation to ensure the inactivation and elimination of pathogenic *Vibrio* spp.**, noting that *Vibrio* spp. have a lower heat tolerance than other foodborne pathogens and cooking temperatures required to assure safe food are likely to be higher than those specifically for *Vibrio* spp.**

~~82. [Water used for cooling fish and fishery products after cooking or blanching should be fit for purpose (in this case, at least clean water).]~~

[Option 1]

82. Water fit-for-purpose should generally be used for cooling seafood products after cooking or blanching. However, potable water should be used when filleted or other seafood products are unpackaged and are intended to be eaten without further cooking or treatment (i.e. ready-to-eat products). Ice used for cooling should be prepared similarly.

[Option 2]

82bis. Water fit-for-purpose, especially clean water or potable water, should be used for cooling seafood products after cooking or blanching. Other sources of water can be used, but only after conducting an in-depth water fit-for-purpose assessment. However, potable water should be used when filleted or other seafood products are unpackaged and are intended to be eaten without further cooking or treatment (i.e. ready-to-eat products). Ice used for cooling should be prepared similarly.

13.2.2.3 Food processing practices

83. Food processing practices should be used to minimize the growth or reduce the level of the pathogenic *Vibrio* spp. in seafood. ~~Food business operator~~**FBO**s can apply ~~appropriate~~ interventions **which are appropriately validated to be capable of controlling *Vibrio* spp.** depending on their ~~actual~~**specific** situation. Examples of these interventions are:

- Minimizing the growth by
  - acidification to pH below 4.8; **~~and~~or**
  - adding permitted food preservatives which have efficacy in preventing the growth of *Vibrio* spp.
- Reducing the level **by**
  - salting to a sodium chloride concentration of more than 10% to control *V. parahaemolyticus*;
  - adding permitted food preservatives which have efficacy in reducing the level of *Vibrio* spp.;
  - exposing seafood to ~~ionising~~ ionizing ~~energy~~radiation, e.g.~~,~~ gamma rays, machine-generated electrons or X-rays;
  - hydrostatic compression (high pressure processing) ~~in the range of 14,500 to 145,000 pound per square inch (100 to 1,000 megapascal (MPa)~~;
  - depuration **of live bivalve molluscs in clean seawater** ~~**or**~~~~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)~~ **~~prepared from clean water and food grade salt~~ under optimal conditions**; ~~and~~or
  - ~~cryogenic~~ individual quick freezing (IQF) involving the use of cryogenic or blast freezing technology to rapidly lower the product temperature below freezing.

84. 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).

85. For example, when freezing 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. *V. parahaemolyticus* and *V. vulnificus* are especially sensitive to cold~~er~~ 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 the organism. When freezing, the following should be considered: freezing temperature, the minimum time that the seafood will be stored frozen~~length of the time~~, initial microbial load, and the rate of temperature decrease[5,6].

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

86bis. **Where microbiological testing is used to support validation or verification activities, appropriate analytical methods should be selected in accordance with Annex II.**

13.2.2.4 Storage

~~87. 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 [water fit for purpose (in this case, at least 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)).~~

[Option 1]

87. Seafood intended for raw consumption should be stored in shallow layers and surrounded by sufficient quantities of ice/ice slurries made from water fit-for-purpose. Potable water should be used when products are unpackaged and are intended to be consumed without further cooking or treatment. Live fish and shellfish should be stored at the lowest temperature tolerable for the species.

[5] FAO and WHO, 2020, Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment ~~series~~Series, No. 20). (See section 3.5).

[6] FAO and WHO, ~~2020~~2021, Advances in science and risk assessment tools for *Vibrio parahaemolyticus* and *V. vulnificus* associated with seafood (Microbiological Risk Assessment ~~series~~Series, No. 35). (Section 3.4).

[Option 2]

87bis. Seafood intended for raw consumption should be stored in shallow layers and surrounded by sufficient quantities of ice/ice slurries made from water fit-for-purpose, especially clean water or potable water. Other sources of water can be used, but only after conducting an in-depth water fit-for-purpose assessment. Potable water should be used when filleted or other seafood products are unpackaged and are intended to be consumed without further cooking or treatment. Live fish and shellfish should be stored at the lowest temperature tolerable for the species.

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

13.2.3 Microbiological[7], physical, chemical and allergen specifications

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

13.2.4 Microbiological contamination

90. Refer to ~~Section 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).

13.2.5 Physical contamination

91. Refer to ~~Section 13.2.5 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).

13.2.6 Chemical contamination

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

13.2.7 Allergen management

93. Refer to ~~Section 13.2.7 the *General Principles of Food Hygiene* (CXC 1-1969),~~ the *Code of Practice on Food Allergen Management for Food Business Operators* (CXC 80-2020) and the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

13.2.8 Incoming material

94. Refer to ~~Section 13.2.8 of the *General Principles of Food Hygiene* (CXC 1-1969) and~~ Section 9.5.1 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

13.2.9 Packaging

95. Refer to ~~Section 13.2.9 of the *General Principles of Food Hygiene* (CXC 1-1969) and~~ Section 9.5.2 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003).

[13.3 Water

96. Refer to ~~Section 13.3 of the *General Principles of Food Hygiene* (CXC 1-1969) and~~ the *Guidelines for the* ~~*s*~~***S****afe* ~~*u*~~***U****se and* ~~*r*~~***R****euse of* ~~*w*~~***W****ater in* ~~*f*~~***F****ood* ~~*p*~~***P****roduction and* ~~*p*~~***P****rocessing* (CXG 100-2023)**, in particular Annex II Fish and Fishery Products, together with the following:**.

13.3.1 In contact with food

~~97. Refer to Section 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.~~

98. Coastal seawaters used at landing docks and at markets ~~have been shown to be~~**can** occasionally ~~contaminated with~~**contain** high level of pathogenic ~~V. parahaemolyticus.~~***Vibrio*** **spp. and** ~~T~~**t**herefore, **should** only ~~clean/potable waters should be used in the post harvest stage~~**be used for onshore processing following a water fit-for-purpose assessment and, if necessary, application of an appropriate disinfection treatment**.

[7] FAO and WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods.* Codex Alimentarius Guideline, No CXG 21-1997. Codex Alimentarius Commission, Rome

13.3.2. As an ingredient

99. ~~Refer to Section 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)~~**Only potable water should be used as an ingredient**.

13.3.3. Ice/ice slurries and steam

100. ~~Refer to Section 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).~~ **Ice and ice slurries used for cooling after cooking or storage should be prepared using water fit-for-purpose, especially clean water or potable water. Other sources of water can be used, but only after conducting an in-depth water fit-for-purpose assessment.**

100bis. Water fit-for-purpose should be used ~~for~~ to generate steam. Potable water or clean water (preferably from freshwater sources to prevent boiler corrosion) should be used where steam comes into direct contact with seafood products or food contact surfaces. Other sources of water can be used, but only after conducting an in-depth water fit-for-purpose assessment.

13.4 Documentation and records

~~101. Refer to Section 13.4 of the *General Principles of Food Hygiene* (CXC 1-1969) in addition to the following.~~

102. Records should show information regarding the control measures being monitored, for example time and temperature, at key process steps for mitigation of pathogenic *Vibrio* spp.

~~**13.5 Recall procedures-removal from the market of unsafe food**~~

~~103. Refer to Section 13.5 of the *General Principles of Food Hygiene* (CXC 1-1969).~~

14. PRODUCT INFORMATION AND CONSUMER AWARENESS

~~**14.1 Lot identification and traceability**~~

104. Refer to Section 14~~.1~~ of the *General Principles of Food Hygiene* (CXC 1-1969)~~.~~**, together with the following:**

~~**14.2 Product information**~~

~~105. Refer to Section 14.2 of the *General Principles of Food Hygiene* (CXC 1-1969).~~

14.3 Product labelling

106. Refer to the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985)~~.~~**, together with the following:**

106bis. Where appropriate, product labels should include information on safe handling practices and storage recommendations.

107. In addition, countries should give consideration to providing information for~~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, information on seafood that is at a high risk of being contaminated with pathogenic *Vibrio* spp., should be ~~labelled~~ provided to alert at-risk consumers to avoid ~~raw consumption or cook~~ **consuming** these products **raw or undercooked, or to cook them thoroughly**, 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 to be applied to the product should be mentioned in the ~~labelling~~ information provided if consumers would be misled by its omission.

14.4 Consumer education

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

109. Programs should be directed at consumers:

- To educate them on household practices and behaviours, as indicated in Five Keys to Safer Food (WHO), to keep the numbers of pathogenic *Vibrio* spp. that may be present in foods as low as possible and to minimize the potential of cross-contamination from seafood, from food handlers, or from utensils (e.g.~~,~~ cutting board), 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 for rapid and even cooling;
- washing and disinfecting hands, utensils and equipment whenever raw seafood is handled and;
- using separate utensils and equipment ~~or clean between~~**for** raw**, undercooked** and cooked seafood**, or cleaning them between uses**.

- 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.

14.4.1 Special attention to susceptible subpopulations

110. 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[8]. Subpopulations with increased susceptibility should follow the advice below:

- Avoid the consumption of raw or ~~partially treated~~**undercooked** seafood.
- Cook seafood thoroughly before consumption.

15. TRANSPORTATION

111. Refer to Section 15 of the *General Principles of Food Hygiene* (CXC 1-1969) and Sections 3.6 and 21 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003)~~.~~**, together with the following:**

112. Transportation is an integral step in the food chain and should be carried out using suitable means~~, and~~**. The** temperature during this period should be as low as possible and should be controlled, monitored and recorded where appropriate.

PART II HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION

16. INTRODUCTION TO HACCP

113. Refer to Section 16 of the *General Principles of Food Hygiene* (CXC 1-1969).

17. PRINCIPLES OF THE HACCP SYSTEM

114. Refer to Section 17 of the *General Principles of Food Hygiene* (CXC 1-1969).

18. GENERAL GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

115. Refer to Section 18 of the *General Principles of Food Hygiene* (CXC 1-1969).

19. APPLICATION

116. Refer to Section 19 of the *General Principles of Food Hygiene* (CXC 1-1969).

~~20. SELECTION AND APPLICATION OF METHODS FOR DETECTION AND ENUMERATION OF PATHOGENIC *VIBRIO* SPP.~~

~~**20.1.1 Purpose of analytical testing**~~

~~117. The purpose of analytical testing for bacterial foodborne pathogens, including pathogenic *Vibrio* spp., can be divided into the following categories:~~

[8] FAO and WHO, 2005, Risk assessment of *Vibrio vulnificus* in raw oysters (Microbiological Risk Assessment Series, No.8).

- harvest area monitoring (to assist with establishing harvest area *Vibrio* spp. management plans, where *Vibrio* abundance can be linked to specific harvest area water temperatures, salinity or other parameters, as determined by the assessment of the area)
- post harvest process verification including end product monitoring (as part of a quality assurance program)
- public health investigation following an incident.

118. Sampling plans and design must consider the purpose for which it will be used.

20.2 Choice of analytical method

119. The choice of analytical method should reflect:

- the type of sample to be tested;
- the purpose for which the data collected will be used (as per paragraph 117);
- the desired level of sensitivity and test frequency;
- whether a presence/absence or quantitative test is more appropriate;
- whether detections of sub-populations (e.g., virulence markers) is necessary; and
- whether typing (e.g., serotype) of pathogenic strains is required.

20.3 Types of analytical methods

120. Additional guidance on selecting analytical methods is available in 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) and 2021, Advances in science and risk assessment tools for *Vibrio parahaemolyticus* and *V. vulnificus* associated with seafood (Section 3.5) (MRA series No.35)

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

Annex I

~~ANNEX ON~~ THE CONTROL MEASURES FOR *VIBRIO PARAHAEMOLYTICUS* AND *VIBRIO VULNIFICUS* IN BIVALVE MOLLUSCS[1]

1. 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*.

2. 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[2] 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 for growth and survival. The control measures outlined in this Annex ~~reflects~~reflect these differences, where they exist. This Annex further provides information that may be of interest to competent authorities, FBOs, consumers, and other interested parties.

3. SCOPE

3. This Annex covers bivalve molluscs that are intended ~~for consumption~~**to be ~~comsumed~~ consumed** ~~in a~~ live, raw, or **after** partial~~ly~~ treat**ment**~~ed state~~. Bivalve molluscs (e.g.~~,~~ clams, mussels and oysters) consumed after 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 **the** levels of, *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs, ~~and thus~~**thereby reducing** 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~~**A** apply to ~~live and raw~~ bivalve molluscs **consumed live and raw** (including those that receive post-harvest processing), while those in Part ~~II~~**B** apply to bivalve molluscs consumed after partial treatment[3].

4. USE

6. This Annex is supplemental to, and should be used in conjunction with, the **main body of these Guidelines** ~~*General Principles of Food Hygiene* (CXC 1-1969), the *Code of Practice for Fish and Fishery Products* (CXC 52-2003),~~ **and ~~the~~** ~~Hygiene s~~**S**ection 6 of the *Standard for Live and Raw Bivalve Molluscs* (CXS 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.

5. GENERAL PRINCIPLES

7. Refer to ~~the~~ Section 5 of the **main body of these** Guidelines ~~*on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*~~.

6. DEFINITIONS

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[1] Phylum Mollusca: Class Bivalvia

[2] ~~Including cooking~~

[3] [3] FAO and WHO, 2011, Risk assessment of *Vibrio parahaemolyticus* in seafood: interpretative summary and technical report. (Microbiological Risk Assessment Series No.16). (Part II – Microbiological ~~Risk~~ risk assessment of *V. parahaemolyticus* in *Anadara granosa* (~~bloody~~ Bloody clam~~s~~).

8. ~~For the purpose of this Annex, the following definitions apply:~~Refer to Section 6 of the main body of these Guidelines~~,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~~ as well as live and raw bivalve molluscs production definitions defined in the *Standard for Live and Raw Bivalve Molluscs* (CXS 292-2008).

A: BIVALVE MOLLUSCS CONSUMED LIVE AND RAW

PART I GOOD HYGIENE PRACTICES

7. INTRODUCTION AND CONTROL OF FOOD HAZARDS

9. Refer to ~~the~~ Section 7 of the **main body of these** ~~the~~ Guidelines. ~~*on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*~~

8. PRIMARY PRODUCTION

9bis. Refer to Section 8 of the main body of these Guidelines, together with the following:

8.1 Environmental control

10. Refer to ~~Section 8.1 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 8.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.~~**, together with the following:**

11. The control measures described in this section generally apply to pre-harvest environmental conditions and practices during and immediately following harvest. 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. The presence of chlorophyll, turbidity, and ~~the~~ bacteriophages ~~are~~**is** known to be related to ~~*Vibrio*~~ the abundance of *V. parahaemolyticus*[4].

12. 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 ***V. parahaemolyticus*** **(**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. The ~~dose~~ 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[5].

13. Monitoring of bivalve molluscs for the levels of ~~total~~ *V. ~~vulnificus~~**parahaemolyticus*** ~~and~~ **(**total and pathogenic**) and** *V. ~~parahaemolyticus~~**vulnificus*** should be conducted periodically over time to determine ~~the~~**their** 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[6]. This information and some factors articulated in paragraph 15 **below** are useful for model inputs and evaluation of model outputs as well as for the application of appropriate controls.

14. The impact of ballast discharge in, or around harvesting areas, should be controlled 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.

15. Factors to be considered in determining the need for controls in a given harvest area include:

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[4] FAO and WHO, 2020, ~~the~~ Risk assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood (Microbiological Risk Assessment series, No. 20). (Section 3.3).

[5] 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).

[6] As an ~~n~~ example, pandemic *V. parahaemolyticus* may require more stringent controls than other strains of pathogenic *V. parahaemolyticus* because epidemiological evidence indicates higher attack rates.

- 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 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 ºC) and *V. vulnificus* (13 ºC), 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 that there are low *V. parahaemolyticus* and *V. vulnificus* levels and few cases of illnesses 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 *V. parahaemolyticus* and *V. vulnificus*~~*Vibrio*~~ differ depending on the range of fluctuations in water temperature and salinity throughout the year[7].

16. The competent authority should inform ~~food business operator~~**FBO**s of the control measures contained in Sections ~~3~~**8**.2 ~~(Hygienic production)~~, ~~3~~**8**.3 ~~(Handling, storage and transportation) and~~**,** ~~5~~**13**.1 ~~(Description of products and process)~~ and ~~5~~**13**.2 ~~(Key aspects of 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.

17. The activities described in this section should be implemented by producers in cooperation with the competent authority.

8.2 Hygienic production

18. Pre-harvest and harvest measures should be applied as necessary based upon the factors identified in Section ~~3~~**8**.1 above, such as:

- Restrict harvest or otherwise prevent use of product for raw consumption (e.g.~~,~~ avoid harvesting from a specified lease/harvest area or divert product for further processing).
- Where possible, cultivate bivalve molluscs below the thermocline where the growth of pathogenic *Vibrio* spp. should not occur.
- Restrict the time from harvest 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).

8.3 Handling, storage and transport

19. Bivalve molluscs destined to be consumed live or untreated raw should be handled separately from those harvested in other areas destined for treatment (including partial treatment) to avoid cross-contamination.

20. 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~~**8**.1 **above**. 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.

[7] 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).

- 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, and the time between harvest and raw consumption should be limited appropriately or the product should undergo additional treatment to reduce **the levels of** pathogenic *Vibrio* ~~levels~~**spp**. 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 harvest, 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.

~~**8.4 Cleaning, maintenance and personnel hygiene**~~

~~21. Refer to the Section 8.4 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*~~

9. ESTABLISHMENT: DESIGN OF FACILITIES AND EQUIPMENT

22. Refer to Section 9 of the **main body of these Guidelines** ~~*General Principles of Food Hygiene* (CXC 1-1969),~~ **and** Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) ~~and Section 9 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*~~.

10. TRAINING AND COMPETENCE

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

11. ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL

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

12. PERSONAL HYGIENE

25. Refer to Section 12 of the **main body of these Guidelines** ~~*General Principles of Food Hygiene* (CXC 1-1969),~~ **and** Section 7 of the C*ode of Practice for Fish and Fishery Products* (CXC 52-2003) ~~and Section 12 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*~~.

13. CONTROL OF OPERATION

25bis. Refer to Section 13 of the main body of these *Guidelines*, together with the following:

13.1 Description of products and processes

26. Refer to ~~Section 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)~~,~~ **and** 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*.~~ **, together with the following:**

27. 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 GHPs 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.

28. Any control measures or practices selected as a partial treatment for *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. 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*.

13.2 Key aspects of GHPs

13.2.1 Time and temperature control

29. Refer to Section 4.1 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003)~~.~~**, together with the following:**

29bis. Time and 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.

13.2.2 Specific process steps

30. Bivalve molluscs destined to be consumed live or untreated raw should be handled separately from those destined for treatment (including partial treatment).

13.2.3 Microbiological[8], physical, chemical and allergen specifications

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

13.2.4 Microbiological contamination

32. Control measures should be in place to avoid ~~cross-~~cross-contamination between bivalve molluscs destined to be consumed live or untreated raw and those that have been subject to treatment (including partial treatment).

14. PRODUCT INFORMATION AND CONSUMER AWARENESS

33. Refer to Section 14 of the **main body of these Guidelines** ~~*General Principles of Food Hygiene* (CXC 1-1969),~~ **and** Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) ~~and Section 14 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.~~**, together with the following:**

34. In addition, programs for consumer information should be directed at consumers with increased susceptibility to contracting vibriosis (see paragraph **110**~~/Section 14.4.1100 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*~~ **of the main body of these Guidelines)** to help consumers make informed choices about purchase, storage, shelf-life labelling and appropriate food preparation, handling and consumption of live and raw bivalve molluscs, taking into consideration the specific regional conditions and consumption habits.

~~**14.1 Lot identification and traceability**~~

~~35. Refer to section 14.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.~~

~~**14.2 Product information**~~

~~36. Refer to section 14.2 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.~~

14.3 Product labelling

~~[8] FAO and WHO. 1997. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods. Codex Alimentarius Guideline*, No CXG 21-1997. Codex Alimentarius Commission, Rome.~~

37. 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**s** ~~1-7 and 2-7~~**7 and 16** of the *Standard for Live and Raw Bivalve Molluscs* (CXS 292-2008).

14.4 Consumer education

~~38. 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*.~~

39. Programmes 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.

15. TRANSPORTATION

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

B. BIVALVE MOLLUSCS CONSUMED ~~IN~~AFTER PARTIAL~~LY~~ TREATMENT~~ED STATE~~[9]

PART I GOOD HYGIENE PRACTICES

7. INTRODUCTION AND CONTROL OF FOOD HAZARDS

9. Refer to ~~the~~ Section 7 of the **main body of these** Guidelines ~~*on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*~~.

8. PRIMARY PRODUCTION

9bis. Refer to Section 8 of the main body of these Guidelines and Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003), together with the following:

8.1 Environmental control

~~41. Refer to Section 8.1 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*.~~

42. The controls described in Section 8 ~~(Primary production)~~ of Part ~~I~~**A** should be implemented. The combination of measures of the treatment and those described in Section ~~III~~**8** 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~~**8** of Part ~~I~~**A**.

43. If data on log reduction achieved by partial treatment is available, predictive tools in Part ~~I~~A could be applicable.

8.2 Hygienic production

~~44. Refer to Section 8.2 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*.~~

45. The control measures described in Section **8**~~III (Primary production)~~ of Part ~~I~~**A** should be implemented to achieve at least an equivalent level of protection for bivalve molluscs to be consumed live or raw even though these bivalve molluscs are to be consumed after partial treatment.

8.3 Handling, storage and transport

~~46. Refer to Section 8.3 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*.~~

47. Control measures described in Section **8**~~III (Primary production)~~ of Part ~~I~~**A** should be implemented to achieve at least an equivalent level of protection for bivalve molluscs to be consumed live or raw even though these bivalve molluscs are to be consumed after partial treatment.

9. ESTABLISHMENT: DESIGN OF FACILITIES AND EQUIPMENT

48. Refer to Section 9 of the **main body of these Guidelines** ~~*General Principles of Food Hygiene* (CXC 1-1969),~~ **and** 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*~~.

10. TRAINING AND COMPETENCE

49. Refer to Section 10 of the **main body of these Guidelines** ~~*General Principles of Food Hygiene* (CXC 1-1969),~~ **and** 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*~~.

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[9] Part ~~II~~ B applies only to products that are consumed after partial ~~treated~~treatment, 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), the *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.

11. ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST CONTROL

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

12. PERSONAL HYGIENE

51. Refer to Section 12 of the **main body of these Guidelines** ~~*General Principles of Food Hygiene* (CXC 1-1969),~~ **and** 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*~~.

13. CONTROL OF OPERATION

52. Refer to Section 13 of the **main body of these Guidelines** ~~*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 *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008) ~~and Section 13 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*, in addition to~~ **together with** the following~~.~~:

13.1 Description of products and process

53. Competent authorities should ensure that the ~~food business operator~~**FBO** is able to verify the delivery of any partial treatment and additional control measures necessary to ensure the safety of the product.

54. 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 GHPs 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.

55. *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 control measure or practice selected as a partial treatment for *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs should be adequately validated to ensure that the control measures are effective and such validated control measures/practices should be implemented under the HACCP system.

13.2 Key aspects of GHPs

13.2.1 Time and temperature control

56. The partial heat treatment of bivalve molluscs should ensure that the internal temperature of the bivalve molluscs reaches the temperature to secure a reduction of *V. parahaemolyticus* and *V. vulnificus*. ~~Achievement of t~~**T**he validated time and temperature treatment should be ~~guaranteed~~**achieved**. After partial heat treatment, growth of *V. parahaemolyticus* and *V. vulnificus* should be controlled.

13.2.2 Specific process steps

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

13.2.4 Microbiological contamination

58. Control measures should be in place to avoid ~~cross~~ cross-contamination between bivalve molluscs before partial treatment and after partial treatment.

14. PRODUCT INFORMATION AND CONSUMER AWARENESS

59. Refer to Section 14 of the **main body of these Guidelines** ~~*General Principles of Food Hygiene* (CXC 1-1969),~~ **and** Section 7 of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003)~~,~~ ~~and Section 14 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*, in addition to~~ **together with** the following~~.~~:

14.3 Product labelling

60. Refer to the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985) and Section ~~2 7~~**16** Labelling ~~in~~**of** the *Standard for Live and Raw Bivalve Molluscs* (CXS 292-2008). Where appropriate, product labels should include information on safe handling practices and storage recommendations.

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

14.4 Consumer education

~~62. 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*.~~

63. 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.

15. TRANSPORTATION

64. Refer to Section 1~~4~~**5** of the **main body of these Guidelines** ~~*General Principles of Food Hygiene* (CXC 1-1969),~~ **and** 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*~~.

PART II HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION

16. INTRODUCTION TO HACCP

65. Refer to Section 16 of the **main body of these Guidelines** ~~*General Principles of Food Hygiene* (CXC 1-1969)~~.

17. PRINCIPLES OF THE HACCP SYSTEM

66. Refer to Section 17 of the **main body of these Guidelines** ~~*General Principles of Food Hygiene* (CXC 1-1969)~~.

18. GENERAL GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

67. Refer to Section 18 of the **main body of these Guidelines** ~~*General Principles of Food Hygiene* (CXC 1-1969)~~.

19. APPLICATION

68. Refer to Section 19 of the **main body of these Guidelines** ~~*General Principles of Food Hygiene* (CXC 1-1969)~~.

~~20. SELECTION AND APPLICATION OF METHODS FOR DETECTION AND ENUMERATION OF PATHOGENIC *VIBRIO* SPP.~~

~~69. Refer to Section 9.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010).~~

Annex II

GUIDANCE ON THE SELECTION AND APPLICATION OF ANALYTICAL METHODS FOR THE DETECTION AND ENUMERATION OF PATHOGENIC *VIBRIO* SPP.

1. **Purpose of analytical testing**

1. The purpose of analytical testing for bacterial foodborne pathogens, including pathogenic *Vibrio* spp., can be divided into the following categories:

- harvest area monitoring (to assist with establishing harvest area *Vibrio* spp. management plans, where *Vibrio* abundance can be linked to specific harvest area water temperatures, salinity or other parameters, as determined by the assessment of the area)
- post-harvest process verification including end-product monitoring (as part of a quality assurance program)
- public health investigation following an incident.

2. Sampling plans and design should consider the purpose for which ~~it~~ they will be used.

2. **Choice of analytical method**

3. The choice of analytical method should reflect:

- the type of sample to be tested;
- the purpose for which the data collected will be used (as per paragraph 1);
- the desired level of sensitivity and test frequency;
- whether a qualitative (detected/not detected) or quantitative test is more appropriate;
- whether detections of sub-populations (e.g. virulence markers) is necessary; and
- whether typing (e.g. serotype) of pathogenic strains is required.

3. **Types of analytical methods**

4. Additional guidance on selecting analytical methods is available in FAO and WHO~~,~~ publications[10,11] ~~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) and 2021, Advances in science and risk assessment tools for *Vibrio parahaemolyticus* and *V. vulnificus* associated with seafood (Section 3.5) (MRA series No.35).~~

5. Research on virulence factors and virulence related genes of *V. parahaemolyticus*, *V. vulnificus*, and *V. cholerae* is ongoing~~,~~. ~~In~~ In some circumstances~~, these~~ certain virulence-associated genes ~~can~~ may be used as ~~PCR~~ molecular targets to ~~assess the pathogenicity of the bacterial~~characterize strains. For example, ISO 21872-1:2017/Amd 1:2023 is ~~A~~ a validated horizontal ~~detection~~ method ~~has been developed and validated by ISO 21872-1:2017/Amd 1:2023, which describes~~for the detection and the identification of ~~the most important virulence factors to be analyzed and screening by~~potentially enteropathogenic *V. parahaemolyticus*, *V. vulnificus*, and *V. cholerae* using biochemical tests, PCR and/or real-time PCR approaches. The method includes detection of key recognized virulence-associated genetic markers by PCR and real-time PCR. Additional genetic targets, including the *tlh* gene, may also be incorporated into multiplex PCR assays to support strain characterization and detection.

[10] 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).
[11] FAO and WHO, 2021, Advances in science and risk assessment tools for *Vibrio parahaemolyticus* and *V. vulnificus* associated with seafood (Microbiological Risk Assessment Series No.35). (Section 3.5).