INTERSTATE SHELLFISH SANITATION CONFERENCE
2001 BIEANNUAL MEETING
Norfolk, VA
JULY 21-27, 2001

The Interstate Shellfish Sanitation Conference deliberated the issues presented to Task Force I and took the following actions. Note: Bold and underline denotes text to be added; ~~strikeout denotes text to be deleted~~.

ISSUE NUMBER: 96-113

SPECIFIC REFERENCE: NSSP Guide, IV. Guidance Documents A.10., page 237.

TEXT OF ISSUE:

REQUESTED ACTION: 1997 Modify NSSP Guide, IV. Guidance Documents A.10., p. 237:

1. APHA-American Public Health Assn. Recommended Procedures for the Examination of Seawater and Shellfish, 4th edition, 1970.

    * Total Coliform Most Probable Number (MPN) Test; Fecal Coliform MPN Test; Standard Plate Count per Gram; **Membrane Filter Methods for Seawater** ~~28-47~~ **28-67**

    * Bioassay for Paralytic Shellfish ...

    * Neurotoxic Shellfish Poison ...

PUBLIC HEALTH SIGNIFICANCE: Significant documentation exists to demonstrate that the Membrane Filter Method provides enumeration of total and fecal coliform organisms equal to or more accurate than the MPN. [1-6] Therefore, use of the membrane filter test affords the same public health protection as the MPN. In some circumstances, the membrane filter test can be more economical. The NSSP Manual Part I should be changed to recognize the use of this method.

References:

1. American Public Health Association. 1992. Standard methods for the examination of water and wastewater, 18th edition. American Public Health Association, Washington, DC.

2. Test methods for E. coli and enterococci in water by membrane filter procedure. EPA publication EPA-800/4-85/076

3. Evans, T.M., M.W. LeChavallier, C.E. Waarvick, and R.J. Seidler, 1981. Coliform species recovered from untested surface water and drinking water by the membrane filter standard and modified most probable number techniques. Appl. Environ. Microbiol. 41-657-663.

4. Jacobs, N.J., W.L. Zeigler, F.C. Reed, T.A. Stukel, and E.W. Rice, 1986. Comparison of membrane filter, multiple-fermentation tube, and presence-absence techniques for detecting total coliforms in small community water systems. Appl. Environ. Microbiol. 51:1007-1012.

5. Morgan, G.B., P. Gubbins, and V. Morgan, 1965. A critical appraisal of the membrane filter technique. Health Lab Sci. 2:227-237.

6. Shipe, E.L. and G.M. Cameron, 1954. A comparison of the membrane filter with the most probable number method for coliform determinations from several waters. Appl. Microbiol. 2:85-88.

ACTION BY 1996 TASK FORCE I: Recommended referral of Issue 96-113 to appropriate committee as determined by the Conference Chairman with the following instructions: Request that EPA, NOAA, and FDA undertake an appropriate literature review and evaluation of the comparability of the MPN and Membrane Filtration methods for total and fecal coliform and report their findings to an ISSC Committee for review. The committee would then work collectively with the 3 agencies to develop recommendations for presentation at the 1997 annual meeting.

ACTION BY 1996 GENERAL ASSEMBLY: Adopted recommendation of 1996 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 1997 MICROBIOLOGICAL COMMITTEE: Recommended referral of Issue 96-113 to appropriate committee as determined by the Conference Chairman with the following instructions: The Executive Director shall request that FDA, EPA, and NMFS conduct a literature review and report their findings to the ISSC by March 1, 1998, and the ISSC shall share the information with the Microbiological Committee as soon as possible so that discussions can take place prior to the 1998 annual meeting.

ACTION BY 1997 TASK FORCE I: Recommended adoption of 1997 Microbiological Committee recommendations on Issue 96-113.

ACTION BY 1997 GENERAL ASSEMBLY: Adopted recommendation of 1997 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 1998 MICROBIOLOGICAL COMMITTEE: Recommended No Action on Issue 96-113. Rationale: This committee cannot make decisions on issues such as this one until the Laboratory Standards Committee has set forth the procedure(s) in which new laboratory methods are adopted into the NSSP. Solutions to this issue and others like it are also being addressed in Issue 97-302.

ACTION BY 1998 TASK FORCE I: Recommended adoption of 1998 Microbiological Committee recommendation.

ACTION BY 1998 GENERAL ASSEMBLY: Adopted recommendation of 1998 Task Force I.

ACTION BY USFDA: Offered the following comments on Issue 96-113:

FDA does not concur with action by the Conference to take "No Action". Issue 96-113 should remain before an appropriate committee of the Conference for future consideration following ISSC development and adoption of criteria for incorporating new laboratory methods into the NSSP.

FDA agrees that the ISSC needs to develop and adopt criteria for incorporating new and alternative laboratory methodologies into the NSSP. Furthermore, FDA supports action by the ISSC to have the Laboratory Methods Committee continue its efforts, under Issue 97-302, to develop such criteria. Once appropriate criteria for incorporating new laboratory methods into the NSSP are adopted, use of the membrane filter method as an acceptable alternative to the MPN test for enumerating coliform bacteria should be reconsidered.

ACTION BY ISSC EXECUTIVE BOARD: Determined that Issue 96-113 will be referred to the Microbiological Committee following final Conference action on Issue 97-302.

ACTION BY 1999 TASK FORCE I: Recommended referral of Issue 96-113 to appropriate committee as determined by the Conference Chairman.

ACTION BY 1999 GENERAL ASSEMBLY: Adopted recommendation of 1999 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 2000 MICROBIOLOGY COMMITTEE:

FINDINGS: The chair distributed a summary report describing the history of this issue. Also distributed were copies of a literature review and recommendations prepared by FDA-EPA-NMFS concerning issue 96-113. The committee reviewed this report and the summary information. Potential deficiencies, advantages and recommendations identified in the FDA-EPA-NMFS report were discussed and included: (1) need to review comparative MPN/membrane filter counts at low levels where critical program decisions are made, (2) need to establish values equivalent to the 90^{th} percentile used with the MPN-based method, (3) need determine the effects of particulates on membrane filter counts, and (4) that consideration be given to rewording issue 96-113 to include an EPA approved membrane filter method (mTEC) because APHA approved membrane filter methods appear inferior. The committee agreed that Table A.10 could not be changed until a formal evaluation of any membrane filter method was undertaken and results presented.

Committee members agreed that the items mentioned in the FDA-EPA-NMFS report require evaluation and that membrane filter methods could potentially reduce the burden of laboratory evaluations and costs. The committee also discussed the recommendation to amend 96-113 to include the mTEC method.

CONCLUSIONS: The committee concluded that the mTEC method was worthy of being considered for incorporation in the NSSP. Accordingly, the committee agreed the method should be reviewed by the Laboratory Methods Review Committee. Furthermore, issue 96-113 should be amended to reference the EPA mTEC method (Improved Enumeration Methods for the Recreational Water Quality Indicators: Enterococci and *Escherichia coli*. USEPA Office of Science and Technology, EPA/821/R-97/004) and reference to the APHA membrane methods deleted.

RECOMMENDATIONS: The committee unanimously recommended (1) not including the reference to membrane filter methods referenced in the APHA (1970) Recommended Procedures for the Examination of Seawater and Shellfish into NSSP Guidance Document A.10., and instead requested a formal evaluation of mTEC as referenced above, and (2) that issue 96-113 be referred to the Laboratory Methods Review Committee for immediate action.

ACTION BY 2000 TASK FORCE I: Recommended adoption of 2000 Microbiology Committee recommendations.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendations of 2000 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 2001 LABORATORY METHODS REVIEW COMMITTEE:

The committee recommended the following:

1. Approve the Laboratory Methods Review Committee's action that accepts the mTEC procedure as an alternative fecal coliform method and establishes materials and a work period for the committee's final review and approval.
2. Support the committee's request for material support from the Executive Office of the ISSC to expand the database from other regions.

ACTION BY 2001 TASK FORCE I: Recommended referral of issue 96-113 to appropriate committee as determined by the Conference Chairman with the recommendations of Laboratory Methods Review Committee as amended:

1. Approve the Laboratory Methods Review Committee's action that accepts the mTEC ~~procedure as an alternative~~ for fecal coliforms ~~method~~ and establishes materials and a work period for the committee's final review and approval.
2. Support the committee's request for material support from the Executive Office of the ISSC to expand the database from other regions.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

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ISSUE NUMBER: 98-107

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter VIII. @. 01.

TEXT OF ISSUE:

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*:

(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 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: Unknown

Proposed
Vibrio parahaemolyticus Prevention Strategies
May 8, 1998

	TRIGGERS	SAMPLING	REGULATORY	EDUCATION
TIER #1	Growing areas/regions historically affected by *V. parahaemolyticus*	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 Issue 98-107 with the following amendments:
~~Modify Model Ordinance Chapter VIII.@.01, by adding new subsection G.:~~

<u>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 an issue to be deliberated at the 2001 Conference.</u>

~~G.~~ **<u>C.</u>** 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 exists, 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 Issue 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 which were adopted in the Interim Control Plan. Many of our concerns were expressed at the Conference during the discussions on this issue 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 which 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 issue 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.

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 will 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 Issue 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 a**n 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 VIBRIO MANAGEMENT COMMITTEE: 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.

(1) 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 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, digoxygenin 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;
      (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.

(1) 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 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.

(a) 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.

(b) 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, digoxygenin 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.

ACTION BY 2001 TASK FORCE I:
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

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.

(1) 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 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, digoxygenin 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. Provided comments. See Attachment at end of Task Force I.

***

ISSUE NUMBER: 00-104

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter V.@.02B.

TEXT OF ISSUE:

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter V.@.02B.:

V.@.02 Contaminant Reduction.
B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. **When the time period for the treatment process exceeds 60 days, an effectiveness study is not required.** The Authority shall ...

PUBLIC HEALTH SIGNIFICANCE: Sixty days is an adequate time period for relayed shellfish to become bacteriologically indistinguishable from native shellfish already in the relay area. Since relay harvest occurs from "moderately", rather than from "grossly" polluted areas, and the Model Ordinance allows relay periods of less than 14 days, a 60-day time period provides an adequate margin of safety.

References:
Becker, Robert E. A Basket Relaying Study Off the Coast of Alabama: Reduction of Coliform Bacteria as a Function of Time and Basket Loading. In the Proceedings of the 10th National Shellfish Sanitation Workshop. pp. 174-181; 1977.

Cook, D.W. and R.D. Ellender. Relaying to Decrease the Concentration of Oyster Related Pathogens. Journal of Food Protection. Vol. 49, No. 3, pp.196-202; 1986.

Son, N.T. and G. H. Fleet. Behavior of Pathogenic Bacteria in the Oyster, *Crassostrea commercialis*, During Depuration, Relaying, and Storage. Applied and Environmental Microbiology. Vol. 40, pp. 994-1002; 1980.

COST INFORMATION: Requiring effectiveness studies for every relay with treatment periods of less than 6 months puts an excessive burden on state programs. Significant laboratory and staff resources could be saved for more critical shellfish sanitation issues if validation studies are required only for relays of 60 days and less.

ACTION BY 2000 TASK FORCE I: Recommended Issue 00-104 be referred to the 2001 ISSC Annual Meeting. Rationale: Issue 00-104 did not meet the criteria outlined for the issues which were to be deliberated at the 2000 ISSC Special Meeting.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force I.

ACTION BY 2001 TASK FORCE I: Recommended adoption of Issue 00-104 as amended:

V.@.02 Contaminant Reduction.

B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The Authority shall...
C. The authority may waive the requirements for a contaminant reduction study if:
   (1) Only microbial contaminants need to be reduced; and
   (2) The shellstock are relayed from a conditionally approved, restricted, or conditionally restricted area meeting the bacteriological water quality for restricted areas used for shellstock depuration per IV@.02.G and IV@.02H; and
   (3) The treatment period exceed 60 days.
D. ~~(C)~~ The time period shall be…
E. ~~(D)~~ When contain relaying …

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action. Comments provided. See Attachment at end of Task Force I.

***

ISSUE NUMBER: 01-101

SPECIFIC REFERENCE: 1997 Guidance documents, A.12 Laboratory Checklist, Preparation of Shellstock, Item No.1.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Item 1: Shucking knives, scrub brushes and blender jars are (autoclave) sterilized for ~~30~~ 15 minutes prior to use.

RATIONALE: All reference materials such as *Standard Methods for the Examination of Water and Wastewater*, and the *AOAC Official Methods of Analysis*, describe the sterilization of empty containers and other items either in a hot air oven or in an autoclave for 15 minutes. It is not known form where this time

period of 30 minutes came. This change is requested to make the procedure consistent with the scientific reference literature.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE I: Recommended adoption of Issue 01-101 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

***

ISSUE NUMBER: 01-102

SPECIFIC REFERENCE: 1997 Guidance documents, A.12 Laboratory Checklist –7 Storage…Item No.4

TEXT OF ISSUE:

REQUESTED ACTION: Modify Item 7: All prepared media stored under refrigeration are held at room temperature ~~incubated at 35°C~~ overnight ~~and allowed to cool to room temperature prior to use~~. Culture tubes containing any type of precipitate or Durham tubes containing air bubbles are discarded.

RATIONALE: The reference used for this item – *Recommended Procedures for the Examination of Sea Water and Shellfish*, 1970, states refrigerated media are to be incubated overnight prior to use. The incubation temperature was not stated. It was thought by the Microbiology Checklist Committee at the checklist's development that the media had to be incubated at 35°C as a means of expelling dissolved air. It does not necessarily work with all media. Brilliant Green Bile Broth is one example. The committee also thought it would help dissolve precipitates, which may have formed in some media as a result of refrigeration. This also does not necessarily work with all media. All other references such as the *EPA's Handbook for Evaluating Water Bacteriological Laboratories*, 1975, state such media are to be incubated or held at room temperature overnight. To be consistent with the scientific literature, it is necessary to make the change. This change will not diminish the program.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE I: Recommended adoption of Issue 01-102 as amended.

All prepared media stored under refrigeration are held at room temperature overnight prior to use. Culture tubes containing any type of precipitate or Durham tubes containing air bubbles are discarded.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

***

ISSUE NUMBER: 01-103

SPECIFIC REFERENCE: 1997 Guidance documents, A.12 Laboratory Checklist, 6 Media Preparation, Item No.12.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Item 12: Media sterility and positive and negative controls are run with each lot of commercially prepared media or are run with each batch of media prepared from its components as a check of media productivity. ~~batch (LST, BGB, EC, A1) Positive and negative control cultures are used as a productivity test~~. Results recorded and records maintained.

RATIONALE: Batch and lot have to be distinguished so that unnecessary testing will not be done in the laboratory. Commercially prepared media has to be subjected to productivity testing only when the lot number changes. With this type of media, only laboratory pure water is added to the premixed *powder* prior to sterilization. After initial lot productivity testing, commercially prepared media should be considered acceptable as long as the pH of each batch falls within the range of prescribed values. Productivity testing after the initial preparation is not necessary, as the components of commercially prepared media do not change. However, productivity testing is required every time a medium is made from individual components. Such a procedure is open to technician error along many steps of the preparation. Such an approach is described in the scientific literature such as *Compendium of Methods for the Microbiological Examination of Foods.* This change better defines the intent of the checklist item and enhance the program.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE I: Recommended adoption of Issue 01-103 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

****

ISSUE NUMBER: 01-104

SPECIFIC REFERENCE: 1997 Guidance documents, A.12 Laboratory Checklist, 5 Sterilization and Decontamination, Item No.19.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Item 19: The sterility of reusable/disposable pipets is determined with each batch / lot ~~at least weekly~~. Results are recorded and maintained.

RATIONALE: When the Microbiology-Checklist was created, disposable pipet~~te~~s were not used at all, except perhaps in a relatively few laboratories. More laboratories are using them in their routine analyses. It is necessary to address the usage of these disposable pipets in the checklist. The sterility of pipet~~te~~s is crucial to the integrity of the bacteriological results obtained. High volume laboratories may process many batches of reusable pipets weekly or some low volume laboratories may only process reusable pipet~~te~~s monthly. Weekly sterility confirmation may not be appropriate. Each batch of reusable pipet~~te~~s and each lot of disposable pipets should be tested for the assurance of sterility. To address these conditions, it is requested that the wording of this item be adjusted to account for the use of disposable pipet~~te~~s and for the frequency of sterility testing. This change will enhance the quality of the program.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE I: Recommended adoption of Issue 01-104 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

***

ISSUE NUMBER: 01-105

SPECIFIC REFERENCE: 1997 Guidance documents, A.12 Laboratory Checklist, 5 Sterilization and Decontamination, Item No.18.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Item 18: Reusable pipets (in canisters) are sterilized in a hot air oven at 170°C for 2 hours ~~or autoclaved for 30 minutes at 121°C and allowed to dry of at least one hour.~~

RATIONALE: All reference materials such as Standard Methods for the Examination of Water and Wastewater, and the AOAC Official Methods of Analysis, describe the sterilization of reusable pipets in only a hot air oven. There is no mention of using an autoclave. The practice of using an autoclave for sterilizing reusable pipets is not described in the scientific literature. It is not known from where this statement came. With the advent of disposable pipets, such a practice is not needed in laboratories without hot air ovens. This change is requested to be consistent with the stated references.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE I: Recommended adoption of Issue 01-105 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

***

ISSUE NUMBER: 01-106

SPECIFIC REFERENCE: 1997 Guidance documents, A.12 Laboratory Checklist, 5 Sterilization and Decontamination, Item No. 16.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Item 16: The sterility of reusable sample containers is determined for each batch/lot.~~monthly~~.

RATIONALE: When the checklist was created, disposable collection containers were not used in the program. With the availability of inexpensive, disposable sterile collection bags and plastic containers, some laboratories have switched to them. Studies indicate it is cheaper to use certain disposables as compared to the washing and sterilizing of reusable items. The checklist needs to address the use of disposable sampling containers. The sterility of the sampling containers is crucial to the integrity of the bacteriological results obtained. Some high volume laboratories may have many batches of reusable containers processed in one month. The checklist item is worded so that only one batch needs to be tested in the month. Each batch of reusable containers and each lot of disposable containers should be tested for the assurance of sterility. To address these conditions, it is requested that the wording of this item be adjusted to account for the use of disposable sampling containers and for the frequency of sterility testing. This change will enhance the quality of the program.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE I: Recommended adoption of Issue 01-106 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

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ISSUE NUMBER: 01-107:

SPECIFIC REFERENCE: 1997 Guidance documents, A.12 Laboratory Checklist, 5 Sterilization and Decontamination, Item No. 15.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Item 15: Reusable sample containers are sterilized for 60 minutes at 170°C in hot air oven or autoclaved for 15~~30~~ minutes at 121°C.

RATIONALE: All reference materials such as *Standard Methods for the Examination of Water and Wastewater,* and the AOAC *Official Methods of Analysis,* describes the sterilization of empty containers either in a hot air oven as described in the item or sterilization in an autoclave for 15 minutes. It is not known from where this time period of 30 minutes came. This change is requested to make the procedure consistent with the scientific reference literature.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE I: Recommended adoption of Issue 01-107 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

***

ISSUE NUMBER: 01-108

TEXT OF ISSUE:

REQUESTED ACTION: Modify Item No. 8: Spore suspensions are used ~~quarterly~~ monthly to evaluate the effectiveness of the autoclave sterilization process. Results are recorded.

RATIONALE: All reference materials such as *Standard Methods for the Examination of Water and Wastewater,* and the AOAC *Official Methods of Analysis,* describes the necessity for a monthly check of the effectiveness of the autoclave. It is not known from where this time period of quarterly came. To be consistent with the references, it is required the change be made. It is appreciated that additional work is required. However, this procedure only enhances our program. As with every other requested change being made, the program becomes more in conformity with other national and international programs.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE I: Recommended adoption of Issue 01-108 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

***

ISSUE NUMBER: 01-109

SPECIFIC REFERENCE: 1997 Guidance documents, A.12 Laboratory Checklist, 4 Sterilization and Decontamination , Item No.4.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Item No. 4. Autoclave(s) provides a sterilizing temperature of 121^{o} C(tolerance of 121$\pm$2^{o} C) as determined ~~monthly~~ weekly using a calibrated working maximum registering thermometer or equivalent (thermocouples, platinum resistance thermometers).

RATIONALE: All reference materials such as *Standard Methods for the Examination of Water and Wastewater*, and the AOAC *Official Methods of Analysis*, describes the necessity for a weekly check of the autoclave with the calibrated maximum registering thermometer or equivalent. It is knot known from where this time period of one month came. To be consistent with the references, it is required the change be made. This change does not require any additional work except the inclusion of the thermometer into an autoclave run and the simple recording of the information onto the appropriate record form. This change will enhance the program.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE: Recommended adoption of Issue 01-109 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

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ISSUE NUMBER: 01-110

SPECIFIC REFERENCE: 1997 Guidance documents, A.12 Laboratory Checklist, 4 Labware Item No. 8.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Item No. 8: In washing reusable pipets, a succession of at least three fresh water rinses ~~with~~ plus a final rinse of distilled/deionized water is used to thoroughly rinse off all the detergents.

RATIONALE: All reference materials such as *Standard Methods for the Examination of Water and Wastewater*, and the AOAC *Official Methods of Analysis*, describe a total of four rinses with the last being the distilled/deionized water rinse for complete detergent removable. The wording of the item was intended to mean that; however, the wording has created confusion for some individuals. This change clarifies the intent of the checklist.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE: Recommended adoption of Issue 01-110 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

***

ISSUE NUMBER: 01-111

SPECIFIC REFERENCE: 1997 Guidance documents, A.12 Laboratory Checklist-- 3 Equipment Item No. 8.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Item No. 8: Balance calibrated ~~quarterly~~ monthly using NIST Class S or ASTM Class 1 or 2 weights or equivalent and records are maintained.

RATIONALE: It is not known from where this time period of quarterly was obtained when the microbiology checklist was developed. All reference materials (*Standard Methods for the Examination of Waster and Wastewater,* the *AOAC Official Methods of Analysis* are two*)* during the Checklist development time to current time require a monthly calibration check to determine the balance is operating properly. The Biotoxin Checklist requires a monthly calibration check. For the sake of consistency with both historical references and the Biotoxin Checklist, it is required the change be implemented. The change enhances and does not diminish the program.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE I: Recommended adoption of Issue 01-112 as amended.

Balance ~~*calibrated*~~ *checked* ~~quarterly~~ monthly using NIST Class S or ASTM Class 1 or 2 weights or equivalent and records are maintained.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

***

ISSUE NUMBER: 01-112

SPECIFIC REFERENCE: 1997 Guidance documents, A.12 Laboratory Checklist-- 3 Equipment Item No. 6.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Item No. 6: Electrode ~~accuracy~~ effectiveness is determined daily or with each use. Method of determination_____.

RATIONALE: The effectiveness of the operation of the electrode rather than electrode accuracy is what is actually being sought with this checklist item. Apparently the two concepts were confused at the time the checklist was being developed, resulting in the current inappropriate wording. Accuracy would be defined as repeated measurements of a known pH solution to see what results the electrode generated. Electrode effectiveness deal with the ability of the electrode to measure milivolts of known buffer solutions, and after

mathematical calculations, result in a slope of between 92 and 102%, depending upon the electrode manufacturer's parameters. This slope reflects how well the electrode is operating. Results outside the slope range means the electrode is not operating correctly. The effectiveness of electrodes diminishes with use and age. It is most important to determine the slope (effectiveness) with every use or on a daily basis. This change more clearly defines what the checklist item intended and will avoid confusion within the program.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE: Recommended adoption of Issue 01-112 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

***

ISSUE NUMBER: 01-113

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter IV @.03A(5) and IV @.02F(6)(b)(iv).

TEXT OF ISSUE:

REQUESTED ACTION: Modify IV @.03A(5) and IV @.02F(6)(b)(iv):

Chapter IV@.03A.(5) Status of Growing Areas. The status of a growing area is separate and distinct from its classification and may be ~~either~~ open**,** closed**,** or inactive for the harvesting of shellstock.

(a) Open Status……
(b) Closed Status…….
(c) Reopened Status…….
(d) Inactive Status. The authority may place an approved or restricted growing area affected by nonpoint sources in the inactive status for up to five years when shellstock harvest is suspended or no longer occurring. Shellstock harvesting shall be closed while an area is in the inactive status. The inactive status must continue for a minimum of one year.
    i. While in inactive status, the required bacteriological sample collection under @.02F(6)(b)(iii) may be reduced to two water samples per station per year collected under the systematic random sample collection strategy. Sanitary survey reports, triennial reevaluations, and annual updates must be completed as required under @.01C.
    ii. The sample collection frequency of six random samples per station per year specified under @.02F(6)(b)(iii) must resume at least six months before an area is reactivated.
    iii. Before an area is reactivated, the results of the most recent 30 samples must be reviewed and comply with the requirements under @.02F.
(e) ~~(d)~~ Remote status……

@.02F(6) Required Sample Collection.

(a) Adverse Pollution Condition Standard
(b) Systematic Random Sampling Standard
    i. Sample station locations……
    ii. Sample collection……
    iii. A minimum of six random samples……
    iv. A minimum of two random samples shall be collected annually from each sample station in the growing area while in the inactive status. The sample collection frequency of six random samples per station per year specified

under @.02F(6)(b)(iii) must resume at least six months before an area is reactivated.

v. ~~(iv)~~ A minimum of 30 most recent ……

PUBLIC HEALTH SIGNIFICANCE: The authority is required to collect a minimum of 6 samples per year per SRS in order to maintain a growing area's classification. If the minimum number of samples per year is not met, the area becomes unclassified (prohibited) and an entire new sampling set of 30 samples must be collected again before the area can be classified. In many classified areas, no harvests are taking place and there are no plans for future harvest. This change will allow states to maintain classifications of inactive areas with a reduced effort and allow field and laboratory resources to be applied to areas that are actively being harvested.

COST INFORMATION: This could reduce the numbers of samples collected in Washington State by more than 500 each year. This would amount to a potential savings of $25,000 or more in field collection and laboratory analyses.

ACTION BY 2001 TASK FORCE: Recommended adoption of Issue 01-113 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action. Provided comments. See Attachment at end of Task Force I.

***

ISSUE NUMBER: 01-114

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter VIII.@.01B.(6) - Patrol of Growing Areas.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter VIII@.O1B:

(6) Patrol officers need not be peace officers as defined by the laws of the State of the Authority, and may include specialists, public officers, and other technical personnel with specialized training on the laws and regulations for shellfish harvesting activities. However, peace officers must be available for enforcement actions to be taken when illegal harvesting activities are found. All patrol ~~O~~officers responsible for the patrol of shellfish growing areas shall obtain the following training:

(a) Basic law enforcement training or training in procedures for notification to law enforcement personnel, before assuming their patrol duties;
(b) Training on shellfish control regulations within the jurisdiction of the patrol agency, before assuming independent patrol duties;
(c) In-service training on the shellfish control regulations within the jurisdiction of the patrol agency, when the regulations change.

PUBLIC HEALTH SIGNIFICANCE: The National Shellfish Sanitation Program was designed to prevent human illness associated with the consumption of raw shellfish, primarily by ensuring that shellfish are harvested from areas free of excessive concentrations of pathogenic microorganisms and poisonous or deleterious substances. Contaminated shellfish can be vectors of disease and cause epidemiological outbreaks. Patrol of shellfish harvesting areas to prevent illegal harvesting is an important component of the NSSP. The Model Ordinance does not provide specific qualifications or a definition for a patrol officer. It had been assumed by some that a patrol officer also had to be a peace officer. However, this has not been the case for all shellfish sanitation programs.

Specialists, public officers, and other technical staff who are not peace officers are effectively used in many other environmental and public health law enforcement programs. In addition, the assumption that a patrol

officer must be a peace officer is contradictory to the concept of a community policing program, which is referred to in VIII.@.01B.(4)(e)(i).

This proposal to change the Model Ordinance language will make a distinction between the definition of patrol officer and peace officer, will provide for the use of personnel who are not peace officers for patrols activities, and will modify the training requirements for patrol officers to accommodate patrol officers who are not peace officers.

COST INFORMATION: Use of trained public officers who are not peace officers is a cost effective measure for providing the necessary protection of public health via routine patrol of shellfish growing areas. A requirement of peace officer status for routine patrol is not compatible with the administrative organization of many states and would impose an unrealistic burden on their shellfish programs to hire and train peace officers for this task, limiting the state's ability to manage existing growing areas and to license new growing areas.

ACTION BY 2001 TASK FORCE: Recommended referral of Issue 01-114 to appropriate committee as determined by the Conference Chairman with the following instructions: Instruct committee to evaluate issues related to proper authority and qualifications for patrol.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

****

ISSUE NUMBER: 01-115

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter VIII.@.01B.(3)(b) - Patrol of Growing Areas.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter VIII@01B:

[NOTE: TEXT OF ISSUE IS TEXT FROM ISSUE 00-102 THAT WAS ACCEPTED AT THE 2000 CONFERENCE IN ARIZONA] **[See 2000 Summary of Actions]**

(3) Exceptions.

(a) Patrol is not required under the following conditions:

(i) There is no shellfish productivity…

(ii) Harvest from the area is not economically feasible…

(iii) The area meets all of the following conditions…

~~(b) Where no natural sets resulting in commercially harvestable quantities of shellfish do not exist and advanced aquaculture methods (e.g. racks, bags, lantern nets, long lines and/or floats) are used in the area, the Authority shall develop and implement a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring, control and surveillance activities that supplement the minimum patrol frequency required of one (1) time per harvestable days.~~

(b) Where natural sets resulting in commercially harvestable quantities of shellfish do not exist and advanced aquaculture methods (e.g. racks, bags, lantern nets, long lines and/or floats) are used in the area:

(i) the Authority shall develop and implement a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring, control and surveillance activities that supplement the minimum patrol frequency required of one (1) time per 30 harvestable days, and

(ii) the Authority may choose to use shellfish program specialists, public officers, and other technical personnel with training in shellfish laws and regulations to perform patrol, monitoring, control, and surveillance activities in

aquaculture areas. The Risk Management Plan shall describe how the use of non-peace officer personnel will be limited to aquaculture areas and how peace officer personnel will be involved when illegal harvesting is discovered.

PUBLIC HEALTH SIGNIFICANCE: The National Shellfish Sanitation Program was designed to prevent human illness associated with the consumption of raw shellfish, primarily by ensuring that shellfish are harvested from areas free of excessive concentrations of pathogenic microorganisms and poisonous or deleterious substances. Contaminated shellfish can be vectors of disease and cause epidemiological outbreaks. Patrol of shellfish harvesting areas to prevent illegal harvesting is an important component of the NSSP. The Model Ordinance does not provide specific qualifications or a definition for a patrol officer. It had been assumed by some that a patrol officer also had to be a peace officer. However, this has not been the case for all shellfish sanitation programs.

Shellfish Program Specialists and inspectors are regulatory personnel and are therefore authorized to enforce sanitation rules of other segments of their state's shellfish program, including aquaculture operations. Specialists, public officers, and other technical staff who are not peace officers are effectively used in many other environmental and public health law enforcement programs. In addition, the assumption that a patrol officer must be a peace officer is contradictory to the concept of a community policing program, which is referred to in III.@.01B.(4)(e)(i).

This proposal to change the Model Ordinance language will make a distinction between the definition of patrol officer and peace officer and will provide for the use of personnel who are not peace officers for patrol activities.

COST INFORMATION: Use of trained public officers who are not peace officers is a cost effective measure for providing the necessary protection of public health via routine patrol of shellfish growing areas. A requirement of peace officer status for routine patrol is not compatible with the administrative organization of many states and would impose an unrealistic burden on their shellfish programs to hire and train peace officers for this task, limiting the state's ability to manage existing growing areas and to license new growing areas.

ACTION BY 2001 TASK FORCE: Recommended No Action. Rationale: Issue 01-115 is adequately addressed in the Model Ordinance.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

***

ISSUE NUMBER: 01-116

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter VIII. @. 01.B.(2)

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter VIII@.01.B:

B. Patrol of Growing Areas.

(1) The Authority shall assure that shellstock are harvested only as provided in this Chapter.

(2) The Authority shall patrol harvest areas classified as restricted, conditionally restricted, or prohibited, or conditionally approved and approved when in the closed status at sufficient intervals to deter illegal harvesting. This patrol activity shall include consideration of the need for night, weekend, and holiday patrols. At a minimum, these growing areas shall be patrolled at the following frequencies except as provided:

RISK CATEGORY	MINIMUM FREQUENCY OF PATROL
LOW	Four times per 30 harvestable days
MEDIUM	Eight times per 30 harvestable days
HIGH	Sixteen times per 30 harvestable days

A patrol is accomplished when the majority of an area is monitored. No more than two patrols can be counted in a 24-hour period, and each must be a separate deliberate effort.

A harvestable day refers to a day during which tidal, weather and other conditions make it possible to harvest shellfish. When tidal, weather or other conditions prohibit harvesting on a particular day, that day is not included in the 30-day period. In the case of a conditional closure (river flood, rainfall, discharge from a wastewater treatment plant etc… only those days that the area is closed will count towards the number of harvestable days. The area shall be patrolled every other day while is in closed status. The authority shall develop and implement a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:

a. description of the area;
b. classification of the area;
c. description of adjacent closed growing areas;
d. method used by growing area personnel to notify the patrol agency when a Conditional Approved or Restricted area is temporarily closed to the public; and
e. monitoring and control or surveillance activities.

PUBLIC HEALTH SIGNIFICANCE: The current patrol requirements do not provide specific criteria to determine the minimum patrol frequency for conditional closure. This issue will provide flexibility to the state to manage patrol frequency for conditional closure

COST INFORMATION: None.

ACTION BY 2001 PATROL COMMITTEE: Recommended No Action. Rationale: The requested modifications in Issue 01-116 are not appropriate at this time.

ACTION BY 2001 TASK FORCE: Recommended adoption of Patrol Committee recommendations on Issue 01-115.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

***

ISSUE NUMBER: 01-117

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter VIII.@.01.B.

TEXT OF ISSUE:

REQUESTED ACTION: Add New Language As Follows**:**

(1) The authority shall meet the following Standardized Evaluation Criteria requirements:

1. Patrol document is updated every year.	KEY item
2. Patrol training meets the NSSP requirements.	KEY item
3. Necessary equipment to meet the patrol frequency requirements.	KEY item
4. Necessary personnel to meet the patrol frequency requirements.	KEY item
5. Necessary transportation to meet the patrol frequency requirements.	KEY item
6.Adequate communication system to meet the patrol frequency.	KEY item
7. Frequency of patrol meets NSSP requirements.	CRITICAL item
8. Formalized MOU with other agency.	KEY item
9. No Risk Management Plan.	CRITICAL item
10. Incomplete Risk Management Risk for aquaculture and remote areas.	OTHER item

(10) The authority shall ensure the following COMPLIANCE CRITERIA procedures are implemented when an FDA evaluation identifies deficiencies with NSSO MO criteria.

a) During the closeout meeting for patrol evaluation, the Shellfish Specialists shall identify any patrol deficiency to the state patrol agency;

b) Within 15 days of the closeout meeting, the Shellfish Specialist should provide a written Program Element Evaluation Report (PEER), including supporting documentation, to the State patrol agency;

c) Within 30 days of receiving the PEER, the State patrol agency should provide a written response that indicates:

(1) the item(s) was corrected;

(2) a correction plan has been developed with a completion date; or

(3) the reasons why the State disagrees with FDA's finding(s).

d) Within 15 days of receipt FDA should review the State response, and respond to the State;

e) Any CRITICAL item deficiency should be corrected within 30 days of acceptance by FDA of the correction plan.

f) Any KEY item deficiency should be corrected by completion date as stated in the correction plan.

g) Any OTHER item deficiency should be corrected within 60 days of acceptance by FDA of the correction plan.

THE SHELLFISH SPECIALIST SHALL BE RESPONSIBLE FOR MONITORING THE PROGRESS OF THE STATE CORRECTION PLAN.

PUBLIC HEALTH SIGNIFICANCE: A problem in the current Model Ordinance Patrol section is the lack of uniform evaluation criteria to determine if a state patrol program meets NSSP MO requirements. The patrol committee jointly with FDA and NMFS personnel has successfully started the process to correct this problem. They developed standardized evaluation criteria to be used by FDA's Shellfish Specialists to determine if a state patrol program is in compliance with the NSSP MO requirements. It is the committee's position that these criteria represent the absolute minimal standards. A state program, which fails to meet any of those criteria, is considered out of compliance with the NSSP.

COST INFORMATION: None.

ACTION BY 2001 PATROL COMMITTEE: Recommended adoption of Issue 01-117 as amended.

Chapter VIII@.01.B

(9) To comply with Standardized Evaluation Criteria, the authority shall ~~requirement~~:

1. Have a patrol policy document	***CRITICAL item***
2. Update patrol document every year.	**KEY item**
3. Meet the NSSP patrol training requirements.	**KEY item**
4. Patrol all areas that require patrol.	***CRITICAL item***
5. Meet NSSP requirements for frequency of patrol.	~~**CRITICAL** **item**~~ ***KEY***
6 .Have formalized MO***A*** with other agency per Chapter VIII@.01.B(5).	**KEY item**
7. *Have a risk management plan per chapter VIII@01.B(3)(b)(c)(d).*	***CRITICAL item***
8. **Have a complete risk management plan per chapter VIII@01.B(3)(b)(c)(d).**	**Other item**

?? **NOTE: All items were re-written to obtain consistent language. (italics, bold)**

The Committee further recommended that Part 10 of Issue 01-117 be incorporated into the NSSP Guide for the Control of Molluscan Shellfish as a guidance document.

ACTION BY 2001 TASK FORCE: Recommended adoption of Patrol Committee recommendations.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

***

ISSUE NUMBER: 01-118

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter VIII. @. 01.B.(3).(b).(i).(c).(i).(ii).(d).(i).(ii).

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter VIII.@01.B(3):

The proposed changes in this issue are for the patrol requirements adopted at the annual 2000 ISSC. Because the issue adopted at the 2000 ISSC is not yet published, the entire issue is included for reference. The new proposed language is shown underlined. Language to be eliminated is shown as strikeout.

(b) Where there are no natural sets resulting in commercially harvestable quantities of shellfish and advanced aquaculture methods (e.g. racks, bags, lantern nets, long lines and/or floats) are used in the area:

(i) The Authority shall develop and implement a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan should describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:

a. description of the area;

b. classification of the area;

c. description of adjacent closed growing areas;
d. procedure use to prevent shellfish from polluted water to be commingled with shellfish from an aquaculture facility;
e. if, the patrol agency receives assistance from other state or federal agencies, a memorandum of agreement must be developed describing responsibilities from each agency. A copy of such MOU must be kept in a central file; and ~~The Risk Management Plan shall~~
f. include monitoring and control of surveillance activities that supplement the minimum patrol frequency required of one (1) time per 30 harvestable days.

(f) If the area is geographically remote, sparsely populated and has limited access (e.g. no or very poor roads) such that the potential for marketing the shellfish is severely restricted:

(i) the area shall be patrolled at the frequencies specified in §B.(2) unless the Authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:

a. description of the area;
b. classification of the area;
c. description of adjacent closed growing areas;
d. if, the patrol agency receives assistance from other state or federal agencies, a memorandum of agreement must be developed describing responsibilities from each agency. A copy of such MOU must be kept in a central file; and

~~(ii) The Risk Management Plan shall~~

e. include monitoring and control of surveillance activities (e.g. airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities, and

(ii) If the Authority has current evidence that commercial illegal harvesting is occurring, the management plan should be reevaluated; and

(iii) the area should be patrolled at least one (1) time per 30 harvestable days.

(d) Where the entire state is closed to harvesting during traditional non-harvesting seasons:

(i) the area shall be patrolled at the frequencies specified in B. (2) unless the Authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and include at least the following:

a. description of the area;
b. classification of the area;
c. description of adjacent closed growing areas;
d. if, the patrol agency receives assistance from other state or federal agencies, a memorandum of agreement must be developed describing responsibilities from each agency. A copy of such MOU must be kept in a central file; and

~~(ii) The Risk Management Plan shall~~

e. include monitoring and control of surveillance activities (e.g. airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities, and

(ii) The area shall be patrolled in low risk areas at least once (1) per 30 harvestable days, for medium risk areas at least twice (2) per 30 harvestable days, and for high risk areas at least four (4) times per 30 harvestable days, and

(iii) If the Authority has current evidence that commercial illegal harvesting is occurring, the state agency shall resume patrol at the frequency specified in B. (2)

PUBLIC HEALTH SIGNIFICANCE: The SSCA shall have adequate means to prevent illegal harvesting. The occurrence of the illegal harvesting is unpredictable and the potential for it to occur exits along coastlines. A Risk Management Plan shall be developed where an aquaculture method is practice, areas are geographically remotes and the entire state is closed to harvesting during traditional non-harvesting seasons. An effective Risk Management Plan shall include monitoring and control of surveillance activities that will be used in lieu of traditional patrol activities. If more than one agency is involved or if local agencies are also involved, the plan should be jointly developed. The Plan should describe the administrative procedures and resources necessary to prevent illegal harvesting and illegal commingling of the product. The current patrol requirements do not provide clear criteria for the Risk Management Plan. This proposed language outlines criteria to be included in the Risk Management Plan.

COST INFORMATION: None.

ACTION BY 2001 PATROL COMMITTEE:
The Committee recommended adoption of Issue 01-118 as amended:

Chapter VIII.@.01.B.(3).(b).(i):

(i) The area shall be patrolled at the frequencies specified in §B. (2) unless the authority develops and implements a Risk Management Plan ~~The Authority shall develop and implement a Risk Management Plan~~ for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities that supplement the minimum required patrol frequency ~~required~~ of one (1) time per 30 harvestable days. The Risk Management Plan at least should include the following:

a. description of the area;
b. classification of the area;
c. description of adjacent ~~closed~~ growing areas;
d. procedure used to prevent shellfish from ~~polluted~~ prohibited or closed waters to be commingled with shellfish from an aquaculture ~~facility~~ area; and +
e. .if, the patrol agency receives assistance from other state, ~~or~~ federal, ~~agencies~~, or tribal agencies, a memorandum of agreement must be developed describing responsibilities ~~from~~ of each agency. A copy of such MOA must be kept in a central file; ~~and, include monitoring and control of surveillance activities that supplement the minimum patrol frequency required of one (1) time per 30 harvestable days.~~

Chapter VIII.@.01.B.(3).(c).(i). (ii). (iii)

(ii) The area shall be patrolled at the frequencies specified in § B. (2) unless the authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities (e.g. airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities, and ~~for~~ the area should be patrolled at least one (1) time per 30 harvestable days. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:

a. description of the area;
b. classification of the area;
c. description of adjacent ~~closed~~ growing areas; and
d. if, the patrol agency receives assistance from other state, ~~or~~ federal, ~~agencies~~ or tribal agencies, a memorandum of agreement must be developed describing responsibilities from each agency. A copy of such MOA must be kept in a central file~~; and~~

iii. (ii)If the Authority has current evidence that commercial illegal harvesting is occurring, the management plan should be reevaluated~~; and~~

(iii) the area should be patrolled at least one (1) time per 30 harvestable days.

Chapter VIII.@.01.B.(3).(d).(i).

(i) The area shall be patrolled at the frequencies specified in § B. (2) unless the authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities (e.g. airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:

a. description of the area;
b. classification of the area;
c. description of adjacent ~~closed~~ growing areas; and
d. if, the patrol agency receives assistance from other state, ~~or~~ federal, ~~agencies~~ or tribal agencies, a memorandum of agreement must be developed describing responsibilities from each agency. A copy of such MOA must be kept in a central file. ~~; and~~

ACTION BY 2001 TASK FORCE I: Recommended adoption of Patrol Committee recommendations.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

***

ISSUE NUMBER: 01-119

SPECIFIC REFERENCE: IV@.03C.(3)(b)(v).

TEXT OF ISSUE:

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter XI. @ 03C.(3)(b) by adding a new subsection as follows:

(v). For growing area seasons of 6 months or less and more than 1 month, the number of water samples required is equal to the number of months the growing area is in the open status of its conditional classification. Samples collected to reopen the conditionally approved area may be used to satisfy the sampling requirement. For growing area seasons 1 month or less, one set of water samples is required when the growing area is in the open status of its conditional classification or within two weeks prior to the area opening, provided the conditional management plan criteria is met.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE I:: Recommended adoption of Issue 01-119 as amended:

Chapter IV ~~XI~~ @.03C
(iv~~v~~) For growing areas ~~seasons~~ in the open status… and more than 1 month, the area will be sampled monthly while open, thus the number of water samples…. Samples collected to reopen …… For growing area ~~seasons~~ in the open status of…..provided the conditional management plan criteria ~~is~~ are met.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Did not concur with Conference action. See comments in attachment at end of Task Force I.

ACTION BY ISSC EXECUTIVE BOARD: Recommended referral of Issue 01-119 to appropriate committee as determined by the Conference Chairman.

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ISSUE NUMBER: 01-120

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter IV – Shellstock Growing Areas, @.04 Marine Biotoxin Control C(1)(a) page 39.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter IV.@.04.A(2) by adding new subsection (d) and renumbering subsequent subsections and rewording new subsection C(5):

@.04 Marine Biotoxin Control.

A. Contingency Plan.

(1) The Authority shall develop and adopt a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas.

(2) The plan shall define the administrative procedures and resources

necessary to accomplish the following:

(a) Initiate an emergency shellfish sampling and assay program;

(b) Close growing areas and embargo shellfish;

(c) Prevent harvesting of contaminated species;

(b) All shellfish product shall adhere to the PSP standards as listed in .04C (1)(a) and shall pertain to product entering commerce and product in commerce for programs under .04A(4) and .04B.

(e) ~~(d)~~ Provide for product recall;

(f) ~~(e)~~ Disseminate information on the occurrences of toxic algal blooms and/or toxicity in shellfish meats to adjacent states, shellfish industry, and local health agencies; and

(g) ~~(f)~~ Coordinate control actions taken by Authorities and federal agencies.

B. Marine Biotoxin Monitoring …

C. Closed Status of Growing Areas.

(1) A growing area, or portion(s) thereof as provided in §A.(4), shall be placed in the closed status for the taking of shellstock when the Authority determines that the level of biotoxin present in shellfish meats is sufficient to cause a health risk. The closed status shall be established based on the following criteria:

(a) The concentration of paralytic shellfish poison (PSP) equals or exceeds 80 micrograms per 100 grams of edible portion of raw shellfish; or

(b) For neurotoxic shellfish poisoning (NSP), the harvesting of shellstock shall not be allowed when:

(i) Any NSP toxin is found in shellfish meats; or

(ii) The cell counts for *Gymnodinium breve* organisms in the water column exceed 5,000 per liter; or

(c) For domoic acid, the toxin concentration shall not be equal to or exceed 20 ppm in the edible portion of raw shellfish.

(3) Upon closing a growing area as outlined in IV.04C(1) the authority shall:

i. Notify receiving states of the problem; and

ii. Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7.

(3)~~(2)~~ For any marine biotoxin-producing organism for which criteria have not been established under this Ordinance, either cell counts in the water column or biotoxin meat concentrations may be used by the Authority as the criteria for not allowing the harvest of shellstock.

(4)~~(3)~~ When sufficient data exist to establish that certain shellfish species can be safely exempted from the marine biotoxin contingency plan, the closed status for harvesting may be applied selectively to some shellfish species and not others.

(5)~~(4)~~ The closed status shall remain in effect until the Authority has data to show that concentrations of PSP have fallen below 80 micrograms for three separate tests collected on three separate days prior to release of product from harvest .~~the toxin content of the shellfish in the growing area is below the level established for closing the area~~.

(6)~~(5)~~ The determination to return a growing area to the open status shall consider whether toxin levels in the shellfish from adjacent areas are declining.

(7)~~(6)~~ The analysis upon which a decision to return a growing area to the open status is based shall be adequately documented.

PUBLIC HEALTH SIGNIFICANCE: .04C(1)(a) addresses the closed growing area status due to PSP, but is silent to the applicability of the 80 microgram standard for product market release and recall purposes, once a monitoring program discloses test results that equal or exceed the 80 microgram standard. Some SSCAs are not using the 80-microgram standard with geoducks to stop product from continuing in commerce, or to recall product already in commerce that exceeds the PSP standard.

FDA COMPLIANCE POLICY GUIDES under Sec. 540.250 Clams, Mussels Oysters, Fresh, Frozen or Canned – Paralytic Shellfish Poison (CPG 7108.20).

REGULATORY ACTION GUIDANCE

The following represents criteria for recommending legal action to CFSAN/Office of Field Programs/Division of Enforcement (HFS-605):

Actionable if one sub from a lot shows paralytic shellfish poison value of 80 micrograms, or more per 100 grams meat when bioanalyzed by current Association of Official Analytical Chemists procedure.

Articles meeting the above criterion represent a potential health hazard. Consequently, recall is the action of choice. Notify CFSAN/Office of Programs/Division of Enforcement (HFS-605) immediately if articles meeting the above criterion are encountered.

The PSP standard needs to be clearly defined in the Model Ordinance for recall and market release.

PSP values of varying levels have caused illness in Alaska. It is important to note the low, less than 80 microgram levels represent the largest frequency of illnesses for the toxicity ranges listed. This trend of low-level illness continues.

No. of Episodes	Time Period	Range of PSP Toxicity
23	1990 - 2000	32 – 80
7	1990 - 2000	81 – 120
13	1991 - 2001	121 – 249

COST INFORMATION: The 2000/2001 geoduck fishery in Alaska had a quota of 286,806 pounds. Harvesters received $4.00 a pound for live product and $1.10 a pound for processed product and one can see the economics of live sales very quickly.

ACTION BY 2001 TASK FORCE: Recommended referral of Issue 01-120, as substituted, to appropriate committee as determined by Conference Chairman.

Substituted Issue 01-120:

REQUESTED ACTION: Modify Chapter IV.@.04.C by adding new subsection (2)(i) and (ii).

@.04 Marine Biotoxin Control.

A. Contingency Plan…….

.

B. Marine Biotoxin Monitoring …

C. Closed Status of Growing Areas……(new section two, renumber subsequent sections)

(2) If shellfish have been placed in commerce from an area that is subsequently closed for harvesting because the level of biotoxins exceed the levels in (1)(a), (b) or (c) of this section, and that product was not tested by the authority under (B), Marine Biotoxin Monitoring, prior to being placed in commerce and found in compliance with the biotoxin levels in (1)(a), (b) or (c), the authority shall:

(i) for all species of shellfish except for geoduck clams, contact the harvester or dealer to initiate the recall.

(ii) take the following recall actions for geoduck clams in commerce with PSP levels equals or exceeds 80 micrograms/ 100 grams of tissue:

(a) If the PSP level in the geoduck clams is 80 – 119 micrograms/100 grams of tissue, the importing state or country shall be made aware of the problem and the buyer must be notified by the shipper and advised to destroy or eviscerate the product.

(b) If the geoduck equals or exceeds 120 micrograms/ 100 grams of tissue, the shipper must immediately initiate a recall. The shipper shall advise the buyer to either destroy or eviscerate the product and must keep records of the notification to the buyer and response from the buyer, of the recall actions.

PUBLIC HEALTH SIGNIFICANCE: .04C(1) addresses when to close a growing area due to marine toxins but is silent as to whether or not product that exceed those levels can be left in commerce once a monitoring program discloses test results that equal or exceed the toxin levels given in the NSSP.

FDA has a Compliance Policy guide relating to PSP which states:

FDA COMPLIANCE POLICY GUIDES under Sec. 540.250 Clams, Mussels Oysters, Fresh, Frozen or Canned – Paralytic Shellfish Poison (CPG 7108.20).

REGULATORY ACTION GUIDANCE
The following represents criteria for recommending legal action to CFSAN/Office of Field Programs/Division of Enforcement (HFS-605):

Actionable if one sub from a lot shows paralytic shellfish poison value of 80 micrograms, or more per 100 grams meat when bioanalyzed by current Association of Official Analytical Chemists procedure.
Articles meeting the above criterion represent a potential health hazard. Consequently, recall is the action of choice. Notify CFSAN/Office of Programs/Division of Enforcement (HFS-605) immediately if articles meeting the above criterion are encountered.

The language being proposed seeks to clarify the actions that need to be taken when biotoxin tolerance levels are exceeded for geoduck clams. This clarification is needed to ensure shellfish shippers do not increase their product liability exposure when geoduck clams are in commerce that may exceed the PSP level in the FDA Compliance Policy Guide.

For geoduck clams, a two-tiered approach is being proposed. It has been demonstrated that when PSP toxins in the geoduck viscera are at levels below 1000 micrograms/100 grams of tissue, there is little or no accumulation in the body meat and siphon. Consequently, laboratory analysis for PSP in geoduck includes only the visceral ball, unlike other bivalves where the entire animal is tested. The majority of consumers eat the body and neck meat only. However, there are some people that report consumption of the viscera as well.

Therefore, if geoduck has been shipped before it is tested and tests reveals the product exceeds 80ug/100 but is below 120, a recall as suggested under the FDA Compliance Policy Guide should not be required. However, the importing state or country should be made aware of the problem and the buyer must be notified by the shipper and required to destroy or eviscerate the product. Only if the geoduck is at or exceeds 120 should a recall be required. In both cases, the shipper must provide the SSCA with records that would consist of copies of the notification to the buyer and the buyer's confirmation to the shipper of the ultimate disposition of the geoduck, or the actions taken to recall the product

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

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ISSUE NUMBER: 01-121 - Referred to Task Force III. See page 140.

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ISSUE NUMBER: 01-122 - Referred to Task Force III. See page 140.

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ISSUE NUMBER: 01-123 - Referred to Task Force III. See pate 141.

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ISSUE NUMBER: 01-124

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter IV, .03C.(3)(b) (iv).

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter IV, .03C.

@.03 Growing Area Classification.

A. …

B. …

C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:

(a) …

(b) Water Sample Collection.

(i) When the conditional management plan is based on the absence of pollution from marinas for certain times of the year, monthly water samples are not required when the growing area is in the open status of its conditional classification provided that at least three of the water samples collected to satisfy the bacteriological standard for the open status are collected when the growing area is in the open status.

(ii) When the conditional management plan is based on the operation and performance of a wastewater treatment plant(s); combined sewer overflow(s); or other point sources of pollution, monthly water samples are required when the growing area is in the open status of its conditional classification.

(iii) If a monthly sample cannot be collected due to environmental constraints, the monthly sampling requirement will be satisfied if an additional water sampling run is conducted the following month.

(iv When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events, stormwater runoff, and seasonal variations, a minimum of five (5) sets of water samples (when the Adverse Pollution Condition sampling regimen is used) or ~~six (6) sets of water samples~~ (when the Systematic Random Sampling regimen is used) are required. ~~The~~ One sample per month shall be collected when the growing area station is in the open status.

PUBLIC HEALTH SIGNIFICANCE: Collection of one sample per month while a station is open for harvest provides sufficient monitoring when the sample is added to a data base of sufficient size to ensure significant environmental parameters are adequately monitored and monthly sampling provides the ability to monitor change of the station over time. During a limited opening of a conditional management area, the collection of 6 sets of samples may be impossible while monthly sampling not only can be conducted but also is adequate.

COST INFORMATION: Not known.

ACTION BY 2001 TASK FORCE: Recommended No Action. Rationale: Issue 01-124 is addressed by Issue 01-119.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

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ISSUE NUMBER: 01-125

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter III Laboratory @.02 Methods (C) Biotoxin (1) page 24; Guidance documents, A.12 Laboratory PSP Evaluation Checklist, Part II – Examination of Shellfish Tissue for PSP Toxin, 2.1.1.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter III.02.C. to read:

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:
(1) The current AOAC and APHA methods used in bioassay for paralytic shellfish poisoning toxins; and
(2) The current APHA method used in bioassay for *Gymnodinium breve* toxins.
(3) When testing for marine biotoxins in geoducks three individual animals must be tested. Each of individual tests must be less than 80 micrograms per l00 grams standard for area to be opened or the product release.

Modify , A.12 Laboratory PSP Evaluation Checklist, Part II – Examination of Shellfish Tissue for PSP Toxin, 2.1.1. to read:

Part II – EXAMINATION OF SHELLFISH TISSUE FOR PSP TOXIN
2.1 Preparation of Sample
1. At least 12 animals are used per sample, except for geoducks which require three individual animals to be tested (3 samples). The number of animals may be adjusted for non-typical species of shellfish other than geoducks if the laboratory ~~or the lab~~ has an appropriate contingency plan. ~~for dealing with non-typical species of shellfish,~~

PUBLIC HEALTH SIGNIFICANCE: Both APHA and AOAC references for PSP are silent to the exact method of testing. No specific language exists whether either compositing (blending) or individual animal testing can be used.

Washington, Alaska and British Columbia use various PSP sampling and monitoring programs. Both Washington and British Columbia use a pre harvest-testing program in order to open an area for harvest. Alaska uses a harvest release program to accept or reject product for live sales. The sampling program in Washington and British Columbia uses three animals for testing by **compositing** all of the visceral balls and extracting a one hundred gram sample for analysis. Alaska tests each animal **individually** and all three tests must be <80 ug/100 grams standard for the product to be released.

The visceral balls of geoducks vary greatly in size so composite sampling does not result in an average value. The Alaska Seafood and Food Safety Laboratory in Palmer, Alaska has routinely seen visceral balls ranging in size from 27 grams to well over 100 grams. Larger visceral balls can have a proportionately greater affect on the composite value.

A high degree of variability exists with geoducks and level of PSP. Pacific geoducks have been reported to have a coefficient of variability of 41% from a paper by White, Shumway, Nassif and Whittaker titled, *VARIATION IN LEVELS OF PARALYTIC SHELLFISH TOXINS AMONG INDIVIDUAL SHELLFISH* from ----*Toxic Phytoplankton Blooms in the Sea* by T.J. Smayda and Y. Shimizu. Also Kelly M. Curtis reports that different levels of variability with geoducks by depth. In the shallow areas she reports a coefficient of variability of 20 -98% while deeper areas showed 18-62% with geoducks in her thesis, *PARALYTIC SHELLFISH TOXIN IN GEODUCK CLAMS (Panope abrupta): VARIABILITY, ANATOMICAL DISTRIBUTION, AND COMPARISON OF TWO TOXICITY TESTING METHODS* published for a Master of Science degree at the University of Washington, 1999 School of Fisheries.

The Alaska Seafood and Food Safety Laboratory in Palmer has performed some composite testing from animals we have tested individually. In every case, the composite value was at the very low end of the three individual samples. In at least one instance, two of the geoducks used were well over the 80 ug/100 gram level but the composite sample level was under. Here is the result of some of that sampling:

Sample 1	124 ug/100 grams
Sample 2	62
Sample 3	78
Composite Result:	98

Sample 1	237 ug/100 grams
Sample 2	157
Sample 3	237
Composite Result::	152

Sample 1	491 ug/100 grams
Sample 2	1123
Sample 3	490
Composite Result:	449
Sample 1	55 ug/100 grams
Sample 2	120
Sample 3	155

COMPOSITE RESULT: 79

Additional information raising questions on the composite method of testing can be found in Kelly Curtis' thesis. As referenced in her study, one days' sampling of ten samples using single animal testing in an area show values of 61, 375, 813, 317, 410, 145, 304, 341, 266 and 274 ug/100 grams of PSP while simultaneous sampling by the Washington Department of Health using composite testing said that toxin levels were non-detectable. She goes on to suggest that "Geoducks should be tested for PSP on an individual basis rather than as composite of 3 samples, to account for the high degree of individual variability seen in this study".

Composite PSP testing allows product to be sold live for human consumption that would otherwise have to be processed because of exceeding the standard. With different size visceral balls and different levels of toxin present, the composite value is not the average. See above information on the sample testing performed by the Alaska Seafood and Food Safety Laboratory. White, et.al. calls for the need of including a large number of animals in composite samples. The entire geoduck is eaten, neck eaten raw, visceral ball in soups or spreads and the body meat textured for clam fritters.

Single animal testing for PSP with geoducks affords the greatest amount of public health protection with a species that has such high variability levels as seen from the two literature citations of Curtis and White et al.

Clear and concise language is needed in Chapter III Laboratory section to specify the methodology to be used for geoducks.

COST INFORMATION: The 2000/2001 geoduck fishery in Alaska had a quota of 286,806 pounds. Harvesters received $4.00 a pound for live product and $1.10 a pound for processed product and one can see the economics of live sales very quickly.

ACTION BY 2001 TASK FORCE: Recommended No Action. Rational: Submitter requests no action on this issue.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference actions.

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ISSUE NUMBER: 01-126

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter III @. 02 C. (2).

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter III @. 02 C. (2) as follows:

(2) The current APHA method used in bioassay for *Gymnodinium breve* toxins. Acetone may be substituted for diethyl ether.

PUBLIC HEALTH SIGNIFICANCE: Extraction using acetone (or other appropriate solvent) is a much safer laboratory procedure than is extraction using diethyl ether. Diethyl ether extraction must occur under an explosion hood and is extremely dangerous to laboratory technicians.

COST INFORMATION: Cost savings would be realized in the laboratories.

ACTION BY 2001 TASK FORCE: Recommended referral of Issue 01-126 to the appropriate committee as determined by Conference Chairman.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference action.

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ISSUE NUMBER: 01-127

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter III, D, 1 and Chapter III, E, 1, 2, and 3.

TEXT OF ISSUE:

REQUESTED ACTION:

?? Modify Chapter III, @.01, by replacing section D, 1:

(D) Laboratory Evaluation.

~~(1) Laboratory Status. Continued acceptance of analytical data in support of the NSSP by the Authority from any operating laboratory is contingent upon the laboratory being found to conform or provisionally conform to NSSP requirements as determined in their most recent laboratory evaluation using the NSSP standardized laboratory evaluation criteria listed in Section IV Guidance Documents A.12.~~ Laboratory status is determined by the number and types of nonconformities found in the evaluation using NSSP standardized criteria contained in the FDA Shellfish Laboratory Evaluation Checklists, Guidance Documents A. 12.

?? Modify Chapter III, @.01,by replacing section E, 1:

E. Time Limit on Laboratory Status.

Conforming Status. ~~A laboratory in conforming status may operate for up to 90 days during which the laboratory must be actively working on an FDA or FDA certified State Shellfish LEO approved action plan to maintain its conforming status. After this period, the laboratory shall be assigned a nonconforming status if all key deficiencies have not been successfully corrected~~. A laboratory found to be in conforming status has up to 90 days to successfully correct all nonconformities noted in the evaluation. After this period, the laboratory's status shall be downgraded to nonconforming if any key nonconformities remain to be successfully corrected. As a result, data being generated by the laboratory is no longer acceptable for use in support of the NSSP.

?? Modify Chapter III, @.01, by replacing section E, 2:

(2) ~~Provisionally Conforming Status. A laboratory in the provisionally conforming status may operate for up to 60 days during which the laboratory must be actively working on a FDA approved action plan that will bring the laboratory into the NSSP conforms status. After this period, the laboratory shall be assigned a status as:~~

~~(a) Conforms if all the critical and key nonconformities have been successfully corrected; or~~

~~(b) Nonconforming if any critical or key nonconformities have not been successfully corrected.~~ Provisionally Conforms status. A laboratory found to be in provisionally conforming status has up to 60 days to successfully correct all nonconformities found. After this period, the laboratory shall be assigned a status of:

(a) Conforms if all the critical and key nonconformities have been successfully corrected; or,
(b) Nonconforming if any critical or key nonconformities remain to be successfully corrected. Consequently, data being generated by the laboratory is no longer acceptable for use in support of the NSSP.

?? Modify Chapter III, @.01, by replacing section E, 3:

Nonconformance~~. Upon determination of nonconforming status, data generated from the laboratory shall not be used in support of the NSSP. If the laboratory wishes to attain conforming status, the laboratory must immediately implement an FDA or FDA certified State Shellfish LEO approved action plan and has up to 30 days to demonstrate successful correction of all critical and key deficiencies. After this period, an onsite re-evaluation should be conducted. Upon re-evaluation, only a status of conforming shall allow data to be accepted in support of the NSSP.~~Upon a determination of nonconforming status, the laboratory has up to 30 days to demonstrate successful correction of all nonconformities found. After this period, if all critical and key nonconformities have been successfully corrected, the status of the laboratory will be upgraded to conforming. However, if any critical or key nonconformities remain to be successfully corrected, the status of the laboratory shall continue to be nonconforming; and, data being generated by the laboratory will cease to be acceptable for use in support of the NSSP.

?? Modify Chapter III, @.01, E by adding paragraph 4 and 5 (new language):

(3) Non conformance…..

(4) When a laboratory is found to be nonconforming either for failure to successfully implement the required corrective action, or for having repeated critical or key nonconformities in consecutive evaluations, the Authority shall ensure that an action plan is developed to correct the situation in an expeditious manner.

(5) When all critical and key nonconformities have been successfully corrected by a nonconforming laboratory, the laboratory will be reevaluated either on-site or through a careful review of appropriate documentation as determined by the FDA or FDA certified State Shellfish LEO. Only a

finding of fully conforming in laboratories whose data has ceased to be acceptable to the NSSP will restore its acceptability for use in the NSSP.

PUBLIC HEALTH SIGNIFICANCE: The purpose of this issue is to clarify both how the laboratory status is determined, what impact correction deadlines have on the operational status of a laboratory and the acceptability of its data for use in support of the NSSP.

COST INFORMATION: Negligible

ACTION BY 2001 TASK FORCE: Recommended referral of Issue 01-127 to appropriate committee as determined by Conference Chairman.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force I.

ACTION BY USFDA: Concurred with Conference Action.

ATTACHMENT – COMMENTS FROM FDA

Issue 98-107:

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.

Issue 00-104:

FDA concurs with action to adopt Issue 00-104. However, in the text of the issue item (E) of Chapter V. @. 02 appears to have been inadvertently omitted. During the next revision of the NSSP Model Ordinance, item E should be changed to item F and retained as one of the satisfactory compliance items of Chapter V. @. 02.

Issue 01-113:

Issue 01-113 provides for the reduction of systematic random water quality sampling to two times per year per sampling station when an area is placed in the "inactive" status. While FDA was initially reluctant to concur with this issue, we believe that controls built into the issue provide assurances that shellfish safety will be maintained.

Issue 01-113 requires that, while in the "inactive" status, a growing area need only be sampled twice per year using a systematic random sampling strategy. Under this reduced sampling frequency it is difficult, if not impossible, to reasonably define bacteriological water quality over time. For this reason Issue 01-113

requires reinstatement of full systematic random sampling at least six months prior to removing the area from the "inactive" status. Additionally, Issue 01-113 requires evaluation of the most recent 30 samples prior to lifting the "inactive" status. This requirement establishes that area water quality meets NSSP standards appropriate to its classification prior to its placement in the "inactive" status.

Given that an area placed in the "inactive" status is closed to shellfish harvesting, it will be incumbent upon the authority to conduct a risk category assessment of the area in accordance with Model Ordinance Chapter VIII. The authority shall then patrol the "inactive" area at a frequency commensurate with that required by its assigned risk category.

Issue 01-119:

FDA does not concur with action taken by the Conference on Issue 01-119. Issue 01-119 proposes to reduce the number of water quality samples required from certain shellfish growing areas to as little as one per year. A reduction in water quality monitoring of this magnitude is not commensurate with the level of public health protection implicit in the NSSP. Few would argue that the most critical element of the NSSP is the growing area classification element and its ability to define areas safe for the taking of shellfish for human consumption. Current NSSP sampling protocols provide health authorities with what FDA considers the minimum set of water quality data needed to ensure continued safety of shellfish from classified growing areas. FDA recommends that this issue be referred to an appropriate committee of the Conference for further deliberation. We strongly urge the ISSC to seriously consider the public health implications associated with reducing existing water sampling requirements of the Model Ordinance.