

Overseas Travel Report

Code of Hygienic Practice for Pathogenic *Vibrio* spp. in Fish and Fishery Products Kyoto, Japan

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Important Notice

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Executive Summary

The Codex Alimentarius Commission is a joint body of the Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO). It develops food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Program. The main purposes of Codex are protecting the health of consumers, ensuring fair trade practices in food trade and promoting coordination of all food standards work undertaken by international governmental and non-governmental organisations.

The Codex Working Group on the Code of Hygienic Practice for *Vibrio* spp. in Seafood was held in Kyoto, Japan on the 3rd to the 6th June, 2008 to develop the early draft of the Code.

Australia was represented on this Working Group because of the potential impact on industry, e.g. the requirement to use unnecessary post harvest treatments and potential market access barriers due to requirements for implementation of the Code in export destinations.

The Code focuses only on product:pathogen combinations that have been subjected to international risk assessments. These assessments may not necessarily reflect the Australian situation. The combinations of main interest, where there is potential for organisms to be detected in Australian products are *V. vulnificus* and *V. parahaemolyticus* in oysters, and *V. cholerae* in prawns.

Several sections of the document indicate that there may be conditions, based on a low level of risk, where monitoring or controls are not applicable. There is potential that some of the seafood industries could be excluded from sections of the Code based on a thorough knowledge of:

- The prevalence of *Vibrio* spp. in their product
- The occurrence of pathogenic isolates
- How the prior two points relate to the ecology of the harvest area, such as salinity and temperature parameters.

There is very limited current data on these pathogens in Australian seafood. It may be beneficial to address these data gaps before the introduction of this Code, particularly in the case of molluscs such as oysters, cockles and abalone and also in the case of warm water prawns. There is potential that the high salinities found in some Australian oyster-growing regions may allow an exemption from adhering to the strict monitoring and post harvest processing recommended as part of the Code.

Microbiological criteria were not set as part of this Code, as the risk reduction would be diverse in different parts of the world. Consequently, methodologies for identification and enumeration of these organisms were not discussed. Whilst this is beneficial for Australia, it also has drawbacks as it removes a point of comparison to debate international product detentions that are not based on actual risk. Furthermore, there is no acceptable methodology specified for evaluating the prevalence and pathogenicity of these organisms.

The Working Group has suggested that a separate Annex be developed for molluscan shellfish, as these products require additional consideration and control measures. Australia should review this Annex thoroughly and consider repeat participation in this Working Group.

Recommendations

- Australia should request that a definition of pathogenic *Vibrio* spp. be provided.
- Australia should request that the word epidemiology be added to Section 2.2 and that the conditions where modifications and amendments are necessary be specified.
- Australia should request that the term disinfected seawater be removed from Section 2.3.
- Australia should review this Annex thoroughly and consider repeat participation in this Working Group.

Introduction

The Codex Alimentarius Commission is a joint body of the Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO). It develops food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Program. The main purposes of Codex are protecting the health of the consumers, ensuring fair trade practices in food trade and promoting coordination of all food standards work undertaken by international governmental and non-governmental organisations.

At the 37th Session of the Codex Committee for Food Hygiene (CCFH) in 2005, the Committee agreed to consider further work on the Discussion Paper on Risk Management Strategies for *Vibrio* spp. in seafood, and identified the United States to prepare the written proposal (ALINORM 5/28/13, para 167; 168). The Codex Committee for Fish and Fishery Products (CCFFP) agreed that further work on risk management of *Vibrio* spp. in seafood was essential and encouraged CCFH to proceed with its work in this area. At the 29th session of the CCFFP, the Committee considered the inclusion of *V. parahaemolyticus* in the Hygiene section of the Draft Standard for Live and Raw Bivalve Molluscs. However, the Committee agreed to defer consideration of a criterion for *V. parahaemolyticus* pending completion of the work undertaken by the CCFH.

The CCFH convened a Working Group on the development of the Code of Hygienic Practice for *Vibrio* spp. in Seafood. The purpose of the new work was to provide member countries and industry, within the framework of a Code of Hygienic Practice, guidance on control of pathogenic *Vibrio* species in seafood. The scope of the document was intended to include finfish, crustaceans and bivalve molluscan shellfish that are marketed in an uncooked state. The new work is envisioned to encompass a base document for the control of all pathogenic *Vibrio* spp., with annexes developed for individual *Vibrio* spp., or for seafood products if CCFH finds that they are necessary to provide more specific guidance.

The CCFFP has requested that the CCFH address the four specific areas put forward by the CCFFP:

1. The identification of effective control measures;
2. The establishment of appropriate microbiological criteria including identification of relevant testing methods;
3. The need for risk managers to establish tolerances, and
4. The consideration of source of seafood as a risk factor impacting the control of pathogenic *Vibrio* spp.

Seafood Services Australia commissioned SARDI to review how this new work may impact Australian fisheries. This identified that, although these species have been detected in Australian seafood, these detections were rare. The report concluded that despite the low prevalence and little associated epidemiology occurring in Australia, that industry could be affected by requirements to use unnecessary post-harvest treatments and may face technical market access barriers, which are not based on risk. Based on this review, AQIS agreed that there was a need for official representation by Australia at this Working Group. The author of this report was asked to attend to provide technical support to the Australian delegation.

Objectives

1. Attend the Codex Committee on Food Hygiene's Working Group on pathogenic marine *Vibrio* spp. and provide specialist technical advice to the delegation leader.
2. Identify areas of future R&D, which will address data gaps in relation to any emerging Codex requirements.
3. Obtain information on emerging/new international standards relevant to market access for Australian seafood exports.

Working Group

The Working Group on Code of Hygienic Practice for *Vibrio* spp. in Seafood, led by Japan was held in Kyoto, Japan on the 3rd to the 6th June, 2008. The Group was chaired by Dr Mitsuaki Nishibuchi, who is a prominent researcher in the area of pathogenic *Vibrio* spp.. In addition to the delegates from 11 countries that attended, there was also representation by the European Community, FAO, the International Commission on Microbiological Specifications for Foods and the Codex Secretariat. A full list of attendees is provided in Appendix 1.

The protocol followed, was to work through the original draft document (Appendix 2), which had been distributed prior to the meeting for comment by Codex, paragraph by paragraph. The following are summaries of important changes and points of interest within the document that are particularly relevant to the Australian seafood industry.

Title

The working group was initially requested to develop a “Code of Practice for *Vibrio* spp.” (ALINORM 08/31/13, para 156). However, the early draft of this document used the title: Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Vibrio* Species in Seafood indicating that the Working Group would be developing a Guideline document, rather than a Code. Consequently, to comply with the original request from CCFH to develop a Code of Practice, a decision was made to change this title to: Proposed Draft Code of Hygienic Practice for Pathogenic *Vibrio* Species in Seafood.

Introduction

The introduction was changed significantly on the last day based on a decision to include the majority of a background document into this section of the document. This section will have to be reviewed thoroughly, although it only provides background information and does not change the scope or requirements of the actual Code.

Objectives

In this section, as in all sections of the document, there are references to pathogenic *Vibrio* spp.. However, there is no definition provided within the Code, despite several representatives

suggesting that it should be provided. The rationale for providing a definition is due to about 12 members of the *Vibrio* genus having the potential to be pathogenic, such as *V. alginolyticus*, which is commonly detected in Australian seafood. However, the intended scope of this document is only *V. parahaemolyticus*, *V. vulnificus* and choleraogenic *V. cholerae*. **Australia should request that a definition of pathogenic *Vibrio* spp. be provided.** Despite this being briefly discussed in the new introduction section, it is important that the term be defined for the purpose of this Code. This is relevant as some of the Australian strains, such as *tdh/trh* negative strains, may not be considered pathogenic.

Scope

The term fish and fishery products was removed from the code and replaced with the word seafood throughout the document. A definition for seafood was then provided that was in line with the CCFPP definition of seafood, which includes fish, shellfish and other aquatic invertebrates from marine and fresh water sources and their products, which are intended for human consumption. The rationale for inclusion of fresh water species lies in the capability of *V. cholerae* to grow in fresh water.

This Code is targeted towards those product:pathogen combinations that have been subjected to international risk assessment. Thus far, work has been undertaken on:

- *V. parahaemolyticus* in raw oysters harvested and consumed in Japan, New Zealand, Australia, Canada and the United States of America.
- *V. parahaemolyticus* in finfish consumed raw.
- *V. parahaemolyticus* in bloody clams harvested and consumed in Thailand.
- *V. vulnificus* in raw oysters harvested and consumed in the United States of America.
- Choleraogenic *V. cholerae* O1 and O139 in warm-water shrimp in international trade.

These documents are in varying stages of completion.

Use of the document

This section remains unchanged, however, it includes an important point for Australia: *The application of these guidelines by countries is likely to require modifications and amendments, taking into account regional differences such as Vibrio spp. prevalence and water temperatures.*

This implies that the application of the Code can be changed in a situation where its implementation is considered unnecessary, which would be advantageous for Australia. **Australia should request that the word epidemiology be added to this sentence and that the conditions where modifications and amendments are necessary be specified.** The rationale for this is that Australia has had relatively few illnesses associated with the consumption of shellfish in comparison with some other locations worldwide. The concept that in some situations the Code will not be applicable is repeated later in the document when wording such as *where relevant* and *where applicable* are used in Section 3.1 Environmental Hygiene. It is likely that identification of applicable or relevant areas would be based on the occurrence of pathogenic isolates or the ecology of an area not being suitable for growth of these organisms, such as in full

strength seawater where the salinity would limit growth. This would result in some systems in Australia being excluded, for example some oyster growing areas that are not impacted by freshwater sources. However, the majority of oyster leases would still be included and some prawn industries and fish producers would also be included. One solution would be for affected fisheries to conduct a risk profile to establish concentrations of these pathogens in their waters and seafood products. However, this would be an expensive process and is compounded by the lack of criteria for comparison coupled with a lack of specifications for appropriate methodologies to assess the presence of these pathogens. In general, Codex standards refer to International Organization for Standardization (ISO) method. However, in the case of marine *Vibrio* spp. these methods are considered to be technically problematic due to potential for improbable numbers. Furthermore, *V. parahaemolyticus* is only considered to be pathogenic if the gene that encodes TDH is present. However, it is only possible to determine the presence of the *tdh* gene using molecular methods that are not included within the ISO standard. The best outcome for Australia would be to present the limited epidemiology associated with Australian seafood, together with data showing a low prevalence of this organism as evidence that we don't need to undertake expensive monitoring and validation processes.

Definition

A new definition for clean water has been provided: *water that does not contain pathogenic microorganisms at levels that compromise food safety, for example potable water, disinfected seawater and artificial seawater.* There was some discussion on this definition, with particular disagreement from Australia. **Australia should request that the term disinfected seawater be removed**, as currently the Code indicates that typical Australian practices of using seawater to process shrimp would be unacceptable.

Key Aspects of Hygiene Control Systems

The second paragraph indicates that this Section is only necessary where *Vibrio* spp. are identified as a hazard.

Microbiological and other specifications

As previously stated, the CCFFP requested that the CCFH address the four specific areas including the establishment of appropriate microbiological criteria including identification of relevant testing methods. There was general agreement that based on risk assessment, it is clear that the risk reduction derived from a certain microbiological criteria was diverse among different parts of the world. Therefore, it is difficult to set criteria that are applicable worldwide. The Working Group agreed not to set criteria at this time. Consequently, methodologies for identification and enumeration of these organisms were not discussed.

The decision to not include microbiological criteria within the standard is generally considered to be advantageous for Australia. However, one drawback is in detainment of seafood in international trade causing product losses and/or decreased customer perception of product. A recent Australian example is where live oysters were identified as being contaminated in Singapore based on the identification of *V. vulnificus*; no concentration was reported. The

Singaporean competent authority then notified all wholesalers in Singapore that South Australian oysters would be subject to point of entry testing, based on a nil tolerance approach, despite not having a domestic standard for these organisms. The presence of *V. vulnificus* in product does not necessarily represent a risk to public health, as these organisms are often detected in low concentrations in seafood. The important factor is the actual concentration of the organism. In this Australian example, product was highlighted as being contaminated, without any detail reported on concentration or where the product was sampled (i.e. at point of entry or at retail). Further to this, Singapore also notified Hong Kong and Japan that they would be testing all South Australian product. Without international standards, we do not have a point of reference as to what is considered an acceptable level. This type of rejection in international trade is increasing. However, there is some potential that recognition of the decision by Codex not to develop criteria for these organisms could assist with negotiations in these situations.

Annex for Molluscan shellfish

Throughout the original draft, there were specifications specifically pertaining to bivalve molluscs. The Working Group decided to make this Code generic in its scope. Consequently, the majority of references to bivalve molluscs have been removed from the Code and the Working Group has recommended to the CCFH that a separate Annex be developed for *V. parahaemolyticus* and *V. vulnificus* in molluscan shellfish as these pathogen:product combinations require additional consideration and control measures. If this Annex is approved by CCFH later this year in the 40th Session of the CCFH in Guatemala, then the Annex will be returned to the Working Group. It is likely that the United States will be asked to prepare the original draft of this document. Then it will be returned to the Working Group in either physical or electronic form for consideration. **Australia should review this Annex thoroughly and consider repeat participation in this working group**, particularly as the United States has one of the largest *Vibrio* problems worldwide and may prefer a prescriptive document.

Progress through the Codex Procedure

The revised draft (Appendix 3) has been submitted to the CCFH for consideration at Step 4 of the Codex at the 40th Session of the CCFH, taking place in Guatemala in December 2008. As discussed previously, if the CCFH approves the recommendation of the Annex, then that document will be developed and will move separately through the Codex procedure, without impeding the progress of the Code.

Technical Uptake

Several of the leading scientists in this area attended the working group. In particular, Dr Angelo DePaola from the United States. The author of this report had the opportunity to discuss methodologies for identification of these pathogens in detail with him. In particular, we discussed the latest method being used in America, which is same the method intended to be used in the current Australian seafood CRC project that aims to develop a Refrigeration Index for oysters. The outcomes of this meeting were extremely good, as we discussed new control DNA currently being used to validate their PCR reactions and also the importance of re-optimising reactions when dye chemistry changes.

Progress Against Objectives

- 1. Attend the Codex Committee on Food Hygiene's Working Group on pathogenic marine Vibrio spp. and provide specialist technical advice to the delegation leader.***

Throughout the Working Group, I was able to brief the lead Australian Delegate, Mr. Paul Vanderlinde of AQIS, on how individual components of the Code could impact on our fisheries, particularly with regard to the types of salinities found in harvesting areas, harvesting practices and also the current status of these pathogens in Australia. In its current form, this is a very generic Code and does not include highly technical aspects, such as definitions of pathogenesis, microbiological criteria and methodologies.

- 2. Identify areas of future R&D, which will address data gaps in relation to any emerging Codex requirements.***

As discussed previously, there will be situations where this Code would not be considered applicable. Consequently, it will be important for fisheries that are likely to be affected, such as oysters, wild harvest of bi-valves, abalone (if it is a molluscan shellfish Annex as apposed to a specific bivalve or oyster Annex) and prawns to 'know their product and harvesting regions'. This will require these fisheries to know the annual prevalence of these bacteria in their product and also the prevalence of pathogenic strains. They will need to know how the prevalence relates to ecological parameters such as salinity and temperature.

- 3. Obtain information on emerging/new international standards relevant to market access for Australian seafood exports.***

There is currently no move to set limits for these bacteria within this Code.

Conclusion

Australia has had significant input into the preparation of this Code. However, Australia needs to closely monitor the progress of the Code through the Codex process. Furthermore, if the bivalve shellfish Annex is approved, Australia should participate in this Working Group again.

There is currently little known about the prevalence of pathogenic *Vibrio* spp. in Australia. It may be beneficial to begin to address these data gaps before the introduction of this Code, particularly in the case of molluscs such as oysters, cockles and abalone and also in the case of warm water prawns.

Itinerary

Saturday 31st May 2008

Travel from Adelaide to Osaka

Sunday 1st June 2008

Travel from Osaka to Kyoto

Monday 2nd June 2008

Find meeting venue

Meeting with the Japan delegation

Tuesday 3rd to Friday 6th June 2008

Attend the Codex Alimentarius Committee on Food Hygiene's Working Group on the development of a Code of Hygienic Practice for pathogenic *Vibrio* spp..

Saturday 7th June 2008

Visit Tsukiji Fish market

Sunday 8th June 2008

Return travel to Adelaide

Appendix 1: Attendees

Annex 2

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Appendix 2: Original Draft Document

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

BACKGROUND

The 32nd session of the CCFH identified *Vibrio parahaemolyticus* in shellfish as one of the priority issues for consideration by the ad hoc Expert Consultation (ALINORM 01/13, para. 18.).

At the 34th session, CCFH agreed to develop a Discussion Paper on Risk Management Strategies for *Vibrio* spp. in seafood (para. 78, ALINORM 03/13). The committee further suggested that the initial focus would be *V. parahaemolyticus* in fish and shellfish as the risk assessments for this bacterium in these products were the most advanced. The committee agreed that a drafting group led by the United States, with the assistance of Denmark, Japan, Malaysia, Mozambique, and Thailand would develop the risk management strategy paper.

After the 35th session, the committee decided to suspend further action on the Discussion Paper until there was dialogue with the Committee on Fish and Fish Products (CCFFP). The paper was therefore not included in the agenda for the 36th session of the committee. After receiving encouragement from the CCFFP that the CCFH should take the lead, the CCFH agreed that the risk profile would be included on the agenda for the 37th session for further discussion and development.

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

At the 37th session of the CCFH, the committee agreed to use the newly established process to consider further work on the Discussion Paper on Risk Management Strategies for *Vibrio* spp. in seafood, and identified the United States to prepare the written proposal (paras. 167-168, ALINORM 5/28/13).

At the 39th session of the CCFH, based on the recommendations of the *ad hoc* working group for establishment of CCFH work priorities, the committee agreed to take up a new work on commodity specific annexes for the Code of Hygienic Practice for Fresh Fruit and Vegetables and on a Code of Hygienic Practice for *Vibrio* spp. in seafood (para. 156, ALINORM 08/31/13).

Although the codes and standards developed by CCFFP provide some information on hygienic practices for seafood products, the level of guidance is not sufficiently detailed in relation to the information needed for a code of hygienic practice that can be used to develop food safety systems based on effective implementation of GHP and HACCP programs. Accordingly, the

purpose of the new work is the development of a “Draft Code of Hygienic Practice for the Control of *Vibrio* spp in Fish and Shellfish.” It is anticipated that this new work would be undertaken in close collaboration with CCFPP.

SECTION I – OBJECTIVES

1.1 THE CODEX GENERAL PRINCIPLES OF FOOD HYGIENE

These guidelines provide advice to governments on a framework for the control of a code of hygienic practice, guidance on control of pathogenic *Vibrio* spp. in seafood, mainly focusing on seafood to be eaten raw, with a view towards protecting the health of consumers and ensuring fair practices in food trade. Their primary purpose of these guidelines is to minimise the likelihood of illness arising from the presence of *Vibrio* spp. in seafood. The guidelines also provide information that will be of interest to the food industry, consumers, and other interested parties.

[The new work is envisioned to encompass a base document for the control of all pathogenic *Vibrio* spp., with annexes developed for individual *Vibrio* species or seafood products if CCFH finds that they are necessary to provide more specific guidance.]

SECTION II – SCOPE, USE AND DEFINITION

2.1 SCOPE

These guidelines are intended for seafood and are applicable throughout the food chain, from primary production through consumption. Based on the results of the FAO/WHO risk assessment, other available risk assessments and epidemiological evaluations, these guidelines will focus on control measures that can be used, where appropriate, to minimize and/or prevent the contamination and/or the growth of *Vibrio* spp. in seafood. These guidelines highlight key control measures that affect key factors that influence the frequency and extent of contamination of seafood with *Vibrio* spp. and thus the risk of foodborne diseases caused by *Vibrio* spp. In many instances, these control measures are articulated in a general manner in the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) as part of the general strategy for control of foodborne pathogens in all foods. In providing these guidelines, it is assumed that these General Principles of Food Hygiene are being implemented. Those principles that are restated reflect the need for special attention for the control of *Vibrio* spp.

Good Hygienic Practices (GHPs) 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 codes of hygienic practice should be suitable to control *Vibrio* spp. in cooked seafood. However, the additional measures described in the following guidelines should be consulted and implemented, as necessary to control *Vibrio* spp. in raw seafood and in ready-to-eat food contaminated from raw seafood.

2.2 USE OF THE DOCUMENT

These guidelines are supplemented 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 is likely to require modifications and amendments, taking into account regional differences such as *Vibrio* spp. prevalence and water temperatures.

2.3 DEFINITIONS

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) apply.

Pasteurized seawater: a seawater received microbiocidal treatment (*e.g.* UV irradiation, heat treatment, chlorination) aimed at reducing the number of pathogenic microorganisms including *Vibrio* spp. in seawater, if present, to a level at which they do not constitute a significant health hazard.

Refrigeration: The lowering of product temperature to limit microbial activity (Code of Hygienic Practice for Milk and Milk Products, CAC/RCP 57–2004).

SECTION III - PRIMARY PRODUCTION

3.1 ENVIRONMENTAL HYGIENE (PRE-HARVEST CONTROL)

The following pre-harvest control measures could be effective in the control of *Vibrio* spp. in seafood:

- Temperature and salinity monitoring of the harvesting area
- Testing for pathogenic *Vibrio* spp. in water and mud/sediment
- Testing for pathogenic *Vibrio* spp. in bivalve mollusc meat

When testing/monitoring parameters go beyond a certain level, closing the harvesting area or issuing a public warning should be considered.

In case the predictive models which indicate the concentration of *Vibrio* spp. in seawater and/or bivalve based on water temperatures and/or salinity are useful tool, the predictive ability would be improved by incorporating local data and considering additional factors such as hydrodynamic effects (occurrence of tidal waves, rainfall) and sunlight.

For seafood cultured in coastal areas, especially in cholera-endemic areas, care should be taken to prevent faecal contamination with cholera-genic *V. cholerae*.

Rational and Caution

Commonly used indicators or organisms for faecal contamination are generally not good measures of contamination by *Vibrio* spp.

The concentrations of *V. parahaemolyticus* and *V. vulnificus* in shellfish may be measured directly or predicted by monitoring temperature and salinity. There will not necessarily be a direct relationship between these surrogate variables and the measured concentrations of pathogenic vibrios for a particular area as there is uncertainty and variability in the current models.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

Refer to the *Code of Practice for Fish and Fishery Products* □ CAC/RCP 52-2003 □

3.3 HANDLING, STORAGE AND TRANSPORT

For the storage and handling of seafood, use of seawater taken near the seashore or from the region near the mouth of drain or river contaminated with sewage should be avoided. Especially, clean pathogen-free water such as potable water, pasteurized sea water, and artificial sea water made from potable water should be used for seafood to be eaten raw, and for preparing ice for such use. Seafood should be chilled immediately after harvest, for example, in an ice-water slurry on vessels and at harvest sites. Packing should be utilized during transportation from harvest to the on-shore market or landing port to prevent fecal contamination with cholerae *V. cholerae*.

For the storage of live fish and shellfish, clean seawater or artificial sea water made from potable water should be used.

At the on-shore market and landing port, potable water, artificial sea water made from potable water or pasteurized sea water should be used for washing fish and shellfish.

The time between harvests to refrigeration or freezing should be minimized, preferably less than 1 hour where ambient temperature is high (*e.g.* over 26°C). Ice can be used efficiently to keep seafood under refrigeration during transportation and selling. For living sea fish and shellfish, live boxes containing pasteurized seawater or artificial seawater prepared from potable water should be used.

For cooked (boiled or blanched) products, ice should be used to facilitate the rapid cooling. Ice made from potable water, artificial sea water made from potable water or pasteurized sea water should be used to minimize cross contamination.

Rational

Coastal seawaters used at landing docks and at markets were shown to be occasionally contaminated with high levels of *V. parahaemolyticus*, in tropic, subtropic and warm area. Therefore, the post-harvest stage may be of particular importance with regard to contamination of finfish and other seafood (FAO/WHO, 2002)

During landing at port market, there were several potential risks for fish to be contaminated by water used. The water used during landing and selling at local port fish market is as follows:

- during selling seafoods at market
- for live box

- for transportation of seafoods.

In the scenario analysis conducted by U.S. FDA *V. parahaemolyticus* oyster risk assessment for the Gulf Coast Louisiana/Summer harvest, the greatest reductions were predicted for shorter times to refrigeration and using cooling with ice compared to cooling under conventional refrigeration. Predicted reduction in *V. parahaemolyticus* illnesses from oysters cooled within 1 hour after harvest ranged from 86% (conventional refrigeration) to 97% (cooling with ice). The lower ambient temperatures associated with the other regions result in predicted reductions that are less dramatic.

The risk assessments done by the U.S. FDA and FAO/WHO on *V. parahaemolyticus* in oyster demonstrated the tremendous influence of storage temperature on the risk of *V. parahaemolyticus* infection associated with oysters. It is therefore necessary to control the time/temperature combination immediately after harvest to consumption (FDA, 2005).

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

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

A carrier of choleraogenic *V. cholerae* should not handle seafood and ice for the storage of seafood, which may result in the contamination of the seafood products with choleraogenic *V. cholerae*.

Rational

In cholera-endemic area asymptomatic carriers play an important role in transmission of the choleraogenic *V. cholerae* (Risk assessment of choleraogenic *V. cholerae* O1 and O139 in warm-water shrimp in international trade (FAO/WHO, MRA series No.8, 2005).

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

Objectives

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

4.1 LOCATION

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

4.1.1 Establishments

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

4.1.2 Equipment

Refer to 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

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

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

Where feasible, the washing areas for food equipment involved in the manufacture of the finished product should be located in a separate room from the finished product processing area.

4.2.2 Internal structures and fittings

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

4.2.3 Temporary/mobile premises and vending machines

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

4.3 EQUIPMENT

4.3.1 General

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

4.3.2 Food control and monitoring equipment

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

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

4.3.3 Containers for waste and inedible substances

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

4.4 FACILITIES

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

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

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

4.4.1 Water supply

Coastal seawaters used at landing docks and at markets were shown to be occasionally contaminated with high level of *V. parahaemolyticus*. Therefore, the post-harvest stage may be of particular importance for preventing seafood from being contaminated with *Vibrio* spp.

An adequate supply of clean pathogen-free water should be available for handling and washing of seafood to reduce bacterial load of *Vibrio* spp. prior to processing.

4.4.2 Drainage and waste disposal

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

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

Separate and adequate facilities should be provided to prevent the contamination by:

- poisonous or harmful substances;
- dry storage of materials, packaging etc.;
- offal and waste materials.

4.4.3 Cleaning

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

4.4.4 Personnel hygiene facilities and toilets

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

4.4.5 Temperature control

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

The facility should be capable of maintaining the temperature of the seafood between 0°C - +10°C for chilled storage, and at or colder than -18°C and with minimal temperature fluctuations for frozen storage.

4.4.6 Air quality and ventilation

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

4.4.7 Lighting

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

4.4.8 Storage

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

- the facility should be capable of maintaining the temperature of the fish between 0°C - +10°C;
- the chill room should be equipped with a calibrated indicating thermometer. Fitting of a recording thermometer is strongly recommended;

Stock rotation plans should ensure proper utilisation of the fish;

The fish should be stored in shallow layers and surrounded by sufficient finely divided ice or with a mixture of ice and of water before processing;

Fish should be stored in a manner that damage will be prevented from over-stacking or over-filling of containers;

SECTION V - CONTROL OF OPERATION

5.1 CONTROL OF FOOD HAZARDS

Control of *Vibrio* spp. for seafood will typically require a stringent application of Good Hygienic Practice and other supportive programs. These prerequisite programs, together with HACCP provide a successful framework for the control of *Vibrio* spp.

The factors and attributes described below are components of Good Hygienic Practice programs that will typically require elevated attention to control *Vibrio* spp. and may be identified as critical control points in HACCP programs where *Vibrio* spp. are identified as a hazard.

This section should be applicable for all establishments, including processing, handling, preparing, and food service/catering business.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Time and temperature control

The temperature of fish and shellfish should be kept below 10°C.

Temperature control could be applied to minimize the growth of *Vibrio* spp. by the management of the environmental temperature of seafood by means of ice, mechanical refrigeration or other appropriate means which is capable of lowering the temperature of the seafood and will maintain it at 10°C or less. Examples of time–temperature matrix for controlling *V. vulnificus* and *V. parahaemolyticus* are shown below.

Rational

The risk of *Vibrio* illness is increased during the warmer months of the year, with the magnitude of this increase a function of the extent to which the growing waters (and air temperature) are at temperatures that support the growth of the pathogen (e.g., temperatures above 10°C).

5.2.2 Specific process steps

5.2.2.1 Washing and processing

Potable water, artificial sea water made from potable water or pasteurized sea water should be used for washing and processing fish and shellfish at processing establishments.

The eviscerated cavity of fish for raw consumption should be thoroughly washed with clean pathogen-free water, preferably with running potable water.

Rational

The results of experimental study showed that washing fish with tap water before preparing could significantly reduce the level of *V. parahaemolyticus* on the fish surface, but did not reduce the levels in gills and intestines. The study also showed that washing with tap water during the process of making *sashimi* was also important. They compared two procedures of preparations, one is washing eviscerated cavity and the other is without washing, were compared and found that the *sashimi* prepared without washing eviscerated cavity was highly contaminated with *V. parahaemolyticus*.

The risk assessments done by FAO/WHO on *V. parahaemolyticus* in finfish eaten raw demonstrated that washing the eviscerated cavity of horse mackerel during the preparation of *sashimi* has a greater impact on reducing the risk of illness. (FAO/WHO, in press)

5.2.2.2 Cooking

Cooking should be carried out to maintain the minimum temperature of 65°C for 1 min at the central part of seafood.

After cooking and blanching, potable water, artificial sea water made from potable water or pasteurized sea water should be used for cooling.

Rational

V. parahaemolyticus is not thermal resistant. Mild heat treatment (5 min at 50°C) of oysters, which causes at least a 4.5 log decrease in the number of viable *V. parahaemolyticus* in oysters, practically eliminates the likelihood of illness occurring (FDA, 2005).

5.2.2.3 Food processing practices

Industry food processing practices (i.e. acidification [pH below 4.8], salting [NaCl concentration of more than 8-10% for *V. parahaemolyticus*], food preservatives, water activity less than 0.94) have been reported to minimize growth of *Vibrio* spp.

Any practice selected should be adequately validated to ensure that the process is effective to control the growth of *Vibrio* spp.¹

The food processing practices should be closely monitored to ensure that *Vibrio* spp. is controlled as intended.

Rational

Low pH is quite lethal to *V. vulnificus* (Koo, *et al.*, 2001), but organisms within the oyster tissues may be protected from acidic hot sauces and other chemicals as these would probably not penetrate to the interior of an oyster (Sun and Oliver, 1994, 1995). (FAO/WHO MRA series No.8, 2005)

V. parahaemolyticus was demonstrated to grow at pH5-11 and at NaCl concentrations of 1-7% (Twedt *et al.*, 1969). Beuchat (1973) reported some strains of *V. parahaemolyticus* could grow at pH 4.8. Other possible inhibitory options have been reported such as glycerin (Chun *et al.*, 1972), high pressure (Baross *et al.*, 1975), UV irradiation (Hackney *et al.*, 1988), basil and sage essential oils (Koga *et al.*, 1999) and mild heating (Beuchat and Worthington, 1976). However, there is little possibility for these options to be implemented during the process of harvesting and consuming raw fish.

5.2.2.4 Freezing

Freezing could be used to reduce the level of *Vibrio* spp. in seafood.

Rational

Freezing oysters at -40°C and storage for 3 weeks achieved a 4 to 5 log reduction in the natural *V. vulnificus* population (Cook and Ruple, 1992). However, the effectiveness of freezing may be reduced in *V. vulnificus* cells subjected to a cold adaptation step of 15°C prior to freezing (Bryan *et al.*, 1999; FAO/WHO MRA Series No. 9, 2005)

The response of *V. parahaemolyticus* to freezing is similar to that of *V. vulnificus* (FDA 2005). Choleraogenic *V. cholerae* is sensitive to freezing and significant reductions in numbers of this organism occur following freezing and frozen storage (FAO/WHO MRA Series No. 9, 2005).

5.2.2.5 Other Technology

For *V. parahaemolyticus*, several possible inhibitory options have been reported such as glycerin, high pressure, UV irradiation, basil and sage essential oils and mild heating.

Any treatment selected to eliminate or reduce *Vibrio* spp. should be adequately validated scientifically to ensure that the process is effective.

¹ See “Guidelines for the Validation of Food Safety Control Measures” (At Step 5/8 of Procedure for final adoption by the 31st Session of the Commission).

The control treatments (heat, pressure, etc.) should be closely monitored to ensure that *Vibrio* spp. is eliminated or reduced as intended and that the product does not undergo textural changes in the flesh that are unacceptable to the consumer.

Rational

Response from the consultation: These may all have the effect of reducing the numbers of pathogenic vibrios but the effectiveness will vary according to the conditions of use, and there may be a need to balance between obtaining the maximum possible reduction in bacterial content and retaining consumer-acceptance of either the product or the process. Reports on the effectiveness of depuration vary greatly and this may again depend on the conditions of use - some reports indicate that proliferation of vibrios may occur during this process. The general opinion of the expert consultation is shown on a qualitative/semi-quantitative basis in the Table below (FAO/WHO, 2002).

The current models could be adapted to enable estimates to be obtained of the effectiveness of the mitigations in reducing illness. With regard to the mitigation of the closure of harvesting areas, estimates could also be obtained of the proportion of harvest lost by application of a particular scenario.

Some of the listed mitigations are also used in combination, e.g. hydrostatic pressure and freezing; depuration and hydrostatic pressure or pasteurization.

TABLE : The comparative effectiveness of a number of mitigation strategies in reducing *Vibrio* spp..

Mitigation	Comparative effectiveness in reducing <i>Vibrio</i> spp.
Hydrostatic pressure	+++
Rapid cooling	+ / ++
Irradiation	+++
Pasteurization	+++
Freezing and thawing	++
Depuration	+ / -
Relay at high salinity for 2 weeks (for <i>V. vulnificus</i>)	++
Commercial heat-treatment	+++
-	no effect
+	some reduction
++	moderate reduction
+++	significant reduction

Table : The comparative effectiveness of a number of mitigation strategies in reducing *Vibrio* spp. (Adopted from FAO/WHO 2002)

Mitigation	Comparative effectiveness in reducing <i>Vibrio</i> spp.
Hydrostatic pressure	+++
Rapid cooling	+ / ++
Irradiation	+++
Pasteurization	+++
Freezing and thawing	++
Depuration	+ / -
Relay at high salinity for 2 weeks (for <i>V.vulnificus</i>)	++
Commercial heat treatment	+++

- :no effect

+ : some reduction

++: moderate reduction

+++: significant reduction

5.2.3 Microbiological and other specifications

Refer to the *Recommended International Code of Practice- General Principles of Food Hygiene, (Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997))*.

5.2.4 Microbiological cross-contamination

Microbiological cross-contamination is a major issue with respect to *Vibrio* spp., especially *V. parahaemolyticus*. It can occur through direct contact with raw fish, personnel, aerosols and contaminated utensils, equipment, *etc.* Cross-contamination can occur at any step where the food is exposed to the environment, including processing, transportation, retail, catering, in restaurants, and in the home through contact with contaminated raw seafood directly or indirectly through water and chopping boards *etc.*

Traffic flow patterns for employees, food products, and equipment should be controlled between raw processing, storage area(s) and finished area(s) to minimise the transfer of *V. parahaemolyticus*. For example, a change of footwear or automated foam sprayers can be an effective alternative to footbaths where people, carts, forklifts and other portable equipment must enter before they reach an area where ready-to-eat seafoods are processed. Another example can be to use a colour coding system to identify personnel assigned to specific areas of the plant.

Where possible, utensils, pallets, carts, forklifts and mobile racks should be dedicated for use in either the raw area or the finished product area to minimise cross-contamination. Where this is not practical, they should be cleaned and disinfected before entry into the finished product area.

5.2.5 Physical and chemical contamination

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

5.3 INCOMING MATERIAL REQUIREMENTS

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

5.4 PACKAGING

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

5.5 WATER

5.5.1 In contact with food

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

5.5.2 As an ingredient

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

5.5.3 Ice and steam

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

5.6 MANAGEMENT AND SUPERVISION

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

5.7 DOCUMENTATION AND RECORDS

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

5.8 RECALL PROCEDURES

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

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

These guidelines are supplemental to those set forth in Section 6 of the *Recommended*

International Code of Practice- General Principles of Food Hygiene (CAC/RCP 1-1969).

6.1 MAINTENANCE AND CLEANING

6.1.1 General

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

6.1.2 Cleaning procedures and methods

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

6.2 CLEANING PROGRAMMES

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

6.3 PEST CONTROL SYSTEMS

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

6.3.1 General

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

6.3.2 Preventing access

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

6.3.3 Harbourage and infestation

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

6.3.4 Monitoring and detection

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

6.3.5 Eradication

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

6.4 WASTE MANAGEMENT

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

6.5 MONITORING EFFECTIVENESS

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

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

7.1 HEALTH STATUS

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

7.2 ILLNESS AND INJURIES

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

7.3 PERSONAL CLEANLINESS

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

7.4 PERSONAL BEHAVIOUR

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

7.5 VISITORS

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

SECTION VIII – TRANSPORTATION

8.1 GENERAL

Refer to the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and to the Section 17 “Transportation” in the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003)

Transportation is an integral step in the food chain and should be controlled, particularly the product temperature which should not exceed 10°C.

Transportation vehicles should be regularly inspected for structural integrity, cleanliness, and overall suitability when unloading ingredients and prior to loading products..

8.2 REQUIREMENTS

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

8.3 USE AND MAINTENANCE

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

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

9.1 LOT IDENTIFICATION

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

9.2 PRODUCT INFORMATION

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

9.3 LABELLING

Countries should give consideration to labelling of certain raw seafood so that consumers can make an informed choice with regard to these products. Where appropriate, product labels should include information on safe handling practices and/or advice on the time frames in which the product should be eaten (General Standard for the Labelling of Prepackaged Foods, *CODEX STAN 1-1985*).

9.4 CONSUMER EDUCATION

Since each country has specific consumption habits, communication programs pertaining to

Vibrio spp. are most effective when established by individual governments.

Programs for consumer information should be directed at consumers:

- to educate them on household practices and behaviours that would specifically keep the numbers of *Vibrio* spp. that may be present in foods, to as low a level as possible and minimize the potential of cross contamination from seafood to the hand of the food handlers, then from the hand to other foods, or from seafood to utensils *e.g.* cutting board, then from the utensils to other foods by:
 - setting refrigerator temperatures so that product temperatures should not exceed 10°C since the growth of *Vibrio* spp. are considerably reduced at temperatures below 10°C;
 - using thermometers inside home refrigerators;
 - preparing, cooking and/or consuming seafood immediately after getting them out of refrigerators;
 - washing and disinfecting the hands, utensils and equipments whenever raw seafood is handled; and
 - separating utensils and equipments for seafood and other foods where possible;
- to help them make informed choices about 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

Additionally, subpopulations with increased susceptibility should be directed;

- to avoid consuming raw or undercooked seafood; and
- to heat seafood thoroughly.

Especially patients with liver disease (*e.g.* cirrhosis), diabetes, gastrointestinal disorders (*e.g.* surgery, ulcers), haematological conditions and immunodeficiency should strictly follow the instruction above since these underlying medical conditions are considered to be the risk factors for *V. vulnificus* infection. *V. vulnificus* is relatively sensitive to heating and inactivated by heating at 50°C for 10 minutes.

SECTION X - TRAINING

10.1 AWARENESS AND RESPONSIBILITIES

Industry (fishermen, primary producers, manufacturers, distributors, retailers and food service/institutional establishments) and trade associations have an important role in providing specific instruction and training for control of *Vibrio* spp.

10.2 TRAINING PROGRAMMES

Personnel involved in the production and handling of raw seafood should have appropriate training in:

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

10.3 INSTRUCTION AND SUPERVISION

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

10.4 REFRESHER TRAINING

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

Appendix 3: Final Documents

Background

1. The 32nd session of the CCFH identified *Vibrio parahaemolyticus* in shellfish as one of the priority issues for consideration by the *ad hoc* Expert Consultation (ALINORM 01/13, para. 18).
2. At the 34th session, CCFH agreed to develop a Discussion Paper on Risk Management Strategies for *Vibrio* spp. in seafood (para. 78, ALINORM 03/13). The Committee further suggested that the initial focus would be *V. parahaemolyticus* in fish and shellfish, as the risk assessments for this bacterium in these products were the most advanced. The Committee agreed that a drafting group led by the United States, with the assistance of Denmark, Japan, Malaysia, Mozambique and Thailand would develop the risk management strategy paper.
3. After the 35th session, the Committee decided to suspend further action on the Discussion Paper until there was dialogue with the Committee on Fish and Fish Products (CCFFP). The paper was therefore not included in the agenda for the 36th session of the Committee. After receiving encouragement from the CCFFP that the CCFH should take the lead, the CCFH agreed that the risk profile would be included on the agenda for the 37th session for further discussion and development.
4. The CCFFP requested that CCFH continue to work on *Vibrio* spp. risk management with emphasis on bivalve mollusks. In particular, to a) assess the outcome of the Risk Assessments on *Vibrio* spp. in seafood and make recommendations on how this should be transformed into Good Hygienic Practices and risk management strategies and b) address the four areas put forward by the CCFFP related to the risk profile for *Vibrio* spp. (para. 128, ALINORM 4/27/18), specifically, (i) the identification of effective control measures; (ii) the establishment of appropriate microbiological criteria including identification of relevant testing methods; (iii) the need for risk managers to establish tolerances, and (iv) the consideration of source of seafood as a risk factor impacting the control of pathogenic *Vibrio* spp.
5. At the 37th session of the CCFH, the Committee agreed to use the newly established process to consider further work on the Discussion Paper on Risk Management Strategies for *Vibrio* spp. in Seafood, and identified the United States to prepare the written proposal (paras. 167-168, ALINORM 5/28/13).
6. At the 39th session of the CCFH, based on the recommendations of the *ad hoc* Working Group for establishment of CCFH work priorities, the Committee agreed to take up a new work on a Code of Hygienic Practice for *Vibrio* spp. in Seafood (para. 156, ALINORM 08/31/13).
7. Although the codes and standards developed by CCFFP provide information on hygienic practices for fish and fishery products, the level of guidance is not sufficiently detailed in relation to the information needed for a code of hygienic practice that can be used to develop food safety systems based on effective implementation of Good Hygienic Practices and HACCP programs. Accordingly, the purpose of the new work became Fish and Shellfish. It is anticipated that this new work would be undertaken in close collaboration with CCFFP.

Working Group Report

8. The Working Group met in Kyoto, Japan, on June 3-6, 2008 (See Annex 2 for the List of Participants). The Working Group accomplished the task given by the CCFH and developed the Proposed Draft Code of Hygienic Practice for Pathogenic *Vibrio* species in Seafood, which is presented in Annex 1.

9. The Working Group agreed with the overall approach taken in the Proposed Draft Code using the structure of the Recommended International Code of Practice-General Principles of Food Hygiene (CAC/RCP 1-1969). It was stressed that the Proposed Draft Code was intended to apply the recommendations of the Recommended International Code of Practice-General Principles of Food Hygiene to the particular control of pathogenic *Vibrio spp.* in seafood. It was also agreed that this Proposed Draft Code provided guidance on how to achieve the general requirements related to hygiene, in various sections of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).
10. The Working Group agreed that the target microbiological hazards of this Proposed Draft Code are pathogenic *V. parahaemolyticus*, *V. vulnificus* and choleraenic *V. cholerae*. The control measures described in this Proposed Draft Code may be applicable to other pathogenic *Vibrio spp.* which may cause adverse health effects to humans. This Proposed Draft Code covers seafood, including finfish and shellfish that are marketed in a live, raw, undercooked and cooked state (para.20, the Proposed Draft Code of Hygienic Practice for Pathogenic *Vibrio spp.* in Seafood)
11. The Working Group agreed to introduce definitions of “refrigeration”, “disinfected seawater”, “clean water”, “artificial seawater” and “seafood”.
12. The Working Group agreed that time and temperature were the most important factors affecting the growth rate of pathogenic *Vibrio spp.* in seafood. In addition, for all seafood, particularly those that are cooked, microbiological cross-contamination is an important issue with respect to pathogenic *Vibrio spp.*, especially *V. parahaemolyticus*.
13. The Working Group agreed to recommend the CCFH to develop an Annex to this Proposed Draft Code. The focus of the Annex should be *V. parahaemolyticus* and *V. vulnificus* in molluscan shellfish, as these pathogens/commodity combinations require additional considerations and control measures. This Annex may possibly be expanded to *V. cholerae* as long as there are sufficient data for the additional elaboration of this Annex.
14. The Working Group agreed not to recommend the CCFH to develop microbiological criteria for *Vibrio spp.* in reply to the request made by the CCFFP. Based on the risk assessment, it was clear that the risk reduction derived from a certain microbiological criteria was diverse among different parts of the world. Therefore it was difficult to set microbiological criteria which were applicable worldwide.
15. The 40th session of the CCFH is invited to consider the Proposed Draft Code with a view towards its further progression in the Codex Step Procedure.

Annexes

Annex 1: Proposed Draft Code of Hygienic Practice for Pathogenic *Vibrio spp.* in Seafood

Annex 2: List of Participants

ANNEX 1

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PATHOGENIC *VIBRIO* SPECIES IN SEAFOOD AT STEP 4 (NOX-2008)

INTRODUCTION

1. During the last several 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*, choleraogenic *Vibrio cholerae*, or *Vibrio vulnificus*. *V. parahaemolyticus* and *V. cholerae* were solely or mainly isolated from gastroenteritis cases that are attributable to consumption of contaminated food (both species) or intake of contaminated water (*V. cholerae*). *V. vulnificus* was primarily reported from extraintestinal infections (septicemia, wounds, etc.) and primary septicemia due to *V. vulnificus* infection was 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 the freshwater environment.
4. It is now possible to differentiate environmental strains of *V. cholerae* and *V. parahaemolyticus* into virulent and avirulent ones based on their ability or inability to produce their major virulence factors. Infection by *V. vulnificus* is characterized by high fatality rate and thus considered an important pathogen but such infections are rare and generally limited to individuals with pre-existing chronic illness or immunocompromised while the pathogenic mechanism of *V. vulnificus* has not been clearly elucidated. However, human clinical strains can generally be distinguished from environmental *V. vulnificus* by molecular methods including rRNA sequence type.
5. The followings are the important characteristics common to *Vibrio* spp.: *Vibrio* spp. are sensitive to low pH but grow well at high pH, and thus infections by *Vibrio* spp. are seldom associated with high acid foods and intake of a large number of viable cells by humans is needed for *Vibrio* pathogens to survive against gastric acid and establish infection; proper cooking of food products readily inactivates *Vibrio* pathogens even in highly contaminated products; hygienic approaches used with food-borne pathogens in general control growth of *Vibrio* pathogens. There are, however, the characteristics specific to each of the three pathogenic species of *Vibrio* that need attention:

Vibrio parahaemolyticus

6. *V. parahaemolyticus* is considered to be part of the autochthonous microflora in the estuarine and coastal environments in the tropical to temperate zones. While *V. parahaemolyticus* typically is undetectable in seawater below 10°C, it could be cultured from sediments throughout the year at temperatures as low as 1°C. *V. parahaemolyticus* is characterized by its fast growth. Its multiplication is more rapid in cooked foods rather than raw foods.
7. The vast majority of strains isolated from patients with diarrhea 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, it has been suggested that 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 diarrhea, 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 environments including seafoods, while they are detected as major strains from feces of patients.
8. *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 diarrheal 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 United States of America elevating the status of *V. parahaemolyticus* 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.
9. From the point of controlling seafood borne *V. parahaemolyticus* illnesses, harvest is probably the most important premise since it is the point when humans take control of *V. parahaemolyticus* levels from nature.
10. Foods associated with illnesses due to consumption of *V. parahaemolyticus* include crayfish, lobster, shrimp, fish-balls, boiled surf clams, jack-knife clams, fried mackerel, mussel, tuna, seafood salad, raw oysters, clams, steamed/boiled crabmeat, scallops, squid, sea urchin, mycids, and sardines. These products include both raw and undercooked seafood products and cooked products that have been substantially recontaminated through contaminated utensils, hands *etc.*

Vibrio cholerae

11. *V. cholerae* is indigenous to fresh and brackish water environments in tropical, subtropical and temperate areas worldwide. Over 200 O serotypes have been established for *V. cholerae*. Strains belonging to O1 and O139 serotypes generally possess the *ctx* gene and produce cholera toxin (CT) and these cholerae strains are responsible for epidemic cholera. Epidemic cholera is confined mainly to developing countries with warm climates. Cholera is exclusively a human disease and human feces from infected individuals are the primary source of infections in cholera epidemics. Contamination of food production environments including aquaculture ponds by patients' feces can indirectly introduce cholerae *V. cholerae* into foods. Concentration of free-living cholerae *V. cholerae* in the natural aquatic environment is low, but *V. cholerae* is known to attach and multiply on zooplankton such as copepods.
12. Seven pandemics of cholera have been recorded since 1823. The first six pandemics were caused by classical biotype strains and the seventh pandemic that started in 1961 and is lasting to date is

due to the El Tor biotype strains. Epidemic cholera can be introduced from abroad by infected travelers, imported foods and through the ballast water of cargo ships. Detection frequencies of cholerae strains of *V. cholerae* from legally imported foods were very low and they have seldom been implicated in cholera outbreaks. *V. cholerae* O139 is responsible for the outbreaks of cholera in the Bengal area since 1992 and this bacterium was spread to other parts of the world through travelers.

13. Some strains belonging to the O serotypes other than O1 and O139 (referred as non-O1/O139) cause food-borne diarrhea that is milder than cholera.
14. Outbreaks of food-borne cholera have been noted quite often in the past 30 years; seafood, including molluscan shellfish, 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 cholerae *V. cholerae* in international trade, it has not been linked to outbreaks and it is rarely found in shrimp in international trade.

Vibrio vulnificus

15. *V. vulnificus* can occasionally cause mild gastroenteritis in healthy individuals, but *V. vulnificus* can cause primary septicemia in individuals with chronic preexisting conditions, especially liver disease or alcoholism, following consumption of raw bivalves. This is a serious, often fatal, disease with the highest fatality rate 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 for *V. vulnificus* 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. Infectious dose for humans is not known.
16. Of three biogroups of *V. vulnificus*, biogroup 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.
17. Foodborne illness from *V. vulnificus* is characterized by sporadic cases and an outbreak has never been reported. *V. vulnificus* was isolated from oysters, other molluscan shellfish, and other seafood worldwide.
18. The densities of *V. vulnificus* are high in oysters at harvest when water temperature exceeds 20°C; *V. vulnificus* multiplies rapidly in oysters if not refrigerated. The *V. parahaemolyticus* risk assessment carried out in the United States found that water temperature influences levels of this pathogen at harvest and air temperature influences growth rate of this pathogen after harvest.

FAO/WHO Risk Assessments

19. FAO/WHO Risk assessments on *Vibrio vulnificus* in raw oysters and cholerae *Vibrio cholerae* O1 and O139 in warm water shrimp in international trade have been recently published (2005)^{2,3}. Additional risk assessments on *V. parahaemolyticus* in raw oyster, finfish and bloody clams have been completed^{4,5,6}. These risk assessments constitute the basis of this Code.

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 cholerae *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 raw oysters. Microbiological Risk Assessment Series, No.XX (In press).

Target Hazards and Target Food

20. This Code is based on key findings and outcomes derived from the FAO/WHO microbiological risk assessment. Because of the available risk assessments and recognitions as a major causative agent of foodborne bacterial illnesses associated with seafood, the target microbiological hazards of this Code are pathogenic *V. parahaemolyticus*, *V. vulnificus* and choleraogenic *V. cholerae*. The control measures described in this Code may be applicable to other pathogenic *Vibrio* spp. which may cause adverse health effects to humans. This Code covers seafood, including finfish and shellfish that are marketed in a live, raw, undercooked and cooked state.

SECTION I – OBJECTIVES

1.1 THE CODEX GENERAL PRINCIPLES OF FOOD HYGIENE

21. The objective of this Code is to apply the recommendations of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) to the particular case of the control of pathogenic *Vibrio* spp. in seafood. It also provides guidance on how to achieve the general requirements contained in the hygiene sections of the Codex commodity standards for fish and fishery products (*Code of Practice for fish and fishery products* (CAC/RCP 52-2003)). This Code provides guidance on control of pathogenic *Vibrio* spp. in seafood, mainly focusing on seafood to be eaten raw or undercooked, with a view towards protecting the health of consumers and ensuring fair practices in food trade. Their primary purpose of this Code is to minimise the likelihood of illness arising from the presence of pathogenic *Vibrio* spp. in seafood. This Code also provides 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. This Code covers seafood, including finfish and shellfish that are marketed in a live, raw, undercooked and cooked state. The target microbiological hazards of this Code are pathogenic *V. parahaemolyticus*, *V. vulnificus* and choleraogenic *V. cholerae*.
23. This Code is intended for seafood and is applicable throughout the food chain, from primary production through consumption. Based on the results of the FAO/WHO risk assessment, as well as other available risk assessments and epidemiological evaluations, this Code will focus on control measures that can be used, where appropriate, to minimise and/or prevent the contamination and/or the growth of pathogenic *Vibrio* spp. in seafood. This Code highlights the key control measures that affect key factors that influence the frequency and extent of contamination with pathogenic *Vibrio* spp. and thus the risk of foodborne diseases caused by pathogenic *Vibrio* spp. In many instances, these control measures are articulated in a general manner in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) as part of the general strategy for the control of foodborne pathogens in all foods. In providing this Code, it is assumed that these *General Principles of Food Hygiene* are being implemented. Those principles that are mentioned reflect the need for special attention for the control of pathogenic *Vibrio* spp.

⁵ FAO and WHO, 20XX. Risk assessment of *Vibrio parahaemolyticus* in raw and undercooked finfish. Microbiological Risk Assessment Series, No.XX (In press).

⁶ FAO and WHO, 20XX. Risk assessment of *Vibrio parahaemolyticus* in *Anadara granosa* (bloody clams). Microbiological Risk Assessment Series, No.XX (In press).

24. 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 codes of hygienic practice should be generally suitable to control pathogenic *Vibrio* spp. in cooked seafood. The additional measures described in this Code should be used as necessary to control pathogenic *Vibrio* spp. in raw and undercooked seafood and in ready-to-eat food contaminated by raw seafood.

2.2 USE OF THE DOCUMENT

25. This Code 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) and the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003). The application of this Code by countries is likely to require modifications and amendments, taking into account regional differences such as the prevalence of pathogenic *Vibrio* spp. and water temperatures.

2.3 DEFINITIONS

26. For the purpose of this Code, 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) apply.

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

Disinfected seawater: Seawater that received microbiocidal treatment (*e.g.*, UV irradiation, heat treatment, chlorination) to reduce the number of pathogenic microorganisms including *Vibrio* spp. in seawater so that they do not constitute a health hazard.

Clean water: water that does not contain pathogenic microorganisms at levels that compromise food safety, for example potable water, disinfected seawater, and artificial seawater.

Artificial seawater: a mixture of dissolved mineral salts made with potable water that simulates seawater.

Seafood: Fish, shellfish and other aquatic invertebrates from marine and fresh water sources and their products which are intended for human consumption⁷.

SECTION III - PRIMARY PRODUCTION

3.1 ENVIRONMENTAL HYGIENE (PRE-HARVEST CONTROL)

27. Refer to Section 3.1 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969). In addition:
28. Generally, pre-harvest controls are more applicable to molluscan shellfish 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.
29. 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

⁷ For the purposes of this Code, fresh water sources are also included in the definition.

should be identified based on epidemiological and exposure studies as well as monitoring of pre-harvest pathogenic *Vibrio* levels.

30. Monitoring of molluscan shellfish at harvest for the levels of pathogenic *Vibrio* spp. should be conducted to determine the regional and seasonal risk of these microorganisms for the application of appropriate controls.
31. When testing/monitoring parameters go beyond a certain level based on the risk assessment, closing the harvesting area or issuing a public warning, restricting the time to refrigeration, diverting product into cooking or post-harvest processing should be considered.
32. In case the predictive models which indicate the concentration of pathogenic *Vibrio* spp. in seawater and/or bivalve based on water temperatures and/or salinity are useful tool, the predictive ability would be improved by incorporating local data and considering additional factors such as hydrodynamic effects (occurrence of tidal waves, rainfall) and sunlight.
33. For seafood grown in coastal locales, especially in cholera-endemic areas, care should be taken to prevent faecal contamination with cholerae *V. cholerae*.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

34. 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

35. For the storage and handling of seafood aboard fishing vessels, the use of seawater taken near the seashore or from the region near the mouth of drain or river contaminated with sewage should be avoided. Especially, clean water should be used for seafood intended to be eaten raw, and for preparing ice for such use. 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.
36. At the landing port, clean water should be used for washing seafood.
37. 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 selling. In areas where cholerae *V. cholerae* are endemic, enclosed packaging should be used to prevent fecal contamination.
38. 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 minimise cross-contamination.
39. For the storage of live fish, clean water should be used to minimise initial cross-contamination from the water.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

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

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

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

Objectives

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

4.1 LOCATION

43. 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

44. 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

45. 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

46. Refer to Section 4.2.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).
47. The following practices should be followed, if possible, for live or raw ready-to-eat and cooked ready-to-eat seafood.
48. Whenever feasible, premises and rooms should be designed to separate processing and finished seafood areas. This can be accomplished in a number of ways, including linear product flow (raw materials to finished products) or physical partitions.
49. Where feasible, the washing areas for food equipment involved in the manufacture of the finished product should be located in a separate room from the finished product processing area.

4.2.2 Internal structures and fittings

50. 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

51. 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

52. 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

53. Refer to Section 4.3.2 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).
54. The chill room should be equipped with a calibrated thermometer.

4.3.3 Containers for waste and inedible substances

55. 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

56. Refer to Section 4.4 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).
57. Adequate facilities should be provided for the handling and washing of products.
58. Suitable and adequate facilities should be provided for storage and/or production of ice.

4.4.1 Water supply

59. An adequate supply of clean water should be available for handling and washing of seafood to reduce bacterial loads of pathogenic *Vibrio* spp. prior to processing.

4.4.2 Drainage and waste disposal

60. All plumbing and waste lines should be capable of coping with peak demands.
61. 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.
62. Separate and adequate facilities should be provided to prevent contamination by offal and waste material.

4.4.3 Cleaning

63. 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

64. 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

65. 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).
66. The *Code of Practice for Fish and Fishery Products* indicates a temperature as close as possible to 0°C. For pathogenic *Vibrio* spp., a temperature of less than 10°C is adequate. The facility should be capable of controlling ambient temperature to ensure that product temperature during processing of raw seafood of less than 10°C.

4.4.6 Air quality and ventilation

67. 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

68. 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

69. 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

70. This section should be applicable from harvest through to food service/catering businesses. Control of pathogenic *Vibrio* spp. 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 pathogenic *Vibrio* spp. in seafood.

71. The factors and attributes described below are components of Good Hygienic Practice programs that will typically require increased attention to control pathogenic *Vibrio* spp. and may be used as critical control points in HACCP programs where pathogenic *Vibrio* spp. are identified as a hazard of concern.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Time and temperature control

72. 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.

5.2.2 Specific process steps

5.2.2.1 Washing and processing

73. Clean water should be used for washing and processing seafood at processing establishments.
74. The eviscerated cavity of fish intended for raw consumption (*e.g.*, preparation of sashimi) should be thoroughly washed with clean, preferably running water.

5.2.2.2 Cooking

75. Time and temperature should be determined for each cooking operation to ensure the inactivation of pathogenic *Vibrio* spp.
76. After cooking and blanching, clean water should be used for cooling.

5.2.2.3 Food processing practices

77. Food processing practices (*e.g.*, acidification to pH below 4.8, salting to NaCl concentration of more than 8-10% for *V. parahaemolyticus*, food preservatives (as established by the CCFA), water activity less than 0.94) can be used to minimise the growth and possibly reduce the levels of pathogenic *Vibrio* spp. in seafood.
78. Freezing could be used to reduce the level of pathogenic *Vibrio* spp. in seafood.
79. For pathogenic *V. parahaemolyticus*, several possible inactivation technologies have been reported such as high pressure, mild heating and gamma irradiation. The use of these technologies should be done in accordance with the legislation of the country of retail sale.
80. Any practice selected to control the growth of pathogenic *Vibrio* spp. should be adequately validated to ensure that the process is effective.
81. The food processing practices should be closely monitored and verified to ensure that pathogenic *Vibrio* spp. are controlled as intended.

5.2.2.4 Storage

82. Seafood intended for raw consumption, as well as other ready-to-eat seafood, should be stored in shallow layers and surrounded by sufficient finely divided ice or with a mixture of ice and water before processing.

83. Seafood should be stored so as to avoid over-stacking or over-filling of containers so that cold air can adequately circulate.

5.2.3 Microbiological and other specifications

84. 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

85. 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).
86. For all seafood, particularly those that are cooked, microbiological cross-contamination is an important issue with respect to pathogenic *Vibrio* spp., especially *V. parahaemolyticus*. It can occur through direct contact with raw fish, personnel, aerosols and contaminated utensils, equipment, etc. Cross-contamination can occur at any step where the food is exposed to the environment, including processing, transportation, retail, catering, in restaurants, and in the home through contact with contaminated raw seafood directly, or indirectly through water, chopping boards, etc.

5.2.5 Physical and chemical contamination

87. 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

88. 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

89. 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

90. 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.
91. Coastal seawaters used at landing docks and at markets have been shown to be occasionally contaminated with high level of pathogenic *V. parahaemolyticus*. Therefore, the post-harvest stage

may be of particular importance for preventing seafood from becoming contaminated with pathogenic *Vibrio* spp.

5.5.2 As an ingredient

92. 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

93. 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

94. 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

95. 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

96. 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

97. 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

98. 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

99. 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).
100. Transportation is an integral step in the food chain and temperature should be controlled and monitored where appropriate, as well as being recorded.

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

9.1 LOT IDENTIFICATION

101. 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

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

9.3 LABELLING

103. Refer to the General Standard for the Labeling of Prepackaged Foods (CODEX STAN 1-1985). Where appropriate, product labels should include information on safe handling practices and storage recommendations.
104. Countries should give consideration to labelling of certain live and raw seafood, so that consumers can make informed choices with respect to the safety and true nature of these products. In particular, any physical or chemical treatment (*e.g.*, heat treatment, high-pressure, irradiation), applied to the product, in addition to normal processing should be mentioned on the label.

9.4 CONSUMER EDUCATION

105. Since each country has specific consumption habits, communication and education programs pertaining to pathogenic *Vibrio* spp. are most effective when established by individual governments.
106. Programs should be directed at consumers:
- to educate them on household practices and behaviours 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 the hand of the food handlers, then from the hand to other foods, or from seafood to utensils (*e.g.*, cutting board), then from the utensils to other foods by:
 - keeping seafood cold to minimise and/or prevent the growth of pathogenic *Vibrio* spp.;
 - by 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 for raw seafood from other ready-to-eat foods 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

107. Liver disease is a prominent risk factor of human infection for pathogenic *Vibrio* spp., especially *V. vulnificus*. Additional risk factors can be observed in the *V. vulnificus* and *V. parahaemolyticus* risk assessments.⁸ Subpopulations with increased susceptibility should strictly follow the advice below:
- avoid the consumption of raw or undercooked seafood; and
 - heat seafood thoroughly.

SECTION X - TRAINING

10.1 AWARENESS AND RESPONSIBILITIES

108. 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).
109. Industry (fishermen, primary producers, manufacturers, distributors, retailers and food service/institutional establishments) and trade associations have an important role to play in providing specific instructions and training for the control of pathogenic *Vibrio* spp.

10.2 TRAINING PROGRAMMES

110. Personnel involved in the 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. cholera* and *V. vulnificus*, its harbourage sites, and its 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

111. 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

112. 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*.

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