GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF PATHOGENIC *VIBRIO* SPECIES IN SEAFOOD

CAC/GL 73-2010

INTRODUCTION

1. During the last few years, there has been an increase in reported outbreaks and cases of foodborne disease attributed to pathogenic *Vibrio* species. As a result, there have been several instances where the presence of pathogenic *Vibrio* spp. in seafood has led to a disruption in international trade. This has been particularly evident with *Vibrio parahaemolyticus* where there has been a series of pandemic outbreaks due to the consumption of seafood, and its emergence has been observed in regions of the world where it was previously unreported. A number of *Vibrio* species are increasingly being recognized as potential human pathogens. The food safety concerns associated with these microorganisms have led to the need for specific guidance on potential risk management strategies for their control.

General Characteristics of Pathogenic Vibrio spp.

2. The genus *Vibrio* contains at least twelve species pathogenic to humans, ten of which can cause food-borne illness. The majority of food-borne illness is caused by *V. parahaemolyticus*, choleragenic *Vibrio cholerae,* or *Vibrio vulnificus*. *V. parahaemolyticus* and *V. cholerae* are solely or mainly isolated from gastroenteritis cases that are attributable to consumption of contaminated food (both species) or intake of contaminated water (*V. cholerae*). In contrast, *V. vulnificus* is primarily reported from extraintestinal infections (septicaemia, wounds, etc.) and primary septicaemia due to *V. vulnificus* infection is often associated with consumption of seafood.

3. In tropical and temperate regions, these species of *Vibrio* occur naturally in marine, coastal and estuarine (brackish) environments and are most abundant in estuaries. Pathogenic *Vibrio* spp., in particular *V. cholerae*, can also be recovered from freshwater reaches of estuaries, where it can also be introduced by faecal contamination. *V. cholerae*, unlike most other *Vibrio* species, can survive in freshwater environments.

4. It is now possible to differentiate environmental strains of *V. cholerae* and *V. parahaemolyticus* between virulent and avirulent strains based on their ability or inability to produce their major virulence factors. The pathogenic mechanisms of *V. vulnificus* have not been clearly elucidated, and its virulence appears to be multifaceted and is not well understood, and therefore all strains are considered virulent.

5. The following are important characteristics common to all *Vibrio* spp. *Vibrio* spp. are sensitive to low pH but grow well at high pH, and thus infections caused by *Vibrio* spp. are frequently associated with low-acid foods. In addition, the ingestion of a large number of viable cells is needed for pathogenic *Vibrio* spp. to survive the acidic environment of the stomach and establish an infection. Cooking of food products readily inactivates *Vibrio* spp. even in highly contaminated products. Hygienic practices used with all food-borne pathogens will in general control the growth of pathogenic *Vibrio* spp.

6. There are, however, characteristics specific to each of the three major pathogenic species of *Vibrio* that require attention as described below.

Vibrio parahaemolyticus

7. *V. parahaemolyticus* is considered to be part of the autochthonous microflora in the estuarine and coastal environments in tropical to temperate zones. While *V. parahaemolyticus* typically is undetectable in seawater at 10°C or lower, it can be cultured from sediments throughout the year at temperatures as low as 1°C. In temperate zones, the life cycle consists of a phase of survival in winter in sediments and a phase of release with the zooplankton when the temperature of the water increases up to 14 - 19 °C. *V. parahaemolyticus* is characterized by its rapid growth under favourable conditions.

8. The vast majority of strains isolated from patients with diarrhoea produce a thermostable direct hemolysin (TDH). It has therefore been considered that pathogenic strains possess a tdh gene and produce TDH, and non-pathogenic strains lack the gene and the trait. Additionally, strains that produce a TDH-related hemolysin (TRH) encoded by the trh gene should also be regarded as pathogenic. Symptoms of *V. parahaemolyticus* infections include explosive watery diarrhoea, nausea, vomiting, abdominal cramps and, less frequently, headache, fever and chills. Most cases are self-limiting, however, severe cases of gastroenteritis requiring hospitalization have been reported. Virulent strains are seldom detected in the environment or in foods, including seafoods, while they are detected as major strains from faeces of patients.

9. *V. parahaemolyticus* was first identified as a foodborne pathogen in Japan in the 1950s. By the late 1960s and early 1970s *V. parahaemolyticus* was recognized as a cause of diarrhoeal disease worldwide. A new *V. parahaemolyticus* clone of O3:K6 serotype emerged in Calcutta in 1996. This clone, including its serovariants, has spread throughout Asia and to the USA, elevating the status of the spread of *V. parahaemolyticus* infection to pandemic. In Asia, *V. parahaemolyticus* is a common cause of foodborne disease. In general, the outbreaks are small in scale, involving fewer than 10 cases, but occur frequently. This pandemic *V. parahaemolyticus* has now spread to at least 5 continents. There is a suggestion that ballast discharge may be a major mechanism for global spread of pandemic *V. parahaemolyticus*, but a possibility of export/import seafood-mediated international spread cannot be ruled out.

10. From the point of controlling seafood-borne *V. parahaemolyticus* illnesses, harvest is probably the most critical stage, since it is from this point onwards that individuals can actually implement measures to control *V. parahaemolyticus*.

11. Foods associated with illnesses due to consumption of *V. parahaemolyticus* include for example crayfish, lobster, shrimp, fish-balls, boiled surf clams, jack-knife clams, fried mackerel, mussel, tuna, seafood salad, raw oysters, clams, steamed/boiled crabmeat, scallops, squid, sea urchin, mysids, and sardines. These products include both raw and partially treated[1] and thoroughly treated seafood products that have been substantially recontaminated through contaminated utensils, hands, etc.

Vibrio cholerae

12. *V. cholerae* is indigenous to fresh and brackish water environments in tropical, subtropical and temperate areas worldwide. Over 200 O serogroups have been established for *V. cholerae*. Strains belonging to O1 and O139 serotypes generally possess the *ctx* gene and produce cholera toxin (CT) and are responsible for epidemic cholera. Epidemic cholera is confined mainly to developing countries with warm climates. Cholera is exclusively a human disease and human faeces from infected individuals are the primary source of infection in cholera epidemics. Contamination of food production environments (including aquaculture ponds) by 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.

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

14. Some strains belonging to the O serogroups other than O1 and O139 (referred as non-O1/non-O139) can cause food-borne diarrhoea that is milder than cholera.

15. Outbreaks of food-borne cholera have been noted quite often in the past 30 years; seafood, including bivalve molluscs, crustaceans, and finfish, are most often incriminated in food-borne cholera cases in many countries. While shrimp has historically been a concern for transmission of choleragenic *V. cholerae* in international trade, it has not been linked to outbreaks and it is rarely found in shrimp in international trade.

Vibrio vulnificus

16. *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 bivalve molluscs. This is a serious, often fatal, disease with one of the highest fatality rates of any known foodborne bacterial pathogen. The ability to acquire iron is considered essential for virulence expression of *V. vulnificus*, but a virulence determinant has not been established and, therefore, it is not clear whether only a particular group of the strains are virulent. The host factor (underlying chronic diseases) appears to be the primary determinant for *V. vulnificus* infection. Incubation period ranges from 7 hours to several days, with the average being 26 hours. The dose response for humans is not known.

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

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

19. The densities of *V. vulnificus* are high in oysters at harvest when water temperatures exceed 20°C in areas where *V. vulnificus* is endemic; *V. vulnificus* multiplies in oysters at a temperature higher than 13°C. The salinity optimum for *V. vulnificus* appears to vary considerably from area to area, but highest numbers are usually found at intermediate salinities of 5 to 25 g/l (ppt: parts per thousand). Relaying oysters to high salinity waters (>32 g/l (ppt: parts per thousand) was shown to reduce *V. vulnificus* numbers by 3–4 logs (<10 per g) within 2 weeks.

FAO/WHO Risk Assessments

20. FAO/WHO risk assessments on *Vibrio vulnificus* in raw oysters and choleragenic *Vibrio cholerae* O1 and O139 in warm water shrimp in international trade have been published (2005)[2,3]. Additional risk assessments on *Vibrio parahaemolyticus* in raw oysters, in raw and undercooked finfish and in Anadera granosa (bloody clams) have been completed[4]. These risk assessments constitute the basis of this Code.

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1 "treated" means any vibriocidal treatment (e.g. heat treatment, high pressure.). Refer to Section 2.3 (definition for "partially treated",

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

3 FAO and WHO, 2005. Risk assessment of choleragenic *Vibrio cholerae* O1 and O139 in warm-water shrimp in international trade. Microbiological Risk Assessment Series, No.9.

4 FAO and WHO, 20XX. Risk assessment of *Vibrio parahaemolyticus* in seafood. Microbiological Risk Assessment Series, No.XX (In press).

SECTION I – OBJECTIVES

21. 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 minimise the likelihood of illness arising from the presence of pathogenic *Vibrio* spp. in seafood. These Guidelines also provide information that will be of interest to the food industry, consumers, and other interested parties.

SECTION II – SCOPE, USE AND DEFINITION

2.1 Scope

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

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

2.2 Use of the document

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

2.3 Definition

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

Definitions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) and the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

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

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

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

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

SECTION III - PRIMARY PRODUCTION

3.1 Environmental hygiene

26. Refer to Section 3.1 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969). In addition:

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

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

29. For monitoring bivalve molluscs, at harvest, refer to the Annex to this Guideline.

30. For seafood grown in coastal localities, especially in cholera-endemic areas, care should be taken to avoid contamination of seafood with faecal choleragenic *V. cholerae*.

3.2 Hygienic production of seafood sources

31. Refer to Section 3.2 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

3.3 Handling , storage and transport

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

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

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

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

36. During on-land transportation from the landing port to the on-shore market and/or processing establishments, in order to minimise 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 minimised. Ice can be used efficiently to keep seafood under refrigeration during transportation and sale. Live fish and shellfish should be transported at the lowest temperature tolerable for the species. Covered containers should be used for transport to prevent contamination.

3.4 Cleaning, maintenance and personnel hygiene at primary production

37. Refer to Section 3.4 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

38. Refer to Section 7.1 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969). A carrier who is excreting choleragenic *V. cholerae* should not handle seafood or ice for the storage of seafood, which may result in the contamination of the seafood with choleragenic *V. cholerae*.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

Objectives

39. Equipment and facilities should be designed, constructed and laid out to minimise cross-contamination and recontamination with pathogenic *Vibrio* spp.

4.1 Location

40. Refer to Section 4.1 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

4.1.1 Establishments

41. Refer to Section 4.1.1 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

4.1.2 Equipment

42. Refer to Section 4.1.2 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

4.2 Premises and rooms

4.2.1 Design and layout

43. Refer to Section 4.2.1 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

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

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

4.2.2 Internal structures and fittings

46. Refer to Section 4.2.2 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

4.2.3 Temporary/mobile premises and vending machines

47. Refer to Section 4.2.3 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

4.3 Equipment

4.3.1 General

48. Refer to Section 4.3.1 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

4.3.2 Food control and monitoring equipment

49. Refer to Section 4.3.2 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

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

4.3.3 Containers for waste and inedible substances

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

4.4 Facilities

52. Refer to Section 4.4 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

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

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

4.4.1 Water supply

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

4.4.2 Drainage and waste disposal

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

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

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

4.4.3 Cleaning

59. Refer to Section 4.4.3 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 3.2.1 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

4.4.4 Personnel hygiene facilities and toilets

60. Refer to Section 4.4.4 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 3.5.1 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

4.4.5 Temperature control

61. Refer to Section 4.4.5 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 4.1 of Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

62. The Code of Practice for Fish and Fishery Products indicates maintaining the product at temperature as close to 0ºC as possible. For pathogenic *Vibrio* spp., a temperature of 10ºC or lower is adequate. In this Code, 10ºC is used as the target temperature to prevent/minimize growth of *Vibrio* spp. However, pathogenic bacteria species such as *Listeria monocytogenes, Clostridium botulinum* and histamine formers may also be hazards in addition to *Vibrio* spp. If this is the case, more strict temperature control, as close to 0ºC as possible, should be implemented. In the case of bivalve molluscs, a different temperature control specified in the Annex would be required. The facility should be capable of controlling ambient temperature to ensure that product temperature during processing of raw seafood is maintained at a temperature of 10ºC or lower.

4.4.6 Air quality and ventilation

63. Refer to Section 4.4.6 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 3.2.2 of Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

4.4.7 Lighting

64. Refer to Section 4.4.7 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 3.2.3 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

4.4.8 Storage

65. Refer to Section 4.4.8 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 3.2.2 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

SECTION V - CONTROL OF OPERATION

5.1 Control of food hazards

66. Refer to Section 5.1 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

5.2 Key aspects of hygiene control systems

5.2.1 Time and temperature control

67. Refer to Section 4.1 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003). Time and temperature are the most important factors affecting the rate of growth of pathogenic *Vibrio* spp. in seafood. At each step the temperature should be controlled and monitored.

5.2.2 Specific process steps

5.2.2.1 Washing and processing

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

5.2.2.2 Cooking

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

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

5.2.2.3 Food processing practices

71. Food processing practices (e.g. acidification to pH below 4.8, salting to a sodium chloride concentration of more than 10% for *V. parahaemolyticus*, food preservatives and/or water activity less than 0.94) can be used to minimise the growth and possibly reduce the levels of pathogenic *Vibrio* spp. in seafood.

72. Freezing could be used to reduce the level or prevent the growth of pathogenic *Vibrio* spp. in seafood.

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

74. Any practice 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 (CAC/GL 69-2008).

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

5.2.2.4 Storage

76. Seafood intended for raw consumption should be stored in shallow layers and surrounded by sufficient quantities of finely crushed ice or with a mixture of ice and 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 (CAC/RCP 52-2003)).

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

5.2.3 Microbiological and other specifications

78. Refer to Section 5.2.3 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969) and the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

5.2.4 Microbiological cross-contamination

79. Refer to Section 5.2.4 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) and Sections 3.2.2 and 3.3.2 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

5.2.5 Physical and chemical contamination

80. Refer to Section 5.2.5 the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 3.2.2 and 3.3.2 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

5.3 Incoming material requirements

81. Refer to Section 5.3 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 8.5.1 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

5.4 Packaging

82. Refer to Section 5.4 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 8.5.2 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

5.5 Water

5.5.1 In contact with food

83. Refer to Section 5.5.1 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969) except cases specified within this Code where clean water could be used.

[5] Section 3.2 of the Risk assessment of *Vibrio vulnificus* in raw oysters (FAO/WHO Microbiological Risk Assessment Series 8); FAO and WHO, 20XX. Risk assessment of *Vibrio parahaemolyticus* in seafood. Microbiological Risk Assessment Series, No.XX (In press); FAO and WHO, 2005. Risk assessment of choleragenic *Vibrio cholerae* O1 and O139 in warm-water shrimp in international trade. Microbiological Risk Assessment Series, No.9.

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

5.5.2 As an ingredient

85. Refer to Section 5.5.2 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

5.5.3 Ice and steam

86. Refer to Section 5.5.3 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

5.6 Management and supervision

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

5.7 Documentation and records

88. Refer to Section 5.7 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

5.8 Recall procedures

89. Refer to Section 5.8 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

90. Refer to Section 6 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 3.4 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

91. Refer to Section 7 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 3.5 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

SECTION VIII – TRANSPORTATION

92. Refer to Section 8 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969) and Sections 3.6 and 17 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

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

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

9.1 Lot identification

94. Refer to Section 9.1 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

9.2 Product information

95. Refer to Section 9.2 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

9.3 Labelling

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

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

9.4 Consumer education

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

99. Programs should be directed at consumers:

- To educate them on household practices and behaviours as indicated in Five Keys to Safer Food (WHO) "that would specifically keep the numbers of pathogenic *Vibrio* spp. that may be present in foods, to as low a level as possible and minimise the potential of cross-contamination from seafood to hands of food handlers, and then from hands to other foods, or from seafood to utensils (e.g., cutting board), and then from utensils to other foods by:
  - keeping seafood cold to minimise 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;
  - washing and disinfecting hands, utensils and equipments whenever raw seafood is handled; and
  - separating utensils and equipment used for raw seafood, from those use for finished product, where appropriate.
- To help them make informed choices about the purchase, storage, shelf-life labelling and appropriate consumption of certain raw seafood that have been identified in relevant risk assessment and other studies, taking into consideration the specific regional conditions and consumption habits.

9.4.1 Special Attention to Susceptible Subpopulations

100. Liver disease is a prominent risk factor for human infection with pathogenic *Vibrio* spp., especially *V. vulnificus*. Additional risk factors include diabetes, haemochromatosis and HIV/AIDSs.[6] Subpopulations with increased susceptibility should follow the advice below:

- Avoid the consumption of raw or partially treated seafood; and
- Cook seafood thoroughly before consumption.

SECTION X – TRAINING

10.1 Awareness and responsibilities

101. Refer to Section 10.1 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 3.8 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

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

10.2 Training programmes

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

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

10.3 Instruction and supervision

104. Refer to Section 10.3 of the Recommended International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

10.4 Refresher training

105. Refer to Section 10.4 of the Recommended International Code of Practice-General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 3.8 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

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

ANNEX ON THE CONTROL MEASURES FOR

Vibrio parahaemolyticus and *Vibrio vulnificus* in Bivalve Molluscs[7]

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[8] for both of these pathogens in many countries, bivalve molluscs are often kept alive out of water for days after harvest at ambient temperatures which allows the growth of *V. parahaemolyticus* and *V. vulnificus*.

SECTION I – OBJECTIVES

2. The purpose of this Annex is to provide guidance on control measures that minimize the risk arising from the presence of pathogenic *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs. It deals with the means to minimize and/or prevent the introduction/contamination and/or the growth of these pathogens, and adequate partial treatment[9] of bivalve molluscs before consumption. Control measures required for these pathogens are similar but not the same to the extent that they have different characteristics on the growth and survival. The control measures outlined in this Annex reflects these differences, where they exist. This Annex further provides information that may be of interest to regulatory authorities, the food industry, consumers, and other interested parties.

SECTION II – SCOPE, DEFINITION AND USE OF THE DOCUMENT

2.1 Scope

3. This Annex covers bivalve molluscs that are intended for consumption in a live, raw, or partially treated state. Bivalve molluscs (e.g. clams, mussels and oysters) consumed after a vibriocidal treatment are not covered in this Annex, noting that the control measures presented in the main documents are sufficient to control the safety of these products. The target microbiological hazards of this Annex are only pathogenic *V. parahaemolyticus* and *V. vulnificus*.

4. This Annex highlights the key control measures that influence the introduction/contamination of and minimize levels of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs and thus the risk of foodborne diseases caused by these pathogens.

5. This Annex provides guidance applicable throughout the food chain, from primary production through to final consumption of bivalve molluscs and particular guidance on post-harvest processing. Controls measures presented in Part I apply to live and raw bivalve molluscs (including those that receive post-harvest processing), while those in Part II apply to bivalve molluscs consumed after partial treatment.[10]

2.2 Definitions

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

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

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

2.3 Use of the document

7. This Annex is supplemental to and should be used in conjunction with the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969), the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003), Hygiene section of the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008) and the *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.

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[7] Phylum Mollusca: Class Bivalvia

[8] FAO/WHO has developed and published Risk assessment of *Vibrio vulnificus* in raw oysters (2005), and Risk assessment of *V. parahaemolyticus* in seafood (in Press). This Annex is based on key findings and outcomes derived from these risk assessments and other relevant epidemiological evaluations.

[9] Including cooking.

[10] Risk assessment of *V. parahaemolyticus* in *Anadara granosa* (bloody clams)

PART I: BIVALVE MOLLUSCS CONSUMED LIVE AND RAW

SECTION III - PRIMARY PRODUCTION

3.1 Environmental hygiene

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

9. The control measures described in this section generally apply to pre-harvest environmental conditions and practices during and immediately following harvest, typically while under the control of the harvester. Effective control measures for *V. parahaemolyticus* and *V. vulnificus* will typically require an evaluation in terms of the risk associated with environmental factors in the harvesting area and harvesting practices based on epidemiology and environmental conditions (i.e. air and water temperature and salinity). An important element in estimating risk is that *V. parahaemolyticus* grows faster and at colder temperatures than *V. vulnificus*. Predictive tools using these environmental monitoring parameters and growth rates as inputs have been elaborated based on the FAO/WHO risk assessments and, when validated, may be used to estimate corresponding *V. parahaemolyticus* and *V. vulnificus* levels and risk. The predictive ability can be improved by incorporating local data and considering additional factor such as hydrodynamic effects (occurrence of tidal waves, rainfall) and sunlight.

10. In cases where predictive models are used to estimate the concentration and risks of pathogenic *Vibrio* spp. in seawater and/or bivalve molluscs based on air and water temperatures and/or salinity, their accuracy would be enhanced by incorporating local data on levels of total and pathogenic *V. parahaemolyticus* and *V. vulnificus* and growth in local bivalve species. Factors such as hydrodynamic effects (e.g. currents, tides, hurricanes and rainfall) and sunlight influences the levels of *Vibrio* spp. The dose response model used in the predictive tool may need modifications based on epidemiology, as regional differences exist in the prevalence of pathogenic strains of *V. parahaemolyticus* and *V. vulnificus* including attack rate relative to exposure to *V. parahaemolyticus* strains occurred in those areas concerned.

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

12. Additionally, there are some indications that *Vibrio* spp. can be introduced into a harvest area through the release of ballast water. Therefore, the impact of ballast discharge in or around the harvesting area should be controlled regarding the presence of *Vibrio* spp., especially in areas that are in close proximity to international shipping lanes.

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

- The number of sporadic illnesses and outbreaks of *V. parahaemolyticus* and *V. vulnificus* associated with bivalve molluscs harvested from a distinct hydrographic area, and whether these illnesses are indicative of an annual reoccurrence or an unusual increase of *Vibrio* spp. illnesses is reported;
- Water temperatures representative of harvesting conditions. Water temperatures below 15ºC [12] for *V. parahaemolyticus* and below 20ºC 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* (10ºC) and *V. vulnificus* (13ºC), which may increase risk regardless of harvest water temperature;
- Harvest practices that allow radiant solar heating to raise temperatures of bivalve molluscs to temperatures above ambient air temperatures prior to harvest (i.e. intertidal harvest) and exposure time;
- Salinity ranges and optima are different for *V. parahaemolyticus* and *V. vulnificus*. Environmental and epidemiological data indicate low *V. parahaemolyticus* and *V. vulnificus* levels and few cases of illnesses are associated with bivalve molluscs when salinity exceeds 35 ppt (g/l) and 30 ppt (g/l), respectively.

14. The competent authority should inform food business operators of the control measures contained in Sections 3.2 (Hygienic production of food sources), 3.3 (Handling, storage and transportation) and 5.1 (Control of food hazards) and 5.2 (Key aspects of hygiene control systems) of this Annex when at least:

- Levels of *V. parahaemolyticus* and/or *V. vulnificus*, or environmental parameters exceed testing/monitoring criteria that are based on risk assessment, if applicable.
- An unusual increase of *Vibrio* spp. illnesses is reported.

15. The activities described in this section should be implemented by producers in cooperation with the regulatory authority having jurisdiction.

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

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

3.2 Hygienic production of food sources

16. Pre-harvest and harvest measures should be applied as necessary based upon the factors identified in Section 3.1 above, such as:

- Restrict harvest or otherwise prevent use of product for raw consumption (e.g. close area to harvest or divert product for further processing).
- Where possible, sink bivalve molluscs below the thermocline where the growth of pathogenic *Vibrio* spp. should not occur
- Restrict the time to refrigeration
- Relay bivalve molluscs to areas where risk is sufficiently reduced (e.g. relay bivalve molluscs with *V. vulnificus* to high salinity offshore waters)

3.3 Handling, storage and transport

17. Bivalve molluscs destined to be consumed live or untreated raw should be handled separately from those destined for post-harvest processing or other treatment to avoid cross contamination.

18. During handling, storage and transport of harvested bivalve molluscs, the following control measures should be applied as necessary based upon the factors identified in Section 3.1. It is important that any control for *V. parahaemolyticus* and/or *V. vulnificus* is not less than that required for the control of any other pathogenic organisms that may be present in bivalve molluscs.

- Limit time from harvest or first exposure to ambient air temperature to initial refrigeration based on modelling and sampling.
- Minimize time and temperature conditions that would allow the growth of *V. parahaemolyticus* and *V. vulnificus* during wet storage of bivalve molluscs.
- Bivalve molluscs are to be transported at the lowest temperature that minimizes growth of *V. parahaemolyticus* and *V. vulnificus*. The time between refrigeration and reaching a temperature that does not support growth of *V. parahaemolyticus* and *V. vulnificus* should be minimized when the temperature of the bivalve molluscs exceeds the minimum growth temperature for pathogenic vibrios, and the time between harvest and raw consumption should be limited appropriately or the product should undergo additional treatment to reduce pathogenic *Vibrio* levels. Special attention should be paid to maintaining the characteristics of bivalve molluscs to be consumed live following Section 7.3 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).
- It may be useful to periodically survey levels of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs at various points in the distribution chain to verify effectiveness of recommended control measures.
- Anyone involved in the handling, storage or transport of bivalve molluscs should be educated in the relationship between temperature control and growth of *V. parahaemolyticus* and *V. vulnificus* and trained in proper handling, storage and transport.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

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

SECTION V - CONTROL OF OPERATION

5.1 CONTROL OF FOOD HAZARDS

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

21. The control measures described in this section generally apply to post-harvest handling and processing. Control of *V. parahaemolyticus* and *V. vulnificus* typically requires the stringent application of Good Hygienic Practices and other supportive programs. These prerequisite programs, together with HACCP, can provide a sound framework for the control of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.

22. Any control measures or practice selected to significantly reduce or limit but not necessarily completely eliminate *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs (e.g. freezing, high pressure and mild heating), should be adequately validated to ensure that the control measure is effective. They should also be approved by the competent authority. Such validated control measures/practices should be implemented under the HACCP system. *V. parahaemolyticus* is generally more resistant than *V. vulnificus* to any given treatment. Therefore, a process that is effective for *V. vulnificus* may not be as effective for *V. parahaemolyticus*.

5.2 Key aspects of hygiene control systems

5.2.1 Time and temperature control

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

5.2.2 Specific process steps

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

5.2.3. Microbiological cross contamination

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

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

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

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

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

SECTION VIII – TRANSPORTATION

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

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

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

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

9.3 LABELLING

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

9.4 CONSUMER EDUCATION

26. 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*.

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

SECTION X - TRAINING

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

PART II. BIVALVE MOLLUSCS CONSUMED IN PARTIALLY TREATED STATE[13]

SECTION III - PRIMARY PRODUCTION

3.1 Environmental hygiene

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

30. The controls described in Section III (Primary production) of Part I should be implemented. The combination of measures of the treatment and those described in Section III of this part should achieve at least an equivalent level of protection to the level of protection provided for raw or live bivalve molluscs in Section III of Part I.

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

3.2 Hygienic production of food sources

32. Refer to Section 3.2 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section 3.2 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

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

3.3 Handling, storage and transport

33. Refer to Section 3.3 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section 3.3 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

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

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

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

SECTION V - CONTROL OF OPERATION

5.1 Control of food hazards

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

37. The controls described in this section generally apply to post-harvest handling and processing. Control of *V. parahaemolyticus* and *V. vulnificus* will typically require the stringent application of Good Hygienic Practices and other supportive programs. These prerequisite programs, together with HACCP, can provide a sound framework for the control of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.

38. *V. parahaemolyticus* is generally more resistant than *V. vulnificus* to any given treatment. Therefore, a process that is effective for *V. vulnificus* may not be as effective for *V. parahaemolyticus*. Any measure or practice to significantly reduce or limit but not necessarily completely eliminate *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs should be adequately validated to assure that the control measures are effective and such validated control measures as practiced should be implemented under an HACCP system.

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

5.2 Key aspects of hygiene control systems

5.2.1 Time and temperature control

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

5.2.2 Specific process steps

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

5.2.3 Microbiological cross contamination

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

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

42. Refer to Section VI of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section VI of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

43. Refer to Section VII of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section VII of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

SECTION VIII – TRANSPORTATION

44. Refer to Section VIII of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section VIII of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

45. Refer to Section 9.1 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section 9.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

9.1 LABELLING

46. Refer to the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and Section II-7 Labelling in the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008). Where appropriate, product labels should include information on safe handling practices and storage recommendations.

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

9.2 CONSUMER EDUCATION

48. 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*.

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

SECTION X - TRAINING

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