

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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Agenda Item 2a)

CX/FFP 03/2

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS

Twenty-sixth Session  
Ålesund, Norway, 13 - 17 October 2003

### MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES<sup>1</sup>

#### A. DECISIONS OF THE COMMISSION CONCERNING THE WORK OF THE COMMITTEE

##### 1. Proposed Draft Amendment to the Standard for Canned Sardines and Sardine-Type Products (*Clupea bentsicki*)

1. The Chairman of the Committee on Fish and Fishery Products, recalled that the 21<sup>st</sup> Session of the Commission had requested that the Accelerated Procedure should generally be used for the inclusion of additional species in relevant standards, and this had been applied to consider *Clupea bentsicki*, as proposed by Chile. In application of its specific procedure, the Committee on Fish and Fishery Products had agreed to propose the inclusion of this species in the Standard for Sardines and Sardine-Type Products. No consensus had been reached in the 23<sup>rd</sup> and 24<sup>th</sup> Sessions of the Commission. The Commission was advised that the Committee had initiated a review of its current procedure for inclusion of additional species in standards.

2. The Delegation of Morocco expressed its objection to the amendment as the procedure had not been followed adequately since no criteria had been defined prior to examination by laboratories and Morocco had not participated in the process. The Delegation indicated that the current list of sardine-type products was based only on the mode of preparation, including species that were not taxonomically related to sardines, and that this created considerable confusion for consumers as to the nature of the product. The delegation therefore stressed the need for the Committee to review the current procedure by defining the scientific evaluation criteria before including any new species in the standard. This position was supported by many delegations.

3. The Delegation of Chile stressed that the current procedure for the inclusion of species had been followed, as the samples had been examined by three authorized laboratories from European countries, that its results should be accepted; and that there was no justification to delay further the process and the amendment should be adopted. This position was supported by several delegations.

4. The Delegation of Italy, speaking on behalf of the Member States of the European Union, supported the revision of the procedure for the inclusion of new species in Codex standards in order to ensure that scientific criteria were applied in the process. The Delegation of Spain and others pointed out that the common name of species should be based on taxonomic criteria and that this was not the case in the present Standard; the revision of the procedure should ensure that the inclusion of species was based on scientific criteria and not on the presentation of the product.

5. The Commission, recognizing that there was no consensus, **agreed** to return the Proposed Draft Amendment to the Standard for Canned Sardine and Sardine Type Products to the Committee on Fish and Fishery Products at Step 3, and **recommended** that the Committee continue its work on the revision of the

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<sup>1</sup> For technical reasons, matters arising from the **Committee on Methods of Analysis and Sampling** will be presented in a separate document (CX/FFP 03/2-Add.2)

procedure for the inclusion of new species. The Delegation of Chile expressed its reservation on this decision (ALINORM 03/41, paras. 35-39).

The Committee is invited to consider how to proceed as regards the Proposed Draft Amendment.

## **2. Draft Code of Practice for Fish and Fishery Products Draft Standard for Boiled Dried Salted Anchovies**

The Commission adopted the Draft Code of Practice and the Draft Standard as proposed by the Committee. Further development of the Code will be considered under **Agenda Item 6**.

## **3. Proposed Draft Model Certificate for Fish and Fishery Products Proposed Draft Amendment to the Standard for Quick Frozen Lobsters**

The Commission adopted both Proposed Drafts at Step 5 as proposed. These texts will be considered under **Agenda Item 4 and 5** respectively.

## **4. New Work**

The Commission approved the elaboration of the Proposed Draft Standard for Sturgeon Caviar and the Proposed Draft Amendment to the Standard for Salted Fish and Dried Salted Fish of the *Gadidae* Family (Sampling and Analysis), that will be considered under **Agenda Item 10 and 11** respectively.

## **B. GENERAL DECISIONS OF THE COMMISSION**

### **1. AMENDMENTS TO THE PROCEDURAL MANUAL<sup>2</sup>.**

#### **Clarification of Rule VI.4 (Voting and Procedures)**

The Commission amended Rule VI.4 on Voting and Procedures to include a reference to Rule X.2 related to the adoption or amendments of Codex standards by consensus

#### **Membership of Regional Economic Integration Organizations**

The Commission amended the Rules on Membership to allow regional economic integration organizations to exercise rights of membership within the Codex Alimentarius Commission and its subsidiary bodies under specific conditions.

#### **Measures to Facilitate Consensus**

The Commission adopted the *Measures to Facilitate Consensus* for inclusion in the Procedural Manual as a general decision of the Commission.

#### **Principles for the Establishment of Methods of Analysis**

The Commission adopted the amendment to the *General Criteria for the Selection of Methods of Analysis using the Criteria Approach*, and the new section addressing *Working Instructions for the Implementation of the Criteria Approach in Codex*.

## **2. RISK ANALYSIS**

The Commission adopted the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (ALINORM 01/41, Appendix IV and Procedural Manual, 13<sup>th</sup> Edition).

## **3. JOINT FAO/WHO EVALUATION OF THE CODEX ALIMENTARIUS AND OTHER FAO AND WHO WORK ON FOOD STANDARDS**

The Commission took several decisions concerning the implementation of the recommendations of the Evaluation, enacting some immediately and requesting the Codex Committee on General Principles to draft the amendments to the Procedural Manual required to implement others. In particular the Commission agreed to:

- Meet annually for the next two years, but that in future each session of the Commission would decide the interval between meetings;
- Request the Executive Committee to meet on a six-monthly basis;

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<sup>2</sup> ALINORM 03/41, paras. 15-31 and Appendices II and III.

- Review the structures and mandates of all Codex committees by 2004;
- Enlarge the Executive Committee by appointing the Regional Coordinators (currently observers) as Members;
- Establish the Executive Committee as the body responsible for standards management;
- Develop improved processes for standards management and monitoring;

The Commission welcomed the progress made on the FAO/WHO Trust Fund for Participation of Developing Countries in Codex Standard Setting Procedures and expressed the hope that it would soon become operational.

The Commission noted the need for timely scientific advice from FAO and WHO on a wide range of issues, but also noted that the Commission (through its Executive Committee) needed to prioritize the requests for such advice.

### **C. MATTERS REFERRED BY OTHER CODEX COMMITTEES**

#### **Committee on Food Hygiene (31<sup>st</sup> Session, January 2003)**

##### **Risk Management Strategies For *Vibrio* Spp.**

In presenting the document on *Vibrio* spp., the delegation of the United States noted that the drafting group had followed the instructions of the 34<sup>th</sup> Session of the CCFH and had focussed on *Vibrio parahaemolyticus* and formulated specific questions for the risk assessors as well as reviewing existing Codex texts for completeness. The delegation noted the need for the consideration of additional data, including input from the Codex Committee on Fish and Fishery Products (CCFFP), if necessary.

The representative of FAO noted ongoing related work in the CCFFP, namely, the proposed draft Standard for Molluscan Shellfish and the revised Code of Practice for Fish and Fishery Products, in particular the section related to the Processing of Molluscan Shellfish. It was noted that the CCFFP would be informed of CCFH work related to risk management strategies for *Vibrio parahaemolyticus* . as well as the results of the Joint FAO/WHO Expert Consultation on Risk Assessment of *Vibrio* spp. in Seafood. The representative of WHO noted several questions posed by the risk assessors to the CCFH as to the scope, approach and preliminary results of the expert consultation, especially as to how it related to ongoing work within the CCFH.

It was suggested that further elaboration of the discussion paper should be suspended until the CCFFP had an opportunity to consider the document and pending the completion of the risk assessment. It was noted that future revisions to the document should focus on risk management strategies. It was also suggested that risk assessments should include adequate data related to the pathogenicity of different *Vibrio* species.

The Committee decided to suspend the further elaboration of the Discussion Paper on Risk Management Strategies for *Vibrio* spp. for the time being, pending the outcome of discussions in the CCFFP and the completion of the risk assessment (ALINORM 03/13A, paras. 56-59).

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The Committee is invited to consider the document from the CCFH (as attached) and provide its advice on risk management strategies for *Vibrio parahaemolyticus*, in conjunction with the Proposed Draft Standard for Molluscan Shellfish and the Proposed Draft Code of Practice for Fish and Fishery Products (section on molluscan shellfish).

This document should also be considered in conjunction with CX/FFP 03/2-Add.1 : Matters Arising from FAO and WHO - Microbiological Risk Assessment of *Vibrio* spp.

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Agenda Item 5 (c)

CX/FH 03/5 - Add.3  
August 2002

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD HYGIENE

Thirty-fifth Session  
Orlando, U.S.A., 27 January - 1 February 2003

### DISCUSSION PAPER ON RISK MANAGEMENT STRATEGIES FOR *VIBRIO* SPP. IN SEAFOOD

(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 34<sup>th</sup> Session, CCFH agreed to develop a Discussion Paper on Risk Management Strategies for *Vibrio* spp. in seafood.<sup>3</sup> The Committee further suggested that the initial focus would be *Vibrio parahaemolyticus* in fish and shellfish as the risk assessments for this organism 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.

#### 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 fish. 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 fish.

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 organism. *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 fish and shellfish, the amount of export, and the number of illnesses. In countries in which *V. parahaemolyticus* is endemic, illnesses due to this organism appear to be increasing and therefore there is the potential for a significant impact on the

<sup>3</sup> ALINORM 03/13, paragraph 78.

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 clams, fried mackerel, mussel, 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 or undercooked seafood products and cooked products that have been substantially recontaminated.

### **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).**

*V. 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 fish or shellfish containing these strains. 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 organism 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 only trait known to reliably distinguish pathogenic from non-pathogenic strains of *V. parahaemolyticus* is the production of TDH, a thermostable direct hemolysin. 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). Additionally, based on the discussion of the expert consultation for *Vibrio* and *Campylobacter* risk assessments held in Geneva, Switzerland in July 2002, it has been 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, O5:K17, O1:K32, O5:K15, O2:K28. Note that, since 1996, serotype transition from O4:K8 to O3:K6 has been noticed in Japan. The transition was observed in both environmental and patient isolates. The O3:K6 strains that have been 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 also been observed in Southeast Asia, India and Japan.

- **Thermal Resistance**

*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 (15).

- Susceptibility to antimicrobial agents

*Vibrio parahaemolyticus* strains are sensitive to most common antibiotics used for treatment. (Tables 2&3) (28, 33).

## 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 special 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 to infection (Table 4) (20). Additionally, 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 organism 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).

- 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) or 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

*V. 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

Foods implicated include molluscan shellfish (especially raw oysters), crustaceans (crab, crayfish, lobster, shrimp), scallops, squid, sea urchins, sardines, mycids, and fish (fish-balls) (Tables 1-2, 7) (4, 7, 8, 13, 18, 31, 38, 39, 40). Recently, sampling studies in the Adriatic Sea demonstrated the presence of *V. parahaemolyticus* in fish, mussels and clams, (4). 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 organisms/g in the majority of lots tested, the study demonstrated that levels can exceed 10,000 organisms/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 than 100 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 organism 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 affect 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.

### **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. 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 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<sup>4</sup>, to reduce the densities and the risks posed by *V. parahaemolyticus* (15).

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 organism. 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 oysters 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 10°C 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

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<sup>4</sup> Process of moving shellfish from contaminated to non-contaminated growing areas for the purpose of removing contaminants.

season to season (15)(Table 5). Different serotypes are found in different countries and in different regions within the same country (15).

#### 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<sup>5</sup> 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, 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

Establishing Codex risk management guidance based on sound scientific information would preclude decisions that are not scientifically defensible, e.g. rejection of certain categories of raw seafood if *V. parahaemolyticus* are detected at low levels. Since *V. parahaemolyticus* is a naturally occurring organism (and its presence in raw, marine seafood does not indicate hygienic failure) and low levels are unlikely *per se* to pose a significant public health risk, management guides based on CODEX risk assessments could serve to alleviate such regulation and thus remove trade barriers.

Importantly, establishing Codex risk management guidance should also assist in establishing good production and processing practices that should help minimize excessive levels of *V. parahaemolyticus*, enhancing public health and facilitating trade.

### 5. Risk Assessment Needs and Questions for the Risk Assessors<sup>6</sup>

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

- The effect of keeping the temperature of seafood throughout distribution and storage lower than 4

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<sup>5</sup> [http://www.fao.org/DOCREP/003/X9800e/X9800e04.htm#P146\\_39176](http://www.fao.org/DOCREP/003/X9800e/X9800e04.htm#P146_39176)

<sup>6</sup> CCFEP has also put forward risk assessment questions to the joint FAO/WHO expert consultation held in Bangkok (ALINORM 03/18, Paragraph 92).

and 10 °C, 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 fish or shellfish meat; suggested are levels of 100, 1000 and 10,000 organisms/gm. The Committee should determine "the point(s)" e.g. harvest, point of sale, or consumption at which these values apply.
- 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
- Additional sources of information and scientific expertise that could be used in developing Codex risk management guidance.
  - EU 2001 Opinion of the Scientific Committee on Veterinary Measures relating to Public Health on *Vibrio vulnificus* and *Vibrio parahaemolyticus* (in raw and undercooked seafood)
  - 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 fish 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 fish 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).
- 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* organisms 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 organism.

## RECOMMENDATIONS

The Committee may wish to consider and recommend the following.

1. Request the Drafting Group established at the 34<sup>th</sup> Session of CCFH to determine, based on a detailed review of existing Codex guidance occurring in codes of hygienic practice and codes of practice, whether such guidance provides sufficient information for the hygienic control of *Vibrio parahaemolyticus* in fish 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 request the 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 10°C, 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 fish or shellfish meat; suggested are levels of 100, 1000 and 10,000 organisms/gm.
  - The effect of different post harvest treatments such as mild heating and high pressure treatment.

The Committee may also wish to 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).
3. 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.

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## TABLES AND FIGURES

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

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

Source: Japanese Ministry of Health, Labor and Welfare



**Table 2. Antibiotic susceptibility of 526 *Vibrio parahaemolyticus* strains isolated from diarrheal patients at 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: Japanese Ministry of Health, Labor and Welfare

**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)

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

Age-group	No. (%) <i>V. parahaemolyticus</i> 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

**Table 5. Annual predicted number of illnesses for each region and season in the U.S.**

<b>Region/Season</b>	<b>Spring</b>	<b>Summer</b>	<b>Fall</b>	<b>Winter</b>
Gulf	1,200	3,000	400	25
Pacific NW	15	50	ND	ND <sup>a</sup>
NE Atlantic	12	30	7	ND
Mid-Atlantic	10	12	ND	ND

**Table 6. Clinical symptoms associated with gastroenteritis caused by *V. parahaemolyticus***

<b>Symptoms</b>	<b>Incidence of symptoms</b>	
	<b>Median</b>	<b>Range</b>
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)**

<b>Location</b>	<b>Type of seafood</b>	<b>Serotype</b>
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.	Mysids	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 (43)**

	Illness	Hospitalization	Death
Days affected by <i>V. para.</i>	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 (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)**

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

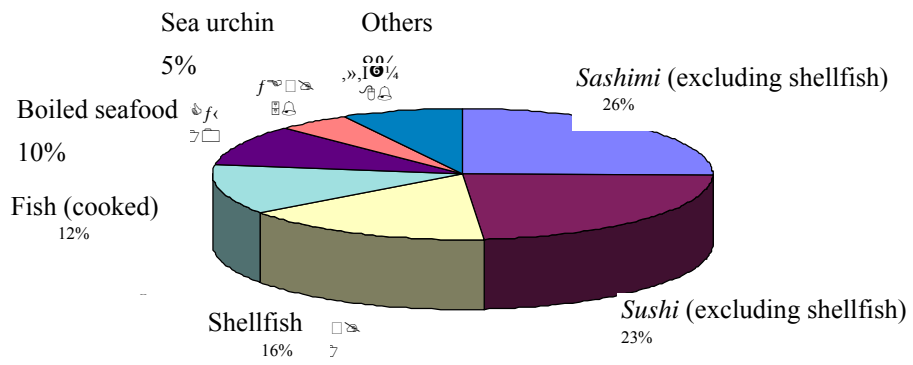


Figure 1. Ratio of occurrence by implicated food group  
 (Source: The Ministry of Health, Labour and Welfare, Japan)

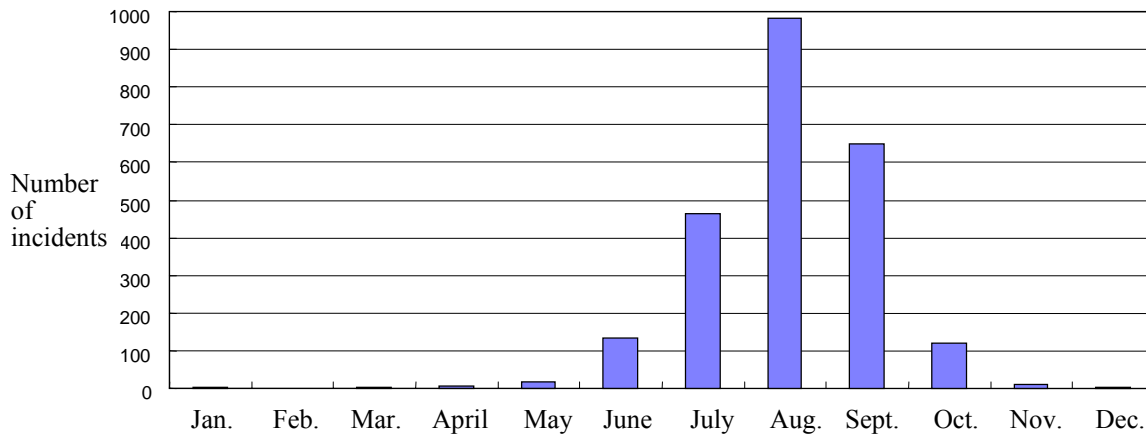


Figure 2. Number of incidents by month  
(Source: The Ministry of Health, Labour and Welfare, Japan)



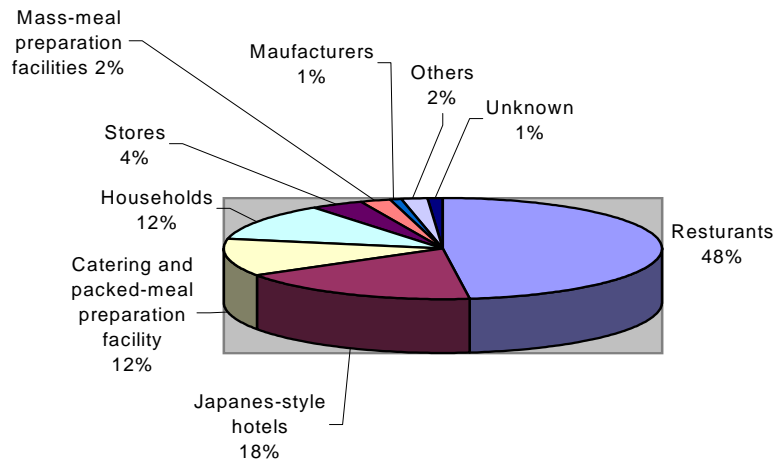


Figure 3. Ratio of occurrence by source facility category