

Proposal Subject: Proposed New Section on *Vibrio parahaemolyticus*

Specific NSSP Guide Reference: Modify Model Ordinance Chapter VIII. @. 01, by adding new Subsection G.

Text of Proposal/ Requested Action Modify Model Ordinance Chapter VIII. @. 01, by adding new subsection G.:

G. Growing Areas Associated with Illnesses Caused by *Vibrio parahaemolyticus*. If the waters of a state have been confirmed as an original source of product associated with two (2) or more *Vibrio parahaemolyticus* illnesses, the Authority shall develop and adopt a *Vibrio parahaemolyticus* contingency plan for all affected marine and estuarine shellfish growing areas.

(1) Each year the Authority shall initiate the following measures in growing areas or at indicator stations during the period of time that those areas have been historically affected by *V. parahaemolyticus*:

Implement an environmental sampling plan for collected and analyzing samples of shellstock from each indicator station to quantitatively monitor *V. parahaemolyticus* levels in shellfish meat from the growing waters; and

(b) Notify the shellfish industry and the local health jurisdictions in the state of the potential for illnesses due to *V. parahaemolyticus* prior to historical times of onset or at a minimum of once a year.

(2) When more than five (5) confirmed illnesses occur within a 30-day period from anywhere in the state which do not meet the definition of an outbreak or more than three (3) confirmed illnesses occur within a seven (7) day period from anywhere in the state which do not meet the definition of an outbreak or more than one shellstock sample at an indicator station is determined to have more than 100 *V. parahaemolyticus* bacteria per gram of meat, the Authority shall implement the following control measures for *V. parahaemolyticus*:

(a) Coordinate collection and analysis of two (2) or more samples of shellstock per month from each indicator station to quantitatively monitor *V. parahaemolyticus* levels in shellfish meat from the growing waters;

(b) Notify members of the shellfish industry in affected areas of the potential problem and recommend to them that shellstock be placed under temperature control of 50° Fahrenheit (10° Centigrade) or less within ten (10) hours of harvest; and

(c) Advise the FDA region, tribal shellfish authorities, members of the shellfish industry in the state, and other Authorities in the region of the potential problem.]

(3) When more than ten (10) confirmed illnesses occur within a 30-day period from anywhere in the state which do not meet the definition of an outbreak or more than six (6) confirmed illnesses occur within a seven (7) day period from anywhere in the state which do not meet the definition of an outbreak, the Authority shall implement the following control measures for *V. parahaemolyticus*:

(a) Coordinate collection and analysis of shellstock samples weekly from each indicator station to identify *V. parahaemolyticus* levels in shellfish meat from the growing waters;

(b) Require shellstock harvested from affected areas be placed under temperature control of 50° Fahrenheit (10° Centigrade) or less within ten (10) hours of harvest;

(c) Notify the ISSC, the FDA region, tribal shellfish authorities, members of the shellfish industry in the state and other Authorities in the region of the potential problem; and

(d) Issue a health advisory to the public about the potential problem and to eat shellfish from the affected areas fully cooked.

(4) When more than twenty (20) confirmed illnesses occur within a 30-day period from anywhere in the state which do not meet the definition of an outbreak or more than ten (10) confirmed illnesses occur within a seven (7) day period from anywhere in the state which do not meet the definition of an outbreak, the Authority shall implement the following control measures for *V. parahaemolyticus*.

(a) Coordinate collection and analysis of shellstock samples weekly

from each indicator station to identify *V. parahaemolyticus* levels in shellfish meat from the growing waters;

(b) Ban harvest of shellstock from affected areas for raw consumption;

(c) Require dealers to label "cook thoroughly" all shucked product and shellstock harvested from affected areas; and

(d) Issue a health advisory to the public about the potential problem and to eat shellfish from the affected areas fully cooked.

(5) When an outbreak is confirmed as defined in Chapter II, Section @. 01 or more than one (1) shellstock sample at an indicator station is determined to have more than 10,000 *V. parahaemolyticus* bacteria per gram of meat, the Authority shall implement the following control measures for *V. parahaemolyticus*:

(a) Conduct an investigation of a confirmed outbreak or of samples exceeding the *V. parahaemolyticus* action level and follow up according to Chapter II.

(b) Coordinate collection and analysis of shellstock samples weekly from each indicator station to identify *V. parahaemolyticus* levels in shellfish meat from the growing waters;

(c) Issue additional health advisories as necessary to inform the public about the problem;

(d) Prepare a written report to the FDA region.

The attached table is provided for easy reference and is not proposed for inclusion in the Model Ordinance.

**Public Health
Significance**

Vibrio parahaemolyticus is a major cause of shellfish-related illness in the United States, especially during warm weather. During the summer of 1997, more than 200 cases of illness were attributed to shellfish harvested from Pacific Northwest waters. Oysters consumed raw were the predominant product implicated.

The Model Ordinance does not specify effective control measures for regional episodes of illnesses caused by *Vibrio parahaemolyticus*, which do not meet the definition of an outbreak in Chapter II. The temperature control measures prescribed for shellstock in Chapter III.03 have proven not to be effective in controlling the hazard. Additional controls are needed to provide public health protection and renew public confidence in shellfish safety.

**Cost Information
(if available)**

Unknown

	TRIGGERS	SAMPLING	REGULATORY	EDUCATION
TIER #1	Growing areas/regions historically affected by <i>V. parahaemolyticus</i>	Implement environmental sampling plan similar to marine biotoxin plan	N/A	Letter/newsletters etc. to industry and local health jurisdictions
TIER #2	More than 5 illnesses within 30 days <u>which do not meet the definition of an outbreak</u> <u>Or</u> More than 3 illnesses within 7 days <u>which do not meet the definition of an outbreak</u> <u>Or</u> More than one sample at an indicator station >100 org./gram	Increase sampling in implicated areas to at least twice a month	Recommend <10 hours to temperature control for shellstock	Advise FDA regions, tribes, industry, and other authorities in the region.
TIER #3	More than 10 illnesses within 30 days <u>which do not meet the definition of an outbreak</u> <u>Or</u> More than 10 illnesses within 7 days <u>which do not meet the definition of an outbreak</u>	Weekly sampling	Require 0 hours to temperature control for shellstock	Notify ISSC, FDA region, tribes, industry, and other authorities in the region, issue-cooking advisory.
TIER #4	More than 20 illnesses within 30 days <u>which do not meet the definition of an outbreak</u> <u>Or</u> More than 10 illnesses within 7 days, <u>which do not meet the definition of an outbreak.</u>	Weekly sampling	Ban harvest of shellstock for raw consumption in affected areas, require dealers to label shucked product for cooking only	Issue cooking advisory.
TIER #5	Confirmed outbreak per Chapter II. §. 01 <u>Or</u> More than one sample >10,000 org./gram	Weekly sampling	Conduct investigation and follow-up per Chapter II.	Continue public outreach; provide written illness report to FDA

Action by 1998 Task Force I

Recommended adoption of Proposal 98-107 with the following amendments:
 Modify Model Ordinance Chapter VIII. @. 01, by adding new subsection G.:

Modify Section IV. of the 1999 NSSP Guide for the Control of Molluscan Shellfish by adding new subsection C. entitled "Interim Control Plan For *Vibrio parahaemolyticus*". In 3 years this ICP shall become a Proposal to be deliberated at the 2001 Conference.

~~G.~~ **C.** Growing Areas Associated with Illnesses Caused by *Vibrio parahaemolyticus*. If the waters of a state have been confirmed as an original source of ~~product~~ **molluscan shellfish** associated with two (2) or more *Vibrio parahaemolyticus* illnesses, the Authority shall develop and adopt a *Vibrio parahaemolyticus* contingency plan for all affected marine and estuarine shellfish growing areas. **If any controls identified below are implemented, they shall stay in effect until such time as determined by the Authority.**

(1) Each year the Authority shall initiate the following measures in growing areas or at indicator stations during the period of time that those areas have been historically **or are currently** affected by *V. parahaemolyticus*:

(a) Implement an environmental sampling plan for collected and analyzing samples of shellstock from each indicator station to quantitatively monitor *V. parahaemolyticus* levels in shellfish meat from the growing waters; **and**

(b) Notify the shellfish industry and the local health jurisdictions in the state of the potential for illnesses due to *V. parahaemolyticus* prior to historical times of onset or at a minimum of once a year.

(2) When more than five (5) confirmed illnesses occur within a 30-day period from ~~anywhere~~ **any harvest area(s)** in the state which do not meet the definition of an outbreak **or** more than three (3) confirmed illnesses occur within a seven (7) day period from ~~anywhere~~ **any harvest area(s)** in the state which do not meet the definition of an outbreak **or more than one shellstock sample at an indicator station is determined to have more than 100 MPN but less than or equal to 1000 MPN** *V. parahaemolyticus* bacteria per gram of meat, the Authority shall implement the following control measures for *V. parahaemolyticus*:

(a) Coordinate collection and analysis of two (2) or more samples of shellstock per month from each indicator station to quantitatively monitor *V. parahaemolyticus* levels in shellfish meat from the growing waters;

(b) Notify members of the shellfish industry in affected areas of the potential problem and recommend to them that shellstock be placed under temperature control of 50° Fahrenheit (10° Centigrade) or less within ten (10) hours of harvest; **and**

(c) Advise the FDA region, tribal shellfish authorities, members of the shellfish industry in the state, and other Authorities in the region of the potential problem.

(3) When more than ten (10) confirmed illnesses occur within a 30-day period from ~~anywhere~~ **any harvest area(s)** in the state which do not meet the definition of an outbreak **or** more than six (6) confirmed illnesses occur within a seven (7) day period from ~~anywhere~~ **any harvest area(s)** in the state which do not meet the definition of an outbreak **or more than one shellstock sample at an indicator station is determined to have more than 1000 MPN but less than or equal to 5000 MPN** *V. parahaemolyticus* bacteria per gram of **meat**, the Authority shall implement the following control measures for *V. parahaemolyticus*:

(a) Coordinate collection and analysis of shellstock samples weekly from each indicator station to identify *V. parahaemolyticus* levels in shellfish meat from the growing waters;

(b) Require shellstock harvested from affected areas be placed under temperature control of 50° Fahrenheit (10° Centigrade) or less within ten (10) hours of harvest;

(c) Notify the ISSC, the FDA region, tribal shellfish authorities, members of the shellfish industry in the state and other Authorities in the region of the potential problem; **and**

(d) Issue a health advisory to the public about the potential problem and to eat shellfish from the affected areas fully cooked. **Encourage the industry to educate wholesalers, retailers, and consumers about the potential problem with recommendations that the product is not consumed raw.**

(4) When more than twenty (20) confirmed illnesses occur within a 30-day period from ~~anywhere~~ **any harvest area(s)** in the state which do not meet the definition of an outbreak **or** more than ten (10) confirmed illnesses occur within a seven (7) day period from ~~anywhere~~ **any harvest area(s)** in the state which do not meet the definition of an outbreak **or more than one shellstock sample at an indicator station is determined to have more than 5000**

MPN but less than or equal to 10,000 MPN *V. parahaemolyticus* bacteria per gram of meat. the Authority shall implement the following control measures for *V. parahaemolyticus*.

(a) Coordinate collection and analysis of shellstock samples weekly from each indicator station to identify *V. parahaemolyticus* levels in shellfish meat from the growing waters;

(b) Ban harvest of shellstock from affected areas for raw consumption;

(c) Require dealers to label "cook thoroughly" all shucked product and shellstock harvested from affected areas; **and educate wholesalers, retailers, and consumers that all shucked product should not be consumed raw.**

(d) Issue a health advisory to the public about the potential problem and to eat shellfish from the affected areas fully cooked.

(5) When an outbreak is confirmed as defined in Chapter II. Section @. 01 or more than one (1) shellstock sample at an indicator station is determined to have more than 10,000 *V. parahaemolyticus* bacteria per gram of meat, the Authority shall implement the following control measures for *V. parahaemolyticus*:

(a) Conduct an investigation of a confirmed outbreak or of samples exceeding the *V. parahaemolyticus* action level and follow up according to Chapter II.

(b) Coordinate collection and analysis of shellstock samples weekly from each indicator station to identify *V. parahaemolyticus* levels in shellfish meat from the growing waters;

(c) Issue additional health advisories as necessary to inform the public about the problem;

(d) Prepare a written report to the FDA region.

(6) In determining whether or not an area can be re-opened, the Authority shall consider the following criteria:

(a) If levels of *Vibrio parahaemolyticus* have increased in samples from the indicator stations in concert with illnesses, reopening of the affected harvest area could occur when levels are reduced to the baseline levels for that harvest area; and/or

(b) *Vibrio parahaemolyticus* strains of virulent genotypes are absent; and/or

(c) If environmental conditions shift to conditions unfavorable for *Vibrio parahaemolyticus* growth (e.g., temperature, salinity) or if environmental conditions shift to those historically unrelated to cases.

(7) When an Authority has implemented control measures for *V. parahaemolyticus* under Section G. (2), (3), (4), or (5), the Authority shall implement a monitoring and enforcement program that investigates possible temperature abuse on product after processing through retail. If current authority does not exist, the ISSC encourages the Authority to adopt an appropriate program.

(8) The Authority can allow for the harvesting of shellfish from areas where control measures have been implemented under Section G. (4) or (5) to go through an approved post harvest treatment process that reduces *V. parahaemolyticus* to non-detectable levels.

The ISSC is directed to manage a national data collection program, as recommended by the Research Guidance Committee, to gather pertinent information that can improve the understanding of *V. parahaemolyticus* illnesses with identified environmental conditions. It is further recommended that the ISSC shall develop and disseminate national protocols for collecting, processing, and transporting of samples and lab testing protocols. The ISSC shall also seek federal assistance to gather existing data including the acquisition of appropriate Department of Defense data. Where data gaps exist, the ISSC shall seek federal funding for data collection.

**Action by 1998
General Assembly**

Adopted recommendation of 1998 Task Force I.

Action by USFDA

Offered the following comments on Proposal 98-107:

FDA wishes to commend the Conference for recognizing that the current NSSP controls do not adequately address the issue of sporadic shellfish related illnesses that do not meet the definition of an outbreak. The "Interim Control Plan for *Vibrio parahaemolyticus*" adopted by the Conference as a guidance document represents a good first step toward the development of a public health control strategy to deal with this naturally occurring pathogen that has been implicated in hundreds of cases of illness during the past two summers.

However, FDA continues to be concerned about the appropriateness and adequacy of the controls that were adopted in the Interim Control Plan. Many of our concerns were expressed at the Conference during the discussions on this Proposal in Task Force I.

The Interim Control Plan relies on numbers of reported illnesses within certain time periods that do or do not meet the definition of an outbreak, as well as *V.p.* levels in shellstock samples, to trigger the controls. This approach is problematic for two reasons. First, it is dependent on timely and uniform reporting of illnesses nationwide, which is currently not a reality. Second, the *V.p.* levels that trigger the various controls are admittedly arbitrary and have no known relation to risk of illness. The 10,000 MPN/gm number in a shellstock sample, which is one of the criteria in the Plan that triggers closure of a harvest area, has traditionally been FDA's "regulatory level" for this pathogen. However, recent information on *V.p.* levels in harvest areas implicated in outbreaks strongly suggests that this number may be too high and also that presence/absence of virulent strains is more relevant than total *Vibrio* counts.

The controls in the Plan as adopted are not, in FDA's opinion, sufficiently protective of the public health. Up to 20 confirmed illnesses in a 30-day period or up to 10 confirmed illnesses in a seven-day period from any harvest area(s) in the state may occur before any harvesting restrictions are imposed. Then the numbers of illnesses exceed these levels, harvesting and sale of shellfish is still permitted. The shellfish is simply required to be labeled "cook thoroughly" and wholesalers, retailers and consumers are to be notified that the product should be cooked.

FDA does not believe that harvest restrictions should be delayed until 20 *V.p.* illnesses are confirmed in a 30-day period or 10 illnesses in a seven-day period. Moreover, FDA does not believe that it is appropriate to ship molluscan shellfish in interstate commerce that is not safe for raw consumption.

The Interim Control Plan also addresses re-opening a harvest area after an outbreak has occurred. The adopted language, which was provided to the Task Force I by FDA during discussions on this issue, attempted to address illness outbreaks involving higher than normal total *V.p.* counts because of environmental conditions in harvest areas (e.g., a hotter than normal summer in the Pacific Northwest), as well as those resulting from the presence of a particularly virulent strain (like 03:K6). Our experience during the illness outbreaks in Galveston Bay and Oyster Bay indicate that the re-opening criteria as written are subject to misinterpretation and need to be clarified. FDA intends to work with the Conference in this regard.

**Action by ISSC
Executive Board**

Appointed *Vibrio parahaemolyticus* Technical Workgroup to address FDA concerns.

**Action By 1999
Vibrio
Parahaemolyticus
Committee**

RECOMMENDATIONS: The committee recommended to Task Force I the following *V.p.* Interim Control Plan replace the ICP guidance document adopted at the 1998 conference and submit it as an proposal for deliberation at the 2001 conference. The committee further recommended that the ISSC continue to provide assistance to states which will enable them to develop the necessary analytical capability as described in the ICP.

~~anywhere~~ **any harvest area(s)** in the state which do not meet the definition of an outbreak ~~or~~ more than six (6) confirmed illnesses occur within a seven (7) day period from ~~anywhere~~ **any harvest area(s)** in the state which do not meet the definition of an outbreak **or more than one shellstock sample at an indicator station is determined to have more than 1000 MPN but less than or equal to 5000 MPN *V. parahaemolyticus* bacteria per gram of meat.** the Authority shall implement the following control measures for *V. parahaemolyticus*:

(a) Coordinate collection and analysis of shellstock samples weekly from each indicator station to identify *V. parahaemolyticus* levels in shellfish meat from the growing waters;

(b) Require shellstock harvested from affected areas be placed under temperature control of 50° Fahrenheit (10° Centigrade) or less within ten (10) hours of harvest;

(c) Notify the ISSC, the FDA region, tribal shellfish authorities, members of the shellfish industry in the state and other Authorities in the region of the potential problem; and

Vibrio parahaemolyticus Interim Control Plan For Oysters

A. Contingency Plan

(1) If the waters of a state have been confirmed as an original source of oysters associated with two or more confirmed V.p. illnesses within the past 3 years, the Authority shall develop and adopt a V.p. contingency plan.

(2) The plan shall define the administrative procedures and resources necessary to accomplish the following:

(a) Identify and define growing areas in the state affected by V.p. based on hydrographic and geographic parameters and other considerations relevant to control of a naturally occurring pathogen.

(b) Conduct a meat sampling and assay program in those areas which have been associated with a V.p. illness;

(c) Close growing areas and embargo product;

(d) Prevent harvesting of affected product; and

(e) Provide for product recall;

(f) Notify the shellfish industry and the local health jurisdictions in the state of the potential for illnesses due to *V. parahaemolyticus* prior to historical times of onset or at a minimum of once a year;

(g) Issue a health advisory to the public about the potential problem, and advise the industry to educate wholesalers, retailers, and consumers about the potential problem, with recommendations that the product not be consumed raw during periods historically affected by V.p.

(3) The plan may include agreements or memoranda of understanding between the Authority and individual oyster harvesters and processors to allow harvesting of oysters from growing areas which have been placed in the closed status, as specified in C for:

(a) post-harvest treatment by a process which has been demonstrated to reduce V.p. levels to non-detectable;

(b) shucking and labeling "for cooking only"; or

(c) under specific circumstances, as approved by the Authority, where the shellstock will be sold to a retailer or food service establishment, food processor, or to a shucker-packer and labeled in accordance with 3 (b).

(d) under specific circumstances, as approved by the Authority, where the shellstock will be cooked and controls exist to ensure cooking.

B. *Vibrio parahaemolyticus* Monitoring

(1) In all areas where V.p. illnesses have occurred, representative samples of oysters shall be collected monthly during harvest periods (as determined by the Authority) and analyzed, using the direct plating procedure and other methods as determined by the Authority. *

(2) In all areas where a confirmed V.p. outbreak has occurred, representative samples of oysters shall be collected during harvest periods as determined by the Authority. Samples shall be collected at intervals determined by the Authority (minimum weekly during months historically associated with an outbreak) and analyzed for total (tlh+ colonies) and virulent (tdh+) V.p. by the procedure and methods prescribed in B. (1) and other methods as determined by the Authority.

(3) In order to determine the number of samples that would be appropriate for V.p. monitoring, the following factors shall be considered:

(a) the size of the growing area;

(b) the amount of shellstock typically harvested from the area;

(c) the sensitivity of the methodology;

(d) the size of the oyster meat samples being analyzed.

(4) In the event that emerging technologies and research identify pathogenic strains other than or in addition to tdh+, the Authority may adopt and FDA may approve other or additional monitoring and control methods for preventing V.p. illnesses

C. Closed Status of Growing Areas Based On Monitoring Results.

(1) The growing area as defined in accordance with A. (2)(a) shall be placed in the closed status for harvest, except as allowed under A (3), if any virulent (tdh+) V.p. as

confirmed by replicate analysis are found in any oyster sample. If any sample shows total V.p. counts above 10,000 CFU/g, then additional samples (twice the number collected as determined by the Authority) shall immediately be collected and analyzed for virulent (tdh+) V.p. Should any of these additional samples show virulence (tdh+), the area would be placed in the closed status.

(2) The closed status shall remain in effect until two consecutive representative samples of shellfish meats, collected a minimum of four days apart, show no tdh+ samples. If any sample shows total V.p. counts above 10,000 CFU/g then additional samples (twice the number collected as determined by the Authority) shall immediately be collected and analyzed for virulent (tdh+) V.p.

(3) The analysis leading to a decision to return a growing area to the open status shall be adequately documented.

D. Illness Outbreak

(1) When a growing area is implicated in a V.p. illness outbreak, the Authority shall follow the procedures prescribed in Chapter II, Section @. 01A through E. If a growing area is closed due to an illness outbreak, the closed status shall remain in effect until two consecutive representative samples of shellfish meats, collected not less than 4 days apart, show no tdh+ samples and no samples with total V.p. counts above 10,000 CFU/g.

(2) If additional confirmed V.p. illnesses occur within 2 weeks of re-opening, they should be considered as a continuation of the illness outbreak. The growing area shall immediately be placed in the closed status, and re-opening may only occur when environmental conditions shift to those unfavorable to the growth of V.p., or the Authority in conjunction with the state epidemiologist develops and implements a sampling plan.

E. Records.

The Authority shall maintain a copy of all of the following records:

(1) All information, including monitoring data, relating to the levels of V.p. in the shellfish growing areas;

(2) Copies of notices placing growing areas in the closed status;

(3) Evaluation reports; and

(4) Copies of notices returning growing areas to the open status.

*[Direct plating procedure by Cook, D.W. et al 1999. Procedure for enumeration of *Vibrio parahaemolyticus* in shellfish meats. A collaborative study by shellfish producing states, FDA and the ISSC; gene probe methods, for total (tlh + colonies) V.p. (McCarthy, S.A. et al 1999. TRS. Appl. Microbial. 28:66-70.); and virulent (tdh+) V.p. (McCarthy, S.A. et al 1999. Abstracts of the 99th General Meeting of the American Society for Microbiology, p.512].

Action by 1999 Task Force I

Recommended adoption of *Vibrio parahaemolyticus* Committee recommendation on Proposal 98-107 as amended:

***Vibrio parahaemolyticus* Interim Control Plan For Oysters (AMENDED BY TASK FORCE I)**

A. Contingency Plan

(1) If the waters of a state have been confirmed as an original source of oysters associated with two or more confirmed V.p. illnesses within the past 3 years, the Authority shall develop and adopt a V.p. contingency plan.

(2) The plan shall define the administrative procedures and resources necessary to accomplish the following:

(a) Identify and define growing areas in the state affected by V.p. based on hydrographic and geographic parameters and other considerations relevant to control of a naturally occurring pathogen.

(b) Conduct an oyster meat sampling and assay program in those areas which have been associated with a V.p. illness;

(c) Close affected oyster growing areas and embargo product;

(d) Prevent harvesting of affected oysters product; and

(e) Provide for oyster product recall **if the oyster growing area is closed as a result of illness**;

(f) Notify the shellfish industry and the local health jurisdictions in the state of the potential for illnesses due to *V. parahaemolyticus* prior to historical times of onset or at a minimum of once a year;

(g) Issue a health advisory to the public about the potential problem and advise the industry to educate wholesalers, retailers, and consumers about the potential problem, with recommendations that the product not be consumed raw during periods historically affected by V.p.

(3) The plan may include agreements or memoranda of understanding between the Authority and individual oyster harvesters and processors to allow harvesting of oysters from growing areas which have been placed in the closed status, as specified in C. for:

(a) post-harvest treatment by a process which has been demonstrated to reduce V.p. levels to non-detectable or;

(b) shucking and labeling "for cooking only"; or

(c) under specific circumstances, as approved by the Authority, where the oyster shellstock will be sold to a retailer or food service establishment, food processor, or to a shucker-packer and labeled in accordance with (3)(b) or.

(d) under specific circumstances, as approved by the Authority, where the oyster shellstock will be cooked and controls exist to ensure cooking.

B. *Vibrio parahaemolyticus* Monitoring.

(1) In all areas where **confirmed** V.p. illnesses have occurred **within the last 3 years**, representative samples of oysters shall be collected monthly during harvest periods (as determined by the Authority) and analyzed, using the direct plating procedure **and gene probe methods for total (tlh+ colonies) V.p. and virulent (tdh+) V.p.** and other methods as determined by the Authority. *

(2) In all areas where a confirmed V.p. outbreak has occurred, representative samples of shellfish shall be collected during harvest periods as determined by the Authority. Samples shall be collected at intervals determined by the Authority (minimum weekly during months historically associated with an outbreak) and analyzed for total (tlh+ colonies) and virulent (tdh+) V.p. by the procedure and methods prescribed in B. (1) and other methods as determined by the Authority.

(3) In order to determine the number of samples that would be appropriate for V.p. monitoring, the following factors shall be considered:

(a) the size of the growing area;

(b) the amount of oyster shellstock typically harvested from the area;

(c) the sensitivity of the methodology;

(d) the size of the oyster meat samples being analyzed.

(4) In the event that emerging technologies and research identify pathogenic strains other than or in addition to tdh+, the Authority may adopt and FDA may approve other or additional monitoring and control methods for preventing V.p. illnesses.

C. Closed Status of Growing Areas Based On Monitoring Results.

(1) The growing area as defined in accordance with A. (2)(a), shall be placed in the closed status for oyster harvest, except as allowed under A. (3), if any virulent (tdh+) V.p. as confirmed by replicate analysis are found in any oyster sample **from the harvest area**. If any sample shows total V.p. counts above 10,000 CFU/g then additional samples (twice the number collected as determined by the Authority) shall immediately be collected and analyzed for virulent (tdh+) V.p. Should any of these additional samples show virulent (tdh+) V.p., the area will be placed in the closed status **for oyster harvest, except as allowed under A. (3).**

(2) The closed status shall remain in effect until two consecutive representative samples of ~~shellfish~~ oyster meats, collected a minimum of four days apart, show no tdh+ samples. If any sample shows total V.p. counts above 10,000 CFU/g then additional samples (twice the number collected as determined by the Authority) shall immediately be collected and analyzed for virulent (tdh+) V.p.

(3) The analysis leading to a decision to return a growing area to the open status shall be adequately documented.

D. Illness Outbreak

(1) When a growing area is implicated in a V.p. illness outbreak, the Authority shall follow the procedures prescribed in Chapter II. Section @. 01A through E. If a growing area is closed due to an illness outbreak, the closed status shall remain in effect until two consecutive representative samples of ~~shellfish~~ **oyster** meats, collected not less than 4 days apart, show no tdh+ samples and no samples with total V.p. counts above 10,000 CFU/g.

(2) If additional confirmed V.p. illnesses occur within 2 weeks of re-opening, they should be considered a continuation of the illness outbreak. The growing area shall immediately be placed in the closed status, and re-opening may only occur when environmental conditions shift to those unfavorable to the growth of V.p., or the Authority, in conjunction with the state epidemiologist, develops and implements a sampling plan.

E. Records.

The Authority shall maintain a copy of all of the following records:

- (1) All information, including monitoring data, relating to the levels of V.p. in the shellfish growing areas;
- (2) Copies of notices placing growing areas in the closed status;
- (3) Evaluation reports; and
- (4) Copies of notices returning growing areas to the open status.

*[Direct plating procedure by Cook, D.W. et al 1999. Procedure for enumeration of *Vibrio parahaemolyticus* in shellfish meats. A collaborative study by shellfish producing states, FDA and the ISSC; gene probe methods, for total (tlh + colonies) V.p. (McCarthy, S.A. et al 1999. TRS. Appl. Microbial. 28:66-70.); and virulent (tdh+) V.p. (McCarthy, S.A. et al 1999. Abstracts of the 99th General Meeting of the American Society for Microbiology, p.512].

**Action By 1999
General Assembly**

Adopted recommendation of 1999 Task Force I

Action By 2000 VMC

Recommended continued oversight of the Interim Control Plan by the Vibrio Management Committee.

**Action By 2000
Task Force I**

Recommended adoption of 2000 Vibrio Management Committee recommendation.

**Action By 2000
General Assembly**

Adopted recommendation of 2000 Task Force I.

Action By USFDA

Concurred with Conference action.

**Action By 2001
Vibrio
Parahaemolyticus
Subcommittee**

The Committee recommended the following:

- Add a new section to the Model Ordinance as Chapter II @. 01 as follows:
The Authority shall assess annually *V. parahaemolyticus* illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all *V. parahaemolyticus* shellfish-associated illnesses reported within the state and from receiving states, the numbers of illnesses per event, actions taken by the Authority in response to the illnesses, and a summary description of the state's shellfish illness reporting procedures, from patient presentation through laboratory diagnosis of food vehicle and etiological agent, to final public health documentation and reporting of specific illnesses to CDC. The initial assessment should be made for the most recent three calendar years and completed by March 1, 2002.
- ❖ Recommended to Task Force I that this section become effective September 1, 2001.
- ❖ Recommended to Task Force I that the V.p. subcommittee be tasked with reviewing the 2002 state reports required under Chapter II@.01 to assess whether future changes to the V.p. interim guidance document and Satisfactory Compliance are needed.
- Recommended the following document be accepted as interim guidance to the states for V.p. illness control.

Interim Guidance for Control of *V. parahaemolyticus*

A. Contingency Plan.

- (1) If the waters of a state have been confirmed as an original source of oysters associated with two or more confirmed *V. parahaemolyticus* illnesses annually in the most recent three years (excluding years when growing areas were closed at least half of the period from June through September), or with an outbreak in the last three years, the Authority should develop and adopt a *V. parahaemolyticus* contingency plan.
- (2) The plan should define the administrative procedures and resources necessary to accomplish the following:
 - (a) Identify and define growing areas in the state affected by *V. parahaemolyticus* based on hydrographic and geological parameters and other considerations relevant to control of a naturally occurring pathogen;
 - (b) Conduct an oyster meat sampling and assay program in those areas which have been associated with a *V. parahaemolyticus* illness;
 - (c) Close affected oyster growing areas;
 - (d) Prevent harvesting of affected oysters;
 - (e) Provide for oyster recall if an oyster growing area is closed as a result of illness;
 - (f) Notify the shellfish industry and the local health jurisdictions in the state of the potential for illnesses due to *V. parahaemolyticus* prior to historical times of onset or at a minimum of once a year;
 - (g) Issue a health advisory to the public about the potential problem and advise the industry to educate wholesalers, retailers, and consumers about the potential problem, with recommendations that oysters not be consumed raw during periods historically affected by *V. parahaemolyticus*.
- (3) The plan may include agreements or memoranda of understanding between the Authority and individual oyster harvesters and processors to allow

harvesting of oysters from growing areas which have been placed in the closed status, as specified in C. for:

- (a) Post-harvest treatment by a process which has been demonstrated to reduce *V. parahaemolyticus* levels in oysters to non-detectable; or,
- (b) Shucking and labeling “for cooking only”; or,
- (c) Under specific circumstances, as approved by the Authority, where the oyster shellstock will be sold to a retailer or food establishment, food processor, or to a shucker-packer and labeled in accordance with (3)(b); or,
- (d) Under specific circumstances, as approved by the Authority, where the oyster shellstock will be cooked and controls exist to ensure cooking.

B. *Vibrio parahaemolyticus* Monitoring

- (1) In all areas where two or more confirmed *V. parahaemolyticus* illnesses have occurred annually in the most recent three years (excluding years when growing areas were closed at least half of the period from June through September), representative samples of oysters should be collected at least monthly during harvest periods historically associated with illnesses and otherwise as determined by the Authority. All samples will be analyzed using the direct plating procedures and gene probe methods or enrichment PCR procedures for total (*tlh*+ colonies) and pathogenic (*tdh*+ colonies) *V. parahaemolyticus* *
- (2) In all areas where a confirmed *V. parahaemolyticus* outbreak has occurred within the last three years, representative samples of oysters should be collected when environmental conditions are favorable for *V. parahaemolyticus* growth and/or periods historically associated with illness as determined by the Authority. Samples should be collected and analyzed weekly during the year of and the first year after an outbreak, and at least monthly during the second and third years after an outbreak. All samples will be analyzed using the direct plating procedures and gene probe methods or enrichment PCR procedures for total (*tlh*+ colonies) and pathogenic (*tdh*+ colonies) *V. parahaemolyticus*.
- (3) In order to determine the number of samples that would be appropriate for *V. parahaemolyticus* monitoring, the following factors should be considered:
 - a. The size of the growing area;
 - b. The amount of oyster shellstock typically harvested from the area;
 - c. The sensitivity of the methodology.
- (4) In the event that emerging technologies and research identify pathogenic strains other than or in addition to *tdh*+ strains, the Authority may adopt and FDA may approve other or additional monitoring and control methods for preventing *V. parahaemolyticus* illnesses.

C. Closed Status of Growing Area Based On Monitoring Results.

The growing area as defined in accordance with A. (2)(a) should be placed in the closed status for oyster harvest, except as allowed under A. (3), if a total of 5 or more pathogenic (*tdh*+) *V. parahaemolyticus* colony-forming units (CFU) per 0.1 gram, confirmed by at least one pathogenic (*tdh*+) *V. parahaemolyticus* CFU per 0.1 gram by replicate analysis, are found for any oyster sample from the harvest area. If any sample shows total (*tlh*+) *V. parahaemolyticus* counts above 5,000 CFU per gram, then additional samples (twice the number collected as determined by the Authority) should immediately be collected and analyzed for pathogenic *V. parahaemolyticus*. Should any of these additional samples show 5 or more pathogenic *V. parahaemolyticus* CFU per 0.1 gram, confirmed by at least one pathogenic *V. parahaemolyticus* by replicate analysis, the area will be placed in

- (1) The closed status for oyster harvest, except as allowed under A. (3).
- (2) The closed status should remain in effect until two consecutive representative samples of oyster meats, collected a minimum of four days apart, show fewer than 5 pathogenic (*tdh*+) *V. parahaemolyticus* CFU in

0.1 gram, or show no pathogenic *V. parahaemolyticus* by replicate analysis. If any sample shows total *V. parahaemolyticus* counts above 5,000 CFU per gram, then additional samples (twice the number collected as determined by the Authority) should immediately be collected and analyzed for pathogenic (*tdh*+) and total (*tlh*+) *V. parahaemolyticus*. Should those samples show fewer than 5 pathogenic (*tdh*+) *V. parahaemolyticus* CFU in 0.1 gram, or show no pathogenic *V. parahaemolyticus* by replicate analysis, the growing area should be opened.

- (3) The analysis leading to a decision to return a growing area to the open status should be adequately documented.

D. Illness Outbreak.

- (1) When a growing area is implicated in a *V. parahaemolyticus* illness outbreak, the Authority shall follow the procedures prescribed in Chapter II Section @.01A through E. If a growing area is closed due to an illness outbreak, the closed status should remain in effect until two consecutive representative samples of oyster meats, collected a minimum of four days apart, show no pathogenic (*tdh*+) *V. parahaemolyticus* CFU in replicate 0.1 gram portions of oyster meat and less than 5,000 total (*tlh*+) *V. parahaemolyticus* CFU per gram.
- (2) If additional confirmed *V. parahaemolyticus* illnesses occur within 2 weeks of re-opening, they should be considered a continuation of the illness outbreak. The growing area should immediately be placed in the closed status, and re-opening may only occur when environmental conditions shift to those unfavorable to the growth of *V. parahaemolyticus*, or the Authority, in conjunction with the state epidemiologist, develops and implements a sampling plan.

E. Records.

The Authority should maintain a copy of all of the following records:

- (1) All information, including monitoring data, relating to the levels of *V. parahaemolyticus* in the oyster growing areas;
 - (2) Copies of notices placing growing areas in the closed status;
 - (3) Evaluation reports; and,
 - (4) Copies of notices returning growing areas to the open status.
- Direct plating procedure by Cook, D.W. et al, 1999. Procedure for enumeration of *Vibrio parahaemolyticus* in shellfish meats. A collaborative study by shellfish producing states, FDA, and the ISSC; gene probe methods for total (*tlh*+ colonies) *V. parahaemolyticus* (McCarthy, S.A. et al, 1999. TRS. Appl. Microbiol.28:66-70) and virulent (*tdh*+ colonies) *V. parahaemolyticus* (McCarthy, S.A. et al, 1999. Abstracts of the 99th General Meeting of the American Society for Microbiology, p.512).
[References for the direct plating, digoxigenin DNA probe method and the enrichment PCR procedure adapted to the VpICP can be provided.]

Recommended to Task Force that advisors with expertise in infectious disease and/or clinical microbiology be added to the subcommittee for their future review of V.p. illness control practices.

**Action By 2001
Vibrio Management
Committee**

Recommended adoption of Vp Subcommittee recommendations as amended:

- Add a new section to the Model Ordinance as Chapter II @. 01 as follows:
The Authority shall assess annually *V. parahaemolyticus* illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all *V. parahaemolyticus* shellfish-associated illnesses reported within the state and from receiving states, the numbers of illnesses per event, actions taken by the Authority in response to the illnesses, and a summary description of the state's shellfish illness reporting procedures, from patient presentation through laboratory diagnosis of food vehicle and etiological agent, to final public health documentation and reporting of specific illnesses to CDC. The initial assessment should be made for the most recent three calendar years and completed by March 1, 2002.

- Recommended to Task Force I that the V.p. subcommittee be tasked with reviewing the 2002 state reports required under Chapter [II@.01](#) to assess whether future changes to the V.p. interim guidance document and Satisfactory Compliance are needed.
- Recommended the following document be accepted as interim guidance to the states for V.p. illness control.

Interim Guidance for Control of *V. parahaemolyticus*

B. Contingency Plan.

- (1) If the waters of a state have been confirmed as an original source of oysters associated with two or more confirmed *V. parahaemolyticus* illnesses annually in the most recent three years (excluding years when growing areas were closed at least half of the period from June through September), or with an outbreak in the last three years, the Authority should develop and adopt a *V. parahaemolyticus* contingency plan.
- (2) The plan should define the administrative procedures and resources necessary to accomplish the following:
 - (a) Identify and define growing areas in the state affected by *V. parahaemolyticus* based on hydrographic and geological parameters and other considerations relevant to control of a naturally occurring pathogen;
 - (b) Conduct an oyster meat sampling and assay program in those areas which have been associated with a *V. parahaemolyticus* illness;
 - (c) Close affected oyster growing areas;
 - (d) Prevent harvesting of affected oysters;
 - (e) Provide for oyster recall if an oyster growing area is closed as a result of illness;
 - (f) Notify the shellfish industry and the local health jurisdictions in the state of the potential for illnesses due to *V. parahaemolyticus* prior to historical times of onset or at a minimum of once a year;
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 - (a) Post-harvest treatment by a process which has been demonstrated to reduce *V. parahaemolyticus* levels in oysters to non-detectable; or,
 - (b) Shucking and labeling “for cooking only”; or,
 - (c) Under specific circumstances, as approved by the Authority, where the oyster shellstock will be sold to a retailer or food establishment, food processor, or to a shucker-packer and labeled in accordance with (3)(b); or,
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- (1) In all areas where two or more confirmed *V. parahaemolyticus* illnesses have occurred annually in the most recent three years (excluding years when growing areas were closed at least half of the period from June through September), representative samples of oysters should be collected at least monthly during harvest periods historically associated with illnesses and otherwise as determined by the Authority. All samples will be analyzed using the direct plating procedures and gene probe methods or enrichment PCR procedures for total (*tlh*+) colonies) and pathogenic (*tlh*+

colonies) *V. parahaemolyticus* *

- (2) In all areas where a confirmed *V. parahaemolyticus* outbreak has occurred within the last three years, representative samples of oysters should be collected when environmental conditions are favorable for *V. parahaemolyticus* growth and/or periods historically associated with illness as determined by the Authority. Samples should be collected and analyzed weekly during the year of and the first year after an outbreak, and at least monthly during the second and third years after an outbreak. All samples will be analyzed using the direct plating procedures and gene probe methods or enrichment PCR procedures for total (*tlh*+) colonies) and pathogenic (*tdh*+) colonies) *V. parahaemolyticus*. *
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 - (b) The amount of oyster shellstock typically harvested from the area;
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In the event that emerging technologies and research identify pathogenic strains other than or in addition to *tdh*+, the Authority may adopt

- (4) and FDA may approve other or additional monitoring and control methods for preventing *V. parahaemolyticus* illnesses.

C. Closed Status of Growing Area Based On Monitoring Results.

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- **Recommended to Task Force that Recommendation 1 (Satisfactory Compliance item) and Recommendation 3 (Interim Guidance for Control of *V. parahaemolyticus*) become effective September 1, 2001.**

Recommended to Task Force that advisors with expertise in infectious disease and/or clinical microbiology be added to the subcommittee for their future review of V.p. illness control practices.

**Action By 2001
Task Force I**

Recommended adoption of Vp Subcommittee recommendations as amended.

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- (2) The closed status should remain in effect until two consecutive representative samples of oyster meats, collected a minimum of four days apart, show fewer than 5 pathogenic (*tdh*+) *V. parahaemolyticus* CFU in 0.1 gram, or show no pathogenic *V. parahaemolyticus* by replicate analysis. If any sample shows total *V. parahaemolyticus* counts above 5,000 CFU per gram, then additional samples (twice the number collected as determined by the Authority) should immediately be collected and analyzed for pathogenic (*tdh*+) and total (*tlh*+) *V. parahaemolyticus*. Should those samples show fewer than 5 pathogenic (*tdh*+) *V. parahaemolyticus* CFU in 0.1 gram, or show no pathogenic *V. parahaemolyticus* by replicate analysis, the growing area should be opened.
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[References for the direct plating, digoxigenin DNA probe method and the enrichment PCR procedure adapted to the VpICP can be provided.]

- Recommended to Task Force that Recommendation 1 (Satisfactory Compliance item) and Recommendation 3 (Interim Guidance for Control of *V. parahaemolyticus*) become effective September 1, 2001.
- Recommended to Task Force that advisors with expertise in infectious disease and/or clinical microbiology be added to the subcommittee for their future review of V.p. illness control practices.
- **Recommended that Task Force request that ISSC and FDA fund studies to develop more effective methods for determining V.p. pathogenicity, including contributing factors which trigger response in the tdh+ gene to become infectious and to study and refine the current methods which have shown to be unreliable in some states.**

The Task Force further recommended clarification of the term replicate as acted upon by the Laboratory Methods Review Committee and as voted upon by General Assembly at the 2000 Annual Meeting.

**** A replicate is defined as 2 filters for tdh analysis from the same homogenate at the same dilution.**

**Action By 2001
General Assembly**

Adopted recommendation of 2001 Task Force I.

Action by USFDA

Concurred with Conference action.

The 1999 ISSC, with concurrence from FDA, adopted a revised *Vibrio parahaemolyticus* Interim Control Plan (ICP) for recommended use by states whose oysters had been associated with two or more *Vibrio parahaemolyticus* illnesses within the past three years. The 1999 Conference further recommended that the ICP be submitted as an issue to the 2001 ISSC and that assistance be provided to states to enable them to develop the necessary analytical capability as described in the ICP for determining total (tlh+) and virulent (tdh+) *Vibrio parahaemolyticus* colonies. During the period between the 1999 and 2001 ISSC, FDA worked with affected states to provide laboratory support and training and assisted the ISSC in producing a laboratory training video. This interim period also provided the needed time for states to administer the ICP, with oversight from the *Vibrio* Management Committee, and gather additional data to assist the 2001 *Vibrio parahaemolyticus* Subcommittee during its deliberation of the *Vibrio parahaemolyticus* ICP issue.

FDA commends the Conference for its deliberative efforts during the period from 1999 to 2001 and during the 2001 ISSC meeting to examine and modify the ICP based on states' experience with the 1999 ICP. FDA concurs with 2001 ISSC action to establish the *Vibrio parahaemolyticus* contingency plan as "Interim Guidance for the Control of *V. parahaemolyticus*" and incorporate language into the NSSP Model Ordinance requiring the annual assessment of *Vibrio parahaemolyticus* illnesses. We believe changes made to the ICP by the 2001 Conference, including: better definition of when states should implement a management plan; establishment of sampling protocols based on recent illnesses, environmental conditions, and periods historically associated with illnesses; closure of growing areas based on the absence or presence of multiple tdh+ colonies; and reopening closed areas based on the absence or presence of multiple tdh+ colonies, are critical to final adoption of the "Interim Guidance" as NSSP Model Ordinance language. FDA recognizes that additional changes to the "Interim Guidance" and Satisfactory Compliance language of the NSSP Model Ordinance may be justified based on assessment of 2002 *Vibrio parahaemolyticus* state reports required under Chapter II of the Model Ordinance. As with *Vibrio vulnificus*, we look ahead favorably to our continued commitment to work closely with the ISSC to adopt Model Ordinance language which improves shellfish safety by reducing the prevalence of pathogenic *Vibrio parahaemolyticus*. In this regard, we plan continued support through active participation on the *Vibrio* Management Committee and *Vibrio parahaemolyticus* Subcommittee.

Action by 2003

1. Retain the current interim guidance for two more years and charge the V.p.

Vp Subcommittee	<p>subcommittee to identify and evaluate alternative control strategies, with a goal of making a recommendation at the 2005 ISSC biennial meeting. The FDA's V.p. risk assessment report with its models will be one important tool in this evaluation of methods to reduce the risk of illness from sporadic cases.</p> <ol style="list-style-type: none"> 2. Request FDA to continue to analyze the costs and benefits associated with different illness control strategies, in addition to those contained in the 2000 Research Triangle Institute study. ISSC assistance in those analyses is important. 3. Recommend the addition of additional Gulf and East Coast state and industry personnel to the subcommittee to better balance the representation. This is very important as any new control measures recommended and approved would affect states and industry nationwide. 4. Recommend the subcommittee meet at upcoming scheduled ISSC Executive Board times and places and continue to act on these recommendations via phone calls and e-mail as needed prior to the 2005 meeting. Further recommend that FDA and ISSC help support travel and expenses of state and industry to such meetings. 5. Clarifications are recommended to the instructions for the data collection form to help ensure that all states report in a complete and standard manner. The changes will be made, reviewed, and finalized prior to the March 2004 Executive Board meeting. Further, Paul Comar will work with the Specialists and ISSC Office to complete the 2002 table and send to the subcommittee by September 15, 2003. Also, it was recommended to add harvest location and date to the Vp In-State Report column. This may be useful in investigations to link environmental measures with the reported illness. 6. Require states to submit their V.p. annual illness data in the approved format to their FDA specialist by March 1 of the following year (2003 data will be reported by March 1, 2004). Cases confirmed after March 1 will be submitted to the FDA specialist as completed. FDA specialists will verify that all data is received by March 1 and notify and rapidly follow-up with any state not providing the information. FDA specialists will provide the illness data for all states in their Region to the ISSC Office no later than May 1. Further, FDA will submit supplemental data of cases confirmed by the states later than May 1 to the ISSC Office as it is submitted to them by states. ISSC will compile and finalize the report no later than July 1 for review by the subcommittee.
Action By 2003 VMC	Recommended adoption of Vp Subcommittee recommendations on Proposal 98-107.
Action By 2003 Task Force I	Recommended adoption of the Vibrio Management Committee recommendations on Proposal 98-107.
Action By 2003 General Assembly	Adopted recommendations of 2003 Task Force I.
Action By USFDA	Concurred with Conference action.
Action by 2005 Vibrio Management Committee	Recommended retaining the current <i>Vibrio parahaemolyticus</i> Interim Control Plan Interim Guidance until the 2007 ISSC Biennial Meeting. States should continue to evaluate controls and monitoring that are effective in minimizing the occurrence of illnesses under various regional and seasonal harvesting and handling practices.
Action by 2005 Task Force I	Recommended adoption of the Vibrio Management Committee recommendations on Proposal 98-107.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force I.
Action by USFDA	FDA concurs with action to retain the <i>Vibrio parahaemolyticus</i> (Vp) Interim Control Plan without change until the 2007 ISSC Biennial Meeting. FDA's concurrence is based on action by the Conference to adopt the VMC recommendation for the Vp Subcommittee to identify and evaluate control strategies that could be implemented on a regional basis to reduce the

risk of *Vp* illnesses from both sporadic cases and outbreaks. Under “Charge 2” of its August 2005 report the VMC identified seven steps to encompass this approach. FDA regards this seven step approach to be a critical component of the ISSC’s goal to develop regional controls to reduce *Vp* illnesses nationally. In particular, measures described in Step ii and iii need immediate consideration to ensure that regional meetings are scheduled in a timely manner and that a complete and consolidated report is available to ISSC members for the 2007 biennial meeting as stipulated in Step vii. Nonetheless, FDA is disappointed that the ISSC did not take more aggressive action to address the significant public health concern of *Vp* illness, as FDA proposed in 05-214, and looks for such action at the 2007 meeting.