codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 13 (a) **CX/FH 05/37/13**
January 2005

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty seventh Session

Buenos Aires, Argentina, 14 – 19 March 2005

DISCUSSION PAPER ON RISK MANAGEMENT STRATEGIES FOR *VIBRIO* SPP. IN SEAFOOD[1]

(Prepared by the United States, with the assistance of Denmark, Japan, Malaysia, Mozambique and Thailand)

BACKGROUND

Over the past several sessions, the Codex Committee on Food Hygiene (CCFH) has increased its commitment to, and the extent of its work in, the field of microbiological risk analysis, particularly with respect to microbiological risk assessment and microbiological risk management. As a component part of this effort, CCFH has identified several pathogen/commodity combinations that present a potential significant public health threat for foods placed into international trade and for which it is appropriate to develop risk management strategies.

At the 34th Session, CCFH agreed to develop a Discussion Paper on Risk Management Strategies for *Vibrio* spp. in seafood.[2] The Committee further suggested that the initial focus would be *Vibrio parahaemolyticus* in fish and shellfish as the risk assessments for this microorganism 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 of 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 United States was the lead country for this document in the past and has continued in this role.

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[1] To be discussed under Agenda Item: Risk Profile of *Vibrio* spp in Seafood.
[2] ALINORM 03/13, paragraph 78.

SCOPE AND RATIONALE

Based on the suggestion of CCFH that the initial work on *Vibrio* spp. focus on *V. parahaemolyticus* in fish and shellfish, this paper discusses the food safety problem involving *V. parahaemolyticus* in shellfish and finfish. The Paper presents a risk profile for the occurrence of *V. parahaemolyticus* in these products. Also presented are recommendations for work that CCFH may wish to undertake in relation to the risk management of *V. parahaemolyticus* shellfish and finfish.

As noted in the risk profile presented below, *V. parahaemolyticus* is an important bacterial seafood-borne pathogen worldwide and warrants attention from CCFH to develop international risk management guidance. In sufficient numbers, *V. parahaemolyticus* generally causes acute gastroenteritis that is self-limiting; however, severe cases require hospitalization and, on rare occasions, septicemia may occur. While there is substantial uncertainty concerning infectious doses, it is generally recognized that the general population is susceptible to infection by this microorganism. *V. parahaemolyticus* foodborne illness has been associated with the consumption of crayfish, lobster, shrimp, fish-balls, boiled surf clams, fried mackerel, mussels, tuna, mycids, squid, sea urchins, sardines, seafood salad and steamed/boiled crabmeat. The economic impact on the country or on trade varies according to the extent of contamination of finfish and shellfish, the amount of export, and the number of illnesses. In countries in which *V. parahaemolyticus* is endemic, illnesses due to this microorganism appear to be increasing and therefore there is the potential for a significant impact on the economy and public health of both the exporting and importing countries due to contaminated fishery products. The food safety problem associated with *V. parahaemolyticus* in seafood warrants the attention of the Committee to consider the need for developing specific risk management guidance information for this pathogen/commodity combination.

***VIBRIO PARAHAEMOLYTICUS* RISK PROFILE**

This risk profile section is a comprehensive description of the food safety problem involving *V. parahaemolyticus*, the commodities and public health impact, including economic impact. It is divided into 6 parts, four risk profile elements, a section on risk assessment needs and questions for the risk assessors, and a section on available information and major knowledge gaps. References are found in Annex 1. Tables and figures are found in Annex 2.

1. Pathogen-food commodity combination(s) of concern

1.1 Pathogen of concern

Vibrio parahaemolyticus

1.2 Description of the food or food product and/or condition of its use with which problems (foodborne illness, trade restrictions) due to this pathogen have been associated.

Foods associated with illnesses due to consumption of *V. parahaemolyticus* include crayfish, lobster, shrimp, fish-balls, boiled surf clams, jack-knife claims, fried mackerel, mussels, tuna, seafood salad, raw oysters, steamed/boiled crabmeat, scallops, squid, sea urchin, mycids, and sardines (4, 7, 8, 13, 18, 31, 38, 39, 41) (Table 7; Figure 1). These products include both raw and incompletely cooked seafood products and cooked products that have been either substantially recontaminated or where low level recontamination has occurred in combination with conditions that support growth to high numbers.

2. Description of the public health problem

2.1 Description of the pathogen including key attributes that are the focus of its public health impact (e.g., virulence characteristics, thermal resistance, antimicrobial resistance).

Vibrio parahaemolyticus is a Gram-negative, halophilic marine bacterium that occurs naturally in estuaries and is, therefore, commonly found in seafood. It was first identified as a foodborne pathogen in Japan in the 1950s (16). By the late 1960s and early 1970s, *V. parahaemolyticus* was recognized as a cause of diarrheal disease worldwide.

Virulence Characteristics

Some strains or types of *V. parahaemolyticus* are pathogenic, and can cause illness in people who eat finfish or shellfish containing these strains in numbers that can cause illness. Several different virulence traits have been associated with the pathogenesis of *V. parahaemolyticus* strains. These include their ability to produce a thermostable direct hemolysin (TDH), once the microorganism has entered the gut and colonized the intestinal cell wall (27); produce a thermostable direct hemolysin related toxin (TRH) (32); invade enterocytes (2); produce an enterotoxin (19); and, d) produce urease (1). Because the latter two characteristics have only recently been investigated, the trait most commonly used to distinguish pathogenic from non-pathogenic strains of *V. parahaemolyticus* is the production of TDH. The vast majority of strains isolated from patients with diarrhea are TDH positive (26, 27, 37). 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 (26). Recently, the expert consultation for *Vibrio* and *Campylobacter* risk assessments held in Geneva, Switzerland in July 2002 suggested that strains that produce TRH should also be regarded as pathogenic.

Serotypes

More than a dozen different serotypes have been associated with outbreaks from different countries. These include: O3:K6, O4:K12, O4:K8, O4:K68, O4:K10, O4:K11, O4:K4, O3:K29, O1:K56, O4:K55, 05:K17, 01:K32, 05:K15, 02:K28. It is worth noting, since 1996, serotype transition from O4:K8 to O3:K6 has been observed in Japan. The transition was observed in both environmental and patient isolates. Serovar O3:K6 isolates detected in the United States, Southeast Asia, and Japan resemble each other and are suspected to have a common source. Recent increases in O4:K68-caused infections have been observed in Southeast Asia, India and Japan.

Thermal Resistance

Vibrio 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 (15).

Susceptibility to antimicrobial agents

Treatment of patients: *Vibrio parahaemolyticus* strains are sensitive to most common antibiotics used for treatment. (Tables 2&3) (28, 33). However, like most foodborne pathogens, the treatment of patients with oral antibiotics is generally contraindicated except in cases of septicemia.

Antimicrobial appropriate for food use: *Vibro parahaemolyticus* is sensitive to a number of antimicrobials commonly employed in food systems (e.g., benzoic acid, sorbic acid).

Susceptibility to food preservation conditions

Vibrio parahaemolyticus strains are sensitive to several common food preservation parameters such as low temperature or acidification.

2.2 Characteristics of the disease, including:

Susceptible populations

Epidemiological data indicate that the whole population is susceptible to infection by *V. parahaemolyticus*. However, immunocompromised consumers are at increased risk for septicemia and other more severe sequelae associated with *V. parahaemolyticus* infections.

Annual incidence rate in humans including, if possible, any differences between age and sex and any differences according to regional and seasonal variations

As noted above, epidemiological data indicate that all age groups are susceptible to infection by *V. parahaemolyticus*, and males and females are equally susceptible (Table 4) (20). The number of illnesses varies with season (Table 5): illness rates are higher during the warmer months periods then during the colder months (45). Regional differences exist not only from country to country, but also among different regions within one country (Table 5). In countries in which *V. parahaemolyticus* is endemic, illnesses due to this microorganism peaked in the late 1990s, but are still reported with a high frequency (Table 8).

Outcome of exposure

Infection usually causes mild gastroenteritis, with an incubation time ranging from 4-96 hours after exposure (5, 6, 22).

Severity of clinical manifestation

Symptoms include explosive watery diarrhea, nausea, vomiting, abdominal cramps and, less frequently, headache, fever and chills (Table 6). Most cases are self-limiting; however, severe cases of gastroenteritis requiring hospitalization have been reported. On rare occasions, septicemia, an illness characterized by fever or hypotension and the isolation of the microorganism from the blood, can occur. In these cases, subsequent symptoms can include swollen, painful extremities with hemorrhagic bullae (18, 22).

Case fatality rate

In the United States, the annual incidence of fatal raw oyster-associated infections from any *Vibrio* species was estimated to be 1.6/1,000,000 oyster-consuming adults (95% CI: 1.3-1.9) (18).

Nature and frequency of long-term complications

Most persons recover after 3 days and suffer no long-term consequences. However, subsequent symptoms including swollen, painful extremities with hemorrhagic bullae (18, 22), as well as reactive arthritis (40) can last months or longer.

Availability and nature of treatment

In most cases of gastroenteritis antibiotic treatment is contraindicated unless symptoms are severe and prolonged. Where treatment is indicated, prompt treatment with antibiotics and oral rehydration solutions (ORS) on IV fluid is available for patients in almost all hospitals.

Percentage of annual cases attributable to foodborne transmission

In some countries such as Japan and Thailand, almost 100% of annual cases are considered to be foodborne. In the United States about 65% of *V. parahaemolyticus* cases are estimated to be foodborne.

2.3 Characteristics of the foodborne transmission

Epidemiology and etiology of foodborne transmission, including characteristics of the food or its use and handling that influence foodborne transmission of the pathogen

Vibrio parahaemolyticus is naturally present in many types of seafood (Table 1). Worldwide, incidents of illnesses have been traced to caterers, manufacturers, households, cafeterias, food stores, restaurants, and street vendors. Outbreaks have involved incidents of cross contamination by raw seafood or processing equipment, improper hygienic practices, inadequate temperature control, and insufficient heating (21, 40). In Japan, incidents attributable to catering and packed-meal manufacturers and households have been increasing since 1996.

Foods implicated

Being an indigenous, aquatic bacterium, the microorganism is commonly isolated from aquatic foods. Sampling studies in the Adriatic Sea demonstrated the presence of *V. parahaemolyticus* in fish, mussels and clams, (4). Foods implicated in disease include molluscan shellfish (especially raw oysters), crustaceans (crab, crayfish, lobster, shrimp), scallops, squid, sea urchins, sardines, mycids, and finfish (fish-balls) (Tables 1-2, 7) (4, 7, 8, 13, 18, 31, 38, 39, 40). Studies in the U.S. demonstrated the presence of *V. parahaemolyticus* in oysters at retail, including restaurants or oyster bars, and wholesale and retail seafood markets (44); in this study, although levels did not exceed 100 microorganisms/g in the majority of lots tested, the study demonstrated that levels can exceed 10,000 microorganisms/g in certain regions.

Frequency and characteristics of foodborne outbreaks.

The frequencies and characteristics of foodborne outbreaks vary widely from region-to-region. In the United States, the first confirmed outbreak occurred in 1971, and between 1973 and 1998, forty more outbreaks were reported to the Centers for Disease Control and Prevention (CDC) from 15 states and territories ranging from 2 to >100 cases per outbreak (13, 14). All involve either the consumption of raw or undercooked seafood or cross-contamination of cooked seafood, and the peak numbers of cases occur during warm weather months. Though sporadic cases caused by *V. parahaemolyticus* are common, outbreaks (see below) occur far less frequently. In Japan, outbreaks caused by *V. parahaemolyticus* usually involve fewer than 10 cases. From 1996-1998, 496 outbreaks were reported, and the peak occurrence for these was August (Figure 2). In Thailand far fewer outbreaks caused by *V. parahaemolyticus* have been reported, no more than 5 per year and most outbreaks affected less than100 patients (30, 36). From the Epidemiological Surveillance Report, during 1995-2001 there were 15 incidents with 1650 patients, and no fatalities (3, 36).

Frequency and characteristics of foodborne sporadic cases

Sporadic cases caused by V. *parahaemolyticus* infections are commonly reported. Most cases present clinically as gastroenteritis, and are rarely fatal. Life threatening septicemia can occur, especially in patients with underlying medical conditions. Sporadic cases occur throughout the year, with peak occurrence in September to October. Many published case reports outline clinical presentations and outcomes of patients with *V. parahaemolyticus*. For example, one report describes a 35-year-old woman who sought medical attention for abdominal pain after she had consumed raw fish (40). *V. parahaemolyticus* was isolated from the stool culture. She was diagnosed as having reactive arthritis induced by *V. parahaemolyticus* infection. Another clinical case report describes a 31-year-old female with a history of alcohol abuse, Hepatitis C virus infection, and cirrhosis, who ingested raw oysters and steamed shrimp 72 hours prior to admission (17). She presented with diarrhea, weakness, leg pain, and urine retention. She developed cardiac arrest and died six days after presentation. *V. parahaemolyticus* was isolated from blood samples.

Epidemiological data from outbreak investigations

In the United States during 1971, 3 outbreaks caused by *V. parahaemolyticus* occurred in Maryland (13). Steamed crabs were implicated in two of the outbreaks after cross-contamination with live crabs. The third outbreak was associated with crabmeat that had become contaminated before and during canning. In 1972, an estimated 600 of 1,200 persons who attended a shrimp feast in Louisiana became ill with *V. parahaemolyticus* gastroenteritis (25). In 1974 and 1975 outbreaks were reported aboard two Caribbean cruise ships, most likely caused by contamination of cooked seafood with seawater from the ships' seawater fire systems (24). In Japan, restaurants account for 48% of outbreaks, hotels 18%, catering and packed-meal sales 12%, and households 12%. Retailers account for only 4%. In some incidents, mass meal preparation facilities and manufacturers also have been implicated as sources (Figure 3). In Thailand, school and college cafeterias account for the highest numbers of outbreaks, and meal preparation manufacturers also have been implicated in some incidents (21, 41).

2.4 Economic impact or burden of the disease

Medical, hospital costs

In the U.S. estimated costs per case of *V. parahaemolyticus* by severity (Table 9), and the estimated total cost of *V. parahaemolyticus* by severity (Table 10) demonstrate that the cost increases with severity of the illness (43).

In Japan, the number of foodborne outbreaks between 1991 and 1997, number of patients involved in each outbreak and the compensation for each case in every incidence that was considered as either bacterial or viral (SRSV) as a causative microorganism was evaluated (46). Table 11 demonstrates the cost of illness due to *V. parahaemolyticus* relative to other foodborne illnesses such as *Salmonella* spp. and pathogenic *E. coli* (46).

Working days lost due to illness, etc

Normally 1-3 days are lost due to illness.

Damage to seafood markets

The economic effects of illnesses reverberate throughout the seafood supply industry causing loss of consumer confidence and concomitant loss of sales. Consequently, a slowing effect for seafood sales overall occurs, which can represent a short-term serious economic loss. In general, the various reports of seafood related illnesses also appear to combine to affect the entire seafood supply in a cumulative fashion, which can lead to long term depressed sales. There is also the risk of unwarranted trade barriers, i.e., when countries apply a microbial standard if that standard is not based upon sound risk management decision wherein justifying the standard as a public health measure. This may lead to unjustified banning of seafood.

3. Food Production, processing, distribution and consumption

3.1 Characteristics of the commodity (commodities) that are involved and that may impact on risk management

Today, processed products comprise the majority of seafood consumed, and processing with mild heat or by freezing can effectively eliminate or reduce the threat from *V. parahaemolyticus* in raw seafood. Preserving seafoods using acid and preservatives may also reduce or eliminate the risk. Even so, raw oysters and clams continue to be extensively consumed and other raw seafood such as Sashimi and Sushi, long popular in Japan (39) (Table 7), are becoming increasingly popular in other countries as well. The consumption of raw seafood is an important factor in the transmission of *V.*

parahaemolyticus illnesses. However, improper cooking and/or re-contamination after cooking also are important factors (11).

3.2 Description of the farm to table continuum including factors which may impact the microbiological safety of the commodity (i.e., primary production, processing, transport, storage, consumer handling practices).

Pre-harvest and harvest

V. parahaemolyticus occurs naturally in estuarine environments and on many types of seafood. Its densities are influenced by water temperature and salinity (29), air temperature (34), tide (23), and plankton (10, 35). The United States *V. parahaemolyticus* risk assessment, found that water and air temperatures at time of harvest are the major factors influencing the initial levels of this pathogen in oysters (15). Temperature control of seafood post-harvest also is important for controlling levels of *V. parahaemolyticus*. Temperature control onboard harvest vessels may be influencing the levels of *V. parahaemolyticus* in seafood if air temperatures are warm and the time between harvest and chilling after landing is extended.

Post-harvest handling and processing

Post-harvest handling and processing factors that affect product safety include the following:

- Quality of water used in washing and processing after harvest;
- Type and adequacy of sanitation measures;
- Proper temperatures during processing, distribution and storage including refrigeration temperatures and, as appropriate, hot-holding temperatures.
- Avoiding cross-contamination. Ensuring all surfaces, baskets, shucking knives, etc., which may have been in contact with raw seafood, are cleaned before use with any additional raw or cooked food/seafood.
- Appropriate labeling to inform product handlers and users.

Several post-harvest treatments, such as mild heat and freezing, have been shown to be effective in reducing *V. parahaemolyticus* levels in oysters (12).

What is currently known about the risk, how it arises with respect to the commodity's production, processing, transport and consumer handling practices, and who it affects.

Major causes of foodborne *V. parahaemolyticus* infections include:

1) Uptake and concentration of the pathogen by raw fish/shellfish from environmental waters

2) Multiplication of *V. parahaemolyticus* and other bacteria under inadequate temperature control after harvest and during distribution.

3) Improper handling practices after harvest, including:

- Lack of knowledge by food handlers at restaurants serving raw seafood.
- Cross contamination and non-sanitary practices by processors, food preparers, and street food vendors.

Summary of the extent and effectiveness of current risk management practices including food safety production/processing control measures, educational programs, and public health intervention programs (e.g., vaccines).

Factors considered as possible influences on the levels of pathogenic *V. parahaemolyticus* at consumption include:

- Levels of *V. parahaemolyticus* at harvest.
- Ambient air temperatures at times of harvest.
- Length of exposure to ambient temperatures from harvest to refrigeration.
- Time required to cool raw, product once refrigerated after harvest.
- For cooked products; recontamination and conditions of time/temperature favoring growth in the interim between recontamination and consumption.
- Post harvest treatments, such as mild heat treatment, freezing, hydrostatic pressure, depuration, and relaying[3], to reduce the densities and the risks posed by *V. parahaemolyticus* (15).
- Further preservation, e.g. acidification, food preservatives, is likely to inhibit growth and mitigate risks, even from products with low contamination levels.

Several countries use different strategies and programs to manage the risks associated with various factors. The United States follows the National Shellfish Sanitation Program (NSSP) time/temperature matrix for control of *V. vulnificus* (42), and measures at harvest also have been established to prevent oyster-borne outbreaks caused by pathogenic *V. parahaemolyticus.* In 1999 the Interstate Shellfish Sanitation Conference (ISSC) adopted an Interim Control Plan for *V. parahaemolyticus*, which was then revised in 2001, based on monitoring when and where historical episodes indicate. Detection of pathogenic *V. parahaemolyticus* (*tdh*+) results in closure of waters to harvesting shellfish until monitoring indicates the pathogen is no longer detectable or until environmental temperatures becomes unfavorable for the proliferation of this microorganism. This plan includes monitoring for total *V. parahaemolyticus* levels. When levels greater than 5,000 total *V. parahaemolyticus* cells/g oyster tissue are found, additional oyster samples are promptly examined for pathogenic *V. parahaemolyticus*.

Japan also monitors for total *V. parahaemolyticus* strains, and new standards for seafood consumed raw include the following:

1) Fewer than 100 *V. parahaemolyticus* MPN/g in seafood for raw consumption.

2) Temperature of seafood is maintained below 10ºC throughout distribution and storage.

3) After harvest and during food preparation fish/shellfish are washed with disinfected seawater or potable water.

Also in Japan, some local governments release warnings, based on conditions such as water temperature, to make the public more aware of the possible risk associated with eating raw seafood taken from waters during these conditions.

4. Other Risk Profile Elements

4.1 Regional differences in the incidence of foodborne illness due to the pathogen

Differences exist among countries and between different regions within the same country. In Japan, *V. parahaemolyticus* is a major cause of gastroenteritis. Conversely, very few cases are reported in Europe. For example, Denmark reported only two cases of gastroenteritis over a 20-year period. In the United States, as shown in the U.S. risk assessment for *V. parahaemolyticus*, incidence varies from region to region and season to season (15)(Table 5). Different serotypes are found in different countries and in different regions within the same country (15). Although, *Vibrio parahaemolyticus* is found in many seafoods in the different regions of the world, it is predominantly associated with oysters in the United States.

[3] Process of moving shellfish from contaminated to non-contaminated growing areas for the purpose of removing contaminants.

4.2 The extent of international trade of the food commodity

International trade of seafood for raw consumption is increasing. The FAO statistics on trade of seafood[4] show exports of fish products expanded to approximately $52 billion in 1999. Developed countries accounted for nearly 85 percent of total imports of fishery products. Japan was the largest, accounting for 25% of the global total, followed by the U.S. accounting for about 16%. . European countries now account for about 35% of the total value of fishery products imported, but about half of these originate from within the EC. Thailand and Norway are the world's major exporters of fish products in value terms, about 15% of total world exports, combined. Thailand exports fresh and cooked frozen shrimp, fresh frozen fish and other kinds of seafood products in considerable amounts each year. Developing countries continue to generate substantial trade surpluses in fish products that are worth between $16-$17 billion annually. This represents a significant source of trade currency earnings. Shrimp accounts for about 20% of the value of exported fishery products over the past 20 years.

Domestic standards for *V. parahaemolyticus* in seafood can affect the ability to import these products and thus impact international trade. Japan's new standard of less than 100 *V. parahaemolyticus* MPN/g will likely affect imports of some raw seafood, particularly during summer months. EU member states do not generally specifically address *V. parahaemolyticus*. However, Denmark exercises some import controls for seafood from non-EU countries, examining about 50% of ready-to-eat seafood for *V. parahaemolyticus* (and other *Vibrio* species), and sporadically testing raw, frozen seafood as well. Denmark allows up to 100 *V. parahaemolyticus*/g whereas some other European countries reject raw seafood if *Vibrio* species are detected.

4.3 Public perceptions of the problem and the risk

The Japanese society recognizes that these infections have become a major social issue and also a serious problem from the viewpoint of health hazards since there is a wide range in age of infected persons including deaths. In the United States, perception of *V. parahaemolyticus* risk appears to be consistent with the level of actual risk. It is believed that the subset of bivalve consumers with knowledge of shellfish as a potential vehicle for foodborne illness could not distinguish *V. parahaemolyticus*, *V. vulnificus*, viruses and pathogenic bacteria as distinct foodborne pathogens, i.e., what agent causes what illness – unless a newspaper article or TV report has just been released in the area. However, the outbreaks in 1997 and 1998 involving several hundred *V. parahaemolyticus* cases have heightened awareness in the United States. This heightened awareness has been most significant among Public Health officials and the shellfish industry.

4.4 Potential public health and economic consequences of establishing Codex risk management guidance

Establishment of Codex risk management guidance will assist in the adoption of good production and processing practices which, in turn, will help minimize excessive levels of *V. parahaemolyticus*, thereby enhancing public health and facilitating trade.

Establishment of Codex risk management guidance based on sound scientific information will helpful avoid decisions based on food safety that are not scientifically defensible , e.g. rejection of certain categories of raw seafood if *V. parahaemolyticus* are detected at low levels, thereby preventing unwarranted interruption of international trade.

5. Risk Assessment Needs and Questions for the Risk Assessors

The impact of the following risk management options on the risk characterization should be developed and compared.

[4] http://www.fao.org/DOCREP/003/X9800e/X9800e04.htm#P146_39176

- The effect of keeping the temperature of seafood throughout distribution and storage lower than 4 and 10 ºC, and at other temperatures that may be widely employed.
- The effect of washing fish/shellfish with disinfected seawater or potable water after harvest or at preparation.
- The impact on the number of foodborne outbreaks that would occur with guidance that allows no more than certain levels of *V. parahaemolyticus* in finfish or shellfish meat; suggested are levels of 100, 1000 and 10,000 microorganisms/gm.
- The effect of different post harvest treatments such as mild heating and high pressure treatment.

6. Available Information and Major Knowledge Gaps

Available information includes the following.

- Draft Risk Assessment on the Public Health Impact of *V. parahaemolyticus* in Raw Molluscan Shellfish prepared by the *V. parahaemolyticus* Risk Assessment Task Force, U.S. Food and Drug Administration (FDA) (15).
- FAO/WHO Risk Assessment on *Vibrio* spp. (work continuing)
- Codex standards and draft codes of practice for fish and fish products.
- Codex Recommended International Code of Practice: General Principles of Food Hygiene and other pertinent Codex commodity codes of hygienic practice.
- Codex codes of practice related to the use of veterinary drugs
- National governmental and/or industry codes of hygienic practice and related information (e.g., microbiological criteria) that could be considered in developing Codex risk management guidance
  - U.S. National Shellfish Sanitation Program (NSSP) (42)
  - U.S. Interstate Shellfish Sanitation Conference (ISSC) Interim Control Plan
  - Danish Food Act
- EU-Commission Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on *Vibrio vulnificus* and *Vibrio parahaemolyticus* (in raw and undercooked seafood), adopted on 19-20 September 2001.
- Report on Preventive Measures for *Vibrio parahaemolyticus* Foodborne Infections by the Committee on Animal Origin Foods under the Food Sanitation Investigation Council (May 2000) (11)

Areas where information is needed that would assist in the development of Codex risk management of *V. parahaemolyticus* in finfish and shellfish and which impact on the risk assessment include the following (list not in priority order).

- Distribution and abundance of pathogenic *V. parahaemolyticus* in finfish and shellfish at harvest, and changes in the levels from pre-harvest through consumption.
- Delineating hygienic control measures for seawater used at fishing ports and fish markets based on microbiological studies.
- Presence/absence of high-risk consumer groups for *V. parahaemolyticus* infection.
- Environmental factors that influence distribution and abundance of pathogenic *V. parahaemolyticus* in the environment for every region and season (i.e. temperature shifts, salinity, animal passage, predation, and introduction of strains from distant areas).

- Rates of hydrographic flushing (water turnover) in shellfish harvest areas based on levels of freshwater flows, tidal changes, winds, and depth of harvesting area.
- Growth and survival of pathogenic *V. parahaemolyticus* in raw oysters and other seafood at various temperatures.
- Industry post harvest handling practices (i.e. time to refrigeration, cool down periods, length of refrigerated storage).
- Industry food processing practices (i.e. acidification, salting, CO2-packaging, food preservatives) and their influence on survival and growth of the bacterium
- Consumption patterns (frequency of raw oyster consumption from different harvest regions or seasons, and consumption by at risk groups).
- Dose-response data: the minimum number of *V. parahaemolyticus* microorganisms required to cause illness, and severity of the illness.
- Potential virulence factors other than TDH (i.e. TRH, urease, enterotoxins, acid adaptation, and invasion of intestinal cells).
- Role of the oyster (physiology, immune status) in levels of *V. parahaemolyticus*.
- Consumer handling of oysters prior to consumption.
- Global public health surveillance of *V. parahaemolyticus* to identify epidemic strains as they emerge.

Additionally, information and/or availability of rapid detection methods for the low concentration of total and pathogenic *V. parahaemolyticus* in seafood, such as PCR or nested PCR would be helpful in improving risk management capabilities for this microorganism.

RECOMMENDATIONS

Based on the findings provide above, the Working Group recommends that the Committee:

1. Review existing Codex guidance occurring in codes hygienic practice and codes of practice to determine whether such guidance provides sufficient information for the hygienic control of *Vibrio parahaemolyticus* in finfish and shellfish and, if not, to recommend specific risk management guidance to be developed by the Committee. Such new work may involve amendments to existing Codex texts or the development of new microbiological risk management guidance. The Committee may wish to consider the benefits of establishing a Drafting Group to develop such guidance. The Committee should consider whether such work should be carried out in conjunction with the Codex Committee on Fish and Fishery Products.

2. Request the FAO/WHO Joint Expert Group on Microbiological Risk Assessment to assess the impact of the following on the risk of *V. parahaemolyticus* to human health.

    - The effect of keeping the temperature of seafood throughout the distribution and storage lower than 4 and 10ºC, and at other temperatures that may be widely employed.
    - The effect of washing fish/shellfish with disinfected seawater or potable water after harvest or at preparation.
    - The impact on the number of foodborne outbreaks that would occur with guidance that allows no more than certain levels of *V. parahaemolyticus* in finfish or shellfish meat; suggested are levels of 100, 1000 and 10,000 microorganisms/gm.
    - The effect of different post harvest treatments such as mild heating and high pressure treatment.

3. Develop and forward additional risk management questions/options on the control of *V. parahaemolyticus* and request an evaluation by the Joint Expert Group on the impact of such management options on the risk of *V. parahaemolyticus* to human health (e.g., monitoring and closing harvest areas when the water reaches a certain temperature known to promote *V. parahaemolyticus* proliferation, closing harvest areas when based on levels of *V. parahaemolyticus* in waters and/or shellfish).

4. Review the areas where information is needed (see Section 6 above) and encourage WHO, FAO and member countries to make all reasonable efforts to fill these data gaps.

ANNEX 1

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ANNEX 2

TABLES AND FIGURES

Table 1. Investigation results of environment/ food sources in Japan (1999)

<table>
<tr><th></th><th></th><th>Total no. of samples</th><th>No. of V. parahaemolyticus positives(%)</th><th>No. of O3:K6TDH + positives(%)</th><th>Notes</th></tr>
<tr><td rowspan="2">Seawater/Sea mud</td><td>7 prefectures</td><td>329</td><td></td><td>10 (3)</td><td>Using beads</td></tr>
<tr><td>5 prefectures</td><td>222</td><td>126 (57)</td><td>1 (0.5)</td><td></td></tr>
<tr><td rowspan="3">Fish</td><td>Coast/Vessels</td><td>23</td><td>12 (52)</td><td>0</td><td rowspan="6">92 samples of a total 189 found Vibrio parahaemoly-ticus positive</td></tr>
<tr><td>Production site markets</td><td>68</td><td>36 (53)</td><td>0</td></tr>
<tr><td>Retailers/ Distribution markets</td><td>48</td><td>12 (25)</td><td>0</td></tr>
<tr><td rowspan="3">Shellfish/ Prawns/ Squid/ Octopus</td><td>Coast/vessels</td><td>19</td><td>18 (95)</td><td>0</td></tr>
<tr><td>Production site markets</td><td>14</td><td>7 (52)</td><td>0</td></tr>
<tr><td>Retailers/ Distribution markets</td><td>17</td><td>7 (41)</td><td>0</td></tr>
<tr><td colspan="2">Distribution markets for shucked shellfish</td><td>144</td><td>41 (29)</td><td>0</td><td>19 testing facilities</td></tr>
<tr><td rowspan="2">Imported ready-to-eat shucked shellfish</td><td>Ark shell</td><td>356</td><td>6 (2)</td><td>0</td><td>Investigation by quarantine station</td></tr>
<tr><td>Sea urchin</td><td>587</td><td>14 (2)</td><td>0</td><td></td></tr>
</table>

Source: Japanese Ministry of Health, Labor and Welfare

Table 2. Antibiotic susceptibility of 526 *Vibrio parahaemolyticus* strains isolated from diarrheal patients at the Bamrasnaradura Infectious Diseases Hospital (BIDH), April 1990-March 1991

Antimicrobial agents	No.% of isolates		
	Resistant	**Intermediate**	**Sensitive**
Ampicillin	514 (97.7)	5 (1.0)	7 (1.3)
Chloramphenicol	1 (0.2)	0(0.0)	525 (99.8)
Colistin	348 (66.2)	119 (22.6)	59 (11.2)
Cotrimoxazole	0 (0.0)	0 (0.0)	526 (100.0)
Gentamicin	0 (0.0)	0 (0.0)	526 (100.0)
Nalidixic acid	0 (0.0)	0 (0.0)	526 (100.0)
Nitrofurantoin	0 (0.0)	0 (0.0)	526 (100.0)
Tetracycline	0 (0.0)	0 (0.0)	526 (100.0)

Source: The Ministry of Public Health, Thailand

Table 3. Antibiotic susceptibility of 300 *Vibrio parahaemolyticus* isolated from raw seafood, April 1991-August 1991 (Pumiprapat *et al.*, 1993)

Antimicrobial Agents	No. (%) of isolates		
	Resistant	**Intermediate**	**Sensitive**
Ampicillin (AM)	272(90.7)	5(1.7)	23(7.7)
Chloramphenicol (C)	3(1.0)	0(0.0)	297(99.0)
Colistin (CL)	244(81.3)	45(15.0)	11(3.7)
Cotrimoxazole (SxT)	10(3.3)	0(0.0)	290(96.7)
Gentamicin (GM)	0(0.0)	0(0.0)	300(100.0)
Nalidixic acid (NA)	4(1.3)	1(0.3)	295(98.3)
Nitrofurantoin (F/M)	6(2.0)	2(0.7)	292(97.3)
Tetracycline (Te)	18(6.0)	0(0.0)	282(94.0)
Norfloxacin (NOR)	0(0.0)	0(0.0)	300(100.0)

Source: The Ministry of Public Health, Thailand

Table 4. Age and sex distribution of diarrheal patients infected with *Vibrio* parahaemolyticus at the Bamrasnaradura Infectious Diseases Hospital (BIDH), April 1990-March 1991 (Nettip et al, 1992)

Age-group	No. (%) *V. parahaemolyticus* positive cases			
	Male	Female	Total	%
≤ 4	8 (57.1)	6 (42.9)	14	2.7
5-9	13 (86.7)	2 (13.3)	15	2.9
10-14	11 (61.1)	7 (38.9)	18	3.4
15-19	24 (60.0)	16 (40.0)	40	7.6
20-24	46 (49.5)	47 (50.5)	93	17.7
25-29	41 (58.6)	29 (41.4)	70	13.3
30-34	30 (51.7)	28 (48.3)	58	11.0
35-39	21 (50.0)	21 (50.0)	42	8.0
40-44	17 (47.2)	19 (52.8)	36	6.8
45-49	12 (44.4)	15 (55.6)	27	5.1
50-54	10 (40.0)	15 (60.0)	25	4.8
55-59	14 (37.8)	23 (62.2)	37	7.0
60-64	8 (42.1)	11 (57.9)	19	3.6
65-69	3 (27.3)	8 (72.7)	11	2.1
70-74	4 (66.7)	2 (33.3)	6	1.1
75-79	3 (60.0)	2. (40.0)	5	1.0
80-84	1 (12.5)	7 (87.5)	8	1.5
85-89	0 (0.0)	2 (100.0)	2	0.4
Total	266 (50.6)	260 (49.4)	526	100.0

Source: The Ministry of Public Health, Thailand

Table 5. Annual predicted number of illnesses associated with oysters harvested from each region and season in the United States

Region	Summer (July to September)	Fall (October to December)	Winter (January to March)	Spring (April to June)	Total
Gulf Coast (Louisiana)	1,409	142	7	502	2,060
Gulf Coast (Non-Louisiana)[a]	293	54	2	187	536
Mid-Atlantic	7	7	<1	5	19
Northeast Atlantic	12	2	<1	4	18
Pacific Northwest (Intertidal)[b]	134	1	<1	19	154
Pacific Northwest (Dredged)[b]	<1	<1	<1	1	<1
TOTAL	1,855	206	9	719	2,787

[a] Includes oysters harvested from Florida, Mississippi, Texas, and Alabama. The time from harvest to refrigeration in these states is shorter than for Louisiana. [b] Oysters harvested using intertidal methods are exposed for longer times before refrigeration compared with dredge methods.

Table 6. Clinical symptoms associated with gastroenteritis caused by *V. parahaemolyticus* in the United States (15)

Symptoms	Incidence of symptoms	
	Median	Range
Diarrhea	98%	80 to 100%
Abdominal cramps	82%	68 to 100%
Nausea	71%	40 to 100%
Vomiting	52%	17 to 79%
Headache	42%	13 to 56%
Fever	27%	21 to 33%
Chills	24%	4 to 56%

Table 7. Incidents where the production sites were identified in the food poisoning source-tracing investigation in Japan (11)

Location	Type of seafood	Serotype
Pacific Ocean offshore → Miyagi Pref	Tuna	O3:K6
City A, Hokkaido	Scallops	O3:K6 and others
City B, Hokkaido	Scallops	O3:K6
City B or C, Hokkaido	Seafood for sushi	O3:K6
City B, Hokkaido	Sea urchin	
Hokkaido	Boiled crab	O3:K6
Aomori Pref.	Sea urchin	O3:K6
Iwate Pref.	Sea urchin	O3:K6
A, Iwate Pref.	Squid	O3:K6
Iwate Pref.	Sea squirt	O3:K6
B, Iwate Pref.	Sea urchin	O3:K6
Iwate Pref.	Sea squirt	O3:K6
Iwate Pref.	Sea urchin	O3:K6
Fukushima Pref.	Surf clam	O3:K6
Niigata Pref.	Sashimi	O3:K6
Wakayama Pref.	Horse mackerel	Various types
Ishikawa Pref.	Rock oyster	
Tottori Pref.	Turban shell	O3:K6
Tottori Pref.	Fresh fish	O3:K6
A, Nagasaki Pref.	Horse mackerel	
B, Nagasaki Pref.	Olive shell	O3:K6
C, Nagasaki Pref.	Horse mackerel	O4:K55
D, Nagasaki Pref.	Sardines	O3:K6
A, Nagasaki Pref.	Jack-knife clam	O4:K8
Kumamoto Pref.	Mycids	O3:K6, O11K？
Surrounding Saishu Island	Squid	O3:K6
Republic of Korea	Sashimi	O3:K6 and others
Republic of Korea	Pen shells	O3:K6, O4:K13
China	Sea urchin	O3:K6 and others
North Korea	Pen shells	O3:K6 and others
China	Sea urchin	O3:K6
Chile	Pickled turban shell	O3:K6, OUT:KUT

Table 8. Changes in the number of *V. parahaemolyticus* infection incidents from 1991 to 2000 in Japan

Fiscal Year	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
No. of incidents	247	99	110	224	245	292	568	839	641	422
No. of patients	8,082	2,845	3,124	5,849	5,515	5,241	6,786	12,318	9,147	3,620

Table 9. Estimates of cost per case of *V. parahaemolyticus* by severity in the United States (43)

	Illness	Hospitalization	Death
Days affected by *V. para.*	6	7	5,110
% Well-being lost/day	42	53	100
Medical costs	$0	$15,927	$0
Total	$1,596	$18,251	$2,746,000

Table 10. Total cost of *V. parahaemolyticus* by severity in the United States (43)

	Range of Cost	Most Direct Estimate of Cost
Illness	$5,886,000 to $9,606,000	$9,606,000
Hospitalization	$493,000 to $639,000	$493,000
Death	$10,983,000 to $30,203,000	$10,983,000
Total	$17,362,000 to $40,448,000	$21,082,000

Table 11. Economic burden of foodborne illness in Japan (46)

Microorganism	**No. Outbreaks**	**No. Cases**	**Cases per Outbreak**	**Total Indemnity (yen)**	**Ave. Compensation per case (yen)**	**Ave. Compensation per outbreak (yen)**
V.parahaemolyticus	299	9560	32	279,147,299	29,200	933,603
Pathogenic *E.coli* (exclude EHEC)	29	5,072	175	72,530,455	14,300	2,501,050
Salmonella spp.	178	11,908	67	583,109,790	48,968	3,275,898

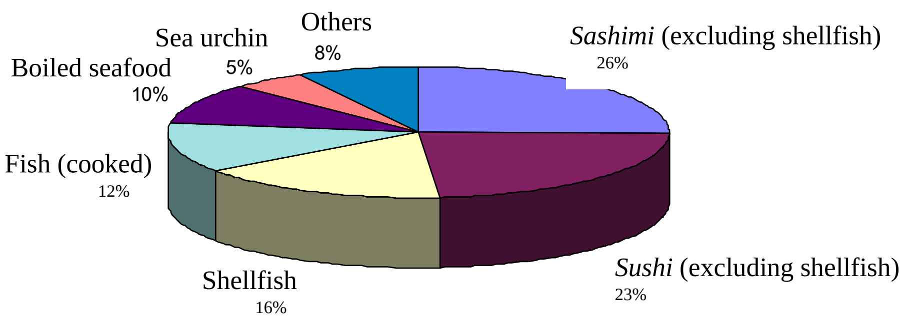

Figure 1. Ratio of occurrence by implicated food group
(Source: The Ministry of Health, Labour and Welfare, Japan)

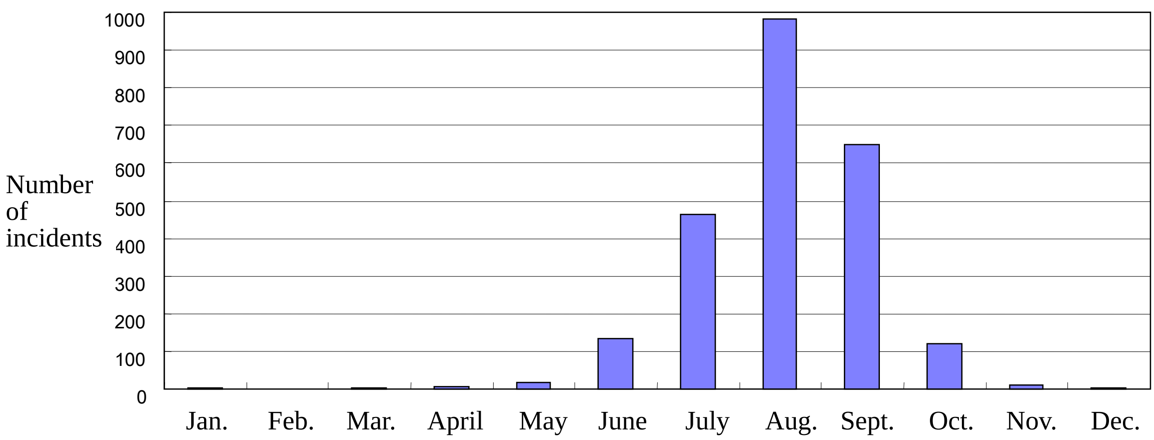

Figure 2. Number of incidents by month
(Source: The Ministry of Health, Labour and Welfare, Japan)

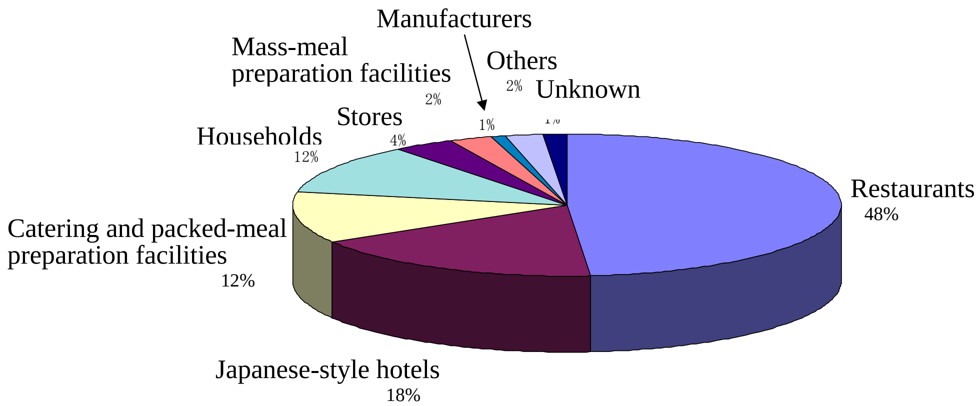

Figure 3. Ratio of occurrence by source facility category in Japan