Interstate Shellfish Sanitation Conference

2007 Summary of Actions

Biennial Meeting
August 11-17, 2007
Albuquerque, New Mexico

209 Dawson Road, Suite 2
Columbia, SC 29223
Phone 803-788-7559 – Fax 803-788-7576
Email issc@issc.org
Website www.issc.org

Interstate Shellfish Sanitation Conference
2007 Summary of Actions
Table of Contents

Proposal #	Proposal Subject	Page
98-107	*Vibrio parahaemolyticus* Interim Control Plan	1
05-100	*Vv* Risk Management Plan for Oysters Exemption for Licensed Shellfish Harvesters and Dealers	23
05-101	Establishment of *Vv* Illness Review Subcommittee	25
05-102	Inconsistent FDA "PEER" on Producing States	28
05-104	Wastewater Treatment Plant Discharges (Viral Pathogens)	32
05-105	Re-Opening Criteria Based on New Indicator of Sewage-Borne Viral Pathogens	34
05-107	Real Time PCR Methods for Determining Levels of *V parahaemolyticus* and *V vulnificus*	37
05-108	Real Time PCR Method for Determining Levels of *V parahaemolyticus*	40
05-109	Rapid Screening Method for ASP	42
05-111	Rapid Extraction Method for PSP and ASP	51
05-113	Microbiology Checklist, Isolation of Male-Specific Coliphage, MSC	59
05-114	Microbiology Method to Determine the Presence of Male Specific Coliphage in Shellfish Meats	65
05-115	Thermazyme™ ACP Test for Use on Thermally Processed Shellfish Products	72
07-100	Illness Outbreaks Associated with Consumption of Shellfish	79
07-101	Laboratory Method Approval – Model Ordinance Chapter III @ .02	80
07-102	Patrol Evaluation Criteria	84
07-103	Laboratory Methods (*Vibrio vulnificus* and *Vibrio parahaemolyticus*)	85
07-104	Adoption of ELISA as Type I NSSP Analytical Method to Replace the Mouse Bioassay for NSP	86
07-105	Adoption of LC-MS as Type I NSSP Analytical Method to Replace the Mouse Bioassay for NSP	88
07-106	Receptor Binding Assay (rba) for PSP as a Type I NSSP Analytical Method	90
07-107	Table 1 Action Levels, Tolerances & Guidance Levels for Poisonous or Deleterious Substances	92
00-201	*Vibrio vulnificus* Risk Management Plan	93
01-206	Conditional Protocol Verification	116
01-224	Establishment of New Post Harvest Treatment Dealer Classification	119
03-203	Identification of Wet Stored Shellstock	123
03-204	Shellstock Tagging of Wet Stored Shellstock	125
03-212	Validation/Verification Interim Guidance	127
05-200	Post Harvest Processing Definitions; Transportation; Labeling	132
05-204	Guidance in the Evaluation of PHPs	136
05-205	Major Revision to Wet Storage Requirements in MO Chapter VII.	137
05-206	Shellstock Identification and Shucked Shellfish Labeling	159
05-209	New Temperature Requirement at Receiving (Shucking and Packing)	161
05-210	Sanitation and HACCP Requirements (Shucking and Packing)	167
05-212-C	Sanitation Requirements Plumbing and Related Facilities (Hand Washing)	179
05-213-C	Control of Employees with Adverse Health Conditions	185
05-215	New Temperature Requirement at Receiving (Repacking of Shucked Shellfish)	190
05-216	Sanitation and HACCP Requirements (Repacking of Shucked Shellfish)	192
05-217	New Temperature Requirement at Receiving (Shellstock Shipping)	201
05-218	Sanitation and HACCP Requirements (Shellstock Shipping)	205
05-219	New Temperature Requirement at Receiving (Reshipping)	215
05-220	Sanitation and HACCP Requirements (Reshipping)	219
05-221	Oyster/Shellfish Gardening	226

Proposal #	Proposal Subject	Page
05-222	Harvester Sanitation Requirements (Control of Shellfish Harvesting)	240
05-223	Containers for Waste Disposal (Control of Shellfish Harvesting)	242
05-224	Freight Forwarding (Transportation	244
05-225	Elimination of Model Ordinance Requirements Already Covered in HACCP	245
05-226	Maintenance Program for *Vibrio vulnificus* Risk Management Plan for Oysters	246
05-227	Labeling of Shucked Shellfish (Name and Certification Number)	248
07-200	Requirements to Conduct Product Recall	249
07-201	Annual *Vp* Illness Data Reporting by States	250
07-202	*Vibrio parahaemolyticus (Vp)* Control Plan	251
07-203	Disposal of Human Sewage from Vessels	258
07-204	Reduction of Time-Temperature Matrix Levels 2 & 3 for *Vibrio parahaemolyticus*	259
07- 205	Label all Packages of Fresh or Frozen Shucked Shellfish with a Consumer Advisory Statement	262
07-206	Post Harvest Processing Reducing *Vv* and *Vp* Levels	263
07-207	NSSP Standardized Shellfish Processing Plant Inspection Form	265
07-208	Protocol for Addressing Positive Coliform Sample in an Artificial Wet Storage Water Body	267
07-209	Validation Verification Revision	270
07-210	Maintenance of Identity of Origin on all Raw Molluscan Shellfish	278
07-211-L	Elimination of the *Vv* and *Vp* Subcommittees	280
05-RN-200	Time Temperature Issues (Transportation)	281
05-RN-201	Temperature Abused Oysters	282
05-RN-202	New Economic Impacts Study of Requiring Post-Harvest Processing of Oysters	284
05-RN-203	Study of the Impact of CA Regulation	286
07-RN-200	Thermal Inactivation Curve of Acid Phosphatase Levels of Imported Shellfish Species.	288
03-302	Constitution, Bylaws, and Procedures Reciprocity and Uniformity	297
03-306	Procedure to Facilitate Discussions of Proposals at ISSC Biennial Meetings	302
05-300	Constitution, Bylaws, and Procedures Executive Board Member Terms	304
05-303	Laboratory Method Acceptance into NSSP	305
05-305	Post Harvest Processing Approved Laboratory Methods	322
05-306	Approved NSSP Laboratory Tests Microbiological and Biotoxin Analytical Methods	323
05-307	Modification of NSSP Standardized Shellfish Processing Plant Inspection Form	324
05-308	ISSC Policy Statement on the “Consumption of Raw Oysters”	327
05-310	Shellfish Sanitation Plant Element Evaluation Criteria	328
07-300	State Laws and Regulations	332
07-301	Constitution, Bylaws, and Procedures ISSC Membership, Registration, and Fees	334
07-302	Constitution, Bylaws, and Procedures State of Pennsylvania	336
07-303	Guidance on Equivalence Criteria for Food	337
07-304	Revisions to Procedure XVI of the Constitution, Bylaws & Procedures of the ISSC	338
07-305	Press Releases	373
05-001	*Vibrio vulnificus* Management Plan for Oysters Unprecedented Regulatory Approach	374
07-001	Leeland Jefferson Wiegardt Memorial Resolution	377
07-002	Lewis A. Byrd Memorial Resolution	378
07-003	Support for the ISSC *Vibrio* Education Program and Request for Continued Funding	379
07-004	Resolution of Appreciation to 2007 ISSC Biennial Meeting Staff and Volunteers	381

Proposal Subject Proposed New Section on *Vibrio parahaemolyticus*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) When more than twenty (20) confirmed illnesses occur within a 30-day period from anywhere in the state which do not meet the definition of an outbreak or more than ten (10) confirmed illnesses occur within a seven (7) day period from anywhere in the state which do not meet the definition of an outbreak, the Authority

shall implement the following control measures for *V. parahaemolyticus*.

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

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

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

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

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

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

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

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

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

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

Public Health Significance

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

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

Cost Information (if available)

Unknown

	TRIGGERS	SAMPLING	REGULATORY	EDUCATION
TIER #1	Growing areas/regions historically affected by *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 which do not meet the definition of an outbreak Or More than 3 illnesses within 7 days which do not meet the definition of an outbreak Or 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 which do not meet the definition of an outbreak Or More than 10 illnesses within 7 days which do not meet the definition of an outbreak	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 which do not meet the definition of an outbreak Or More than 10 illnesses within 7 days, which do not meet the definition of an outbreak.	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 Or More than one sample >10,000 org./gram	Weekly sampling	Conduct investigation and follow-up per Chapter II.	Continue public outreach; provide written illness report to FDA

Action by 1998 Task Force I

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) When more than twenty (20) confirmed illnesses occur within a 30-day period from ~~anywhere~~ **any harvest area(s)** in the state which do not meet the definition of an outbreak or

more than ten (10) confirmed illnesses occur within a seven (7) day period from ~~anywhere~~ **any harvest area(s)** in the state which do not meet the definition of an outbreak **or more than one shellstock sample at an indicator station is determined to have more than 5000 MPN but less than or equal to 10,000 MPN *V. parahaemolyticus* bacteria per gram of meat,** the Authority shall implement the following control measures for *V. parahaemolyticus*.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Action by 1998 General Assembly Adopted recommendation of 1998 Task Force I.

Action by USFDA

Offered the following comments on Proposal 98-107:

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

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

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

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

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

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

Action by ISSC Executive Board

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

Action By 1999 *Vibrio Parahaemolyticus* Committee

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

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

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

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

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

***Vibrio parahaemolyticus* Interim Control Plan For Oysters**

A. Contingency Plan

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

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

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

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

(c) Close growing areas and embargo product;

(d) Prevent harvesting of affected product; and

(e) Provide for product recall;

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

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

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

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

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

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

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

B. *Vibrio parahaemolyticus* Monitoring

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

(2) In all areas where a confirmed V.p. outbreak has occurred, representative samples of oysters shall be collected during harvest periods as determined by the

Authority. Samples shall be collected at intervals determined by the Authority (minimum weekly during months historically associated with an outbreak) and analyzed for total (tlh+ colonies) and virulent (tdh+) V.p. by the procedure and methods prescribed in B. (1) and other methods as determined by the Authority.

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

(a) the size of the growing area;

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

(c) the sensitivity of the methodology;

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

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

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

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

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

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

D. Illness Outbreak

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

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

E. Records.

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

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

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

(3) Evaluation reports; and

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

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

(McCarthy, S.A. et al 1999. Abstracts of the 99th General Meeting of the American Society for Microbiology, p.512].

Action by 1999 Task Force I

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

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

A. Contingency Plan

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

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

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

(b) Conduct 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 VMC Recommended continued oversight of the Interim Control Plan by the Vibrio Management Committee.

Action By 2000 Task Force I

Recommended adoption of 2000 Vibrio Management Committee recommendation.

Action By 2000 General Assembly

Adopted recommendation of 2000 Task Force I.

Action By USFDA

Concurred with Conference action.

Action By 2001 *Vibrio Parahaemolyticus* Subcommittee

The Committee recommended the following:

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

  - ❖ Recommended to Task Force I that this section become effective September 1, 2001.
  - ❖ Recommended to Task Force I that the V.p. subcommittee be tasked with reviewing the 2002 state reports required under Chapter II@.01 to assess whether future changes to the V.p. interim guidance document and Satisfactory Compliance are needed.

- Recommended the following document be accepted as interim guidance to the states for V.p. illness control.

  Interim Guidance for Control of V. parahaemolyticus

  A. Contingency Plan.
  (1) If the waters of a state have been confirmed as an original source of oysters associated with two or more confirmed *V. parahaemolyticus* illnesses annually in the most recent three years (excluding years when growing areas were closed at least half of the period from June through September), or with an outbreak in the last three years, the Authority should develop and adopt a *V. parahaemolyticus* contingency plan.
  (2) The plan should define the administrative procedures and resources necessary to accomplish the following:
  (a) Identify and define growing areas in the state affected by *V. parahaemolyticus* based on hydrographic and geological parameters and other considerations relevant to control of a naturally occurring pathogen;
  (b) Conduct an oyster meat sampling and assay program in those areas which have been associated with a *V. parahaemolyticus* illness;
  (c) Close affected oyster growing areas;
  (d) Prevent harvesting of affected oysters;
  (e) Provide for oyster recall if an oyster growing area is closed as a result of illness;
  (f) Notify the shellfish industry and the local health jurisdictions in the state of the potential for illnesses due to *V. parahaemolyticus* prior to historical times of onset or at a minimum of once a year;
  (g) Issue a health advisory to the public about the potential problem and advise the industry to educate wholesalers, retailers, and

consumers about the potential problem, with recommendations that oysters not be consumed raw during periods historically affected by *V. parahaemolyticus*.

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

(a) Post-harvest treatment by a process which has been demonstrated to reduce *V. parahaemolyticus* levels in oysters to non-detectable; or,

(b) Shucking and labeling "for cooking only"; or,

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

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

B. *Vibrio parahaemolyticus* Monitoring

(1) In all areas where two or more confirmed *V. parahaemolyticus* illnesses have occurred annually in the most recent three years (excluding years when growing areas were closed at least half of the period from June through September), representative samples of oysters should be collected at least monthly during harvest periods historically associated with illnesses and otherwise as determined by the Authority. All samples will be analyzed using the direct plating procedures and gene probe methods or enrichment PCR procedures for total (*tlh*+ colonies) and pathogenic (*tdh*+ colonies) *V. parahaemolyticus* *

(2) In all areas where a confirmed *V.parahaemolyticus* outbreak has occurred within the last three years, representative samples of oysters should be collected when environmental conditions are favorable for V. parahaemolyticus growth and/or periods historically associated with illness as determined by the Authority. Samples should be collected and analyzed weekly during the year of and the first year after an outbreak, and at least monthly during the second and third years after an outbreak. All samples will be analyzed using the direct plating procedures and gene probe methods or enrichment PCR procedures for total (*tlh*+ colonies) and pathogenic (*tdh*+ colonies) *V. parahaemolyticus.*

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

a. The size of the growing area;

b. The amount of oyster shellstock typically harvested from the area;

c. The sensitivity of the methodology.

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

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

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

Should any of these additional samples show 5 or more pathogenic *V. parahaemolyticus* CFU per 0.1 gram, confirmed by at least one pathogenic *V. parahaemolyticus* by replicate analysis, the area will be placed in

(1) The closed status for oyster harvest, except as allowed under A. (3).

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

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

D. Illness Outbreak.

(1) When a growing area is implicated in a *V. parahaemolyticus* illness outbreak, the Authority shall follow the procedures prescribed in Chapter II Section@.01A through E. If a growing area is closed due to an illness outbreak, the closed status should remain in effect until two consecutive representative samples of oyster meats, collected a minimum of four days apart, show no pathogenic (*tdh*+) *V. parahaemolyticus* CFU in replicate 0.1 gram portions of oyster meat and less than 5,000 total (*tlh*+) *V. parahaemolyticus* CFU per gram.

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

E. Records.

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

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

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

(3) Evaluation reports; and,

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

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

  [References for the direct plating, 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.

In the event that emerging technologies and research identify pathogenic strains other than or in addition to *tdh*+ strains, the Authority may adopt

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

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

(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* ounts 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;

(4) Evaluation reports; and,

(5) 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.

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

FDA commends the Conference for its deliberative efforts during the period from 1999 to 2001 and during the 2001 ISSC meeting to examine and modify the ICP based on states'

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

Action by 2003 Vp Subcommittee

1. Retain the current interim guidance for two more years and charge the V.p. subcommittee to identify and evaluate alternative control strategies, with a goal of making a recommendation at the 2005 ISSC biennial meeting. The FDA's V.p. risk assessment report with its models will be one important tool in this evaluation of methods to reduce the risk of illness from sporadic cases.
2. Request FDA to continue to analyze the costs and benefits associated with different illness control strategies, in additon to those contained in the 2000 Research Triangle Institute study. ISSC assistance in those analyses is important.
3. Recommend the addition of additional Gulf and East Coast state and industry personnel to the subcommittee to better balance the representation. This is very important as any new control measures recommended and approved would affect states and industry nationwide.
4. Recommend the subcommittee meet at upcoming scheduled ISSC Executive Board times and places and continue to act on these recommendations via phone calls and e-mail as needed prior to the 2005 meeting. Further recommend that FDA and ISSC help support travel and expenses of state and industry to such meetings.
5. Clarifications are recommended to the instructions for the data collection form to help ensure that all states report in a complete and standard manner. The changes will be made, reviewed, and finalized prior to the March 2004 Executive Board meeting. Further, Paul Comar will work with the Specialists and ISSC Office to complete the 2002 table and send to the subcommittee by September 15, 2003.
   Also, it was recommended to add harvest location and date to the Vp In-State Report column. This may be useful in investigations to link environmental measures with the reported illness.
6. Require states to submit their V.p. annual illness data in the approved format to their FDA specialist by March 1 of the following year (2003 data will be reported by March 1, 2004). Cases confirmed after March 1 will be submitted to the FDA specialist as completed. FDA specialists will verify that all data is received by March 1 and notify and rapidly follow-up with any state not providing the information. FDA specialists will provide the illness data for all states in their Region to the ISSC Office no later than May 1. Further, FDA will submit supplemental data of cases confirmed by the states later than May 1 to the ISSC Office as it is submitted to them by states. ISSC will compile and finalize the report no later than July 1 for review by the subcommittee.

Action By 2003 VMC

Recommended adoption of Vp Subcommittee recommendations on Proposal 98-107.

Action By 2003 Task Force I	Recommended adoption of the Vibrio Management Committee recommendations on Proposal 98-107.
Action By 2003 General Assembly	Adopted recommendations of 2003 Task Force I.
Action By USFDA	Concurred with Conference action.
Action by 2005 Vibrio Management Committee	Recommended retaining the current Vibrio parahaemolyticus Interim Control Plan Interim Guidance until the 2007 ISSC Biennial Meeting. States should continue to evaluate controls and monitoring that are effective in minimizing the occurrence of illnesses under various regional and seasonal harvesting and handling practices.
Action by 2005 Task Force I	Recommended adoption of the Vibrio Management Committee recommendations on Proposal 98-107.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force I.
Action by USFDA	FDA concurs with action to retain the *Vibrio parahaemolyticus (Vp)* Interim Control Plan without change until the 2007 ISSC Biennial Meeting. FDA's concurrence is based on action by the Conference to adopt the VMC recommendation for the *Vp* Subcommittee to identify and evaluate control strategies that could be implemented on a regional basis to reduce the risk of *Vp* illnesses from both sporadic cases and outbreaks. Under "Charge 2" of its August 2005 report the VMC identified seven steps to encompass this approach. FDA regards this seven step approach to be a critical component of the ISSC's goal to develop regional controls to reduce *Vp* illnesses nationally. In particular, measures described in Step ii and iii need immediate consideration to ensure that regional meetings are scheduled in a timely manner and that a complete and consolidated report is available to ISSC members for the 2007 biennial meeting as stipulated in Step vii. Nonetheless, FDA is disappointed that the ISSC did not take more aggressive action to address the significant public health concern of *Vp* illness, as FDA proposed in 05-214, and looks for such action at the 2007 meeting.
Action by 2007 Vibrio Management Committee	Recommended that Proposal 98-107 remain in effect until 6 months after FDA concurrence with Proposal 07-202, if adopted. If Proposal 07-202 is not adopted then Proposal 98-107 shall remain in effect. There will be no need for Proposal 98-107 if Proposal 07-202 is adopted. The Committee wants to ensure that there is no lapse in *Vp* control.
Action by 2007 Joint Session Task Force I and Task Force II	Recommended adoption of the Vibrio Management Committee recommendation on Proposal 98-107.
NOTE:	*It is procedurally improper to adopt action on Proposal 98-107 which is contingent upon an action on Proposal 07-202. To allow the General Assembly to address Proposal 98-107 in a manner consistent with the Committee recommendation, the Chairman will interpret the Committee action on Proposal 98-107 as a recommendation to retain the Vp control on an interim basis. Proposals 98-107 and 07-202 will be considered separately with Proposal 07-202 being considered first. Should the General Assembly adopt Proposal 07-202, an acceptable action on Proposal 98-107 could be for the Control Plan to be in effect until six (6) months after FDA concurs with the Summary of Actions.*
Action by 2007 General Assembly	Adopted Task Force I and II recommendation that Proposal 98-107 will continue as Interim *Vibrio parahaemolyticus* Control Plan for six (6) months after FDA concurrence of the Summary of Actions, which will allow Proposal 07-202 to become effective.

Action by	December 20, 2007
USFDA	Concurred with Conference action.

Proposal Subject	*Vibrio vulnificus* Risk Management Plan for Oysters exemption for licensed shellfish harvesters and certified dealers who produce fewer than 1.5 million raw oysters per year and/or sell all of their oysters directly to retailers.
Specific NSSP Guide Reference	Change Model Ordinance by adding Chapter II@.04 New B.
Text of Proposal/ Requested Action	Add a new section Chapter II@.04 B. Exemptions. This section does not apply to licensed shellfish harvesters and certified shellfish dealers who produce fewer than 1.5 million raw oysters per year and/or sell all of their oysters directly to retailers.
Public Health Significance	The *Vibrio vulnificus* Risk Management Plan for Oysters was introduced to the ISSC as being modeled after the U.S. Egg Safety Action Plan. The NSSP which has been in existence since 1925 is far more restrictive than FDA's October 2004 proposed rule for Egg Safety and the Prevention of Salmonella Enteritidis in Shell Eggs During Production and certain egg producers. The most recent data from the Centers for Disease Control and Prevention (CDC) show that SE illnesses have essentially remained steady for the past several years. CDC estimated that 118,000 illnesses were caused by consumption of SE-contaminated eggs in 2001. Accordingly, FDA believes that further actions to improve egg safety--building upon the safe consumer handling labeling and egg refrigeration at retail rule of 2000--are the most effective way to achieve our public health goals of a 50% reduction in overall salmonellosis and a 50% reduction in SE outbreaks by 2010. In comparison to an annual average of less than 40 *V.v.* infections to high-risk consumers that are attributed to shellfish, approximately half of those persons infected die, there are approximately 40,000 cases of salmonellosis reported in the United States annually. Because many milder S.E.cases are not diagnosed or reported, the actual number of S.E. infections may be thirty or more times greater. It is estimated that approximately 600 persons die each year with acute salmonellosis. Just as with *V.v.* infections, Salmonellosis infections are more common in the summer than winter. Young children, the elderly, and the immunocompromised are the most likely to have severe S.E. infections. Since the FDA has proposed a rule that exempts certain egg producers from the rule and the rule is far less burdensome to the egg industry than the *Vibrio vulnificus* Risk Management Plan for Oysters is on the Gulf oyster industry, an exemption should be given to oyster producers as suggested.
Cost Information (if available)	None
Action by 2005 Task Force I	Recommended referral of Proposal 05-100 to the appropriate committee as determined by the Conference Chairperson.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force I.
Action by USFDA	Concurred with Conference action.
Action by 2007 Vibrio Management Committee	Recommended adoption of Proposal 05-100 as a research need. More data is needed on the number of small harvesters and the number of small dealers; the percentage of all harvesters and dealers in the affected states that are in this category; the number of illnesses attributable to these small harvesters or dealers; other food commodities that allow exemptions from public health requirements based on the small size of the harvester/producer/processor; and the pathogens of concern with these other foods.

Action by 2007 Task Force I	Recommended adoption of the Vibrio Management Committee recommendation on Proposal 05-100.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject	Establish a *Vibrio vulnificus* Illness Review Subcommittee within the Vibrio Management Committee
Specific NSSP Guide Reference	Chapter IV. Naturally Occurring Pathogens
Text of Proposal/ Requested Action	.02 *Vibrio vulnificus* Management Plan Insert a new section (d) and re-letter the remaining sections. (d) Creation of a working group to work collectively with the FDA and CDC to review and approve all *Vibrio vulnificus* illness information prior to it being presented to the *Vibrio vulnificus* subcommittee.
Public Health Significance	With illness reduction goals in place the Conference should, through a working group, review and approve all of the *Vibrio vulnificus* illness cases that the FDA and CDC are presenting to the *Vibrio vulnificus* subcommittee.
Cost Information (if available)	None
Action by 2005 Task Force I	Recommends adoption of Proposal 05-101 as submitted.
Action by 2005 General Assembly	Recommended referral of Proposal 05-101 to the appropriate committee as determined by the Conference Chairperson.
Action by USFDA	Concurred with Conference action.
Action by *Vv* Illness Criteria Review Workgroup	Recommended adoption of Vv Illness Criteria (see below).

CRITERIA FOR INCLUDING VV CASES IN ILLNESS REDUCTION CALCULATIONS AND DETERMINING SOURCE STATES

1. Each case that is considered must be reported on a Center for Disease Control and Prevention Cholera *Vibrio* Illness Surveillance Report (COVIS) Form CDC 52.79.
2. Each case must also be listed be on the FDA (Glatzer's) database (NSSP Guide for the Control of Molluscan Shellfish Guidance Documents Chapter IV .02).
3. The ISSC committee to review reported *Vv* illnesses to determine the appropriateness of inclusion into the database used for illness reduction calculations must have access to the COVIS form for each case (patient names and other necessary information appropriately redacted). The ISSC addendum form is also provided, where available. This access to the COVIS form is critical for adequate interpretation of the data collected during the state epidemiological investigation.
4. The ISSC *Vv* Illness Review Committee will complete the following criteria table for each case. These tables serve as documentation.
5. For cases to be included in illness reduction calculations the following criteria must be met:
    - Item 1-4 and 5a must be answered yes.
    - Should the COVIS form include information that suggests other exposures that may be responsible for the Vv illness further investigation may occur. Consultation with State Shellfish Control Authorities and Epidemiologist from the state is encouraged to determine which exposure should be recorded as the cause of illness. Should oyster consumption not be determined to be the cause of illness the case will not be counted. Should there be disagreements with the inclusion of a case; the disagreeing party may request a review. The request must include a rationale for the review and should be addressed to the Executive Board Chairman.

- If 5b is no, other exposures should be considered. If no other exposures exist, case will not be counted.
- Should the only exposure be consumption of cooked oysters or unknown 5b will be checked yes.

***Vibrio vulnificus* Criteria Table**			
Case Identifier / Number	**Criteria Status Determination**		
Criteria	**Yes**	**No**	**Unknown**
1. Etiologically Confirmed	☐	☐	☐
2. Septicemia Illness	☐	☐	☐
3. Reporting State (CA, FL, LA, TX)	☐	☐	☐
4. Commercial Harvest from US Production	☐	☐	☐
5. Exposures			
a. Onset Consistent with Consumption of Oysters (within last 4 days)	☐	☐	☐
b. Raw or undercooked oysters	☐	☐	☐
6. Traceback Information			
a. Were shipping tags available or was other traceback information reported	☐	☐	☐
b. State of harvest and harvest area (s)			☐
c. Harvest date (s)			☐
d. From what State waters did the oysters originate			☐
7. Case Determination			
a. Is case included in Vv illness reduction Calculations	☐	☐	
b. Is case attributed to a single source state	☐	☐	

Instructions for completing Criteria Table:

- Check YES if Criterion is confirmed from the COVIS form or addendum.
- Check NO if Criterion is not confirmed from the COVIS form or addendum.
- Check UNKNOWN if Criterion is not clear or absent from the COVIS form or addendum.
- No Criterion can have more than one check entered.
- Each Criterion must have one check entered (YES, NO, or UNKNOWN).

These criteria tables will be used to review reported *Vv* illnesses to determine the appropriateness of inclusion into the database used for illness reduction calculations and will also be used for identifying other source states.

Action by 2007 Vibrio Management Committee

Recommended adoption of Proposal 05-101 as amended. In addition, the Vibrio Management Committee recommended appointment of a committee that will consist of three (3) epidemiologists and advisors as appropriate. The Committee will use this form to screen cases for the purposes of determining if a case is attributable to a single source state as well as whether the case is includable in the *Vv* Illness Reduction Goals. In addition, to ensure uniformity, the form shall be used for screening 2007-2008 cases and that cases from the baseline will be screened using the same form. See below.

CRITERIA FOR INCLUDING VV CASES IN ILLNESS REDUCTION CALCULATIONS AND DETERMINING SOURCE STATES

1. Each case that is considered must be reported on a Center for Disease Control and Prevention Cholera *Vibrio* Illness Surveillance Report (COVIS) Form CDC 52.79.
2. Each case must also be listed be on the FDA (Glatzer's) database (NSSP Guide for the Control of Molluscan Shellfish Guidance Documents Chapter IV .02).
3. The ISSC committee to review reported *Vv* illnesses to determine the appropriateness of inclusion into the database used for illness reduction calculations must have access to the COVIS form for each case (patient names and other necessary information appropriately redacted). The ISSC addendum form is also provided, where available. This access to the COVIS form is critical for adequate interpretation of the data collected during the state epidemiological investigation.
4. The ISSC *Vv* Illness Review Committee will complete the following criteria table for each case. These tables serve as documentation.

5. For cases to be included in illness reduction calculations the following criteria must be met:
   - Item 1-4 and 5a must be answered yes.
   - Should the COVIS form include information that suggests other exposures that may be responsible for the Vv illness further investigation may occur. Consultation with State Shellfish Control Authorities and Epidemiologist from the state is encouraged to determine which exposure should be recorded as the cause of illness. Should oyster consumption not be determined to be the cause of illness the case will not be counted. Should there be disagreements with the inclusion of a case; the disagreeing party may request a review. The request must include a rationale for the review and should be addressed to the Executive Board Chairman.
   - If 5b is no, other exposures should be considered. If no other exposures exist, case will not be counted.
   - Should the only exposure be consumption of cooked oysters or unknown 5b will be checked yes.

Vibrio vulnificus Criteria Table

Case Identifier / Number	**Criteria Status Determination**		
Criteria	**Yes**	**No**	**Unknown**
1. Etiologically Confirmed	☐	☐	☐
2. Septicemia Illness	☐	☐	☐
3. Reporting State (CA, FL, LA, TX)	☐	☐	☐
4. Commercial Harvest from US Production	☐	☐	☐
5. Exposures			
a. Onset Consistent with Consumption of Oysters ~~(within last 4 days)~~	☐	☐	☐
b. Raw or undercooked oysters	☐	☐	☐
6. Traceback Information			
a. Were shipping tags available or was other traceback information reported	☐	☐	☐
b. State of harvest and harvest area (s)			☐
c. Harvest date (s)			☐
~~d. From what State waters did the oysters originate~~			☐
7. Case Determination			
a. Is case included in Vv illness reduction Calculations	☐	☐	
b. Is case attributed to a single source state	☐	☐	

Instructions for completing Criteria Table:
- Check YES if Criterion is confirmed from the COVIS form or addendum.
- Check NO if Criterion is not confirmed from the COVIS form or addendum.
- Check UNKNOWN if Criterion is not clear or absent from the COVIS form or addendum.
- No Criterion can have more than one check entered.
- Each Criterion must have one check entered (YES, NO, or UNKNOWN).

These criteria tables will be used to review reported *Vv* illnesses to determine the appropriateness of inclusion into the database used for illness reduction calculations and will also be used for identifying other source states.

Action by 2007 Task Force I Recommended adoption of the Vibrio Management Committee recommendation on Proposal 05-101.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force I.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject	Inconsistent FDA "PEER" on Producing States
Specific NSSP Guide Reference	Model Ordinance IV, Chapter 1.01
Text of Proposal/ Requested Action	Call upon the ISSC to request the FDA to provide the Patrol Committee with the individual PEER for all producing states. Charge the Patrol Committee with making further recommendations to the FDA for standardization of Specialist training and PEER review.
Public Health Significance	N/A
Cost Information (if available)	None
Action by 2005 Task Force I	Proposal 05-102 was referred to Task Force III.
Action by 2005 Task Force III	Recommended referral of Proposal 05-102 to the NSSP Evaluation Criteria Committee to review and develop recommendations to improve consistency in evaluation of the patrol element. It is also recommended that the committee membership include members with patrol expertise.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force III.
Action by USFDA	While FDA agrees with Conference action to refer Proposal 05-102 to the NSSP Evaluation Criteria Committee for review and development of recommendations to improve consistency in evaluation of the patrol element, we request that the ISSC Executive Board consider the following alternative approach by FDA. At the 2005 Biennial Meeting FDA committed to work internally to address state program evaluation and reporting inconsistencies brought to our attention through Proposal 05-102. Shortly after the ISSC meeting we established an internal work group to develop an evaluation and reporting guidance document. This approach, which has been used successfully by FDA under the National Conference on Interstate Milk Shipments (NCIMS), will specifically outline Agency expectations relative to state evaluations, reporting, and follow-up activities. FDA Shellfish Specialists and states will use the guidance document to ensure a more standardized evaluation process. In addition to ISSC concerns relative to the patrol element, the FDA work group will develop guidance for the plant sanitation and growing area elements as well. Once FDA has completed its drafting of the guidance document it will be shared with the ISSC for review and comment prior to finalization and implementation. FDA is confident that this approach will be most effective for addressing evaluation inconsistencies.
Action by 2007 NSSP Evaluation Criteria Committee	The NSSP Evaluation Criteria Committee recommended that the following criteria be used by the USFDA in evaluating the State Patrol Element. FDA should provide a report to the ISSC regarding the effectiveness of the criteria. **<u>ISSC Patrol Evaluation Guidance</u>** I. Patrol Evaluation Criteria 1. Legal Penalties – Chapter VIII. @.01 A. (2) (c) Are there penalties in place to address illegal harvest? **Compliance Criteria:** The patrol element will be deemed in compliance if laws and regulations exist that

provide penalties for controlling harvest from harvest restricted areas. **[Critical]**

2. Notification of Harvest Restricted Areas – Chapter VIII. @.01 A. (2) (d)
Is the industry notified of the boundaries of Harvest Restricted Areas? – Chapter VIII. @.01 E. (2)
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the appropriate State Authority demonstrates that the industry has been notified of the boundaries. **[Critical]**

3. Comprehensive Listing of Harvest Restricted Areas – Chapter VIII. @ .01
Does the Patrol Agency have a comprehensive listing of Harvest Restricted areas?
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when it is determined that the State Authority has a comprehensive listing of all Harvest Restricted areas. **[Critical]**

4. Patrol Policy Document – Chapter VIII. @.01 B. (7)
   a. Does the Patrol Agency have a patrol policy document?
   Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the State Authority provides a patrol policy document. **[Key]**
   b. Is the patrol policy document complete?
   Compliance Criteria: The patrol element will be deemed in compliance with this requirement when it is determined that the patrol policy document includes all items in Chapter VIII. @.01 B. (7) listed below. **[Key]**
      (1) Citation of the law providing the legal basis for enforcement authority
      (2) Citation of the laws and regulations, including penalties, which are directly related to effective control of illegal harvest activities;
      (3) The organizational structure of the unit responsible for patrol activities, including;
         (a) Patrol unit(s) name, address, and phone number;
         (b) The roster and chain of command;
         (c) Area assignments that support the frequencies of patrol delineated in B.(2); and
         (d) A listing of specific vessels, vehicles, and equipment that support the frequencies of patrol delineated in B.(2);
      (4) Summaries of training in shellfish patrol techniques;
      (5) The methods used to inform officers of growing area classifications and status,
      and of any special activities licensed in the area;
      (6) A listing of growing areas where patrol is required;
      (7) An identification of any patrol problems;
      (8) The type and frequency of reporting by patrol personnel;
      (9) Copy of agreements with other agencies responsible for shellfish control activities; and
      (10) Citations/summons for the past year. If available, this information may include:
         (a) The number of convictions or dismissals;
         (b) Fines in dollar amount;
         (c) Equipment or property confiscations and forfeitures;
         (d) License suspensions or revocations; and
         (e) Jail sentences; and
         (f) Written warnings.
   c. Is the patrol policy document updated annually?
   Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the State Authority can determine that the patrol policy document is updated every calendar year. **[Key]**

5. Officer Training – Chapter VIII. @.01 B. (6)
Has the Patrol Agency met the NSSP patrol training requirements?
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Patrol Agency can demonstrate that all officers have met or are scheduled for the training requirements of Chapter VIII. @.01 B. (6) before assuming their patrol duties **[Key]**
   a. Basic law enforcement training, 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

6. Patrol Frequency – Chapter VIII. @.01 B. (2)

   a. Has the agency determined risk categories for all harvest restricted areas? – Chapter VIII. @.01 B. (4)?
   Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the State Authority assigns risk categories for each harvest restricted area and provides a listing of those categories. **[Critical]**
   b. Does a risk management plan exist if required? – Chapter VIII. @.01. B. (3) (c) and (d)
   Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Patrol Authority has conducted a Risk Management Plan for all areas that are not patrolled at the frequency required in Chapter VIII. @.01 B. (2). **[Critical]**
   c. Has the patrol frequency requirement been met in all areas? – Chapter VIII. @.01 B. (3) (b), (c), and (d)
   Compliance Criteria: The patrol element will be deemed in compliance as follows:
      (i) When the State Authority achieved 95-100 percent of required patrols in all harvest restricted areas the program is considered to be in conformance with NSSP patrol frequency requirements.
      (ii) When the State Authority achieved 80 – 94 percent of required patrols in all harvest restricted areas the program is considered to be in non-conformance with NSSP patrol frequency requirements. **[Key]**
      (iii) When the State Authority achieved <80 percent of required patrols in all harvest restricted areas the program is considered to be in major non-conformance with NSSP patrol frequency requirements. **[Critical]**

7. Memorandum of Understanding/Agreements – Chapter VIII. @.01 B. (5)
If enforcement of shellfish regulations is shared with another agency(s), is there a formalized MOA/MOU with the other agency(s)?
Compliance Criteria: The patrol element will be deemed in compliance when the authority has developed a Memorandum of Understanding/Agreement with all Authorities which have delegated patrol responsibilities. **[Key]**

II. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above patrol evaluation criteria.

1. The overall Patrol Program element will be assigned one of the following designations:

a. **Conformance:** The program is in compliance with all of the criteria listed above.
b. **Conformance with Deficiencies:** The program only has minor deficiencies associated with a key compliance item.
c. **Non-Conformance:** The program has:
   (1) at least one (1) critical deficiency;
   (2) two (2) or more key deficiencies; or
   (3) a repeat **[Key]** deficiency from the previous evaluation.
d. **Major Non-Conformance:** The program has multiple deficiencies, key or critical, that suggests the program has become ineffective to control harvest in harvest restricted waters.

2. During the closeout meeting for patrol evaluation, the Shellfish Specialists shall identify any patrol deficiency to the state patrol agency;
3. Within 30 days of the closeout meeting, the Shellfish Specialist shall provide a written Program Element Evaluation Report (PEER), including supporting documentation, to the State patrol agency;
4. Within 30 days of receiving the PEER, the State patrol agency shall provide a written response that indicates:
   - The item(s) was corrected;
   - A correction plan has been developed with a completion date; or,
   - The reasons why the State disagrees with FDA's finding(s).
5. Within 15 days of receipt FDA shall review the State response, and respond to the State;
6. Any CRITICAL item deficiency shall be corrected within 30 days of acceptance by FDA of the correction plan;
7. Any KEY item deficiency shall be corrected within one year of acceptance by FDA of the correction plan.
8. FDA shellfish specialists shall be responsible for monitoring the progress of state action plans.
9. Patrol Program recommendations addressing improvements not associated with the criteria included in Section I or recommendations addressing improvements beyond the requirements of the Model Ordinance should be submitted to the State Authority in correspondence separate from the Patrol Element Evaluation Report.

The NSSP Evaluation Criteria Committee will address the items listed below as they continue to develop evaluation criteria for all program elementa.

Other Chapter VIII. Requirements for Evaluation

(1) Licensing of Harvesters
(2) Vessels – Chapter VIII. .02 B.
   a. Are vessels inspected?
   b. Do boats have approved means of human sewage disposal?
(3) Shellstock Washing – Chapter VIII. .02 D.
(4) Shellstock Identification – Chapter VIII. .02 E.
(5) Temperature Control – Chapter VIII.03
(6) Harvester Education Materials

Action by 2007 Task Force I Recommended adoption of the Evaluation Criteria developed by the NSSP Evaluation Criteria Committee on Proposal 05-102 with an effective date of October 1, 2007.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force III.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject Wastewater Treatment Plant Discharges

Specific NSSP Guide Reference NSSP Guide Chapter IV. Shellstock Growing Areas
@ .03 Growing Area Classification. C. Conditional Classifications. (2) Management Plan Required. (a) (ii); and
E. Prohibited Classification. (5) Wastewater Discharges.

Text of Proposal/ Requested Action

Chapter IV. Shellstock Growing Areas @ .03 Growing Area Classification.

C. Conditional Classifications. (2) Management Plan Required.

(a) For management plans based on wastewater treatment plant function, performance standards that include:

(i) Peak effluent flow, average flow, and infiltration flow;
(ii) Bacteriological **or viral** quality of the effluent;
(iii) Physical and . . .

Chapter IV. Shellstock Growing Areas @ .03 Growing Area Classification.

E. Prohibited Classification. (5) Wastewater Discharges.

(b) The determination of the size of the area to be classified as Prohibited adjacent to each outfall shall include the following minimum criteria:

(i) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the bacteriological **or viral** quality of the effluent;
(ii) The decay rate . . .

Public Health Significance Some of the new wastewater treatment technologies, such as membrane bioreactors, produce bacteria-free effluent. However, the effluent may still contain pathogenic viruses. The Model Ordinance should be amended to acknowledge the potential impact of enteric viruses and allow the use of microorganisms other than bacteria to help determine the size of the area to be classified as prohibited adjacent to a wastewater treatment plant outfalls. For the sake of consistency, the Model Ordinance should also be amended to allow the viral quality of effluent to be used in conditionally approved area management plans.

The number of shellfish-associated illnesses caused by enteric viruses is rising, while those caused by bacteria appear to be decreasing (Richards, G.P. 1985. Outbreaks of shellfish-associated enteric illness in the U.S. J. Food Prot. 48:815-23). This and other references to virus associated illnesses in shellfish are discussed in Chapter 3 of Environmental Indicators and Shellfish Safety (Hackney and Pierson 1994).

Cost Information (if available) Not available. However, state shellfish authorities that do not have the resources to evaluate virus discharges from wastewater treatment plants are allowed to continue using (only) bacteriological quality of the effluent for these two M.O. requirements.

Action by 2005 Task Force I Recommended No Action on Proposal 05-104. Rationale - The National Shellfish Sanitation Program (NSSP) has no viral indicator standards.

Action by 2005 General Assembly Recommended referral of Proposal 05-104 to the appropriate committee as determined by the Conference Chairman.

Action by USFDA Concurred with Conference action.

Action by 2007 Growing Area Classification Committee Recommended adoption of Proposal 05-104 as submitted.

Action by 2007 Task Force I	Recommended adoption of Growing Area Classification Committee recommendation on Proposal 05-104.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject Re-Opening Criteria Based on New Indicator of Sewage-Borne Viral Pathogens

Specific NSSP Guide Reference NSSP Guide Model Ordinance Chapter IV. Shellstock Growing Areas
@ .03 Growing Area Classification A. General (5) Status of Growing Areas
(c) Reopened Status

Text of Proposal/ Requested Action

Change the word, "~~or~~" from the end of (i) to "**and**;"

Add a new (ii) as follows:

ii. **For emergency closures (not applicable for conditional closures) of harvest areas caused by the occurrence of sewage contamination events, such as sewage collection system failures, the analytical sample results shall not exceed background levels or a level of 50 male-specific coliphage per 100 grams from shellfish samples collected no sooner than 7 days after contamination has ceased and from representative locations in each growing area potentially impacted; or**

Change the existing ~~(ii)~~ to **(iii)**, and the existing ~~(iii)~~ to **(iv)**.

NOTE: An analytical method for shellfish meats and a draft laboratory checklist are separately proposed to enable the use of the new, optional re-opening criteria.

Public Health Significance

The absence of bacterial pathogens such as *Salmonella* species can be reliably determined using the coliform bacterial indicators of the National Shellfish Sanitation Program (NSSP). However, when growing areas are implicated as the source of shellfish causing illness consistent with viral etiology, the NSSP requires closure for a minimum of 21 days.[1] That is because viruses and bacteria persist differently in growing waters and in shellfish[2,3,4,5], it takes considerably longer for shellfish to eliminate viruses[2,3,4,5], and the coliform bacterial indicators of contamination currently stipulated in the NSSP do not index risks from enteric viral pathogens very well[3,6,7]. This means that if open harvest areas become unexpectedly contaminated, the likelihood exists that viral pathogens may remain viable in shellfish long after growing waters appear safe according to the NSSP bacteriological criteria. Recognizing these facts, and lacking an alternative viral indicator or any other reasonable way to judge, the NSSP has stipulated 3 weeks as the criterion for achieving safe shellfish when viral pathogens are known or suspected to be involved.[1]

The NSSP needs an alternative viral indicator. Coliform bacteria do not reliably reflect the presence or absence of viral pathogens such as Noroviruses and hepatitis A[2,3,6]. Events such as sewage spills and bypasses, sewer pipe breaks, sewage pumping and lift station leaks, and wastewater treatment plant failures can heavily contaminate shellfish areas, at least temporarily. Every harvest area even remotely impacted by sewage effluent is at risk for a lengthy closure if and when a mishap in the sewage collection system or at the sewage treatment plant occurs. Already some State Shellfish Control Authorities (SSCA) have issued 3 week emergency closures to harvest areas after power failures disrupted sewage treatment and following pipe ruptures and sewage spills. When such contamination events occur, there currently is no choice. In the absence of an alternative viral indicator, there exists no way under the NSSP to judge whether a lengthy closure can be avoided. Logically, if the NSSP had an indicator that better resembled the enteric viral pathogens of concern, then lengthy closures might be averted.

Male-specific coliphage:
Studies[4,7,8,9,10] demonstrate that a group of bacterial viruses called male-specific coliphage (MSC) appear to be good candidates as an alternative viral indicator in the NSSP. That is, MSC appear to be conservative indicators of sewage-borne enteric viral pathogens in shellfish and can be relied upon to indicate the virtual absence of these viral pathogens when derived from sewage. MSC occur universally in sewage in large numbers[6]. They only replicate in F+ (palliated) *E. coli* cells but do not reproduce below 30°C[5,,11,12]. Quantitative analysis for MSC is easy, inexpensive, and takes only 18-24 hours[13,14]. MSC persist in

waters and in shellfish much like the infectious hepatitis and Norwalk-like viruses of concern to the NSSP[2,3,4,8]. The physical size and shape of most MSC closely resemble those of these pathogens as well, and they all contain RNA as their genetic material[5]. More importantly, studies further show that when shellfish are contaminated with sewage, male-specific coliphage provide a better measure of the potential presence of enteric viruses than do coliform bacteria[4,8].

To establish an alternative safety standard for shellfish based on MSC, a quantitative relationship between measurable levels of the indicator and the absence of viral pathogens is needed. Researchers in the United Kingdom studied shellfish harvested over a 2 year period, and their findings[7] show that when mean levels of F+ RNA bacteriophage remained below 50 per 100 grams; Norwalk-like viruses were not detected in any samples. Conversely, when the mean level of MSC exceeded 125 per 100 gram, 37% of the same shellfish samples were positive for enteric viruses. These data provide a scientific basis for establishing a level of MSC, one that is readily detectable and that provides a measurable indication that the sewage contamination levels in shellfish are below the threshold for containing enteric viral pathogens. Applied as an indicator following sewage contamination events in the

U.S., if the levels of MSC are found below 50 per 100 grams throughout the harvest area, then those shellfish should be as safe from sewage-borne enteric viral pathogens as they are under normal conditions.

Limitations of MSC:
Though abundant in sewage, sewerage collections systems, and most wastewater effluents, the MSC group is not reliably detected in fresh human waste, small point sources, vessel discharges, and vomit, all of which can transmit viral pathogens.[5,10] Therefore, it is not proposed as an index of enteric viral pathogens from these sources. Nonetheless, MSC are a useful alternative indicator for signaling the presence of sewage contamination in shellfish, and provide a science-based means for determining whether shellfish areas are safe from viral pathogens, such as Noroviruses and hepatitis A viruses, following sewage contamination events.

Proposal of Male-specific Coliphage as an Indicator:
It is proposed that MSC can, at the discretion of the SSCA, be used as an alternative to the 3 week period for re-opening shellfish areas to harvest activities after a sewage contamination event causes emergency closure. This re-opening option is based upon analytical results from shellfish samples collected at least 7 days after contamination has ceased and from representative locations in the growing area, whereby no samples exceed background levels or a level of 50 MSC per 100 grams.

Benefits:
The MSC option for re-opening could decrease currently practiced closure periods by as many as 13 days.
References:
[1] NSSP Model Ordinance, Chapter II @.01 H (2).
[2] Sobsey, M.D., A.L. Davis, and V.A. Rullman. 1987. Persistence of hepatitis A virus and other viruses in depurated eastern oysters. Proc. Oceans '87, Halifax, Nova Scotia. 5:1740-1745.
[3] Richards, G.P. 1988. Microbial purification of shellfish: a review of depuration and relaying. J. Food Prot. 51:218-251.
[4] Burkhardt, W., III, S.R. Rippey, and W.D. Watkins. 1992. Depuration rates of northern quahogs, *Mercenaria mercenaria* (Linnaeus, 1758), and eastern oysters, *Crassostrea virginica* (Gmelin, 1791), in ozone- and ultraviolet light-disinfected seawater systems. J. Shellfish Res. 11:105-109.
[5] Dore, W.J. and D.N. Lees. 1995. Behavior of *Escherichia coli* and male-specific bacteriophage in environmentally contaminated bivalve molluscs before and after depuration**.** Appl. Environ. Microbiol. 61: 2830-2834.
[6] Goyal, S.M., C.P. Gerba, and G. Britton (Eds). 1987. Phage Ecology. John Wiley &

Sons, New York.
[7] Dore, W.J., K. Henshilwood, and D.N. Lees. 2000. Evaluation of F-Specific RNA Bacteriophage as a candidate human enteric virus indicator for bivalve molluscan shellfish. Appl. Environ. Microbiol. 66(4):1280-1285.
[8] Cabelli, V.J. 1988. Microbial indicator levels in shellfish, water, and sediments from the upper Narragansett Bay conditional shellfish-growing area. Report to the Narragansett Bay Project, Providence, RI.
[9] Burkhardt, W., III, W.D. Watkins, and S.R. Rippey. 1992. Seasonal effects on accumulation of microbial indicator organisms by *Mercenaria mercenaria*. Appl. Environ. Microbiol. 58:826-831.
[10] Calci, K.R., W. Burkhardt III, W.D. Watkins, and S.R. Rippey. 1998. Occurrence of male-specific bacteriophage in feral and domestic animal waste, human feces, and human-associated wastes. Appl. Environ. Microbiol. 64:5027-5029.
[11] Novotny, C. P. and K. Lavin. 1971. Some effects of temperature on the growth of F pili. J. Bacteriology. 107: 671- 682.
[12] Woody, M.A. and D.O. Cliver. 1995. Effects of temperature and host cell growth phase on replication of F-specific RNA coliphage Qβ. Appl. Environ. Microbiol. 61:1520-1526.
[13] DeBartolomeis, J. and Cabelli, V.J. 1991. Evaluation of an *Escherichia coli* host strain for enumeration of F male-specific bacteriophages. Appl. Environ. Microbiol. 57:1301-1305.
[14] Method 1601: Male-specific (F+) and Somatic Coliphage in Water by Two-step Enrichment Procedure, USEPA, EPA 821-R-01-030, April 2001.

Cost Information (if available)

The proposal provides optional re-opening criteria that are not required. Therefore, there are no added costs to State programs or industry. However, State laboratories that do not have requisite equipment already would incur such costs if the State chooses to implement the optional re-opening criteria described.

Action by 2005 Task Force I

Recommended referral of Proposal 05-105 to the appropriate committee as determined by the Conference Chairperson.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force I.

Action by USFDA

Concurred with Conference action.

Action by 2007 Growing Area Classification Committee

Recommended referral of Proposal 05-105 to the appropriate Committee as determined by the Conference Chairman. Additionally, the Committee recommended the Executive Board establish a work group to evaluate the appropriateness of MSC as a viral indicator, and to identify appropriate applications. The workgroup should report its findings at the March 2008 Board meeting.

Action by 2007 Task Force I

Recommended adoption of the Growing Area Classification Committee recommendation on Proposal 05-105.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force I.

Action by USFDA

December 20, 2007
Concurred with Conference action.

Proposal Subject Real Time PCR Methods for Determining Levels of *V. parahaemolyticus* and *V. vulnificus*

Text of Proposal/ Requested Action

Real time PCR methods provide additional options to currently used methods for identification of *V. parahaemolyticus* and *V. vulnificus* in shellfish. The use of real time PCR could reduce the time and cost of analysis while providing more reliability for detection and identification of these organisms in the environment as well as in Post Harvest Processed (PHP) products. The following methods are submitted for consideration, under Procedure XVI, by the ISSC Laboratory Methods Review Committee for identification and characterization of suspect bacterial isolates and direct analysis of APW enrichments from MPN analysis.

Real time PCR assays for total V. vulnificus (SYBR green and taqman) developed at the University of Florida (2,3,4) and at the University of Alabama-Birmingham (7).

Real time multiplex PCR assays (taqman) for total and pathogenic *V. parahaemolyticus* developed at FDA GCSL (8) and at the University of Alabama-Birmingham (1,6,9).

Real time PCR offers rapid, quantitative analysis for detection of a number of food-borne pathogens. The University of Florida and the University of Alabama at Birmingham have developed real time PCR assays for detection of the *V. vulnificus* vvh gene (2,3,4,7). The proposed methods can be used either in a Taqman or SYBR green format and could be applied in an MPN format as an alternate confirmation tool for identification of bacterial isolates in the validation and verification of PHP oysters. There is also the potential to significantly reduce the

workload and time needed for analysis by using the PCR methods directly on APW enrichments, thus eliminating the need for streaking for isolation on selective media.

FDA has developed a multiplex real time PCR assay for *V. parahaemolyticus* species identification (*tlh*), virulence characterization (*tdh* and *trh*) and an internal amplification control to detect false negatives that could result from the presence of PCRinhibitors in the sample matrix (9). Currently the ISSC uses a DNA probe colony hybridization assay for quantifying total and pathogenic *V. parahaemolyticus* in oysters at harvest for the Interim Control Plan. The same method is also used for determining levels of *V. parahaemolyticus* after PHP. While this method can be completed in 24h, variations in signal strength sometimes complicate interpretations, especially at low colony numbers where this method is normally applied. Conversion of the *V. parahaemolyticus* procedure to an MPN format would also permit utilization of the same validation and verification procedures as used with *V. vulnificus*.

The University of Alabama at Birmingham has developed a method for the detection of *V. parahaemolyticus* in oysters using multiplexed real time PCR with taqman fluorescent probes (1,6,9). The current ISSC adopted procedure uses a colorimetric DNA probe colony hybridization assay for the detection of total and pathogenic *V. parahaemolyticus* targeting *tlh* and *tdh* genes. However, with this multiplex method, targeting additional genes, it is possible to achieve a comprehensive detection of all pathogenic forms of *V. parahaemolyticus* known to date in a single reaction tube by real-time Taqman-PCR method. The proposed method developed by the University of Alabama – Birmingham uses a multiplexed Taqman PCR-based detection of total (targeting *tlh* gene), pathogenic (targeting *tdh* and *trh* genes), and pandemic strains of *V. parahaemolyticus* O3:K6 serotype (targeting ORF8 gene) in a single reaction that could potentially be applied for routine monitoring of molluscan shellfish for this pathogen. This method appears to be specific and can be used for the detection of <10 cfu *V. parahaemolyticus* following overnight enrichment in T_1N_1 broth. Further, this method has the potential to confirm MPN enrichment method of detection of this pathogen by direct amplification of the targeted genes without further culture-based confirmation. The multiplexed PCR method of detection of total and pathogenic strains including the pandemic strain of *V. parahaemolyticus* is rapid; detection can be achieved in real-time amplification of the targeted genes; specific for the targeted pathogen; and

sufficiently sensitive in enriched oyster homogenate to consider as an alternate method of detection of this important pathogen.

Each of the proposed PCR methods were designed for use on the Cepheid Smart Cycler and would require some modifications to be used on other instruments. A review package including performance attributes will be provided for each method prior to the 2005 Conference.

References:

1. Bej, A.K., D.P. Patterson, C.W. Brasher, M.C.L. Vickery, D.D. Jones, C.A. Kaysner. 1999. Detection of total and hemolysin-producing *Vibrio parahaemolyticus* in shellfish using multiplex PCR amplification of *tl*, *tdh*, and *trh*. *Journal of Microbiological Methods* 36:215-225.
2. Campbell, M.S. and A.C. Wright. 2003. Real-time PCR analysis of *Vibrio vulnificus* from oysters. Appl.Enviro.Microbiol. 69:7137-7144.
3. Calero, A. G. (Wright, A. C., advisor). 2003. Application of molecular detection methods to most probable number (MPN) enumeration of *Vibrio vulnificus* in oysters. M.S. Thesis, University of Florida http://etd.fcla.edu/UF/UFE0002740/calero_a.pdf.
4. Harwood V. J., Gandhi, J. P., and Wright, A. C. 2004. Methods for Isolation and Confirmation of *Vibrio vulnificus* from Oysters and Environmental Sources: A Review. *J. Microbiol. Methods*. 59: 301-16.
5. Mead, P.S., L. Slutsker, V.Dietz., L.F. McGaig, J.S. Bresee, C. Shapiro, P.M. Griffin, and R.V. Tauxe. 1999. Food-related illness and death in the United States. Emerg.Infect.Dis. 5:607-625.
6. Myers, M., G. Panicker, A.K. Bej. 2003. Detection of newly emerged pandemic *Vibrio parahaemolyticus* O3:K6 pathogen in pure cultures and seeded Gulf waters using PCR. *Applied and Environmental Microbiology* 69:2194-2200.
7. Panicker, G., M.L. Myers, and A.K. Bej. 2004. Rapid detection of *Vibrio vulnificus* in shellfish and Gulf of Mexico water by real-time PCR. Appl.Enviro.Microbiol. 70:498-507.
8. Vickery, M.C.L., G.M. Blackstone, J.L. Nordstrom, and A. DePaola. 2003. Detection and quantification of total and potentially virulent *Vibrio parahaemolyticus* using a 4-channel multiplex real-time PCR targeting the *tl, tdh*, and *trh* genes and a novel PCR internal control. ASM Annual Meeting, Washington, DC, May 18-22, 2003.
9. Ward, L.N. and A. K. Bej. Detection of total and pathogenic *V. parahaemolyticus* in shellfish using multiplexed real-time pCR with Taqman fluorescent probes. (In preparation).

Public Health Significance

V. parahaemolyticus is the leading cause of bacterial gastroenteritis and *V. vulnificus* is the leading cause of death associated with seafood consumption in the US (5). ISSC has an ICP for Vp and has developed validation and verification of PHP for both organisms. Real time PCR is faster and more reliable than current methods but is not yet approved by ISSC. Approval of one or more of the proposed real time PCR methods would provide a faster and more reliable means of enumerating *V. vulnificus* and *V. parahaemolyticus* while offering an equivalent level of public health protection for consumers of raw molluscan shellfish.

Cost Information (if available)

None

Action by 2005 Laboratory Methods Review Committee

Recommended Proposal 05-107 be referred to the appropriate committtee as determined by the Conference Chairman, with further direction to the Executive Office to organize a meeting of the Laboratory Methods Committee within six (6) months of the conclusion of this Biennial Meeting.

Action by 2005 Task Force I

Recommended adoption of the Laboratory Methods Review Committee recommendation on Proposal 05-107

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force I.

Action by USFDA

Concurred with Conference action.

Action by 2007 Laboratory Methods Review Committee

Recommended no action on Proposal 05-107. Rationale – Inadequate data submission. The methods proposed in Proposal 05-107 would be very useful to the NSSP. The submitter will be requested to provide additional data to the Executive Office for approval consistent with Procedure XVI.

Action by 2007 Task Force I

Recommended adoption of Laboratory Methods Review Committee recommendation of no action on Proposal 05-107.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force I.

Action by USFDA

December 20, 2007
Concurred with Conference action with the following comments and recommendations for ISSC consideration.

The Conference has made considerable progress in its efforts to recognize new and developing analytical methods for the detection of indicators, pathogens, and marine toxins. Much credit goes to the Laboratory Methods Review Committee and its leadership for ensuring a scientifically defensible process for adopting analytical methods under the NSSP.

At the 2007 meeting numerous analytical methods were proposed for ISSC adoption. However, many of these methods were lacking the validation and associated data needed by the Laboratory Methods Review Committee to make a final determination regarding their efficacy for use in the NSSP. As a result the General Assembly voted "No Action" on analytical method Proposals 05-107, 05-108, 05-109, 05-111, 05-113, and 05-114. It is FDA's understanding that the intent of the "No Action" vote was not to remove these Proposals from ISSC deliberation as "No Action" normally suggests, but rather to maintain them before the Conference pending submission of additional data for further consideration. The Voting Delegates, by requesting the Proposal submitters provide additional data to the Executive Office for methods approval consistent with Procedure XVI, clearly recognized the importance and utility of these methods and intended to maintain them before the Conference for possible adoption following additional data submission. FDA requests that the ISSC Executive Board confirm FDA's understanding of this outcome. FDA fully supports such a Conference action and encourages the Executive Office to pursue submission of additional data as necessary to move forward with acceptance of these methods.

Proposal Subject	Real Time PCR Method for Determining Levels of *V. parahaemolyticus*
Text of Proposal/ Requested Action	With the advent of real-time PCR assays, it is now possible to conduct more rapid and accurate screening for *Vibrio parahaemolyticus* within 24 hour time frame. Real-time PCR assays are generally less labor intensive and less time consuming then the traditional biochemical assays that have been used to detect total *Vibrio parahaemolyticus.* The State of Washington Department of Health has developed a multiplex real time PCR assay for the detection of *Vibrio parahaemolyticus* (VP) using the Applied Biosystem Taqman Platform. This assay targets two species identification markers (*tlh* and *gyrase B*) for total VP, the virulence marker (*tdh*), and a *16S* target that is specific for five species (V. *parahaemolyticus*, V. *alginolyticus*, V. *furnissii*, V. *harveyi*, V. *fluvialis*) within the genus.
Public Health Significance	*Vibrio parahaemolyticus* continues to cause food borne outbreaks globally due to the consumption of raw or undercooked oysters[i, ii]. Current molecular methods can of differentiate between pathogenic (tlh+, tdh+) and non-pathogenic (tlh+, tdh-) organisms but real-time PCR procedures are not fully approved by the ISSC. This real-time PCR assay, if approved, would improve the turn around time for results for public health protection and seafood safety. [i]Wong, H.C., S. H. Liu, et al. (2000). Characteristics of Vibrio parahaemolyticus O3:K6 from Asia." Appl Environ Microbiol **66**(9): 3981-6. [ii]DePaola, A., C. A. Kaysner, et al. (2000). "Environmental investigations of Vibrio parahaemolyticus in oysers after outbreaks in Washington, Texas, and New York (1997 and 1998)." Appl Environ Microbiol **66**(11): 4649-54.
Cost Information (if available)	None
Action by 2005 Laboratory Methods Review Committee	Recommended Proposal 05-108 be referred to the appropriate committtee as determined by the Conference Chairman, with further direction to the Executive Office to organize a meeting of the Laboratory Methods Committee within six (6) months of the conclusion of this Biennial Meeting.
Action by 2005 Task Force I	Recommended adoption of the Lab Methods Review Committee recommendation on Proposal 05-108.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force I.
Action by USFDA	Concurred with Conference action.
Action by 2007 Laboratory Methods Review Committee	Recommended no action on Proposal 05-108. Rationale – Inadequate data submission. The methods proposed in Proposal 05-108 would be very useful to the NSSP. The submitter will be requested to provide additional data to the Executive Office for approval consistent with Procedure XVI.
Action by 2007 Task Force I	Recommended referral of Proposal 05-108 to an appropriate committee as determined by the Conference Chairman.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.
Action by USFDA	December 20, 2007 Concurred with Conference action with the following comments and recommendations for ISSC consideration.

The Conference has made considerable progress in its efforts to recognize new and developing analytical methods for the detection of indicators, pathogens, and marine toxins. Much credit goes to the Laboratory Methods Review Committee and its leadership for ensuring a scientifically defensible process for adopting analytical methods under the NSSP.

At the 2007 meeting numerous analytical methods were proposed for ISSC adoption. However, many of these methods were lacking the validation and associated data needed by the Laboratory Methods Review Committee to make a final determination regarding their efficacy for use in the NSSP. As a result the General Assembly voted "No Action" on analytical method Proposals 05-107, 05-108, 05-109, 05-111, 05-113, and 05-114. It is FDA's understanding that the intent of the "No Action" vote was not to remove these Proposals from ISSC deliberation as "No Action" normally suggests, but rather to maintain them before the Conference pending submission of additional data for further consideration. The Voting Delegates, by requesting the Proposal submitters provide additional data to the Executive Office for methods approval consistent with Procedure XVI, clearly recognized the importance and utility of these methods and intended to maintain them before the Conference for possible adoption following additional data submission. FDA requests that the ISSC Executive Board confirm FDA's understanding of this outcome. FDA fully supports such a Conference action and encourages the Executive Office to pursue submission of additional data as necessary to move forward with acceptance of these methods.

Proposal Subject Rapid Screening Method for ASP

Specific NSSP Guide Reference NSSP Guidance Documents, Chapter II

CONSTITUTION BY-LAWS and PROCEDURES of the INTERSTATE SHELLFISH SANITATION CONFERENCE
PROCEDURE XVI. PROCEDURE FOR ACCEPTANCE AND APPROVAL OF ANALYTICAL METHODS FOR THE NSSP
And:
NATIONAL SHELLFISH SANITATION PROGRAM
2003 MODEL ORDINANCE

III. LABORATORY
@.02 Methods.

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 *Karemia breve* toxins.

Text of Proposal/ Requested Action For many years, there has been an expression of need by regulatory agencies and industry to develop a test to monitor ASP levels with precision and accuracy.

The method developed by Jellett Rapid Testing Ltd has been presented to the ISSC and other regulatory bodies over the past several years. In cooperation with individuals, governments and those organizations, the analytical method has been refined and improved. The Rapid Test kits have been tested in several states and foreign countries, and JRT has some internal papers, including one done by Mike Quilliam, that are now in preparation and should be submitted/in press by the time of the ISSC meeting. There are some talks coming up ICMSS, CWHMA where the ASP test will be presented, and from which there will be proceedings later this year or early next year.

It should be noted that this test is built on the same platform by the same company, and uses a similar format to the Jellett Rapid Test for PSP that is already accepted by the ISSC.

The CONSTITUTION BY-LAWS and PROCEDURES of the INTERSTATE SHELLFISH SANITATION CONFERENCE allow the ISSC, through the Laboratory Methods Review Committee, to accept analytical methods that are sufficiently validated but are not AOAC or APHA methods. This is defined in the Constitution, PROCEDURE XVI. PROCEDURE FOR ACCEPTANCE AND APPROVAL OF ANALYTICAL METHODS FOR THE NSSP. Two possible reasons for considering a method are found in Subdivisions i and ii.

Subdivision i. Meets immediate or continuing need;
Subdivision ii. Improves analytical capability under the NSSP as an alternative to other approved or accepted method(s)

Currently, Table 4 of Chapter II.10 allows the use of any "Peer recognized HPLC Methods with or without clean up." for ASP analysis. The need for standard methods has been expressed by regulatory agencies, governmental organizations and industry for many years. The Jellett Rapid Test for ASP has been validated over a wide geographic area to demonstrate its simplicity, reliability, precision and accuracy. As a result of ongoing improvements and demonstrations of efficacy, and the need that has been expressed by industry and state agencies, the Jellett Rapid Test for ASP is presented as a screening method for the NSSP as a Type III or Type IV method.

Please see attached additional information.

Suggested wording:

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 Karemia breve toxins.
   (3) The Jellett Rapid Test for ASP may be used as a screening method for ASP toxins by regulatory and industry laboratories.

Public Health Significance

Currently, only data from certified laboratories conducting ASP analyses using any "Peer recognized HPLC Methods with or without clean up" are considered reliable and acceptable. Because of many significant constraints, in practical terms, this means that only state laboratories (in the US, governmental laboratories in other countries) can provide acceptable data at this time using methods not specifically defined by the ISSC. Acceptance of the Jellett Rapid Test for ASP would allow harvesters, processors, and regulatory agencies to screen for ASP with an accepted standardized method that provides valid useable data.

The Jellett Rapid Test for ASP was developed over several years in answer to the oft-stated need for a rapid, reliable, non-animal analytical method. The Jellett Rapid Test for ASP is not meant to be a definitive "Standard Method", but rather to augment "Peer recognized HPLC Methods…" by providing an additional tool that is currently not available.

Possible applications for The Jellett Rapid Test for ASP include:

- as a method of screening out negative samples in shellfish regulatory labs;
- as a harvest management tool at aquaculture facilities or in wild shellfish harvest areas (especially nearshore areas) to determine if shellfish are free of ASP and safe to harvest; as a quality control tool for shellfish processing plants, distributors and wholesalers to ensure incoming shellfish are free of ASP toxins before processing or further distribution (this test could become part of the plant's HACCP program);
- as a tool for water classification for biotoxins;
- to assist in site selection for aquaculture activity;
- as a screening tool for toxic phytoplankton in seawater to provide an early warning for shellfish growers; and
- as a research tool for broad scale ecological monitoring.

The rationale for using the Jellett Rapid Test for ASP is that the kits provide a cost-effective screen (especially in low-volume laboratories) for ASP that can provide a standardized test for screening and substantially reduce the cost of analyses. The same extract is used for the Rapid Test that is used for HPLC, so the Jellett Rapid Method extract can easily be sent for a confirmation in another lab if necessary. As a harvest management tool, the use of the Jellett Rapid Test for ASP will supplement regulatory agency efforts and help prevent the harvest of contaminated product. Having the ability to conduct tests using an accepted standardized method will allow those processors who choose to use this test to demonstrate that they are truly controlling for ASP hazards in the harvested shellfish.

The Jellett Rapid Test for ASP could be used to build long-term databases on a broader scale than a regulatory lab can afford and, by using a standardized method, will provide consistent results. These databases could be supplemented with industry testing in areas where there is no testing currently. This would extend, augment and strengthen the current food safety system broadening and refining the food safety net by increasing the number of testing sites and generating long term data in more areas.

HPLC is expensive and highly technical, requiring a large capital and personnel investment. HPLC machines, like other analytical equipment, also break down regularly. Therefore there needs to be backup HPLC machines OR other methods available.

A simple, rapid, effective, reliable test, available to all harvesters, regulators, and processors,

would increase the monitoring and reduce the chance that shellfish containing ASP toxins above the regulatory limit would be harvested or marketed.

Cost Information (if available)

Each test kit costs $20 (**€18)**. It has been reported that each analysis using the HPLC costs approximately $140 per test. History has shown that large numbers of ASP monitoring samples are negative. The costs cited do not take into account the costs associated emergency closures, recalls, or providing medical care to those affected by toxic shellfish. Also, some states are interested in the test because they do not have to invest in HPLC technology if they have the Rapid Test as an alternative.

Action by 2005 Laboratory Methods Review Committee

Recommended that Proposal 05-109 be referred to the appropriate committee as determined by the Conference Chairman.

Action by 2005 Task Force I

Recommended adoption of the Laboratory Methods Review Committee recommendation on Proposal 05-109.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force I.

Action by USFDA

Concurred with Conference action.

Action by 2007 Laboratory Methods Review Committee

Recommended no action on Proposal 05-109. Rationale – Method needs modification because of changes to the antibody. In addition, there is insufficient data to demonstrate acceptability to the Conference. The submitter is requested to provide data to the Executive Office for approval.

Action by 2007 Task Force I

Recommended referral of Proposal 05-109 to an appropriate committee as determined by the Conference Chairman.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force I.

Action by USFDA

December 20, 2007
Concurred with Conference action with the following comments and recommendations for ISSC consideration.

The Conference has made considerable progress in its efforts to recognize new and developing analytical methods for the detection of indicators, pathogens, and marine toxins. Much credit goes to the Laboratory Methods Review Committee and its leadership for ensuring a scientifically defensible process for adopting analytical methods under the NSSP.

At the 2007 meeting numerous analytical methods were proposed for ISSC adoption. However, many of these methods were lacking the validation and associated data needed by the Laboratory Methods Review Committee to make a final determination regarding their efficacy for use in the NSSP. As a result the General Assembly voted "No Action" on analytical method Proposals 05-107, 05-108, 05-109, 05-111, 05-113, and 05-114. It is FDA's understanding that the intent of the "No Action" vote was not to remove these Proposals from ISSC deliberation as "No Action" normally suggests, but rather to maintain them before the Conference pending submission of additional data for further consideration. The Voting Delegates, by requesting the Proposal submitters provide additional data to the Executive Office for methods approval consistent with Procedure XVI, clearly recognized the importance and utility of these methods and intended to maintain them before the Conference for possible adoption following additional data submission. FDA requests that the ISSC Executive Board confirm FDA's understanding of this outcome. FDA fully supports such a Conference action and encourages the Executive Office to pursue submission of additional data as necessary to move forward with acceptance of these methods.

Laycock, Maurice V., Joanne F. Jellett, W. Hywel Morgan. 2004. Characteristics and Applications of the Jellett Rapid Tests for PSP and ASP. *In:* Holland, Patrick and Michael A. Quilliam, (Eds.) Proceedings 2nd HABTech 2003 Workshop, Nelson, New Zealand. Nov 26-30, 2003.

Characteristics and Applications of the Jellett Rapid Tests for PSP and ASP

Maurice V. Laycock, Joanne F. Jellett*, W. Hywel Morgan
Jellett Rapid Testing Ltd, Chester Basin, Nova Scotia, Canada

Abstract
The Jellett Rapid Tests for PSP and ASP toxins were tested with calibration standards to investigate sensitivities to individual toxins spiked into mussel extracts at concentrations around the regulatory limits. PSP test strips showed their highest sensitivity to saxitoxin (Stx) and gonyautoxins-2 and -3 (Gtx2/3) and were least sensitive to Gtx1/4 and neosaxitoxin (Neo). Sensitivities were intermediate to mixtures of Stx with Neo and to Gtx1/4 with Gtx2/3, which are more typical of naturally occurring PSP toxin profiles. All of the PSP toxins that were tested gave positive responses at or below the regulatory limit. The ASP test detected domoic acid at around 5 $\mu g.g^{-1}$, well below the regulatory limit. Uses for the Rapid Tests for screening in regulatory laboratories and testing in field conditions for PSP toxins and domoic acid in shellfish and phytoplankton are discussed.

Key words
Paralytic shellfish poisoning (PSP), amnesic shellfish poisoning (ASP), lateral flow immunochromatography (LFI), saxitoxin, domoic acid, test kits.

Introduction

Shellfish toxicity and food safety have been monitored successfully by mouse bioassays (AOAC, 1999) for more than fifty years. The current trend toward replacement methods has resulted in the development of more sophisticated methods such as liquid chromatography with mass spectrometric or fluorescence detectors. They not only provide a higher degree of accuracy and sensitivity but individual toxins can be identified in complex mixtures. However, aside from the high capital cost of the instruments, their maintenance and requirement for a well equipped laboratory and trained staff, sample clean up has been an on going problem. Antibody methods, such as ELISA require little sample preparation and equipment is relatively inexpensive. However, ELISA methods are slow and cannot be easily carried out outside the laboratory, or in unskilled hands.

Lateral flow immunochromatography (LFI) is an alternative format for antibody detection of shellfish toxins. The self-contained simplicity and reliability of these test strips has found applications in many areas such as screening for illicit drugs and home pregnancy testing. They are essentially yes/no tests engineered to indicate a specific analyte concentration. We have developed LFI tests for PSP and ASP toxins and one for DSP toxins is being developed. The absence of a coloured test line on the strip indicates that the sample contained the toxin at a concentration around half the regulatory limit. Because most samples tested by regulatory agencies are negative, LFI tests can be used to screen a large number of samples quickly and only those with toxin concentrations above or approaching regulatory limits need to be tested further, thereby speeding through-put, reducing costs and the number of mice used in bioassays. In addition to growing acceptance of the PSP and ASP test strips by regulatory agencies, they are also being tested in isolated communities, by shellfish farmers and for phytoplankton monitoring.

The Jellett Rapid Test for PSP (formerly, MIST Alert) is based on antibodies that recognise all of the saxitoxin (Stx) and neosaxitoxin (Neo) analogues, but not equally. Our first publication (Laycock et al., 2001) describing the characteristics of the PSP test showed relative sensitivities to a range of purified PSP toxins. All fell within the regulatory limit. Sensitivities to Neo and its 11-sulphated gonyautoxin analogues (Gtx1/4) were about five fold less than to Stx and its analogues. Detection levels for the sulfamate analogues of Stx (C1/2 and B1) fell between the two (Gtx2/3 and Gtx1/4) extremes. The PSP test has been subjected to extensive field trials (Jellett et al., 2002; MacIntosh et al., 2002) which showed no false negatives in over two thousand samples. Extracts containing only Gtx1/4 or Neo are rare but if encountered at concentrations close to the regulatory limit, would they fall within the detection limit of the test? We have examined this question with spiked samples containing only Gtx1/4 and Neo and the effect of the presence of other PSP toxins in the profile.

The ASP test has also been subjected to independent testing and shown to be easy to use and reliable (MacIntosh and Smith, 2002). The detection limits of the ASP test were examined in a similar manner to the PSP test with a calibration standard and the data are presented.

Materials and Methods

The LFI test strips are manufactured by Jellett Rapid Testing Ltd. with stringent quality control to ensure reproducibility. Test strips are contained in plastic cassettes with a sample well and a window. A test line (T-line) and a control line (C-line) can be seen in the window about 15 min after applying a sample. In the absence of toxin, both lines can be seen. For samples containing toxin in concentrations greater than the regulatory limit, no T-line appears, and only the C-line is seen. No clean-up is necessary but extracts must be diluted to 20% (1:5) for PSP and to 10% (1:10) for ASP with a buffer solution supplied with the tests to ensure the proper solution conditions for the test to function. This is indicated by the formation of a visible C-line.

Non-toxic mussels were homogenised and extracted by the AOAC extraction procedures for PSP with 0.1 N HCl (AOAC, 1999). Samples of this control extract were spiked with purified PSP toxin calibration solutions obtained from the National Research Council of Canada. The total molar concentration of separate or mixed toxins was the same for each spiked extract. A series of dilutions was prepared from the highest concentration of 3200 nM with control extract. The prepared samples were then diluted 1:5 with buffer solution. Test units were removed from their sealed pouches and 100 µl of the buffered samples was applied to each sample well. After 15 min, test and control lines were fully developed and the results digitised using a conventional computer scanner. T-line intensities were measured using Softmax Pro software (Molecular Devices, CA). Five replicate measurements were taken and each converted to percent of the maximum line intensity at zero toxin concentration.

For ASP, a non-toxic mussel homogenate was extracted into four volumes (1:5) of 50% aqueous methanol. A sample of this methanolic extract was spiked with a calibration standard of domoic acid to equivalent of 20 $\mu g.g^{-1}$ tissue and a dilution series was prepared by serial dilution using the non-toxic, control extract. A running buffer solution designed for the ASP test was then added (1:10) to the different concentrations in the series. Samples (100 µl) at each concentration were applied to the test strips and the results recorded by scanning.

Results

PSP

The five values for T-line colour were plotted against toxin concentration in spiked extracts before dilution 1:5 with the running buffer. The slopes and positions of the different curves reflect the proportions of toxins recognised differently by the antibodies. Plots of T-line intensities against toxin concentrations showed a lower sensitivity to Neo than to Stx, so that a weak T-line persisted with samples containing Neo alone at 1300 nM. This is approximately at the PSP regulatory limit of 80 µg per 100 g tissue (calculated for Stx as the free base) in an AOAC extract. The test showed the highest sensitivity to Stx and the plot from samples containing only Stx is shown together with that for Neo in Fig. 1A to illustrate the range of sensitivities.

Data for the sensitivities to Gtx2/3 and Gtx1/4 are plotted together in Fig. 1B. The PSP test had the lowest sensitivity to Gtx1/4. At the regulatory limit for Stx (1300 nM), T-line intensity was reduced to about 60% of that obtained with a non-toxic sample and 90% at twice that concentration. At 1300 nM Gtx2/3 reduced the T-line by 95%. Responses to equimolar mixtures of Stx with Neo and Gtx1/4 with Gtx2/3 are shown in Fig. 1C. Both curves indicate 90% reduction of T-line intensity for total toxin concentrations at the regulatory limit. A reduction of T-line intensity of 50% is interpreted as positive. Toxin concentrations at 50% decrease in T-line intensity are shown on the graphs by narrow vertical lines.

ASP

The sensitivity of the ASP test was well within the regulatory limit of 20 $\mu g.g^{-1}$. Figure 2 shows that in samples containing 5 $\mu g.g^{-1}$ in a methanol extract, the T-line intensity was 80% reduced, and 90% at 10 $\mu g.g^{-1}$, from that obtained with non-toxic extracts. The domoic acid concentration in methanolic extracts that resulted in a 50% decrease in T-line intensity, which is interpreted as positive, was 2.5 $\mu g.g^{-1}$. Spiked AOAC extracts were also tested. The tissue concentration in an AOAC extract is 2.5 times that in a methanolic extract and the 50% T-line was around 1.0 $\mu g.g^{-1}$. The ASP test was found to be more susceptible to a matrix effect with higher concentrations of tissue causing a decrease in C and T-line intensities. This difference between extraction methods was common with 1:5 dilutions in running buffer but not at with 1:10 dilutions. The latter dilution therefore was adopted for the ASP test.

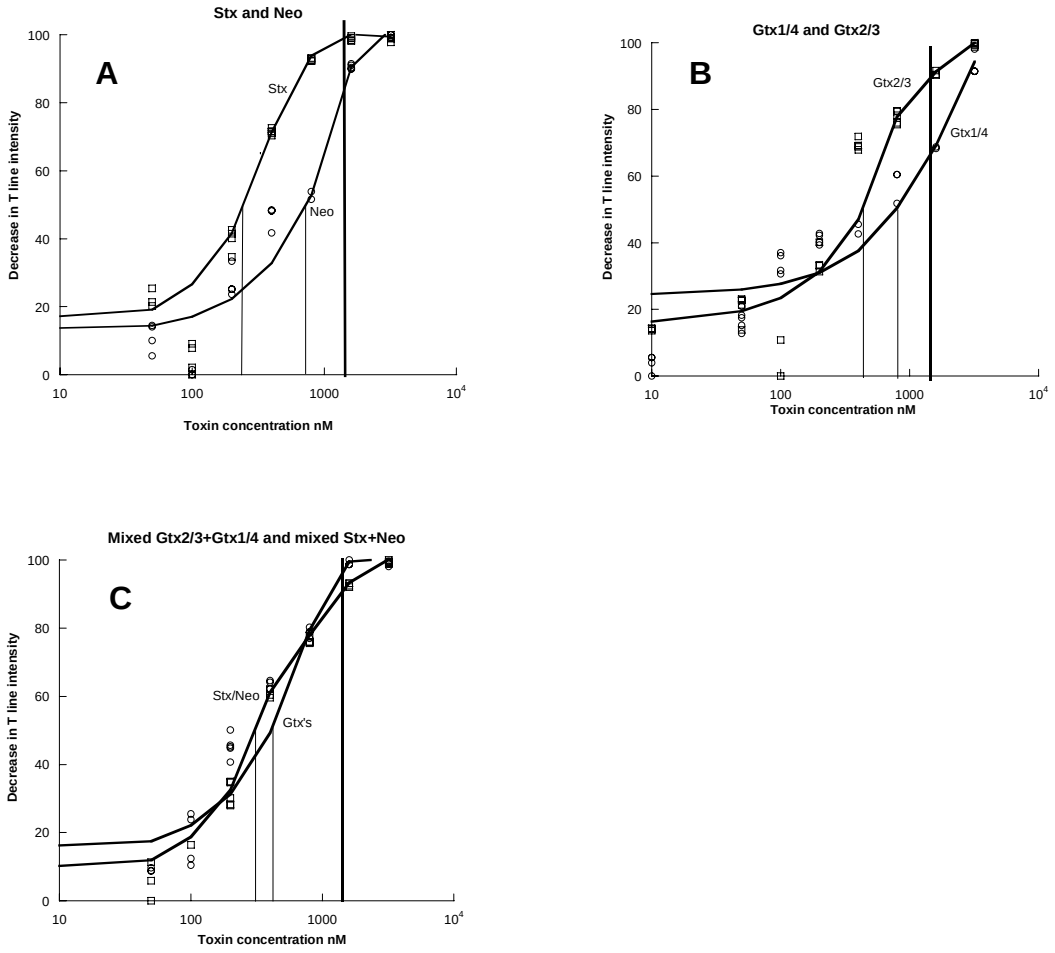


Figure 1.
Non-toxic mussel homogenate was extracted by the AOAC method into an equal volume of 0.1 M HCl. Samples were spiked with NRC certified toxin standards to 3200 nM. Dilution series were prepared by mixing with non-toxic extract. The extracts containing different toxin concentrations were then mixed 1:5 with PSP running buffer solution and 100 µl applied to the test strips. After 20 min. T line intensities were measured by scanning into a computer and digitising (Softmax, Molecular devices, CA). The regulatory limit of 80 µg/100 g is indicated by the heavy vertical line and fine vertical lines indicate toxin concentrations at 50% decrease in T-line intensity.

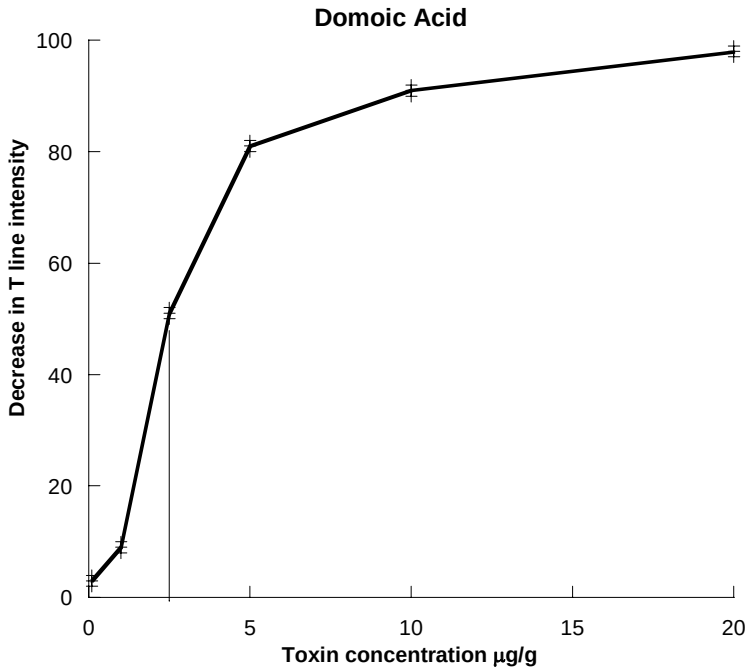


Figure 2.
Non-toxic mussel homogenate was extracted into four volumes of 50% methanol a sample spiked with domoic acid to 20 µg/g homogenate. Serial dilutions were made with non-toxic extract and mixed with ASP running buffer solution. A sample (100 µl) of each solution was applied to each test strip. Line intensities were measured as described in the legend to Fig. 1. The regulatory limit for ASP is 20 µg/g. The vertical line indicates the toxin concentration at 50% decrease in T-line intensity.

Discussion
The Jellett Rapid Tests for PSP and ASP are designed to indicate the presence of toxins in shellfish and phytoplankton at concentrations around half the regulatory limit for Stx and domoic acid in shellfish. Experiments with purified PSP toxins show that responses to different analogues are not equal (Laycock, et al., 2001). Also, at toxin concentrations around the regulatory limit T-line intensities may be intermediate. At lower and higher concentrations the T-line is either equal in intensity to the control line or it is absent. The recommended way to interpret tests that show T-lines of intermediate intensity is by comparison with the C line. In the absence of toxin T and C-line intensities are equal. If the T-line appears to be 50% or less intense than the C-line the test is considered to be positive, indicating that the extract contained significant amounts of the toxin. If no T-line appears, toxin concentrations may be well above the regulatory limit. In this case, concentrations may be estimated by making serial dilutions with non-toxic extract. The recommended dilution with running buffer solution (1:5 for PSP and 1:10 for ASP) should be maintained and serial dilutions are prepared with non-toxic extract. A lower ratio of buffer to extract will increase the concentration of toxin in the sample but, depending on the extracted tissue, a matrix effect may be seen by diminished control line intensity.

The PSP test is least sensitive to Gtx1/4 and Neo. However, these analogues rarely occur in the absence of Stx, and more especially Gtx2/3, which is the most common of all the PSP toxins found in shellfish. The Rapid Test for PSP has shown the highest sensitivity for both of these toxins. Experiments to examine test responses to samples containing toxin profiles such as those for which the test is least sensitive were possible only with samples spiked with purified toxins of known concentrations. The results presented here show that only for extracts containing Gtx1/4 alone, at concentrations close to the regulatory limit, the test response may be intermediate between clearly positive or negative. The effect of mixed toxins increased sensitivity to samples containing Gtx1/4 and Neo. This is

illustrated in Fig. 3 in which equimolar concentrations of Gtx2/3 with Gtx1/4 and Stx with Neo resulted in responses well within the regulatory limit. In an earlier publication (Laycock et al., 2001) the test was called MIST Alert but is now the Jellett Rapid Test for PSP. It should be noted that the earlier data were presented as toxin concentration before dilution (1:5) with running buffer solution. Current test strips are similar to those produced earlier with comparable sensitivities to the different PSP toxin analogues. Sensitivities to the sulfamate toxins C1/2 and B1 are not presented here but as shown earlier they fall between Neo and Stx. The decarbamoyl analogues of Stx have also been tested and responses were very similar to their corresponding carbamates.

Both the PSP and ASP tests have been subjected to extensive independent field trials (Jellett et al., 2002; MacIntosh et al., 2002; MacIntosh and Smith, 2002) with naturally occurring toxic shellfish. Based on the encouraging results of these trials the Rapid Tests for shellfish toxins are being adopted for routine use in monitoring programs. The test strips provide a reliable screening tool for regulatory agencies, costing significantly less than alternatives for shellfish monitoring, such as the mouse bioassay or HPLC. Screening out the high proportion of negative samples to be tested further not only reduces the overall cost it also increases the rate at which samples can be monitored. In addition to testing for toxins in shellfish the Rapid Tests can be used to test for toxicity in samples from plankton nets. *Alexandrium* and *Pseudo-nitzschia* cells were easily extracted into 0.1 M acetic acid without mechanical disruption providing a simple and sensitive field method for phytoplankton monitoring (Rafuse et al., 2002).

The Rapid Tests are essentially self-contained and extracts can be tested without laboratory equipment, allowing their use at shellfish farms, on boats, beaches or camps. However, for use in field conditions the preparation of shellfish extracts is more difficult than in a laboratory. Ineffective extraction could lead to false negatives, especially for samples with toxin concentrations close to the test strip detection limit. Kits are supplied with detailed instructions about making extracts from shellfish or plankton as extraction is a crucial part of the test procedure.

Acknowledgements
The authors thank Dr. Michael Quilliam for the toxin standards used in this study and for his continuing support. Dorothy Easy and Mary Anne Donovan provided technical help.

References

Association of Official Analytical Chemists International, 1999. Official Method 959.08-paralytic shellfish poison, biological method, 17th ed., Official Methods of Analysis, vol.1 Arlington, VA.

Jellett, J.F., Roberts, R.L., Laycock, M.V., Quilliam, M.A., Barrett, R.E., 2002. Detection of paralytic shellfish poisoning (PSP) toxins using MIST Alert™, a new rapid test in parallel with the regulatory AOAC® mouse bioassay. Toxicon. 40, 1407-1425.

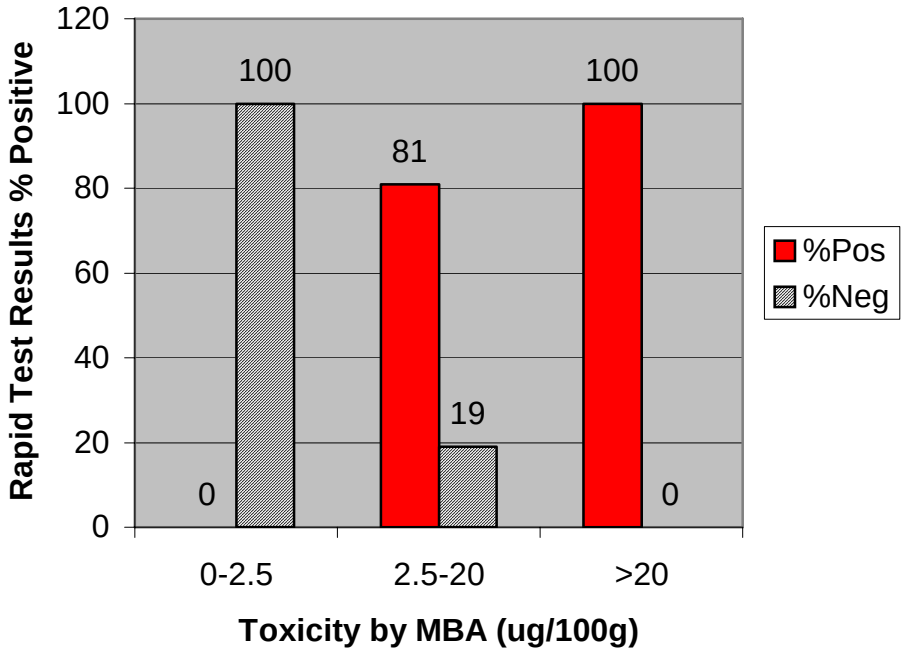
Laycock, M.V., Jellett, J.F., Belland, E.R., Bishop, P.C., Theriault, B.L., Russell-Tattrie, A.L., Quilliam, M.A., Cembella, A.D., Richards, R.C., 2001. MIST Alert™: A Rapid Assay for Paralytic Shellfish Poisoning Toxins. Proceedings of the 9th International Conference on Harmful Algal Blooms, Hobart, Australia, 7-11 February 2000, Hallegraeff, G.M. Blackburn, S.I. Bolch, L.J., Lewis, R.J. (Eds) IOC of UNESCO, 2001.

Mackintosh, F.H., Gallacher, S., Shanks A.M., Smith, E.A., 2002. Assessment of MIST Alert™, a Commercial Qualitative Assay for Detection of Paralytic Shellfish Poisoning Toxins in Bivalve Molluscs. Journal of AOAC International. 85, 632-641.

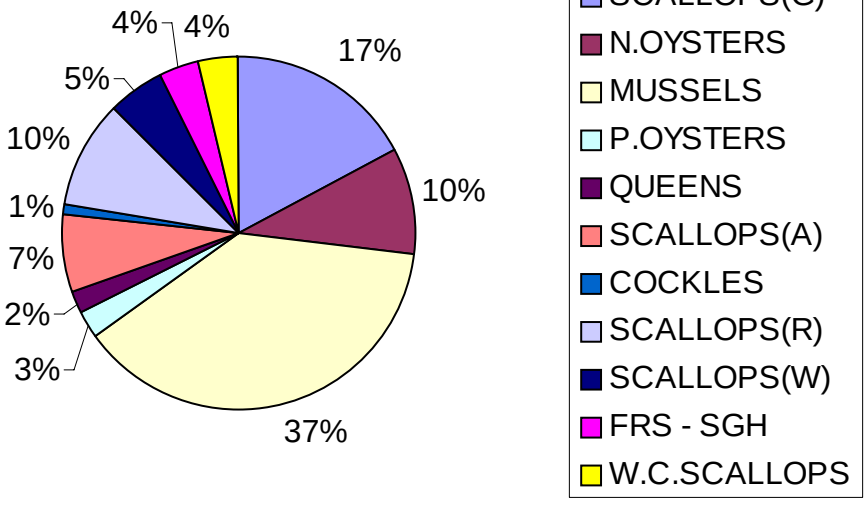
Mackintosh F.H., Smith, E.A., 2002. Evaluation of MIST Alert™ Rapid Test Kits For the Detection of Paralytic and Amnesic Shellfish poisoning Toxins in Shellfish. Journal of Shellfish Research. 21, 455-460.

Rafuse, C., Cembella, A.D., Laycock, M.V., Jellett, J.F., 2002. Rapid Monitoring of Toxic Phytoplankton and Zooplankton with a Lateral-Flow Immunochromatographic Assay for ASP and PSP Toxins. In: Steidinger, K. (Ed) Proceedings of the 10th International Conference on Harmful Algal Blooms St. Petersburg, Florida. Oct 21-25, 2002. Intergov. Oceanogr. Comm, UNESCO, Paris, in press.

Detection of ASP in Shellfish Tissue
from UK



Tissue Types from UK
(n= 111)



Proposal Subject Rapid Extraction Method for PSP and ASP

Specific NSSP Guide Reference

Specific Model Ordinance Reference: NSSP Guidance Documents, Chapter II

CONSTITUTION BY-LAWS and PROCEDURES of the
INTERSTATE SHELLFISH SANITATION CONFERENCE
PROCEDURE XVI. PROCEDURE FOR ACCEPTANCE AND APPROVAL OF ANALYTICAL METHODS FOR THE NSSP

And:

NATIONAL SHELLFISH SANITATION PROGRAM
2003 MODEL ORDINANCE

III. LABORATORY
@.02 Methods.

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 *Karemia breve* toxins.

Text of Proposal/ Requested Action

Marine biotoxins affect farmed and wild fish and shellfish, as well as having a deleterious effect on humans. Jellett Rapid Testing has designed and developed rugged tests for the presence of Paralytic Shellfish Poison, Amnesic Shellfish Poison and Diarrhetic Shellfish Poison (under development at the time of this submittal). To facilitate the use of these tests in the field (for aquaculturists, campers, regulatory officials, etc.), Jellett Rapid Testing has developed a "low-tech" rugged alternative to the standard AOAC method designed to extract the toxins in the field as well as the laboratory. The AOAC method requires the sample to be boiled in acid at low pH and the pH adjusted with strong acids. This requires a fully equipped laboratory and significant safety precautions. The JRT Rapid Extraction Method was designed for use in remote areas, with little sophisticated backup support, by average individuals with little training and education. It is faster, less labor-intensive and less expensive than the other available method.

The rapid extraction method requires vinegar and rubbing alcohol to extract the toxins. A simple, rapid, safe method such as this would make rapid tests for marine biotoxins available in remote areas, to fishermen, aquaculturists, and regulatory officials on an instant basis.

The method developed by Jellett Rapid Testing Ltd has been presented to regulatory bodies over the past several years. In cooperation with individuals, governments and those organizations, the analytical method has been refined and improved. The Rapid Extraction Method is being tested in several states and foreign countries. Publications will be forthcoming.

The CONSTITUTION BY-LAWS and PROCEDURES of the INTERSTATE SHELLFISH SANITATION CONFERENCE allows the ISSC, through the Laboratory Methods Review Committee, to accept analytical methods that are sufficiently validated but are not AOAC or APHA methods. This is defined in the Constitution, PROCEDURE XVI. PROCEDURE FOR ACCEPTANCE AND APPROVAL OF ANALYTICAL METHODS FOR THE NSSP. Two possible reasons for considering a method are found in Subdivisions i and ii.

Subdivision i. Meets immediate or continuing need;
Subdivision ii. Improves analytical capability under the NSSP as an alternative to other approved or accepted method(s)

Currently, only the AOAC extraction for PSP and ASP are accepted. The need for a simple safe extraction method has been expressed by regulatory agencies, governmental organizations and industry for many years. The Jellett Rapid Extraction Method is being validated over a wide geographic area to demonstrate its simplicity, reliability, precision and

accuracy. As a result of demonstrations of efficacy and the need that has been expressed by industry and state agencies, the Jellett Rapid Extraction Method is presented as an alternative extraction method for PSP and ASP for the NSSP as a Type III or Type IV method.

Please see attached additional information.

Suggested wording:

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 *Karemia breve* toxins.
   (3) The Jellett Rapid Extraction Method may be used for extracting PSP and ASP toxins from Shellfish by regulatory and industry laboratories.

Public Health Significance

Currently, only the AOAC extraction for PSP and ASP analyses are accepted. Because of many significant constraints, in practical terms, this means that analyses can be conducted only in laboratories, and then under dangerous conditions. Acceptance of the Jellett Rapid Extraction Method for PSP and ASP would allow harvesters, processors, and regulatory agencies to screen for PSP and ASP with an accepted standardized method that provides valid useable data.

The Jellett Rapid Extraction Method for PSP and ASP was developed over several years in answer to the oft-stated need for a rapid, reliable, rugged, simple and safe sample preparation method. The Jellett Rapid Extraction Method for PSP and ASP is not meant to be a definitive "Standard Method", but rather to provide a supplementary extraction method that can be used in the field as well as in the lab.

Possible applications for The Jellett Rapid Extraction Method for PSP and ASP include:

- as a supplement to analytical methods of screening out negative samples in shellfish regulatory labs;
- as a harvest management tool at aquaculture facilities or in wild shellfish harvest areas (especially near shore areas) to supplement available methods to determine if shellfish are free of PSP or ASP and safe to harvest;
- as a supplement to quality control methods for shellfish processing plants, distributors and wholesalers to ensure incoming shellfish are free of PSP and ASP toxins before processing or further distribution (this test could become part of the plant's HACCP program);
- as a supplement to analytical methods for water classification for biotoxins; and
- as a supplement to analytical methods for broad scale ecological monitoring.

The rationale for using the Jellett Rapid Extraction Method for PSP and ASP is that the method provides a rapid, reliable, rugged, simple, safe and cost-effective extraction method (especially in low-volume laboratories) for PSP and ASP that can supplement accepted tests and substantially reduce the cost of analyses. Used in conjunction with other rapid methods, the Jellett Rapid Extraction Method for PSP and ASP will supplement regulatory agency efforts and help prevent the harvest of contaminated product. Having the ability to conduct tests using an accepted rapid extraction method will allow those processors who choose to use this test to demonstrate that they are truly controlling for PSP and ASP hazards in the harvested shellfish.

The Jellett Rapid Extraction Method for PSP and ASP could contribute to building long-term databases on broader scales than a regulatory lab can afford and, by using an accepted standardized method, will provide consistent results. These databases could be supplemented with industry testing in areas where there is no testing currently. This would extend, augment and strengthen the current food safety system broadening and refining the food safety net by increasing the number of testing sites and generating long term data in more areas.

A simple, rapid, rugged, effective, reliable, safe and cost-effective extraction method, available to all harvesters, regulators, and processors, would increase the monitoring and reduce the chance that shellfish containing ASP toxins above the regulatory limit would be harvested or marketed.

Cost Information (if available)

It is difficult to determine exact costs because many government cost models do not consider capitol costs. Both extraction methods are the same through puree step, the chemicals used in both cases are minimal, as is the cost of incidental equipment (blender, pipettes, etc.). However, a comparison of time required using the Rapid Extraction Method (Add rapid liquid; Filter) with the time required using the AOAC Extraction (Add HCL; Boil; Wait; Filter; Pour in tube; Check PH) shows a significant difference. Our experience shows that it takes about 22 minutes for this portion of the AOAC extraction while it takes less than 2 minutes to complete the Jellett Rapid Extraction Method. At a salary of $33 / hour, that is a savings of $11.00 per sample extract.

Action by 2005 Laboratory Methods Review Committee

Recommended referral of Proposal 05-111 to the appropriate committee as determined by the Conference Chairman.

Action by 2005 Task Force I

Recommended adoption of the Laboratory Methods Review Committee recommendation of Proposal 05-111.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force I.

Action by USFDA

Concurred with Conference action.

Action by 2007 Laboratory Methods Review Committee

Recommended no action on Proposal 05-111. Rationale – Alternative extraction method for JRT PSP should be adopted to expand utility of the test; however there are insufficient data for acceptance at this time. The submitter will send data to the Executive Office for Conference approval.

Action by 2007 Task Force I

Recommended referral of Proposal 05-111 to an appropriate committee as determined by the Conference Chairman.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force I.

Action by USFDA

December 20, 2007
Concurred with Conference action with the following comments and recommendations for ISSC consideration.

The Conference has made considerable progress in its efforts to recognize new and developing analytical methods for the detection of indicators, pathogens, and marine toxins. Much credit goes to the Laboratory Methods Review Committee and its leadership for ensuring a scientifically defensible process for adopting analytical methods under the NSSP.

At the 2007 meeting numerous analytical methods were proposed for ISSC adoption. However, many of these methods were lacking the validation and associated data needed by the Laboratory Methods Review Committee to make a final determination regarding their efficacy for use in the NSSP. As a result the General Assembly voted "No Action" on analytical method Proposals 05-107, 05-108, 05-109, 05-111, 05-113, and 05-114. It is FDA's understanding that the intent of the "No Action" vote was not to remove these Proposals from ISSC deliberation as "No Action" normally suggests, but rather to maintain them before the Conference pending submission of additional data for further consideration. The Voting Delegates, by requesting the Proposal submitters provide additional data to the Executive Office for methods approval consistent with Procedure XVI, clearly recognized the

importance and utility of these methods and intended to maintain them before the Conference for possible adoption following additional data submission. FDA requests that the ISSC Executive Board confirm FDA's understanding of this outcome. FDA fully supports such a Conference action and encourages the Executive Office to pursue submission of additional data as necessary to move forward with acceptance of these methods.

Lab #	CFIA Sample #	CFIA Result HPLC (µg/g)	Jellett Result Approx. (µg/g)
04-01847	1	24.1	16-24
04-02156	2	1.4	0-4
04-01784	3	70.0	72-80
04-01968	4	71.9	72-92
04-01647	5	8.9	12-16
04-02328	6	9.3	6.4-11.2
04-02467	7	4.2	6.0-7.2
04-01646	8	31.2	40-64
04-02351	9	9.4	9.6-12
04-02238	10	4.7	4-5.6
04-01862	11	96.7	60-80
04-02240	12	10.3	12-20
04-01750	13	30.7	24-32
04-02231	14	2.5	0-4
04-01969	15	40.1	64-72

Jellett Rapid Testing Ltd.: NOAA Study - JREM Trial
Sample Record Sheet - Homogenate
State of Alaska - Department of Environmental Conservation

	Collection		Homogenization			Jellett Test						MBA Test					
Sample ID	**Date**	**Species**	**Field / Site / Lab Name**	**Date**	**Size of Sample (mL)**	**Field / Site / Lab Name**	**Date**	**Batch # - Test**	**Batch # - Buffer**	**Result (1=Pos, 0=Neg)**	**Intensity of C Line as % of T**	**Lab Name**	**Date**	**Toxin Standard Used**	**# of Mice Dead**	**Result (µg/100g)**	**# of Mice Sick**
20053168-C	3/06/05	Geoduck Viscera	ADEC-EHL	3/14/05	66[2]	ADEC-EHL	3/14/05	40000-13Aug04	40005-05Nov04	1	0%	ADEC-EHL	03/15/05	FDA	3	71	0
20053169-C	3/06/05	Geoduck Viscera	ADEC-EHL	3/14/05	495	ADEC-EHL	3/14/05	40000-13Aug04	40005-05Nov04	1	<10%	ADEC-EHL	03/15/05	FDA	3	39	0
20053170-C	3/06/05		ADEC-EHL	3/14/05	650	ADEC-EHL	3/14/05	40000-13Aug04	40005-05Nov04	1	0%	ADEC-EHL	03/15/05	FDA	3	71	0
20053183-C	3/13/05	Geoduck	ADEC-EHL	3/15/05	416	ADEC-EHL	3/15/05	40000-13Aug04	40005-05Nov04	1	>0%, <25%	ADEC-EHL	03/15/05	FDA	3	70	0
20053184-C	3/13/05	Geoduck	ADEC-EHL	3/15/05	632	ADEC-EHL	3/15/05	40000-13Aug04	40005-05Nov04	1	0%	ADEC-EHL	03/15/05	FDA	3	54	0
20053185-C	3/14/05	Geoduck	ADEC-EHL	3/15/05	561	ADEC-EHL	3/15/05	40000-13Aug04	40005-05Nov04	1	0%	ADEC-EHL	03/15/05	FDA	3	72	0
20053186-C	3/15/05	Geoduck	ADEC-EHL	3/15/05	301	ADEC-EHL	3/15/05	40000-13Aug04	40005-05Nov04	1	0%	ADEC-EHL	03/15/05	FDA	3	90	0
20053137	03/06/05	Oyster	ADEC-EHL	03/08/05	150	ADEC-EHL	03/08/05	40000-13Aug04	40005-05Nov04	INV	C <25% T	ADEC-EHL	03/08/05	FDA	0	NDT	0
20053136	03/06/05	Oyster	ADEC-EHL	03/08/05	500	ADEC-EHL	03/08/05	40000-13Aug04	40005-05Nov04	N/A INV	C <25% T	ADEC-EHL	03/08/05	FDA	0	NDT	0
20053138	03/05/05	Oyster	ADEC-EHL	03/08/05	500	ADEC-EHL	03/09/05	40000-13Aug04	40005-05Nov04	INV	C <25% T	ADEC-EHL	03/08/05	FDA	0	NDT	0
20053142	03/06/05	Oyster	ADEC-EHL	03/09/05	50	ADEC-EHL	03/09/05	40000-13Aug04	40005-05Nov04	INV	C <50% T	ADEC-EHL	03/09/05	FDA	0	NDT	0
20053124-C	3/5/05	Geoduck	ADEC-EHL	3/7/05	495	ADEC-EHL	3/7/05	40000-13Aug04	40005-05Nov04	1	0%	ADEC-EHL	03/07/05	FDA	3	117	0
20053125-C	3/5/05	Geoduck	ADEC-EHL	3/7/05	404	ADEC-EHL	3/7/05	40000-13Aug04	40005-05Nov04	1	75%	ADEC-EHL	03/07/05	FDA	3	58	0
20053006	2/29/05	Oyster	ADEC-EHL	3/3/05	125	ADEC-EHL	3/3/05	40000-13Aug04	40005-05Nov04			ADEC-EHL	3/3/05	FDA	0	NDT	0
20053040-C	03/01/05	Geoduck Viscera	ADEC-EHL	03/02/05	545	ADEC-EHL	03/02/05	40000-13Aug04	40009-06Oct04	1	50%	ADEC-EHL	03/02/05	FDA	3	86	0
20053039-C	03/01/05	Geoduck Viscera	ADEC-EHL	03/02/05	340	ADEC-EHL	03/02/05	40000-13Aug04	40009-06Oct04	1	10%	ADEC-EHL	03/02/05	FDA	3	175	0
20053007-C	02/26/05	Geoduck Viscera	ADEC-EHL	02/28/05	750	ADEC-EHL	03/01/05	40000-13Aug04	40009-06Oct04	1	25%	ADEC-EHL	02/28/05	FDA	3	59	0
20053010-C	02/26/05	Geoduck Viscera	ADEC-EHL	02/28/05	750	ADEC-EHL	03/01/05	40000-13Aug04	40009-06Oct04	1	<25%	ADEC-EHL	02/28/05	FDA	3	65	0
2005301-C	02/27/05	Geoduck Viscera	ADEC-EHL	02/28/05	750	ADEC-EHL	03/01/05	40000-13Aug04	40009-06Oct04	1	0%	ADEC-EHL	02/28/05	FDA	3	151	0

Jellett Rapid Testing Ltd.: NOAA Study
JREM Trial Sample Record Sheet - Homogenate
California - Microbial Disease Lab

	Collection		Homogenization			Jellett Test						MBA Test					
Sample ID	Collection Date	Species	Field / Site / Lab Name	Date	Size of Sample (mL)	Field / Site / Lab Name	Date	Batch # - Test	Batch # - Buffer	Result (1=Pos, 0=Neg)	Intensity of C Line as % of T	Lab Name	Date	Toxin Standard Used	# of Mice Dead	Result µg/100g	# of Mice Sick
05E-00110	02/05/05	LBMU	CA-DHS-EMDS	02/09/05	>130	CA-DHS-EMDS	02/09/05	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	2/09/05	FDA	0	<36	0
05W-00099	02/01/05	SSMU	CA-DHS-EMDS	02/02/05	>130	CA-DHS-EMDS	02/02/05	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	02/02/05	FDA	0	<34	0
05E-00096	02/28/05	CBMU	CA-DHS-EMDS	02/02/05	>130	CA-DHS-EMDS	02/02/05	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	02/02/05	FDA	0	<36	0
05W-00093	02/01/05	SBMU	CA-DHS-EMDS	02/02/05	>130	CA-DHS-EMDS	02/02/05	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	02/02/05	FDA	0	<36	0
05W-00079	01/25/05	SSMU	CA-DHS-EMDS	01/26/05	>130	CA-DHS-EMDS	01/26/05	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	1/26/05	FDA	0	<35	0
05W-00076	01/22/05	CBMU	CA-DHS-EMDS	01/26/05	>130	CA-DHS-EMDS	01/26/05	40000-8/13/04	40005-9/7/04	1	50%	CA-DHS-EMDS	01/26/05	FDA	3	39	0
05W-00069	01/24/05	SBMU	CA-DHS-EMDS	01/26/05	>130	CA-DHS-EMDS	01/26/05	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	01/26/05	FDA	0	<36	3
05W-00059	01/18/05	SSMU	CA-DHS-EMDS	01/19/05	>130	CA-DHS-EMDS	01/19/05	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	1/19/05	FDA	0	<35	3
05W-00055	01/14/05	CBMU	CA-DHS-EMDS	01/18/005	>130	CA-DHS-EMDS	01/18/05	40000-8/13/04	40005-9/7/04	1	25%	CA-DHS-EMDS	01/18/05	FDA	3	37	
05W-00052	01/17/05	SBMU	CA-DHS-EMDS	01/18/05	>130	CA-DHS-EMDS	01/18/05	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	01/18/05	FDA	0	<36	0
05W-00025	1/10/05	SBMU	CA-DHS-EMDS	1/12/05	>130	CA-DHS-EMDS	1/12/05	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	1/12/05	FDA	0	<35	0
05W-00023	1/11/05	SSMU	CA-DHS-EMDS	1/12/05	>130	CA-DHS-EMDS	1/12/05	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	1/12/05	FDA	0	<36	0
05W-00020	1/7/05	CBMU	CA-DHS-EMDS	01/11/05	>130	CA-DHS-EMDS	01/11/05	40000-8/13/04	40005-9/7/04	1	25%	CA-DHS-EMDS	1/11/05	FDA	3	44	0

Jellett Rapid Testing Ltd.: NOAA Study
JREM Trial Sample Record Sheet - Homogenate
California - Microbial Disease Lab (CONTINUED)

	Collection		Homogenization			Jellett Test						MBA Test					
Sample ID	**Collection Date**	**Species**	**Field / Site / Lab Name**	**Date**	**Size of Sample (mL)**	**Field / Site / Lab Name**	**Date**	**Batch # - Test**	**Batch # - Buffer**	**Result (1=Pos, 0=Neg)**	**Intensity of C Line as % of T**	**Lab Name**	**Date**	**Toxin Standard Used**	**# of Mice Dead**	**Result µg/100g**	**# of Mice Sick**
05W-00011	1/3/05	SBMU	CA-DHS-EMDS	1/5/05	>130	CA-DHS-EMDS	1/5/05	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	1/5/05	FDA	0	<34	0
05W-00007	1/4/05	SSMU	CA-DHS-EMDS	1/5/05	>130	CA-DHS-EMDS	1/5/05	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	1/5/05	FDA	0	<34	0
05W-00002	12/30/04	CBMU	CA-DHS-EMDS	1/04/05	>130	CA-DHS-EMDS	1/04/05	40000-8/13/04	40005-9/7/04	0	75%	CA-DHS-EMDS	1/04/05	FDA	2	36	1
04W-01458	12/28/04	SSMU	CA-DHS-EMDS	12/29/04	>130	CA-DHS-EMDS	12/29/04	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	12/29/04	FDA	0	<36	0
04W-01454	12/27/04	SBMU	CA-DHS-EMDS	12/29/04	>130	CA-DHS-EMDS	12/29/04	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	12/29/04	FDA	0	<36	0
04W-01457	12/24/04	CBMU	CA-DHS-EMDS	12/28/04	>130	CA-DHS-EMDS	12/28/04	40000-8/13/04	40005-9/7/04	1	<25%	CA-DHS-EMDS	12/28/04	FDA	3	42	0
04W-1446	12/21/04	SSMU	CA-DHS-EMDS	12/22/04	>130	CA-DHS-EMDS	12/22/04	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	12/22/04	FDA	0	<34	0
04W-01436	12/20/04	SBMU	CA-DHS-EMDS	12/21/04	>130	CA-DHS-EMDS	12/21/04	40000-8/13/04	40005-9/7/04	0	75%	CA-DHS-EMDS	12/21/04	FDA	0	<34	3
04W-01399	12/13/04	SBMU	CA-DHS-EMDS	12/14/04	>130	CA-DHS-EMDS	12/15/04	40000-8/13/04	40005-9/7/04	1	50%	CA-DHS-EMDS	12/15/04	FDA	2	35	0
04W-01421	12/11/04	CBMU	CA-DHS-EMDS	12/15/04	>130	CA-DHS-EMDS	12/15/04	40000-8/13/04	40005-9/7/04	1	0%	CA-DHS-EMDS	12/15/04	FDA	3	48	0
04W-01424	12/14/04	SSMU	CA-DHS-EMDS	12/15/04	>130	CA-DHS-EMDS	12/15/04	40000-8/13/04	40005-9/7/04	0	100%	CA-DHS-EMDS	12/15/04	FDA	0	<35	0

Proposal Subject	Method to determine the presence of Male Specific Coliphage in shellfish meats and the Microbiology Checklist for Male-specific Coliphage (MSC)
Specific NSSP Guide Reference	None submitted
Text of Proposal/ Requested Action	The laboratory procedure is based on the methods described in Burkhardt, W., III, W.D. Watkins, and S.R. Rippey. 1992. Seasonal effects on accumulation of microbial indicator organisms by *Mercenaria mercenaria*. Appl. Environ. Microbiol. 58:826-831; DeBartolomeis, J. and Cabelli, V.J. 1991. Evaluation of an *Escherichia coli* host strain for enumeration of F male specific bacteriophages. Appl. Environ. Microbiol. 57: 1301-1305; Burkhardt, W. III *Enumeration of Male-specific Bacteriophage in water and shellfish tissue.* 2004. Gulf Coast Seafood Laboratory, Office of Seafood, U.S. Food and Drug Administration, Dauphin Island, AL. 31 pg. The laboratory procedure is to be reviewed by the Laboratory Methods Review Committee for consideration as a Type IV Method according to Procedure XVI. The Laboratory Evaluation Checklist - Pages 2, 16, 17, and 18, Microbiology of the Guidance Documents, Chapter II. Growing Areas, .11 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists is attached. It includes a section for the Male-specific Coliphage (MSC). MSC is an important microorganism for monitoring the microbial quality of waters (e.g., sewage treatment, growing area, etc.).
Public Health Significance	FDA is submitting a proposal to ISSC to allow MSC to be used as a re-opening criterion in cases where unexpected, unusual sewage contamination occurs that may have impacted shellfish harvest areas (not for conditional re-openings). State Laboratory Managers and Laboratory Evaluation Officers need this document to correctly perform the analysis and to evaluate any laboratory performing the Coliphage (Bacteriophage) procedure.
Cost Information (if available)	None
Action by 2005 Laboratory Quality Assurance Committee	Recommended referral of Proposal 05-113 to the appropriate committee as determined by the Conference Chairman.
Action by 2005 Task Force I	Recommended adoption of the Laboratory Quality Assurance Committee recommendation on Proposal 05-113.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force I.
Action by USFDA	Concurred with Conference action.
Action by 2007 Laboratory Methods Review Committee	Recommended no action on Proposal 05-113. Rationale - The "no action" on Proposal 05-114 eliminated the need for checklist adoption. The submitter will submit the checklist with the data for method approval to the Executive Office for Conference approval consistent with Procedure XVI.
Action by 2007 Task Force I	Recommended adoption of the Laboratory Methods Review Committee recommendation of no action on Proposal 05-113.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.

Action by USFDA

December 20, 2007

Concurred with Conference action with the following comments and recommendations for ISSC consideration.

The Conference has made considerable progress in its efforts to recognize new and developing analytical methods for the detection of indicators, pathogens, and marine toxins. Much credit goes to the Laboratory Methods Review Committee and its leadership for ensuring a scientifically defensible process for adopting analytical methods under the NSSP.

At the 2007 meeting numerous analytical methods were proposed for ISSC adoption. However, many of these methods were lacking the validation and associated data needed by the Laboratory Methods Review Committee to make a final determination regarding their efficacy for use in the NSSP. As a result the General Assembly voted "No Action" on analytical method Proposals 05-107, 05-108, 05-109, 05-111, 05-113, and 05-114. It is FDA's understanding that the intent of the "No Action" vote was not to remove these Proposals from ISSC deliberation as "No Action" normally suggests, but rather to maintain them before the Conference pending submission of additional data for further consideration. The Voting Delegates, by requesting the Proposal submitters provide additional data to the Executive Office for methods approval consistent with Procedure XVI, clearly recognized the importance and utility of these methods and intended to maintain them before the Conference for possible adoption following additional data submission. FDA requests that the ISSC Executive Board confirm FDA's understanding of this outcome. FDA fully supports such a Conference action and encourages the Executive Office to pursue submission of additional data as necessary to move forward with acceptance of these methods.

.11 – Laboratory Evaluation Checklist – Microbiology - 2

Check the applicable analytical methods:			
	Multiple Tube Fermentation Technique for Seawater (APHA)[PART II]		
	Multiple Tube Fermentation Technique for Seawater Using MA-1 [PART II]		
	Multiple Tube Fermentation Technique for Shellfish Meats (APHA)[PART III]		
	Standard Plate Count for Shellfish Meats [Part III]		
	Elevated Temperature Coliform Plate Method for Shellfish Meats [PART III]		
	Male Specific Bacteriophage for Shellfish Meats [PART III]		
PART 1 – QUALITY ASSURANCE			
CODE	**REF**		**ITEM**
K	8, 11		**Quality Assurance Plan**
			1. Written Plan (Check √ those items which apply.)
			a. Organization of the laboratory
			b. Staff training requirements
			c. Standard operating procedures
			d. Internal quality control measures for equipment calibration, maintenance, repair and for performance checks.
			e. Laboratory safety
			f. Internal performance assessment
			g. External performance assessment
C	8		2. QA Plan Implemented
K	11		3. Participates in a proficiency testing program annually. Specify Program(s)_____
CODE	**REF.**		**Work Area**
O	8, 11		1. Adequate for workload and storage.
K	11		2. Clean, well lighted.
K	11		3. Adequate temperature control.
O	11		4. All work surfaces are nonporous, easily cleaned and disinfected.
K	11		5. Microbiological quality and density of air is < 15 colonies/plate in a 15 minute exposure determined monthly and results recorded.
O	11		6. Pipet aid used, mouth pipetting not permitted.

CODE	REF.		Bacteriological Examination of Shellfish by Male-specific Bacteriophage
			Equipment & Supplies
			SEE PAGE 3, 4 & 5 FOR RELEVENT EQUIPMENT ITEMS.
K	31		1. Sample containers are sterile, made of glass or some other inert material (i.e., polypropylene), hold 100-125 mL, and treated with sodium thiosulfate.
C	27,28,29,30		2. The refrigerated centrifuge must have the capacity to accommodate the amount of shellfish samples required for procedure, perform at 9000 x G, and maintain a temperature of 4°C ± 1°C.
C	27,28,29,30		3. The water bath must be able to maintain 44-46°C and 50-52°C temperature ranges.
K	9		4. The level of water in the water bath covers the level of liquid and agar in the containers and culture tubes.
K	13		5. Working thermometers are tagged with identification, date of calibration, calibrated temperature and correction factor.
K	4		6. All working thermometers are appropriately immersed.
K	11		7. A standards thermometer has been calibrated by NIST or one of equivalent accuracy at the points -20°, 0°, 35°, 44.5°C, 50° and 121°C. Calibration records maintained.
K	9		8. Standards thermometer is checked annually for accuracy by ice point determination. Results recorded and maintained. Date of most recent determination _____.
K	13		9. Incubator, freezer, refrigerator, autoclave and water bath working thermometers are checked annually against the standards thermometer at the temperatures at which they are used. Records maintained.
C	32		10. Sterile 0.22 or 0.45µm pore size filters are used to prepare the antibiotic solutions using sterile disposable syringes. Check sterility of each lot.
K	27,28,29,30, 31		11. Pre-sterilized plastic or sterile glass syringes are used to filter sterilize the stock antibiotic solution. Check sterility of each lot.
K	31		12. Colonies are counted with the aid of magnification or light box device.
C	32		13. Balance provides a sensitivity of at least 0.01 g.
C	31		14. The temperature of the incubator is maintained at 35-37°C.
K	27,28,29		15. Reusable or disposable pipets-pipettors are used and sterility is checked with each lot.
K	2727,28,29		16. Sterile disposable 15 and 50 mL centrifuge tubes are used and sterility is checked with each lot.
			Media Preparation and Storage
			SEE PAGES 5 & 6 FOR RELEVENT MEDIA PREPARATION AND STORAGE ITEMS.
K	27,28,29		1. Media is prepared from individual components.
K	27,28,29		2. Media is prepared and sterilized according to the method procedure.
C	27,28,29		3. Streptomycin/ Ampicillin solution is added after the autoclaved bottom agar has tempered to 44 – 46 ° C.
O	27,28,29		4. Storage of MSB bottom agar under refrigeration does not exceed 1 month.
O	27,28,29		5. Unsterilized DS soft agar is stored in a – 20° C freezer for up to 1 month
K	27,28,29		6. The DS soft agar is removed from the freezer and sterilized for 15 minutes at 121° C before use.
O	27,28,29		7. Storage of Growth broth in the refrigerator in loosely capped tubes/bottles does not exceed 1 month and in screw capped tubes/bottles does not exceed 3 months.
C	27,28,29		8. Host *stock E. coli* F_{amp} is ATCC 700609.
K	27,28,29		9. The host stock used for growth broth host cells is less than 1 week old.
O	27,28,29		10. Media is warmed to room temperature before use.
			Preparation of Shellstock for Examination
K	2, 11		1. Shucking knives, scrub brushes and blender jars are (autoclave) sterilized for 15 minutes prior to use.

O	2		2. Blades of shucking knives are not corroded.
O	9		3. Prior to scrubbing and rinsing debris off shellstock, the hands of the analyst are thoroughly washed with soap and water.
O	2		4. The faucet used to provide the potable water for rinsing the shellstock does not contain an aerator.
K	9		5. Shellstock are scrubbed with a stiff, sterile brush and rinsed under water of drinking water quality.
O	9		6. Shellstock are allowed to drain in a clean container or on clean towels prior to opening.
K	9		7. Prior to opening, the hands (or gloved hands) of the analyst are thoroughly washed with soap and water and rinsed in 70% alcohol.
K	9		8. Shellstock are not shucked directly through the hinge.
C	9		9. Contents of shellstock (liquor and meat) are shucked into a sterile, tared blender jar or other sterile container.
K	9		10. At least 12 shellstock are used for analysis.
K	2, 19		11. The sample is weighed to the nearest 0.1 gram
C	9		12. Samples are blended at high speed for 60 seconds.
K	9		13. For other than shellstock, APHA *Recommended Procedures* is followed for the examination of freshly shucked and frozen shellfish meats.
		Sample Analysis	
C	27,28,29		Samples are analyzed according to the approved method.
K	27,28,29		Growth Broth is tempered to 35 – 37° C and vortexed (or shaken) to aerate prior to inoculation
K	27,28,29		Several host cell colonies are transferred to a tube of growth broth to provide log phase growth host cells for sample procedure.
C	27,28,29		Growth broth with host cells is incubated 35 – 37° C for 4 to 6 hours to provide culture in log phase growth.
C	27,28,29		The host cell growth broth is not shaken.
O	27,28,29		At least 30 to 50 grams of blended shellfish meat is weighed into sterile centrifuge tubes; weight is recorded .
C	27,28,29		The blended shellfish meat is centrifuged for 15 minutes at 9000 x g at 4° C.
K	27,28,29		Only supernatant is pipetted off and weight recorded.
K	27,28,29		Supernatant is allowed to warm to room temperature – 20 to 30 minutes.
K	27,28,29		The autoclaved DS soft agar is tempered and held at 50 – 52° C throughout sample procedure.
K	27,28,29		The supernatant is shaken or vortexed before adding to DS soft agar.
K	27,28,29		At least, a total of 7.5 ml of shellfish meat supernatant are plated.
C	27,28,29		2.5 ml of sample are added to 2.5 ml of DS soft agar and 0.2 ml of log phase host cell in growth broth while in the tempering waterbath.
C	27,28,29		DS soft agar/sample/host cell mixture is gently rolled between palms to mix.
C	27,28,29		The soft agar mixture is overlaid bottom agar and swirled gently to distribute.
K	27,28,29		Negative and positive control plates accompany samples.
K	27,28,29		Growth broth is used for negative (blank) control plates.
K	27,28,29		MS2 male specific bacteriophage is used as the positive control.
K	27,28,29		A negative control plate is the first plate and the last plate.
K	27,28,29		The positive control plate is set up after all samples and just before the final negative plate.
C	27,28,29		All plates are incubated at 35 – 37° C for 16 to 20 hours.
		Computation of Results	
C	31		1. Circular zones of clearing (of any diameter) in lawn of host bacteria are plaques.
C	32		2. The desired range of 30 to 300 PFU per plate. If the count exceeds the upper range or if the plaques are not discrete, results should be recorded as *too numerous to count* (TNTC).
K	27		3. The equation used is:

			$\text{PFU/100grams} = \frac{\text{Avg of plate counts}}{\text{ml analyzed/plate}} \times \frac{\text{grams of homogenate}}{\text{grams of supernate}} \times 100$
O	**9**		**2. Round off at the end of your computation using the information in *Recommended Procedures for the Examination For Sea Water and Shellfish*.**
K	**27**		**4. Results are reported as PFU/ 100 g for shellfish samples.**

REFERENCES	
1.	*Compendium of Methods for the Microbiological Examination of Foods*, 2nd Edition, APHA. 1984.
2.	Good Laboratory Practice.
3.	"Interim Guides for the Depuration of the Northern Quahog, *Mercenaria mercenaria*, Northeast Marine Health Sciences Laboratory, North Kingstown, RI. 1968.
4.	NBS *Monograph 150*, U.S. Department of Commerce, Washington, D.C. 1976.
5.	*Official Methods of Analyses of the Association of Official Analytical Chemists*, 17th Edition, 2000. Chapter 17.305, page 22.
6.	*Proceedings of the 8th National Shellfish Sanitation Workshop.* 1974.
7.	Public Health Service, *Public Health Report,* Reprint #*1621.* 1947.
8.	*Quality Assurance Principles for Analytical Laboratories*, Association of Official Analytical Chemists. 1991.
9.	*Recommended Procedures for the Examination of Sea Water and Shellfish*, 4th Edition, American Public Health Association. 1970.
10.	Shellfish Sanitation Interpretation #SS-39, Interstate Shellfish Sanitation Conference, 1986.
11.	*Standard Methods for the Examination of Water and Wastewater*, 18th Edition, APHA/WEF/AWWA. 1992.
12.	Title 21, Code of Federal Regulations, Part 58, "Good Laboratory Practice for Nonclinical Laboratory Study", Washington, D.C.
13.	*Standard Methods for the Examination of Dairy Products*, 16th Edition, APHA. 1992.
14.	Fisher, J. 1985. "Measurement of pH". *American Laboratory*. 16:54-60.
15.	Consult pH electrode product literature.
16.	AOAC Methods Validation and Technical Programs – Criteria for Laboratories Performing Food Testing. 1999
17.	*Handbook for Evaluating Water Bacteriological Laboratories*. 1975. US EPA, 670/9-75-006.
18.	Adams, W.N., 1974. NETSU. Personal communication to Dr. Wallace Andrews, FDA.
19.	*Bacteriological Analytical Manual*. 1995. FDA, 8th Edition, AOAC, Arlington,VA.
20.	*NSSP Guide to the Control of Molluscan Shellfish*. 1997. FDA/ISSC.
21.	*Microbiological Methods for Monitoring the Environment, Water and Wastes*. 1978. US EPA, EPA/600/8/78/017.
22.	Furfari, Santo. March 21, 1972. Personal Communication to Dan Hunt, FDA.
27.	**Burkhardt, W. III *Enumeration of Male-specific Bacteriophage in water and shellfish tissue*, 2004. Gulf Coast Seafood Laboratory, Office of Seafood, U.S. Food and Drug Administration (or just FDA), Dauphin Island, AL. 31 pg.**
28.	**Burkhardt, W., III, W.D. Watkins, and S.R. Rippey. 1992. Seasonal effects on accumulation of microbial indicator organisms by Mercenaria mercenaria. Appl. Environ. Microbiol. 58:826-831.**
29.	**Cabelli, V.J. 1988. Microbial indicator levels in shellfish, water, and sediments from the upper Narragansett Bay conditional shellfish-growing area. *Report to the Narragansett Bay Project*, Providence, RI.**
30.	DeBartolomeis, J. and Cabelli, V.J. 1991. Evaluation of an *Escherichia coli* host strain for enumeration of F male-specific bacteriophages. Appl. Environ. Microbiol. 57:1301-1305.
28.	**United States Environmental Protection Agency, *Method 1601: Male-specific (F+) and Somatic Coliphage in Water by Two-step Enrichment Procedure,* EPA 821-R-01-030, EPA, Washington, DC, April 2001.**
29	**United States Environmental Protection Agency, *USEPA Manual of Methods for Virology*, Chapter 16, EPA 600/4-84/013 (N16), Washington DC, June 2001.**

NSSP Form LAB-100 rev. 2005-02-18

Proposal Subject	Method to Determine the Presence of Male Specific Coliphage in Shellfish Meats and the Microbiology
Specific NSSP Guide Reference	NSSP Guidance Documents Chapter II. Growing Areas .10 Approved Laboratory Tests
Key Words	Microbiology Method Isolation of Male-specific Coliphage, MSC
Public Health Significance	FDA is submitting a proposal to ISSC to allow MSC to be used as a re-opening criterion in cases where unexpected, unusual sewage contamination occurs that may have impacted shellfish harvest areas (not for conditional re-openings). The MSC method must be reviewed and adopted prior to use in determining the acceptability of shellfish growing waters for reopening.
Cost Information (if available)	Not available
Action by 2005 Laboratory Methods Review Committee	Recommended referral of Proposal 05-114 to the appropriate committee as determined by the Conference Chairman.
Action by 2005 Task Force I	Recommended adoption of the Laboratory Methods Review Committee recommendation on Proposal 05-114.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force I.
Action by USFDA	Concurred with Conference action.
Action by 2007 Laboratory Methods Review Committee	Recommended no action on Proposal 05-114. Rationale – The data necessary to approve the method is not available. The submitter will send data to the Executive Office for Conference approval consistent with Procedure XVI.
Action by 2007 Task Force I	Recommended referral of Proposal 05-114 to an appropriate committee as determined by the Conference Chairman.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.
Action by USFDA	December 20, 2007 Concurred with Conference action with the following comments and recommendations for ISSC consideration. The Conference has made considerable progress in its efforts to recognize new and developing analytical methods for the detection of indicators, pathogens, and marine toxins. Much credit goes to the Laboratory Methods Review Committee and its leadership for ensuring a scientifically defensible process for adopting analytical methods under the NSSP. At the 2007 meeting numerous analytical methods were proposed for ISSC adoption. However, many of these methods were lacking the validation and associated data needed by the Laboratory Methods Review Committee to make a final determination regarding their efficacy for use in the NSSP. As a result the General Assembly voted "No Action" on analytical method Proposals 05-107, 05-108, 05-109, 05-111, 05-113, and 05-114. It is FDA's understanding that the intent of the "No Action" vote was not to remove these Proposals from ISSC deliberation as "No Action" normally suggests, but rather to maintain them before the Conference pending submission of additional data for further consideration. The Voting Delegates, by requesting the Proposal submitters provide additional data to the

Executive Office for methods approval consistent with Procedure XVI, clearly recognized the importance and utility of these methods and intended to maintain them before the Conference for possible adoption following additional data submission. FDA requests that the ISSC Executive Board confirm FDA's understanding of this outcome. FDA fully supports such a Conference action and encourages the Executive Office to pursue submission of additional data as necessary to move forward with acceptance of these methods.

Enumeration of Male- specific bacteriophage in water and shellfish tissue

William Burkhardt III, Ph.D.
U.S. Food and Drug Administration,
Gulf Coast Seafood Laboratory
Dauphin Island, Alabama

What are male- specific (f-specific) bacteriophage?

•Lytic viruses of bacteria- (killing of host bacteria)

E. coli and S. typhimurium

(production of E. coli pili*)*

•Requires a piliated host cell for adsorption, they do not attach to cell surface (somatic).

•Requires host cell in log- phase of growth- cells do not produce pili at < 30°C

•Optimal growth temperature: 35- 37°C.

•Plaque size is generally self- limiting

Two Predominant Host Strains

•*E. coli* HS(pFamp)RR

- Resistant to Streptomycin and Ampicillin

•*Salmonella typhimurium* WG49

Result of mating: *E. coli* WG27 (piliated)

x

S. typhimurium WG45

-Resistant to Naladixic acid and Kanamycin

--Pili production in each strain is plasmid mediated

Media Composition
E. coli Famp

Bottom Agar

•Tryptone 10.0 g
•Dextrose 1.0 g
•NaCl 5.0 g
•Agar 15.0 g
••Water 1000 ml

•Autoclave 121°C 15 min
- temper to 50°C.
•Add 0.05 g Streptomycin sulfate
0.05 g Ampicillin (aseptically)

DS Soft Agar

•Tryptone 10.0 g
•Dextrose 1.0 g
•NaCl 5.0 g
•1M $CaCl_2$ 0.5 ml
•Agar 7.0 g

••Water 500 ml
••Boil- Dispense in 2.5 ml aliquots (16 x 100 ml tubes) and freeze (-20°C)
••Autoclave prior to use;
temper to 50- 52° C

Growth broth- same formulation as Bottom Agar w/o agar or antibiotics

Media Composition
S. typhimurium WG49
Bottom Agar

•Trypticase Peptone	10.0 g
•Yeast Extract	1.0 g
•Dextrose	1.0 g
•NaCl	8.0 g
•Agar	15.0 g
••Water	1000 ml

•Autoclave 121°C 15 min
- temper to 50°C.
•Add 0.10 g Naladixic Acid
0.02 g Kanamycin sulfate (aseptically)

DS Soft Agar

•Trypticase Peptone	10.0 g
•Yeast Extract	1.0 g
•Dextrose	1.0 g
•NaCl	5.0 g
•1M $CaCl_2$	0.5 ml
•Agar	7.0 g
••Water	500 ml

••Boil- Dispense in 2.5 ml aliquots (16 x 100 ml tubes) and freeze (-20°C)
••Autoclave prior to use;
temper to 50- 52° C

Growth broth- same formulation as Bottom Agar w/o agar or antibiotics

Differentiation of RNA and DNA Bacteriophage

•RNAse Type I-A Sigma # R4875
••Final conc= 100ug/ ml of media
•Stock concentration= 10 mg/ml (100X)
••Dissolve at a conc. of 10 mg/ml in 0.01 M Sodium Acetate (pH 5.2); Boil for 15 min and allow to cool to RT; PH by adding 0.1 vol of 1M Tris HCl (pH 7.4)
••Store @ -20C

Propagation of *E. coli* Famp

Bottom Agar Streak plate-
Transfer preferable < 1 week old.
•Broth Growth medium tempered to 35- 37°C- vortex to aerate.
•Using 10ul loop collect material from of several colonies and transfer to broth medium.
•Shake briefly to mix, then incubate at 35- 37°C for 4-6 hours
(turbidity ≈ 10^7cells/ ml; O.D @540 nm= 0.4)

% RECOVERY OF BACTERIOPHAGE F-2W/ VARIOUS AGES OF FAMP CULTURE

Age of a 10 ml host cell culture(h)	% Recovery (Mean ± SD)3.0
	105.4 ± 2.5
3.5	97.4 ± 2.2
4.0	96.0 ± 2.8
4.5	95.0 ± 3.3
5.0	92.5 ± 1.2
6.0	90.9 ± 1.8

Adapted from DeBartolomeis, 1999

For MSB density determinations in shellfish tissue

1. Homogenize by blending 12 shellfish for 1 min at high speed.
2. Aliquot 30- 50 g from each sample into centrifuge bottle.
3. Centrifuged for 15 min. @ 9,000 x g; 4°C.
4. Collect and weigh supernatant in a sterile container.
5. Allow supernatant to warm to RT (20- 30 min)
6. Combine 2.5 ml aliquot of supernatant, 2.5 ml DS Soft agar (tempered to 52°C) and 0.2 ml of *E. coli* HS(pFamp)RR
7. Overlay onto a tryptone agar plate containing streptomycin/ ampicillin (50 µg/ml final).
8. Plates are inverted and incubated for 18- 24 h @ 35- 37°C

Information needed for

Bacteriophage density determinations:

Plate counts of plaques
g Shellfish homogenate centrifuged
g Shellfish supernatant recovered

Calculations

MSB/ 100 grams=

1) Ave PFU/ plate ÷ number of ml added/ plate= Average PFU/ml

2) Average PFU/ml x grams of supernatant x $\frac{100 \text{ g}}{\text{g homogentate}}$ = PFU/ 100 g

Example: Plate counts- 75, 73,80; 2.5 ml/ plate
50 g homogenate; 33 g supernatant

76 ÷ 2.5 x 33 g supernatant x $\frac{100 \text{ grams}}{50 \text{ g homogenate}}$ = 2006 PFU/ 100 grams

To determine level of sensitivity

3 plates containing 0, 0, 0; 2.5 ml/ plate
50 g Homogenate; 33 g Supernatant
Assume 1 plaque on 1 plate then calculate
1÷ 3 plates ÷ 2.5 ml x 33 x (100 ÷ 50) =
Reported as < 9 pfu/ 100 grams

For MSB density determinations in low contaminated water- Concentration technique

1. Weigh 100 ml of water in a sterile container centrifuge bottle.
2. Allow water to warm to RT (20- 30 min).
3. Add 1g tryptone and 1 g beef extract to water aliquot, shake to dissolve.
4. Add 10 ml of *E. coli* Famp culture- Do not shake
5. Incubate at 35- 37°C for 50 min - rotate at 100 rpm.
6. Centrifuged for 15 min. @ 9,000 x g; 4°C.

For MSB density determinations in highly contaminated water (> 100 pfu/ 100 ml)

1. Allow an aliquot of water to warm to RT (20- 30 min)
2. Combine 2.5 ml aliquot of supernatant, 2.5 ml DS Soft agar (tempered to 52° C), and 0.2 ml of *E. coli* HS(pFamp)RR
3. Overlay onto a tryptone agar plate containing streptomycin/ ampicillin (50µg/ml final).
4. Plates are inverted and incubated for 18- 24 h @ 35- 37°C

Problems that may arise

Multiple layers are formed after centrifugation

Reason- glycogen- lipids associated w/ shellfish physiological state

Sliding pellet- not solid

Reason- waited too long to remove supernatant

Clumping Agar

Reason- sample was too cool

Runny plaques

Reason- wet plates; too much condensation

No plaques/ individual bacterial colonies on agar plates

Reason- no phage present or inadequate amount host cell

Ways of Enhancing Plaque Visibility

Addition of 2,3,5- triphenyl tetrazolium chloride (TTC), 1% solution in ethanol
65 ul / tube of tempered DS soft agar
Assuming: 2.5 ml of DS agar and
2.5 ml sample
or

Grams Safrin 1:100 in water- differentiates lawn from plaque

Storage of *E. coli* Famp
Selective pressure- Streptomycin and Ampicillin
Bottom Agar Streak Plate
Storage: Refrigerator (2-3 weeks)
•Tryptic Soy Agar Deep w/ Mineral oil overlay
Storage: Room temperature in Dark (2-5 years +)
•Addition of glycerol (10% final) into broth culture. Storage: Freeze at - 80°C (Indefinite?)
Source of Bacterial Host Strains

•*E. coli* HS(pFamp)R; ATCC #700891
•*Salmonella choleraesuis* subsp. *choleraesuis* (Smith) Weldin serotype Typhimurium aka WG49; ATCC #700730

Types and Sources of Positive MSB Controls

Bacteriophage MS2; ATCC# 15597-B1
Bacteriophage Fd; ATCC# 15669 -B2
Municipal Wastewater

Bacteriophage Stability in Shellfish Homogenate

		Time (h)		
Temperature	**Addition**	**0**	**4**	**10**
1- 3 °C	**-**	**2.57**	**2.58**	**2.42**
25°C	**-**	**3.81**	**3.64**	
25°C	**Log Famp[a]**	**3.81**	**3.86**	**3.89 (24h)**
35°C		**3.81**	**3.45[b]**	

[a]Famp added at a density of 270 cells/ g
[b]Significant decrease at 95% Confidence limit

Bacteriophage Stability in Shellfish Supernatant

		Time (h)		
Temperature	**Addition**	**0**	**4**	**24**
25°C	**-**	**3.81**	**3.74**	**2.60[b]**
25°C	**Log Famp[a]**	**3.81**	**3.13[b]**	**2.90[b]**
35°C	**-**	**3.81**	**3.73**	**2.90[b]**
35°C	**Log Famp[a]**	**3.81**	**3.56[b]**	**5.51[c]**

[a]Famp added at a density of 270 cells/ g
[b]Significant decrease at 95% Confidence limit
[c]Significant increase at 95% Conifidence limit

Proposal Subject	Thermazyme™ ACP Test
Specific NSSP Guide Reference	NSSP Guide Documents Chapter II. Growing Areas .10 Approved Laboratory Tests
Text of Proposal/ Requested Action	Advanced Instruments, Inc. request ISSC adoption of this method for use in the National Shellfish Sanitation Program.
Public Health Significance	Thermazyme™ ACP Test will provide the basis for determining if shellfish have been thermally processed. This test will allow decisions to be based on a rapid, quantitative method rather than sensory related methods.
Cost Information (if available)	Not available
Action by 2005 Laboratory Methods Review Committee	Recommended the Conference direct the ISSC Executive Office to continue to investigate the issue of standards and pursue the development of standards and report back to the Laboratory Methods Committee with progress on the issue in six (6) months.
Action by 2005 Task Force I	Recommended adoption of the Laboratory Methods Review Committee recommendation for Proposal 05-115.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force I.
Action by USFDA	Concurred with Conference action.
Action by 2007 Laboratory Methods Review Committee	Recommended referral of Proposal 05-115 to the Executive Board for consideration for interim approval. Insufficient data at this time to approve this method under Procedure XVI. Need AP curves at 145 for 15 seconds for each type of shellfish.
Action by 2007 Task Force I	Recommended adoption of the Laboratory Methods Review Committee recommendation on Proposal 05-115.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.
Action by USFDA	December 20, 2007 Concurred with Conference action.

ADVANCED INSTRUMENTS, INC.

RECEIVED JUN 2 8 2004

June 25, 2004

Ken Moore
Executive Director
Interstate Shellfish Sanitation Conference
209-2 Dawson Drive
Columbia, SC 29223

Dear Mr. Moore:

Due to the advice of the USFDA Office of Seafood, I am writing this letter to request a review and approval of the Thermazyme™ ACP Test for use on thermally processed (cooked versus raw) shellfish products in order to make decisions based on a rapid, quantitative method rather than sensory related methods.

I have enclosed some literature and materials to demonstrate how the Fluorophos® ALP Test and Thermazyme ACP Test have brought value to the dairy and meat processing industries as an assessment tool for determining lethality of the kill step and finished product analysis.

Catherine Cutter, Ph.D documents the current situation in the seafood industry and has scientifically demonstrated that the Thermazyme ACP Test could also be utilized to advance the cause of food safety, thereby protecting consumers by minimizing the potential of under processed products making it into distribution channels.

Please have this method reviewed and approved for its use by seafood processors and agencies interested in maintaining the highest level of public safety.

I will be out of the office from June 28-July 6th. For assistance you may contact Eileen Garry, R&D Lab Manager, Advanced /Instrument, Inc. at 781-320-9000 X2118 or email eileeng@aicompanies.com or Gary Wolf, Regional Shellfish Specialist, FDA Office of Seafood, Vorhees, NJ, at 856-783-1420 X13 or Email - gwolf@ora.fda.gov.

I look forward to speaking with you about this exciting opportunity for the industry and thank you for your attention to this important development.

Sincerely,

Kenneth F. Micciche
Director of Marketing
Advanced Instruments, Inc.
Office – 781-471-2145
Facsimile 781-320-8181
Cell 781-354-9739

Delta Instruments FISKE ASSOCIATES Spiral Biotech

Two Technology Way • Norwood, Massachusetts 02062, USA • www.aicompanies.com
781-320-9000 • 800-225-4034 • Fax 781-320-8181

RECEIVED JUN 2 8 2004

LEAST COST FORMULATIONS, LTD.
824 Timberlake Drive, Virginia Beach, VA 23464-3239
Tel: (757) 467-0954 Fax: (757) 467-2947
E-mail: office@lcftld.com URL: http://lcfltd.com/

TECHNICAL REPORT

NUMBER: TR203 DATE: 04 May 24

TITLE: Performance characteristics of the ThermaZyme® acid phosphatase ("ACP") measurement system on seafood.

AUTHOR: R. A. LaBudde

ABSTRACT: Data from a recent study of the use of the ThermaZyme® acid phosphatase measurement system on seafood was analyzed to assess relevant performance characteristics such as accuracy and precision, false positive and false negative error rates and other parameters. Although the data in the study were limited, some quantitative assessment of these parameters was possible.

KEYWORDS: 1) THERMAZYME 2) ACP 3) EPT

REL.DOC.:

REVISED: 04 May 28

Copyright 2004 by Least Cost Formulations, Ltd.
All Rights Reserved

INTRODUCTION

The use of heat-labile enzymes in the determination of cook endpoint temperatures has a long history in the food industry [1-13]. Heat lethality in bacteria is believed to be due primarily to denaturation of cellular enzymes, so verification of destruction of such enzymes is highly correlated to bacterial destruction.

Catalase (meat), alkaline phosphatase (milk) and acid phosphatase (various foods) have been used as surrogates to verify post-process that adequate pasteurization has taken place [2-12].

The ThermaZyme® system, distributed by Advanced Instruments, is based on the fluorometric measurement of acid phosphatase ("ACP") enzyme. Several validation studies have been published for the system involving a variety of food products.

Recently, a study by Cutter and Miller [1] has investigated ACP for endpoint temperature verification in seafood.

BACKGROUND ASSUMPTIONS RELATED TO ACP IN SEAFOOD

The performance characteristics and inferences with respect to ACP in seafood are based entirely on the work done by Cutter and Miller [1]. In particular, the population of inference is limited to those sources of supply locally available to these authors. However, in recommended use, the method may be calibrated using samples of control raw material and cook EPT determination to establish a standard curve for the relevant population of inference.

PERFORMANCE CHARACTERISTICS IN SEAFOOD

The ThermaZyme system may be used to verify endpoint temperatures in two different ways:

1. INFERENTIAL: Was the food processed to a specific minimum endpoint temperature ("EPT") or higher?
2. ESTIMATION: What was the highest equivalent endpoint temperature to which the food was exposed?

A. ACCURACY:

The ThermaZyme Test System can detect as low as 0.1 U/kg of sample, based on a 1:3 initial dilution.

Based on the Cutter and Miller data [1], estimation of endpoint temperature is subject to the following precisions, based on each test comprising the average of 5 replications:

PRECISION OF ENDPOINT TEMPERATURE			
Seafood	*Range*	*Standard error of fit*	*95% Confidence Interval of EPT*
Clams	130-165 F	9.1 F	+/- 8.6 – 14.9 F
Lobster	140-165 F	5.4 F	+/- 6.1 – 13.9 F
Oysters	140-175 F	3.8 F	+/- 3.4 – 5.9 F
Shrimp	140-165 F	5.4 F	+/- 6.1 – 13.9 F

B. SPECIFICITY:

For the inference that raw seafood has been cooked to a specified minimum EPT:

RAW SEAFOOD COMPARED TO MINIMUM ENDPOINT TEMPERATURE		
Seafood	*Minimum EPT*	*False Positive Rate*
Clams	130 F	0.0064%
Lobster	140 F	0.0987%
Oysters	150 F	1.7385%
Shrimp	140 F	0.3711%

C. PRECISION:

Based on the Cutter and Miller data [1], estimation of endpoint temperature is subject to the following precisions, based on each test comprising the average of 5 replications:

PRECISION OF ENDPOINT TEMPERATURE			
Seafood	*Range*	*Standard error of fit*	*95% Confidence Interval of EPT*
Clams	130-165 F	9.1 F	+/- 8.6 – 14.9 F
Lobster	140-165 F	5.4 F	+/- 6.1 – 13.9 F
Oysters	140-175 F	3.8 F	+/- 3.4 – 5.9 F
Shrimp	140-165 F	5.4 F	+/- 6.1 – 13.9 F

D. SENSITIVITY:

The ThermaZyme Test System can detect as low as 0.1 U/kg of sample, based on a 1:3 initial dilution.

E. SELECTIVITY:

The test is specific for the ACP enzyme involved and has no interferences from other compounds.

F. ASSAY INTERVAL:

Each test involves comminution of the bulk sample, possible draining, weighing of a 0.8 g specimen, dilution with standard reagents, homogenization and measurement in the fluorometer. Total time expended per sample is less than 10 minutes for one replicate and an additional 5 minutes for each further replicate.

G. ASSAY COST:

Reagent costs per replicate are approximately $3.00 with approximately 1/6 hr of analyst time.

H. COMPARABILITY:

Alternative methods of verifying EPT are limited. The most obvious being Aerobic Plate Count ("APC") microbial determination. In this case, the analysis cost is approximately $1.00-$2.00 in supplies and 1/6 hr of analyst time per replicate. For viral determinations, the cost would be significantly higher ($30-$100).

I. OTHER STUDIES:

See references [2-13] for studies based on acid or alkaline phosphatase as a means of cook endpoint temperature determination in various meat and dairy products.

J. REGULATORY APPROVALS:

1. AOAC First Action, 1991.
2. AOAC Final Action, 1995. Method 979.13.
3. International Dairy Federation, 1992.
4. Interstate Milk Shippers, 1993.
5. ISO/DIS 11816-2, 2001.
6. FDA, 1995. (Cheese)
7. NCIMS, 2001. (Cream)

REFERENCES

1. Cutter CN and Miller BJ. 2003. Use of an acid phosphatase assay to detect deviations in thermal processing of seafood. J Assoc Food and Drug Officials 67(4):1-14.
2. Davis CE. 1998. Fluorometric determination of acid phosphatase in cooked, boneless, nonbreaded broiler breast and thigh meat. J AOAC Inter 81(4):887-906.
3. Davis CE and Townsend WE. 1994. Rapid fluorometric analysis of acid phosphatase activity in cooked poultry meat. J Food Prot 57:1094-1097.
4. Lyon BG et al. 2001. Acid phosphatase activity and color changes in consumer-style griddle-cooked ground beef patties. J Food Prot 64:1199-1205.
5. Wang SF et al. 1996. Proteins as potential endpoint temperature indicators for ground beef patties. J Food Sci 61(1):5-7.
6. Wilson CE et al. 2002. Influence of Listeria spp. contamination on end-point temperature determination in broiler breast patties by a fluorometric acid phosphatase assay.
7. Cohen EH. 1969. Determination of acid phosphatase activity in cooked hams as an indicator of temperature attained during cooking. Food Tech 23:101-104.
8. Kormendy L et al. 1987. Determination of the extent of heat treatment in canned hams by use of the phosphatase test. Meat Sci 19:77-?.
9. Lint J. 1965. The determination of the acid phosphatase activity in canned hams. Report 25/65A, Danish Meat Products Laboratory, Royal Veterinary and Agricultural College, Denmark.
10. Rocco RM. 1990. Fluorometric analysis of alkaline phosphatase in fluid dairy products. J Food Prot 53:588-591.
11. Rocco RM. 1990. Fluorometric determination of alkaline phosphatase in fluid dairy products: collaborative study. J AOAC 73:842-849.
12. Anonymous. 1986. Determination of internal cooking temperature (acid phosphatase activity). Revised Basic Chemistry Laboratory Guidebook (rev. March 1986), USDA-FSIS No. 3.018:3-49.
13. Jones DR et al. 2002. Variations in levels of acid phosphatase present in chicken whole leg meat. Poultry Sci 81(10):1567-1570.

Proposal Subject

Illness Outbreaks Associated with Consumption of Shellfish

Specific NSSP Guide Reference

NSSP Model Ordinance Chapter II. Risk Assessment and Risk Management
@.01 Outbreaks of Shellfish-Related Illness

Text of Proposal/ Requested Action

C. When the investigation outlined in @.01 B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:

(1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status;

(2) When the investigation indicates the threat of illness is species specific, then a species-specific closure only may be instituted by the Authority and with concurrence from FDA.

~~(2)~~**(3)** Notify receiving states and the FDA that a potential health risk is associated with shellfish harvested from the implicated growing area;

~~(3)~~**(4)** As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and

~~(4)~~**(5)** Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 Code of Federal Regulations Part 7.

Public Health Significance

The basis for this addition is to allow the authority to limit closure of a growing area to specific shellfish species based on a risk assessment conducted by the Authority. This revision would allow the authority the ability to determine the epidemiological association between illness outbreak and shellfish consumption relative to shellfish species and their natural growing area characteristics, product handling, processing, and distribution without closing an entire growing area to all species. This approach would be similar to the Biotoxin closure procedures.

Cost Information (if available)

Specific cost information has not been calculated as it would vary significantly by operation and location. The west coast industry and regulatory agencies, tribal and non-tribal, have all been parties to this effort and generally believe that this is a workable part of a solution to this concern.

Action by 2007 Task Force I

Recommended adoption of Proposal 07-100 as amended.

G. Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or biotoxins, the authority ~~shall:~~

(1) **Shall** follow an existing marine biotoxin contingency plan, if appropriate.
(2) **Shall** collect and analyze samples relevant to the investigation, if appropriate.
(3) **Shall** keep the area closed until it has been determine that levels of naturally occurring pathogens and/or biotoxins are not a public health concern.
(4) **May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific.**

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force I.

Action by USFDA

December 20, 2007
Concurred with Conference action.

Proposal Subject Laboratory Method Approval

Specific NSSP Guide Reference NSSP Guide Model Ordinance Chapter III. Laboratory @.02 Methods

Text of Proposal/ Requested Action

At the request of the Executive Board of the ISSC, in November of 2005 the Method Validation Protocol Workgroup was formed to address the issue of method approval within the NSSP and to develop criteria for method validation. The workgroup developed a complete method validation protocol package that included a comprehensive checklist for method developers, definitions of validation criteria, a detailed protocol for submission of a method for review and SOP's to specifically address *Vibrio* PCR methods. In April of 2006 the Executive Board granted interim approval of these documents for use in the ISSC (submitted as a separate proposal for conference approval). The Laboratory Methods Review Committee (LMR) recognized that the interim approved Single Lab Validation Protocol package required changes to Chapter III. Laboratory @.02 Methods of the NSSP Model Ordinance to conform to the new protocol for method approval.

In addition, in response to the Executive Board's interim approval of non-validated, unapproved methods, the LMR committee recommends the following changes to Chapter III as a mechanism to advise the Executive Board on approval of emerging methods or methods needed for immediate need of the ISSC.

Chapter III. Laboratory

@.02 Methods

A. Microbiological. Methods, practices, and procedures for the analyses of shellfish and shellfish growing or harvest waters shall be the methods ~~required by~~ **validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests**.

B. Chemical and Physical.
   (1) Methods for the analysis of shellfish and shellfish growing or harvest waters shall:
      (a) Be the current AOAC or APHA method for all physical and chemical measurements; and
      (b) Express results of all chemical and physical measurements in standard units, and not instrument readings.
   (2) When an AOAC or APHA method is not available, EPA methods may be used.
   (3) If a method is not approved or validated by AOAC, APHA, or EPA then the method shall be validated in accordance with Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC.

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:
   (1) The current AOAC and APHA methods used in the bioassay for paralytic shellfish poisoning toxins: and

   (2) The current APHA method used in **the** bioassay for ~~*Karemia breve*~~ ***Karenia brevis***; toxins**; or**
   (3) Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.

D. Emerging Methods.
When there is an immediate need and no NSSP approved methods exists, and the ISSC considers allowing an unapproved or non-validated method to be used for a specific purpose, the minimum requirements as defined in the Lab Method Review Committee Advisory for Emerging Methods will be provided. Within two years of the initial allowed use of the method, the entire Single Lab Validation Protocol shall be submitted.

Public Health Significance

The proposed changes will help to ensure that only analytical methods found to be fit for purpose will be used for regulatory monitoring in the NSSP.

Cost Information (if available)

None

Action by 2007 Laboratory Methods Review Committee

Chapter III. Laboratory
@.02 Methods

A. Microbiological. Methods, practices, and procedures for the analyses of shellfish and shellfish growing or harvest waters shall be the methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.

B. Chemical and Physical.
(1) Methods for the analysis of shellfish and shellfish growing or harvest waters shall:
(a) Be the current AOAC or APHA method for all physical and chemical measurements; and
(b) Express results of all chemical and physical measurements in standard units, and not instrument readings.
(2) When an AOAC or APHA method is not available, EPA methods may be used.
(3) If a method is not approved or validated by AOAC, APHA, or EPA then the method shall be validated in accordance with Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC.

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:
(1) The current AOAC and APHA methods used in the bioassay for paralytic shellfish poisoning toxins: and

(2) The current APHA method used in the bioassay for *Karenia brevis*; toxins; or
(3) Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.

D. Emerging Methods.
When there is an immediate need and no NSSP approved methods exists, and the ISSC considers allowing an unapproved or non-validated method to be used for a specific purpose, the minimum requirements as defined in the Lab Method Review Committee Advisory for Emerging Methods will be provided **as follows**.

- **Name of Method**
- **Date of Submission**
- **Specific purpose or intent of the method for use in the NSSP**
- **Step by step procedure including equipment, reagents and safety requirements necessary to run the method**

- **Data generated in the development and/or trials of the method and/or comparing to approved methods if applicable**
- **Any peer reviewed articles detailing the method**
- **Name of developer(s)/submitters**
- **Developer/submitter contact information**

Within two years of the initial allowed use of the method, the entire Single Lab Validation Protocol shall be submitted. **The Lab Methods Review Committee will report to the Executive Board on the status of the Single Lab Validation data submission.**

Action by 2007 Task Force I

Recommended adoption of Proposal 07-101 as amended.

Chapter III. Laboratory
@.02 Methods

A. Microbiological. Methods, practices, and procedures for the analyses of shellfish and shellfish growing or harvest waters shall be the methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.

B. Chemical and Physical.
(1) Methods for the analysis of shellfish and shellfish growing or harvest waters shall:
(a) Be the current AOAC or APHA method for all physical and chemical measurements; and
(b) Express results of all chemical and physical measurements in standard units, and not instrument readings.
(2) When an AOAC or APHA method is not available, EPA methods may be used.
(3) If a method is not approved or validated by AOAC, APHA, or EPA then the method shall be validated in accordance with Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC.

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:
(1) The current AOAC and APHA methods used in the bioassay for paralytic shellfish poisoning toxins: and

(2) The current APHA method used in the bioassay for *Karenia brevis*; toxins; or
(3) Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.

D. Emerging Methods.
When there is an immediate **or critical** need and no NSSP approved methods exists, and the ISSC **Executive Board** considers allowing an unapproved or non-validated method to be used for a specific purpose, the minimum requirements as defined in the Lab Method Review Committee Advisory for Emerging Methods will be provided **to the Executive Board and shall contain the following criteria:** ~~as follows~~.
- Name of Method
- Date of Submission
- Specific purpose or intent of the method for use in the NSSP

- Step by step procedure including equipment, reagents and safety requirements necessary to run the method
- Data generated in the development and/or trials of the method and/or comparing to approved methods if applicable
- Any peer reviewed articles detailing the method
- Name of developer(s)/submitters
- Developer/submitter contact information

Within two years of the initial allowed use of the method, the entire Single Lab Validation Protocol **should** ~~shall~~ be submitted. The Lab Methods Review Committee will report to the Executive Board on the status of the Single Lab Validation data submission.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force I.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject Patrol Evaluation Criteria

Specific NSSP Guide Reference Model Ordinance Chapter VIII Control of Shellfish Harvesting @ .01 Control of Shellstock Growing Areas

Text of Proposal/ Requested Action

B. Patrol of Growing Areas.

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

(a) Have a patrol policy document (~~Critical item~~ **Key**);
(b) Update patrol documents every year (Key item);
(c) Meet NSSP patrol training requirements (Key item);
(d) Patrol all areas that require patrol (Critical item);
(e) Meet NSSP requirements for frequency of patrol (Key item);
(f) Have formalized Memorandum of Agreement with other agency per Chapter VIII@.01B(5) (Key item);
(g) Have a risk management plan per chapter VIII@.01B(3)(b)(c)(d) (Critical item); and
(h) Have a complete risk management plan per Chapter VIII@.01B(3)(b)(c)(d) (Other item).

~~D. Penalties.~~

~~(1) The Authority shall develop a written guideline or enforcement policy which is used to recommend penalties to the courts.~~

~~(2) Authority shall insert appropriate references to its penalties.~~

~~E.~~**D.** Identification of Certain Growing Areas.

(1) The Authority shall chart, describe, and mark the boundaries of growing areas classified as restricted, conditionally restricted, or prohibited, or in a closed status. The boundary descriptions shall:

(a) Be marked by fixed objects or landmarks; or
(b) Be described in a manner which allows easy recognition; and
(c) Allow successful prosecution of any illegal commercial harvesting activity.

(2) The Authority:

(a) Shall notify harvesters of the boundaries established under §E.(1) by dissemination of information with licenses, publication, or direct notification including registered mail; and
(b) May use warning signs.

~~F.~~**E .** Prohibited Classification. The Authority shall exercise effective supervision over each depletion or seed gathering operation and maintain complete written documentation.

Public Health Significance The NSSP Evaluation Criteria Committee identified these needed changes.

Cost Information (if available)

Action by 2007 Task Force I Recommended adoption of Proposal 07-102 as submitted.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force I.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject Laboratory Methods *(Vibrio vulnificus and Vibrio parahaemolyticus)*

Specific NSSP Guide Reference Model Ordinance Chapter XVI. Post Harvest Processing
A. If a dealer elects…

Text of Proposal/ Requested Action

(1) Have a HACCP plan approved by the Authority for the process that ensures that the target pathogen(s) are at safe levels for the at risk population in product that has been subjected to the process.

(a) The dealer must demonstrate that the process reduces the level of *Vibrio vulnificus* in the processed product to non-detectable (<30 MPN/gram) and the process achieves a minimum 3.52 log reduction, to be determined by use of the *Vibrio vulnificus* FDA approved EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th Edition, 1992, or ~~other method approved for NSSP use~~ **the MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, followed by confirmation using biochemical analyses or by the DNA alkaline phosphatase labeled gene probe (vvhA)**.

(b) The dealer must demonstrate that the process reduces the level of *Vibrio parahaemolyticus* in the processed product to non-detectable (<30 MPN/gram) and the process achieves a minimum 3.52 log reduction **Vibrio parahaemolyticus levels are to be determined using the MPN format with confirmation by biochemical analysis, gene probe methodology, or PCR methods as they are listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent**.

Public Health Significance

Cost Information (if available)

Action by 2007 Task Force I Recommended referral of Proposal 07-103 to an appropriate committee as determined by the Conference Chairman.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force I.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject

Adoption of ELISA as a Type I NSSP Analytical Method to Replace the Mouse Bioassay for Monitoring NSP-Causing Toxins in Molluscan Shellfish

Specific NSSP Guide Reference

NSSP Guidance Documents Chapter II Growing Areas
.10 Approved NSSP Laboratory Tests

Text of Proposal/ Requested Action

Request adoption of enzyme linked immunosorbent assay (ELISA) as a Type I NSSP analytical method for neurotoxic shellfish poisoning (NSP) toxins in molluscan shellfish, under NSSP Guidance Documents Chapter II.10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods.

An AOAC collaborative study is planned for the ELISA method. Drs. Jerome Naar and Francie Coblentz at UNCW will be the Principle Investigators. A single lab validation of the method is nearing completion, prior to submission to the AOAC Methods Committee for approval to run the collaborative trial. Results of the AOAC collaborative study will be provided to the ISSC for review by the Laboratory Methods Review Committee.

Public Health Significance

Accumulation of the breve toxins, the toxins responsible for Neurotoxic Shellfish Poisoning (NSP) in shellfish can cause illness in human consumers. Monitoring for NSP toxicity is essential to assure the safety of bivalves harvested for food and to protect the industry by sustaining consumer confidence.

The mouse bioassay for NSP has served well since it was developed in the 1970s. The assay is relatively simple, able to detect dangerous levels of toxicity, and appears to be an accurate measure of human oral potency. Nevertheless, there has long been a need for detection methods that are more sensitive and more precise, that do not require live test animals, while still providing an accurate measure of human oral potency. Motivation for finding alternatives includes the ethical concerns and negative public perceptions focused on test methods that use live animals.

The ELISA for NSP provides an excellent alternative to the mouse bioassay, offering far greater sensitivity, greater accuracy, and a reliable measure of toxin contamination in shellfish. In the format developed at the UNCW, it offers very high throughput.

Because of the higher throughput, the use of the ELISA as screening method will allow monitoring programs to increase their capacity to monitor shellfish beds after blooms of breve toxin-producing algae while minimizing the use of live animals. This will allow for shellfish to be tested at shorter time intervals to potentially expedite reopenings.

The ELISA in its current mode is best suited to use in a central lab to which samples are sent. Since this is the way in which most toxin monitoring is now conducted, the ELISA can, with suitable equipment and training, be used where mouse bioassays are currently conducted. In Florida, the state that is the most routinely affected by Karenia brevis red tides, shellfish testing is conducted by the Fish and Wildlife Conservation Commission at the Fish and Wildlife Research Institute (FWRI), which is already equipped and familiar with the use of the ELISA. Researchers from FWRI have been involved in the development of this assay and its current validation.

Implementation:
Progress in implementation of the ELISA has been greatly facilitated by the support from NOAA and the Fish and Wildlife Research Institute, which has funded projects to assist the development and the validation of this assay. Drs. Naar and Coblentz are planning an AOAC collaborative study of the ELISA with the technical support form various investigators from UNCW, FWRI, FDA and US Army. The AOAC task force on marine biotoxin detection methods, led by Dr. James Hungerford, has identified AOAC validation of the ELISA as a high priority.

Some comparisons of the ELISA with:

Receptor Binding Assay:

A preliminary study performed by several investigators under the lead of Dr Robert Dickey FDA, demonstrated ELISA provides similar results as the receptor binding assay; however, the ELISA does not require the use of any radioactive material.

HPLC/MS:

Side by side analysis of shellfish extracts by ELISA and HPLC-MS was conducted by the FDA and reveal good correlation betweens both methods
However, HPLC/MS require careful filtration of the sample, which is a significant cost, and provide a single path, so throughput per instrument is dependent on run time. Equipment cost and operator skill requirements are also much higher.

Cost Information (if available)	None
Action by 2007 Laboratory Methods Review Committee	Recommended referral of Proposal 07-104 to an appropriate committee as determined by the Conference Chairman.
Action by 2007 Task Force I	Recommended adoption of the Laboratory Methods Review Committee recommendation on Proposal 07-104.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject

Adoption of LC-MS as a Type I NSSP Analytical Method to Replace the Mouse Bioassay for Monitoring NSP

Specific NSSP Guide Reference

NSSP Guidance Documents Chapter II Growing Areas
.10 Approved NSSP Laboratory Tests

Text of Proposal/ Requested Action

Request adoption of liquid chromatrography-mass spectrometry (LC-MS) as a Type I NSSP analytical method for neurotoxic shellfish poisoning (NSP) toxins in molluscan shellfish, under NSSP Guidance Documents Chapter II.10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods.

An AOAC collaborative study is planned for the LC-MS method. Dr. Steven M. Plakas at FDA will be the Principle Investigator. A single lab validation of the method is nearing completion, prior to submission to the AOAC Methods Committee for approval to run the collaborative trial. Results of the AOAC collaborative study will be provided to the ISSC for review by the Laboratory Methods Review Committee.

Public Health Significance

Neurotoxic shellfish poisoning (NSP) is caused by consumption of shellfish contaminated with algal brevetoxins. Monitoring for NSP toxicity is essential to assure the safety of bivalves harvested for food and to protect the industry by sustaining consumer confidence.

The mouse bioassay for NSP toxic shellfish has served well since it was developed in the 1960s. The assay is relatively simple and detects dangerous levels of toxins. However, there has long been a need for detection methods that are more sensitive and precise, that do not require live test animals, while still providing a reliable measure of human oral potency. Motivation for finding alternatives includes ethical concerns and negative public perceptions focused on test methods that use live animals.

The LC-MS method provides an excellent alternative to the mouse bioassay, offering far greater sensitivity and specificity. Greater sensitivity provides a higher level of assurance that growing areas can be closed before violative product is harvested, and enable growers to harvest product while still safe in anticipation of a closure. Greater specificity enables unambiguous identification of toxins present as indicators of human oral potency.

The LC-MS in its current mode is best suited to use in a central lab to which samples are sent. Since this is the way in which most toxin monitoring is now conducted, LC-MS can, with suitable equipment and training, be used as a direct replacement for the mouse bioassay in many existing biotoxin management programs. The principal limitation of LC-MS is the high initial cost of capital equipment.

Implementation:
A single lab validation of the LC-MS method is now in progress. An AOAC collaborative study of the method is planned. The AOAC task force on marine biotoxin detection methods, led by Dr. James Hungerford, has identified validation of the LC-MS method as a high priority.

Validity:
The idea that the LC-MS provides a valid measure of toxicity of brevetoxin-contaminated shellfish arose from a systematic study of the fate of these toxins in the Eastern oyster, along with comparison of alternative methods to that of mouse bioassay of field samples. LC-MS and ELISA data correlated well with other, and with those of mouse bioassay. LC-MS provides unambiguous identification of brevetoxins, while other in vitro methods and mouse bioassay cannot.

Some comparisons of the LC-MS method with:

Mouse bioassay:
The mouse bioassay gives a useful, approximate answer quickly and will reliably detect a

dangerously toxic sample. However, LC-MS offers high specificity and is much more sensitive (by several orders of magnitude). Field studies in Eastern oyster have provided a useful approximation of the levels of toxin by LC-MS equivalent to the toxicity guidance level by mouse bioassay.

Immunoassays:
In field studies of Eastern oyster, LC-MS data were highly correlated with those of enzyme-linked immunoassay (ELISA). ELISA, as performed, measures a composite of brevetoxins present in the sample that share common structural features, while LC-MS offers a higher level of specificity. However, ELISA can be portable and performed by persons with little training, under field conditions.

Receptor binding assay (RBA):
RBAs are generally believed to reflect toxin potencies better than the structurally-based methods (LC-MS and ELISA). However, in field studies with Eastern oyster, mouse bioassay data were more highly correlated with LC-MS, compared with RBA. RBA also has the disadvantage of requiring the use of radioactive materials, which adds considerable costs. Appropriate procedures for the receipt, use and disposal of radioactive materials must be implemented to satisfy regulatory requirements.

Cost Information (if available)
None

Action by 2007 Laboratory Methods Review Committee
Recommended referral of Proposal 07-105 to an appropriate committee as determined by the Conference Chairman.

Action by 2007 Task Force I
Recommended adoption of the Laboratory Methods Review Committee recommendation on Proposal 07-105.

Action by 2007 General Assembly
Adopted recommendation of 2007 Task Force I.

Action by USFDA
December 20, 2007
Concurred with Conference action.

Proposal Subject Receptor Binding Assay (rba) for PSP as a Type I NSSP Analytical Method

Specific NSSP Guide Reference NSSP Guidance Documents Chapter II Growing Areas
.10 Approved NSSP Laboratory Tests

Text of Proposal/ Requested Action Adopt the receptor binding assay (rba) as a Type I NSSP analytical method for PSP testing for use as an alternative to and improvement over the AOAC mouse bioassay under NSSP Guidance Documents Chapter II.10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods.

An AOAC collaborative study is planned for the rba. Dr. Fran Van Dolah at NOAA will be the Principle Investigator. Dr. Van Dolah is nearing completion of a single lab validation, using a HOAc extraction, prior to submission to the Method Committee for approval to run the collaborative trial. Results of the AOAC collaborative study will be provided to the ISSC for review by the Laboratory Methods Review Committee.

Public Health Significance Accumulation of the saxitoxins, the toxins responsible for Paralytic Shellfish Poisoning (PSP) in shellfish can cause illness and death in human consumers. Monitoring for PSP toxicity is essential to assure the safety of bivalves harvested for food and to protect the industry by sustaining consumer confidence.

The mouse bioassay for paralytic shellfish poison (PSP) has served well since it was developed in the 1930s. The assay is relatively simple, quickly detects dangerous levels of toxicity, and appears to be an accurate measure of human oral potency. Nevertheless, there has long been a need for detection methods that are more sensitive, more precise, do not require live test animals, while still providing an accurate measure of human oral potency. Motivation for finding alternatives includes the ethical concerns and negative public perceptions focused on test methods that use live animals.

The receptor binding assay (rba) for PSP provides an excellent alternative to the mouse bioassay, offering far greater sensitivity, greater accuracy, and a reliable measure of human oral potency. In the format developed at the NOAA/Charleston laboratory, it offers very high throughput.

The greater sensitivity of the rba will allow monitoring programs to detect the arrival of a PSP event earlier than is possible with the mouse bioassay. By providing more latitude between the detection limit and regulatory limit this will provide a higher level of assurance that growing areas can be closed before violative product is harvested and will also allow growers to get product out of the water while still safe in anticipation of a closure.

The rba in its current mode is best suited to use in a central lab to which samples are sent. Since this is the way in which most toxin monitoring is now conducted, the rba can, with suitable equipment and training, be used as a direct replacement for the mouse bioassay in many existing biotoxin management programs.

The principal limitation of the rba is that, in its current form, it requires the use of radioactive material. Although the amounts of radioactivity are miniscule and the risk negligible, appropriate procedures for the receipt, use, and disposal of radioactive materials must be implemented to satisfy regulatory requirements. This is a small cost, but must still be recognized. While efforts are underway to develop methods that have the benefits of the receptor assay without requiring radioactive materials, they have not advanced sufficiently to justify delaying implementation of the rba in its current format.

Implementation:
Progress in implementation of the rba has been greatly facilitated by the support of the International Atomic Energy Agency, which has funded several technical cooperation projects to assist developing nations in both setting up the rba and in establishing the necessary infrastructure to ensure that its employment will be useful. As a part of the IAEA

program, Dr. Fran Van Dolah is planning an AOAC collaborative study of the rba. The AOAC task force on marine biotoxin detection methods, led by Dr. James Hungerford, has identified AOAC validation of the rba as a high priority.

Molecular basis for validity:
The idea that the rba was a fundamentally valid measure of toxicity of the saxitoxins to mammals arose from a systematic study of structure/activity relationships among carefully purified and characterized saxitoxins aimed at understanding the reasons for differences in observed toxicity to mice and, ultimately, the nature of the highly selective interaction with the binding site. In the course of this work it was found that the mouse intraperitoneal potencies of the various saxitoxins corresponded well with their binding affinities in the rba.

Some comparisons of the rba with:

Mouse bioassay:
The mouse bioassay gives a useful, approximate answer more quickly and will reliably detect a dangerously toxic sample, while the rba produces more results per day, can produce a large number of precise results much more quickly, and is much more sensitive. The limit of sensitivity for the rba is ca 0.5nM STX, vs 0.5 micromolar STX for the mouse bioassay. As usually applied, the rba is 10x to 100x more sensitive than the mouse bioassay.

Immunoassays:
The response spectrum of the rba is better matched to human oral potency than the immunoassays now available so, while the rba can be considered an accurate measure of human oral potency, the accuracy of an immunoassay depends on which toxins are present in the sample and may not accurately reflect toxicity to consumers. On the other hand, some immunoassays can be portable and can be performed by persons with little training, under field conditions.

HPLC, LC/MS:
Both methods are analyses, rather than assays, and thus determine the concentrations of individual toxins. This information can be vital for research and can be useful in regulatory applications. However, HPLC and LC/MS require careful filtration of the sample, which is a significant cost, and provide a single path, so throughput per instrument is dependent on run time. Equipment cost and operator skill requirements are also much higher, particularly for LC/MS.

Cost Information (if available)

Action by 2007 Laboratory Methods Review Committee
Recommended referral of Proposal 07-106 to an appropriate committee as determined by the Conference Chairman.

Action by 2007 Task Force I
Recommended adoption of the Laboratory Methods Review Committee recommendation on Proposal 07-106.

Action by 2007 General Assembly
Adopted recommendation of 2007 Task Force I.

Action by USFDA
December 20, 2007
Concurred with Conference action.

Proposal Subject	Deletions and Additions to Table 1 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood
Specific NSSP Guide Reference	NSSP Guidance Documents Chapter II. Growing Areas .04 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood
Text of Proposal/ Requested Action	Delete arsenic, cadmium, chromium, lead, and nickel from Table 1 - Action Levels, Tolerances and Guidance Levels for Poisonous and Deleterious Substances in NSSP Guidance Documents Chapter II.04. Add the following chemicals and chemotherapeutic drugs and the associated safety level to Table 1 - Action Levels, Tolerances and Guidance Levels for Poisonous and Deleterious Substances in NSSP Guidance Documents Chapter II.04: Carbaryl in oysters - 0.25 ppm Endothall and its monomethyl ester in all fish - 0.1 ppm Chloramphenicol in all fish - no residue Clenbuterol in all fish - no residue Diethylstilbestrol (DES) in all fish - no residue Demetridazole in all fish - no residue Ipronidazole and other nitroimidazoles in all fish - no residue Frazolidone and other nitrofurans in all fish - no residue Fluoroquinilones in all fish - no residue Glycopeptides in all fish - no residue Delete the less than symbol in front of 20 MU/100 g for Neurotoxic Shellfish Poisoning (NSP) in Table 1 - Action Levels, Tolerances and Guidance Levels for Poisonous and Deleterious Substances in NSSP Guidance Documents Chapter II.-04.
Public Health Significance	Acceptable levels established in the FDA guidance documents for each of the five elements to be deleted were intended only as general guidance. Use of these Guidance Documents as a general formula for calculating levels of concern is somewhat subjective based on the particular circumstances under which they are applied, for example, the rate of consumption. Furthermore, in the 14 years since their publication, new scientific data and information has rendered them somewhat obsolete and in need of revision. Until such time as they can be updated with current information and science, FDA toxicologists have determined the safe levels set forth in them for molluscan shellfish are inappropriate. Addition to the NSSP of the two named chemicals and the nine chemotherapeutic drugs is in keeping with establishment of FDA and EPA safety levels for their presence in shellfish meats and with their citation in the FDA Seafood HACCP Fish and Fisheries Products Hazards and Controls Guide.
Cost Information (if available)	None
Action by 2007 Task Force I	Recommended referral of Proposal 07-107 to an appropriate committee as determined by the Conference Chairman.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject *Vibrio vulnificus* Risk Management Plan

Specific NSSP Guide Reference 1999 Model Ordinance Chapter II

Text of Proposal/ Requested Action Modify 1999 Model Ordinance Chapter II. by adding new Section @. 04:

Chapter II. Risk Assessment and Risk Management.

@. 04 *Vibrio vulnificus* Risk Management

Risk Management Plan

(1) For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state, the Authority shall develop and implement a *Vibrio vulnificus* risk management plan. Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met.

(2) The plan may include the following elements and shall define the administrative procedures and resources necessary to accomplish (i.e., establish and maintain) them;

(a) Education/Consumer intervention;

(b) Pre-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock; and

(c) Post-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock.

(3) The plan shall include controls and interventions that are designed to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported in core states from the consumption of commercially harvested raw or undercooked oysters by 40 percent by the end of 2005 and by 60 percent by 2007. The rate of illness shall be calculated as the number of illnesses divided by the production of oysters from the states bordering the Gulf of Mexico, based on National Marine Fisheries Service landing data. Core states shall be Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama. The baseline data for measuring illness reduction shall be the reported illnesses in the core states for the period 1996 to 1999, inclusive, as compiled by the Southeast Regional Office of the U.S. Food and Drug Administration. The data used for measuring goal attainment shall begin with 2001 data. See §B. (1) below.

(4) At a minimum, the plan shall include the following controls and interventions:

(a) Education/Consumer intervention - Implementing ~~of those~~ portions of the ISSC Education/Consumer Intervention Plan that are relevant to the state;

(b) Pre-harvest Controls - Based on the results of the annual FDA state shellfish program evaluation, assuring that all certified dealers comply with the time/temperature requirements contained in VIII.03, IX.05, XI.01A. (3), XII.01A. (3), XIII.01A. (3), and XIV.01A. (3). *[Ed. note: see proposed language for XI.01A. (3), XII.01A. (3), XIII.01A. (3), and XIV.01A. (3) in Issue 00-208.]*

(c) Post-harvest Controls

(i) Providing assistance, as necessary, for the further study of dockside icing to investigate its effects on shelf-life and variations in the effectiveness of the method as a result of seasonal and regional differences;

(ii) Implementing dockside icing requirements if the study results

are favorable and illness reduction targets are not met as described in §(5) below;

(iii) Supporting, as necessary, the commercialization of existing post-harvest technologies and the development of new technologies;

(iv) Providing incentives to add refrigeration capacity to harvest vessels; and

(v) Selecting and preparing for the implementation of one or more of the controls contained in II. @. 04A. (6), in case such implementation becomes necessary, as described in that paragraph.

(5) If the illness reduction goal contained in II. @. 04A. (3) is less than 25 percent by the end of Year 4 (2004); the goal must be reassessed through a thorough review of the more intensive epidemiological investigations of illnesses for years 2001-2004.

[Submitter's note: The details of this more intensive epidemiological investigation are being discussed by the Vibrio Management Committee (VMC). Final recommendations will be made available following the VMC meeting on June 13 and 14.]

(6) Affected states must implement one or more of the following control strategies on January 1, 2008, if the illness reductions fail to meet the requirements of §(5) above.

[*Submitter's note: The Committee is discussing multiple options for appropriate control strategies. They include:*

(a) Labeling oysters when water temperatures reach a certain level (65□ Fahrenheit is being discussed);

(b) Requiring post-harvest treatment when water temperatures exceed a certain level (65□ Fahrenheit is being discussed);

(c) Closing growing areas when water temperatures exceed a certain level (65□ Fahrenheit is being discussed);

(d) Labeling shellfish, "For shucking and cooking only" based on Vibrio vulnificus levels in meats;

(e) Requiring post-harvest treatment based on levels of Vibrio vulnificus in meats at harvest;

(f) Closing growing areas based on Vibrio vulnificus levels in meats at harvest;

(g) Labeling oysters "For shucking and cooking only" during certain months;

(h) Requiring post-harvest treatment during certain months;

(i) Closing certain shellfish growing areas during certain months.

Submitter's note: Final recommendations will be made available following the VMC meeting on June 13 and 14.]

Epidemiological Plan

(1) Core states referenced in §A. above will administer a survey to determine the Vibrio vulnificus disease reporting practices in each state for the period 1996-1999. The development and implementation plan for the survey will be initiated through the ISSC with participation of state public health officers, epidemiologists and others as determined. Continued surveillance will be necessary to indicate changes to reporting practices during 2000-2007. This is fundamental to establishing the illness baseline as described in §A. (3) above and in tracking future illness report data.

(2) Beginning in calendar year 2001, a new shellfish-borne Vibrio vulnificus disease investigation team will rapidly investigate any case of etiologically confirmed shellfish-borne Vibrio vulnificus septicemia illnesses in core states. This team will gather customary

epidemiological information as well as the level of awareness of risk in those who have suffered etiologically confirmed shellfish-borne Vibrio vulnificus septicemia illnesses. The ISSC will assist in initiating this team.

Public Health Significance

This plan is aimed at reducing exposure to *Vibrio vulnificus*, especially in at-risk populations. These controls, by potentially decreasing exposure, can in turn potentially reduce oyster-borne *Vibrio vulnificus* septicemia illnesses.

Cost Information (if available)

Unknown

Action by 2000 Vibrio Management Committee

Recommended adoption of 00-201 as substituted by the Vibrio Management Committee (VMC).

Text of Proposal:
Modify Model Ordinance Chapter II. by adding Section @. 04:

@. 04 *Vibrio vulnificus* Risk Management

(A) For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement *a Vibrio vulnificus* risk management plan.

(B) The plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction program. The goal of the program will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported in core states (Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama) from the consumption of commercially harvested raw or undercooked oysters by 40 percent, collectively, by the end of 2005 and by 60 percent, collectively, by the end of 2007. The rate of illness shall be calculated as the number of illnesses adjusted for population and rate of reporting divided by the production of oysters from the states bordering the Gulf of Mexico, based on National Marine Fisheries Service landing data verified by Silver Spring, Maryland, headquarters. The goal may be reevaluated prior to the year 2005 and adjusted in the event that new science, data or information becomes available.

(C) The plan shall also include identification and preparation for implementation of one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent illness reduction goal not be achieved by 2007. This portion of the plan shall be completed no later than December 2006. The temperature and month-of the-year parameters identified in the following controls may be adjusted as needed to achieve the established illness reduction goal.

(1) Labeling all oysters, "For shucking by a certified dealer," when the Average Monthly Maximum Water Temperature exceeds 75°F;

(2) Subjecting all oysters to an Authority-approved post-harvest treatment that reduces the *Vibrio vulnificus* levels to 3MPN/g or less," when the Average Monthly Maximum Water Temperature exceeds 75°F;

(3) Closing shellfish growing areas when the Average Monthly Maximum Water Temperature exceeds 75°F;

(4) Labeling all oysters, "For shucking by a certified dealer," during

the months of May through September, inclusive;
(5) Subjecting all oysters to a post-harvest treatment that is both approved by the Authority and reduces the *Vibrio vulnificus* levels to 3MPN/g or less during the months of May through September, inclusive;
(6) Closing shellfish growing areas during the months of May through September, inclusive.

Modify the NSSP Guide for Control of Molluscan Shellfish by adding the following Guidance Document (numbering to be determined at time of publication of the next revision).

***Vibrio vulnificus* Management Guidance Document**

***Vibrio vulnificus* Management**

The voting delegates at the 1999 Annual Meeting in New Orleans created the Vibrio Management Committee (VMC). At the 2000 annual meeting the voting delegates will be asked to adopt the VMC's recommendation of reducing the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia. The goal is to reduce those illnesses reported in core states (Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama) from the consumption of commercially harvested raw or undercooked oysters by 40 percent by the end of 2005 and by 60 percent by the end of 2007. The Core States are the states that have consistently reported *Vv* cases since 1995. The rate of illness shall be calculated as the number of illnesses adjusted for population and rate of reporting divided by the production of oysters from the states bordering the Gulf of Mexico, based on National Marine Fisheries Service landing data verified by Silver Spring, Maryland, headquarters. This adjustment will be performed in consultation with statisticians and epidemiologists from core states and federal agencies. The baseline data and all future data for measuring illness reduction shall be the reported illnesses in the core states for the period 1996 to 1999, inclusive, as compiled by the Southeast Regional Office of the U.S. Food and Drug Administration. The data used for measuring goal attainment shall begin with 2001 data. The formula for calculating for the rate of illness is as follows:

$$\frac{\text{(number of cases) x (CDC adjustment factor)}}{\text{population}}$$

$$\frac{\qquad\qquad\qquad\qquad\qquad\qquad}{\text{production}}$$

The VMC members will include, at a minimum, industry and state shellfish control authority representatives from *Vibrio vulnificus* Illness Source and Core States, FDA, NOAA, EPA, CDC, state epidemiologists; as well as industry and shellfish control representatives from other regions. *Vibrio vulnificus* Illness Source States are those states reporting 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state. Core states are Florida, Texas, California, Louisiana, Georgia, South Carolina and Alabama. Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met.

The VMC will meet at least annually to develop and approve work plans and review progress. The first plan will be in place for a one-year period, followed by three biennial plans. The first work plan and progress review period will be from January 2001 to December 31, 2001. The next work plan period will be from January 1, 2002 to December 31, 2003, January 1, 2004 to December 31, 2005; then January 1, 2006 to December 31, 2007.

Work plans will include goals, tasks, performance measures and assessment methods to track and achieve progress towards the illness reduction goals. The work plans will be developed by the VMC and approved by the VMC membership. The chair of the VMC will deliver a written annual progress report, including a summary of the previous year's progress made in the education program, to the ISSC March executive board meeting. The report shall be made available to the general membership. The biennial work plan structure, outlined below, provides adaptive management and assures consistent progress towards the illness reduction goals.

Work plans developed by the VMC shall include the following elements and shall define the administrative procedures and resources necessary for accomplishment (i.e. establishment and maintenance):

(a) An ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* infection. The Education Program's objectives will be 1) to increase the target audience's awareness that eating raw oysters can be life-threatening to them, and; 2) to change the at-risk group's oyster-eating behavior, i.e., to reduce or stop eating raw oysters. The ISSC Education Committee and the *Vibrio vulnificus* Education Subcommittee will assist in the development and oversight for this program.

(i) The Consumer Education Program will focus educational efforts in the Core States. The Education Program will make educational materials available to states upon request.

(ii) Educational approaches will emphasize partnerships with health and advocacy organizations, and include dissemination of printed materials, posting materials on the Internet, broadcast of television spots, press releases, and other measures deemed effective such as the USDA Physician Notification Program.

(iii) Periodic administration of Behavior Risk Factor State Surveys (BRFSS) and other survey assessments at the state level shall be explored as a means of assessing the effectiveness of educational interventions.

(b) Administration of a survey to determine the current *Vibrio vulnificus* disease reporting and education in each state;

(c) Creation of a shellfish-borne *Vibrio vulnificus* disease investigation team that will be available to assist in collection of epidemiological information associated with confirmed shellfish-borne *Vibrio vulnificus* septicemia illness. This team will assist in gathering customary epidemiological information as well as the level of awareness of risk in those who have suffered etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses. A small ISSC team with recognized epidemiological officers will assist in rapid investigation of any case. This team will work cooperatively with existing local, state and federal disease investigation programs.

(d) Industry-implemented post-harvest controls to reduce *Vibrio*

vulnificus **levels in oyster shellstock which may include: time-temperature, post harvest treatment (i.e. hydrostatic pressure, cool pasteurization, IQF, and irradiation--pending approval), rapid chilling and other emerging technologies.**

(e) To encourage implementation of post harvest controls the Conference will pursue options such as SBA low interest loans; revolving loans; cost sharing; demonstration projects; state-industry partnerships; FDA label incentives; PHT specific growing area classifications; targeted time/temperature assessment by FDA during annual shellfish program evaluations; assistance, as necessary, for the further study and possible implementation of dockside icing to investigate its effects on shelf life and variations in the effectiveness of the method as a result of seasonal and regional differences and incentives to add refrigeration capacity to harvest vessels. The goal will be to provide incentives necessary to post-harvest treat 20 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a source state by the end of the third year (December 31, 2003). The assessment will include the capacity of all operational plants and the capacity of plants under construction. Should the 20 percent goal not be accomplished, the VMC will pursue additional incentives to achieve the goals.

(f) A VMC compilation and review of the data on rates of illness will be made available to the ISSC at the ISSC Biennial meeting following the year in which the data was gathered. In the event that the data is not available at the time of the meeting, the VMC shall meet and review the data when it becomes available and issue a compilation report, which will be made available to the entire ISSC membership. In the event there is no Biennial meeting scheduled for a certain year, the VMC shall meet and review the data when it becomes available and issue a compilation report which will be made available to the entire conference.

(g) A VMC evaluation of the effectiveness of reduction efforts will be conducted at the end of the fifth year (December 31, 2005). The evaluation will determine whether the 40 percent, 5-year illness reduction goal or education/consumer intervention or post harvest controls performance measures set forth in prior work plans have been achieved. Should the VMC evaluation indicate the 40 percent, 5 year goal has not been accomplished, the committee will identify additional harvest controls in the 2006 - 2007 work plan to assure achievement of the 60 percent illness reduction goal by the close of the seventh year. In addition, the VMC will evaluate the requirements in Section 04.C. with the possibility of changing the controls to achieve remaining illness reduction goals.

PUBLIC HEALTH SIGNIFICANCE: The purpose of the National Shellfish Sanitation Program is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state cooperation and uniformity of State Shellfish Programs. This includes protection of the public health by reducing the prevalence of food borne hazards. Complete elimination of illness is difficult to attain but public health programs should be designed to provide the greatest level of public health protection possible. The vision of public health officials must focus on maximizing protection with the most practical public health measures available. This plan is designed to assure a significant reduction in *Vibrio vulnificus*

septicemia illnesses through a combination of consumer education, processing incentives and, if necessary, mandatory harvesting or processing controls.

COST INFORMATION: Unknown.

In addition the Committee recommended:

(1) Issue 00-201 become effective October 1, 2000; and the requirement for the *Vibrio vulnificus* Management Plans specified in Section .04A. be developed by these states by April 1, 2001;
(2) Establish a new VMC technical subcommittee that would come up with a list of research and market-related questions and needs relative to the design of a PHT incentive program; and
(3) Ensure that the VMC establishes and performs all necessary evaluations of goals, tasks, performance measures, assessment measures and data collection elements contained in the new Model Ordinance Section @. 04 *Vibrio vulnificus* Risk Management, and in the *Vibrio vulnificus* Management Guidance Document.

Action by 2000 Task Force II

Recommended adoption of Issue 00-201 as substituted by the Vibrio Management Committee (VMC) and further amended as follows:

TEXT OF PROPOSAL:

Modify Model Ordinance Chapter II. By adding Section @. 04:

@. 04 *Vibrio vulnificus* Risk Management **for Oysters**.

(A) For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement *a Vibrio vulnificus* risk management plan.

(B) The plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction program. **The Plan shall include, at a minimum, the ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses.** The goal of the Vibrio Risk Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses, reported in core states, ~~which may include (Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama) to be determined by the VMC after a thorough review of statistical and epidemiological information~~ from the consumption of commercially harvested raw or undercooked oysters by 40 percent, collectively, by the end of 2005 and by 60 percent, collectively, by the end of 2007. **The core states include Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama. The list of core states may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate.** The rate of illness shall be calculated as the number of illnesses adjusted for population and rate of reporting divided by the production of oysters from the states bordering the Gulf of Mexico, based on National Marine Fisheries Service landing data verified by Silver Spring, Maryland, headquarters. The goal may be reevaluated prior to the year 2005 and adjusted in the event that new science, data or information becomes available.

(C) The plan shall also include identification and preparation for implementation of

one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent ~~illness~~ **rate of illness** reduction goal not be achieved by 2007. This portion of the plan shall be completed no later than December 2006. The temperature and month-of the-year parameters identified in the following controls may be adjusted as needed to achieve the established illness reduction goal.

(1) Labeling all oysters, "For shucking by a certified dealer," when the Average Monthly Maximum Water Temperature exceeds 75°F;
(2) Subjecting all oysters **intended for the raw, half-shell market** to an Authority-approved post-harvest treatment that reduces the *Vibrio vulnificus* levels to 3MPN/g or less," when the Average Monthly Maximum Water Temperature exceeds 75°F;
(3) Closing shellfish growing areas **for the purpose of harvest of oysters intended for the raw, half-shell market** when the Average Monthly Maximum Water Temperature exceeds 75°F;
(4) Labeling all oysters, "For shucking by a certified dealer," during the months of May through September, inclusive;
(5) Subjecting all oysters **intended for the raw, half-shell market** to a post-harvest treatment that is both approved by the Authority and reduces the *Vibrio vulnificus* levels to 3MPN/g or less during the months of May through September, inclusive;
(6) Closing shellfish growing areas **for the purpose of harvesting oysters intended for the raw, half-shell market** during the months of May through September, inclusive.

Modify the NSSP Guide for the Control of Molluscan Shellfish by adding the following Guidance Document (numbering to be determined at time of publication of the next revision.)

***Vibrio vulnificus* Management Guidance Document**

***Vibrio vulnificus* Management**

The voting delegates at the 1999 Annual Meeting in New Orleans created the Vibrio Management Committee (VMC). At the 2000 annual meeting the voting delegates will be asked to adopt the VMC's recommendation of reducing the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia. The goal is to reduce ~~those~~ **the rate of** illness reported in core states ~~from~~ **due to** the consumption of commercially harvested raw or undercooked oysters by 40 percent by the end of 2005 and by 60 percent by the end of 2007. The Core States are the states that have consistently reported *Vibrio vulnificus* cases since 1995. **The list of core states may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate.** The rate of illness shall be calculated as the number of illnesses adjusted for population and rate of reporting divided by the production of oysters from the states bordering the Gulf of Mexico, based on National Marine Fisheries Service landing data verified by Silver Spring, Maryland, headquarters. This adjustment will be performed in consultation with statisticians and epidemiologists from core states and federal agencies. The baseline data and all future data for measuring illness reduction shall be the reported illnesses in the core states for the period 1996 to 1999, inclusive, as compiled by the Southeast Regional Office of the U.S. Food and Drug Administration. The data used for measuring goal attainment shall begin with 2001 data. The formula for calculating the rate of illness is as follows:

$$\frac{\text{(number of cases) x (}\sim\!\!\text{CDC}\sim\!\!\text{ illness reporting adjustment factor)}}{\text{population}}$$

$$\frac{}{\text{production}}$$

The VMC members will include, at a minimum, **balanced representation from** industry and state shellfish control **authorities** from *Vibrio vulnificus* Illness Source and Core States, FDA, NOAA, EPA, CDC, state epidemiologists; as well as industry and shellfish control representatives from other regions. *Vibrio vulnificus* Illness Source States are those states reporting 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state. Core states are Florida, Texas, California, Louisiana, Georgia, South Carolina and Alabama **or those states determined to be appropriate after a thorough review of epidemiological and statistical data.** Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met.

Recognizing the increasing importance and roles for the VMC, the Committee leadership will be expanded and structured in a similar manner as stated in the ISSC By-Laws for Task Forces (reference: ISSC By-Law, Article I Task Forces). The VMC Chair shall alternately be selected from a state shellfish control authority and from industry. The Board Chairman, with approval of the Board, shall appoint a VMC Chair and Vice-Chair. If the VMC Chair represents a state shellfish control authority, the Vice-Chair shall be an industry representative. At the end of the VMC Chair's term of office, the Vice Chair will become Chairman and a new Vice Chair will be appointed who represents the same segment of the Conference as the outgoing VMC Chair. A VMC Chair and Vice Chair should be appointed before October 1, 2000 in order to be consistent with plans for annual VMC meetings and with the effective date of *Vibrio vulnificus* Risk Management Plans. Likewise, the term of office should be for (2) years.

The VMC will meet at least annually to develop and approve work plans and review progress. The first plan will be in place for a one-year period, followed by three biennial plans. The first work plan and progress review period will be from January 2001 to December 31, 2001. The next work plan period will be from January 1, 2002 to December 31, 2003, January 1, 2004 to December 31, 2005**;** then January 1, 2006 to December 31, 2007.

Work plans will include goals, tasks, performance measures and assessment methods to track and achieve progress towards the illness reduction goals. The work plans will be developed by the VMC and approved by the VMC membership. The chair of the VMC will deliver **a written annual progress report, including a summary of the previous year's progress made in the education program, to the ISSC March executive board meeting. The report shall be made available to the general membership. The biennial work plan structure, outlined below,** provides adaptive management and assures consistent progress towards the illness reduction goals.

Work plans developed by the VMC shall include the following elements and shall define the administrative procedures and resources necessary for accomplishment (i.e. establishment and maintenance):

(a) An ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* infection. The Education Program's objectives will be 1) to increase the target audience's awareness that eating raw, untreated oysters can be life-threatening to them, and; 2) to change the at-risk group's oyster-eating behavior, i.e., to reduce or stop eating raw, untreated oysters. The ISSC Education Committee and the *Vibrio vulnificus* Education Subcommittee will assist in the development and oversight for this program.

(i) The Consumer Education Program will focus educational

efforts in the Core States. The Education Program will make educational materials available to states upon request.

(ii) Educational approaches will emphasize partnerships with health and advocacy organizations, and include dissemination of printed materials, posting materials on the Internet, broadcast of television spots, press releases, and other measures deemed effective such as the USDA Physician Notification Program.

(iii) Periodic administration of Behavior Risk Factor State Surveys (BRFSS) and other survey assessments at the state level shall be explored as a means of assessing the effectiveness of educational interventions.

(b) Administration of a survey to determine the current *Vibrio vulnificus* disease reporting and education in each state.

(c) Creation of a shellfish-borne *Vibrio vulnificus* disease investigation team that will be available to assist in collection of epidemiological information associated with confirmed shellfish-borne *Vibrio vulnificus* septicemia illness. This team will assist in gathering customary epidemiological information as well as the level of awareness of risk in those who have suffered etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses. A small ISSC team with recognized epidemiological officers will assist in rapid investigation of any case. This team will work cooperatively with existing local, state and federal disease investigation programs.

(d) Industry-implemented post-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock which may include: time-temperature, post harvest treatment (i.e. hydrostatic pressure, cool pasteurization, IQF, and irradiation--pending approval), rapid chilling and other emerging technologies.

(e) To encourage implementation of post harvest controls the Conference will pursue options such as ~~SBA low interest loans; revolving loans; cost sharing; demonstration projects; state industry partnerships;~~ **market development;** FDA label incentives; PHT specific growing area classifications; targeted time/temperature assessment by FDA during annual shellfish program evaluations; assistance, as necessary, for the further study and possible implementation of dockside icing to investigate its effects on shelf life and variations in the effectiveness of the method as a result of seasonal and regional differences and incentives to add refrigeration capacity to harvest vessels. The goal will be to provide incentives necessary to post-harvest treat 20 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a source state by the end of the third year (December 31, 2003). The assessment will include the capacity of all operational plants and the capacity of plants under construction. Should the 20 percent goal not be accomplished, ~~the VMC will pursue additional incentives to achieve the goals.~~ **the VMC will investigate and report their findings as to why the goal was not reached.**

(f) The VMC will develop a list of issues relating to public health, various technologies; including Post-harvest treatments; marketability; shelf -life and similar matters that lend themselves

to investigation. The VMC will work with FDA, NOAA, CDC, EPA, the shellfish industry and other entities as appropriate to obtain or facilitate the investigation of the issues listed and take the results into account as it develops plans or recommended Issues for the ISSC.

~~(f)~~**(g)** A VMC compilation and review of the data on rates of illness will be made available to the ISSC at the ISSC Biennial meeting following the year in which the data was gathered. In the event that the data is not available at the time of the meeting, the VMC shall meet and review the data when it becomes available and issue a compilation report, which will be made available to the entire ISSC membership. In the event there is no Biennial meeting scheduled for a certain year, the VMC shall meet and review the data when it becomes available and issue a compilation report which will be made available to the entire conference.

~~(g)~~**(h)** A VMC evaluation of the effectiveness of reduction efforts will be conducted at the end of the fifth year (December 31, 2005). The evaluation will determine whether the 40 percent, 5-year ~~illness reduction~~ goal to **reduce the rate of illness** or education/consumer intervention or post harvest controls performance measures set forth in prior work plans have been achieved. Should the VMC evaluation indicate the 40 percent, 5 year goal has not been accomplished, the committee will identify additional harvest controls in the 2006 - 2007 work plan to assure achievement of the 60 percent ~~illness~~ reduction **in the rate of illness** goal by the close of the seventh year. In addition, the VMC will evaluate the requirements in Section 04.C. with the possibility of changing the controls to achieve remaining illness reduction goals.

PUBLIC HEALTH SIGNIFICANCE: The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state cooperation and uniformity of State Shellfish Programs. This includes protection of the public health by reducing the prevalence of food borne hazards. Complete elimination of illness is difficult to attain but public health programs should be designed to provide the greatest level of public health protection possible. The vision of public health officials must focus on maximizing protection with the most practical public health measures available. This plan is designed to assure a significant reduction in *Vibrio vulnificus* septicemia illnesses through a combination of consumer education, processing incentives and, if necessary, mandatory harvesting or processing controls.

COST INFORMATION: Unknown.
The Task Force further recommended adoption of the 2000 Vibrio Management Committee recommendations # 1, 2, and 3.

Action by 2000 General Assembly

The 2000 General Assembly referred Issue 00-201 to appropriate committee as determined by the Conference Chairman.

Action by USFDA

Concurred with Conference action.

Action by 2001 Vibrio vulnificus Subcommittee

Recommended adoption of Issue 00-201 as amended and presented in the 2001 Issue packet:

TEXT OF PROPOSAL:

Modify Model Ordinance Chapter II. By adding Section @. 04:

@. 04 *Vibrio vulnificus* Risk Management for Oysters.

(A) For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement *a Vibrio vulnificus* risk management plan.

(B) The Source State's *Vibrio vulnificus* management plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction program. The Plan shall include, at a minimum, the ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses. The goal of the *Vibrio vulnificus* Risk Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by ~~core reporting states, collectively~~ California, Florida, Louisiana, Texas, from the consumption of commercially harvested raw or undercooked oysters by 40 percent, ~~collectively, by the end of~~ for years 2005 and 200~~5~~6 (average) and by 60 percent for years 2007 and ~~collectively, by the end of~~ 200~~7~~8 (average~~) from the current rate of 0.306/million~~ from the average illness rate for the years 1995 - 1999 of 0.306/million~~. The core reporting states include Florida, Texas, California, and Louisiana.~~ The list of ~~core reporting~~ states (California, Florida, Louisiana, Texas) used to calculate rate reduction may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The illness rate shall be calculated as the number of illnesses per unit of population. The goal may be reevaluated prior to the year 200~~5~~6 and adjusted in the event that new science, data or information becomes available.

(C) The Source States' *Vibrio vulnificus* management plan shall also include identification and preparation for implementation of one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent rate of illness reduction goal not be achieved collectively by 200~~7~~8. The control measures identified in the plan shall be appropriate to the state and reflect that state's contribution to the number of Vv illnesses and the controls that have been implemented by each state. This portion of the plan shall be completed no later than December 200~~6~~7. The temperature and month-of the-year parameters identified in the following controls may be adjusted by the ISSC Executive Board as recommended by the Vibrio Management Committee (VMC) on a state by state basis, as needed to achieve the established illness reduction goal. The adjustment to the State's plan can take into account the illness rate reduction that has occurred since the last review of the plan.

(1) Labeling all oysters, "For shucking by a certified dealer," when the Average Monthly Maximum Water Temperature exceeds 75°F;

(2) Subjecting all oysters intended for the raw, half-shell market to an Authority-approved post-harvest treatment that reduces the *Vibrio vulnificus* levels to 3MPN/g or less," when the Average Monthly Maximum Water Temperature exceeds 75°F;

(3) Closing shellfish growing areas for the purpose of harvest of oysters intended for the raw, half-shell market when the Average Monthly Maximum Water Temperature exceeds 75°F;

(4) Labeling all oysters, "For shucking by a certified dealer," during the months of May through September, inclusive;

(5) Subjecting all oysters intended for the raw, half-shell market to a post-harvest treatment that is both approved by the Authority and reduces the *Vibrio vulnificus* levels to 3MPN/g or less during the months of May

through September, inclusive;
(6) Closing shellfish growing areas for the purpose of harvesting oysters intended for the raw, half-shell market during the months of May through September, inclusive.

Modify the NSSP Guide for the Control of Molluscan Shellfish by adding the following Guidance Document (numbering to be determined at time of publication of the next revision.)

***Vibrio vulnificus* Management Guidance Document**

***Vibrio vulnificus* Management**

The voting delegates at the 1999 Annual Meeting in New Orleans created the Vibrio Management Committee (VMC). Subsequently, *Vibrio vulnificus* and *Vibrio parahaemolyticus* subcommittees have been charged to develop appropriate illness control measures for these two pathogens. The VMC provides guidance and oversight to the subcommittees. Subcommittee recommendations are reviewed by the VMC before submittal to Task Forces. At the 2001 annual meeting, Task Forces will review the VMC's recommendation of reducing the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia with the intention to submit the recommendation to the voting delegates. The goal is to reduce the rate of illness reported in ~~core reporting states~~ California, Florida, Louisiana and Texas due to the consumption of commercially harvested raw or undercooked oysters by 40 percent by the end of 200~~5~~6 and by 60 percent by the end of 200~~7~~8. ~~The Core Reporting States are Louisiana, California, Florida, and Texas. The list of core reporting.~~ The list of states may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The rate of illness shall be calculated as the number of illnesses adjusted for population. This adjustment will be performed in consultation with statisticians and epidemiologists from ~~core reporting states~~ California, Florida, Louisiana and Texas and Federal agencies. The baseline data and all future data for measuring illness reduction shall be the reported illnesses in the ~~core reporting states~~ California, Florida, Louisiana and Texas for the period 1995 to 1999, inclusive, as compiled by the Southeast Regional Office of the U.S. Food and Drug Administration. The data used for measuring goal attainment shall begin with 200~~1~~2 data. For the purpose of maintaining an accurate count of the number of illnesses report by each state (California, Florida, Louisiana and Texas) ~~Core Reporting State~~, the following will apply:

(a) Illness cases counted are those reported by ~~Core Reporting States~~ California, Florida, Louisiana and Texas;
(b) Each illness case is recorded under the state that reports it;
(c) Each case is not counted more than once; and
(d) In the event more than one report per case is filed, the case is recorded under the state of diagnosis.

The formula for calculating the rate of illness is as follows:

$$\frac{\text{(number of cases)}}{\text{population}}$$

The ~~VMC~~ Vv subcommittee members will include, at a minimum, balanced representation from industry and state shellfish control authorities from *Vibrio vulnificus* Illness Source States ~~and Core Reporting States~~ California, Florida, Louisiana and Texas, FDA, NOAA, EPA, CDC, state epidemiologists; as well as industry and shellfish control representatives from other regions. *Vibrio vulnificus* Illness Source States are those states reporting two (2) or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state. ~~Core reporting states are Florida, Texas, California, and Louisiana, or those states determined to be appropriate after a thorough review of epidemiological and statistical data.~~ Etiologically confirmed means those cases in which

laboratory evidence of a specific agent is obtained and specified criteria are met.

Recognizing the increasing importance and roles for the, the Committee leadership will be expanded and structured in a similar manner as stated in the ISSC By-Laws for Task Forces (reference: ISSC By-Law, Article I Task Forces). The VMC Chair shall alternately be selected from a state shellfish control authority and from industry. The Board Chairman, with approval of the Board, shall appoint a VMC Chair and Vice-Chair. If the VMC Chair represents a state shellfish control authority, the Vice-Chair shall be an industry representative. At the end of the VMC Chair's term of office, the Vice Chair will become Chairman and a new Vice Chair will be appointed who represents the same segment of the Conference as the outgoing VMC Chair. A VMC Chair and Vice Chair should be appointed before October 1, 200~~0~~1 in order to be consistent with plans for annual VMC meetings and with the effective date of *Vibrio vulnificus* Risk Management Plans. Likewise, the term of office ~~should~~ shall be for (2) years.

The VMC will meet at least annually to develop and approve annual VMC work plans for *Vibrio vulnificus* illness reduction and review progress. ~~The first plan will be in place for a one-year period, followed by three biennial plans.~~ A series of work plans, each covering a one-year period shall be adopted. The first work plan and progress review period will ~~be from January 2001 to December 31, 2001.~~ cover a seventeen-month period from August 1, 2001 to December 31, 2003 followed subsequently by annual work plans. ~~The next work plan period will be from January 1, 2002 to December 31, 2003, January 1, 2004 to December 31, 2005; then January 1, 2006 to December 31, 2007.~~

Work plans will include goals, tasks, performance measures and assessment methods to track and achieve progress towards the illness reduction goals. The work plans will be developed by the VMC and approved by the VMC membership. The chair of the VMC will deliver a written annual progress report, including a summary of the previous year's progress made in the education program, to the ISSC March executive board meeting. The report shall be made available to the general membership. The ~~biennial~~ annual work plan structure, outlined below, provides adaptive management and assures consistent progress towards the illness reduction goals. If annual assessment of progress towards achieving the illness rate reduction goals show inadequate progress the VMC shall incorporate actions into current and subsequent work plans to assure success in achieving those goals. In addition, if annual review shows inadequate progress the VMC will develop issues for deliberation at the 2005 biennial meeting to consider actions such as:

- increased educational efforts,
- limited harvest restriction,
- reduction in time from harvest to refrigeration,
- phased-in post-harvest treatment requirements, or
- other equivalent controls.

Work plans developed by the VMC shall include the following elements and shall define the administrative procedures and resources necessary for accomplishment (i.e. establishment and maintenance):

(a) An ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* infection. The Education Program's objectives will be 1) to increase the target audience's awareness that eating raw, untreated oysters can be life-threatening to them, and; 2) to change the at-risk group's oyster-eating behavior, i.e., to reduce or stop eating raw, untreated oysters. The ISSC Vibrio Management Committee and the *Vibrio vulnificus* Education Subcommittee will ~~assist~~ evaluate Year 2001 survey results ~~will be~~ and compare~~d to~~ them with the Year 2003 or 2004 survey results to ~~demonstrate that determine~~ the effectiveness in meeting the two objectives of the *Vv* education effort: (1) Show 40% increase in awareness of risk from Vv; and (2) Show 15% increase in at-risk

consumers no longer eating raw oysters while minimizing impacts to non-at-risk consumer raw oyster consumption. ~~in the development and oversight for this program~~.

(i) The Consumer Education Program will focus educational efforts ~~in the Core Reporting States~~ California, Florida, Louisiana and Texas. The Education Program will make educational materials available to additional states upon request.

(ii) Educational approaches will emphasize partnerships with health and advocacy organizations, and include dissemination of printed materials, posting materials on the Internet, broadcast of television spots, press releases, and other measures deemed effective such as the USDA Physician Notification Program.

(iii) Survey assessments at the state level shall be used as a means of assessing the baseline knowledge and effectiveness of educational interventions.

(b) Administration of a survey to determine the current *Vibrio vulnificus* disease reporting and education in each state;

(c) Creation of a ~~A committee~~ working group ~~will be created~~ to work cooperatively with local, state, and federal agencies and ~~program~~ programs to assist in the collection of environmental and epidemiological data to further expand on the current information available. A coordinator may be utilized to facilitate the activities of this ~~subcommittee~~ working group to develop standardized collection of environmental and epidemiological information from harvest to consumer.

(d) Industry-implemented post-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock which may include: time-temperature, post harvest treatment (i.e. hydrostatic pressure, cool pasteurization, IQF, and irradiation--pending approval), rapid chilling and other emerging technologies.

(e) Pursuit of ISSC options ~~To encourage implementation of post-harvest controls the Conference will pursue options~~ such as industry education and communication; FDA label incentives; PHT specific growing area classifications; targeted time/temperature assessment by FDA during annual shellfish program evaluations; assistance, as necessary, for the further study and possible implementation of dockside icing to investigate its effects on shelf life and variations in the effectiveness of the method as a result of seasonal and regional differences and incentives to add refrigeration capacity to harvest vessels. The goal will be to provide incentives necessary to post-harvest treat 20 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a ~~source state~~ Source State by the end of the third year (December 31, 200~~3~~4. The assessment will include the capacity of all operational plants and the capacity of plants under construction. Should the 20 percent goal not be accomplished, the VMC will investigate and report their findings as to why the goal was not reached.

(f) Development by the VMC of ~~The VMC will develop~~ a list of issues relating to public health, various technologies~~;~~ including Post-harvest treatments; marketability; shelf -life and similar matters that lend themselves to investigation. The VMC will work with FDA, NOAA, CDC, EPA, the shellfish industry and other entities as appropriate to obtain or facilitate the investigation of the issues listed and take the results into account as it develops plans or recommended Issues for the ISSC.

(g) Provision for a ~~A~~ VMC compilation and review of the data on rates of illness which will be made available to the ISSC at the ISSC Biennial meeting following the year in which the data was gathered. In the event that the data is not available at the time of the meeting, the VMC shall meet and review the data when it becomes available and issue a compilation report, which will be made available to the entire ISSC membership. In the

event there is no Biennial meeting scheduled for a certain year, the VMC shall meet and review the data when it becomes available and issue a compilation report which will be made available to the entire ~~conference~~ membership.

(h) Provision for a ~~A~~ VMC evaluation of the effectiveness of reduction efforts which will be conducted at the end of the fifth year (December 31, 200~~5~~6). The evaluation will determine whether the 40 percent, 5-year goal to reduce the rate of illness or education/consumer intervention or post harvest controls performance measures set forth in prior work plans have been achieved. Should the VMC evaluation indicate the 40 percent, 5 year goal has not been accomplished, the committee will identify additional harvest controls in the 200~~6~~7 - 200~~7~~8 work plan to assure achievement of the 60 percent reduction in the rate of illness goal by the close of the seventh year. In addition, the VMC will evaluate the requirements in Section 04.C. with the possibility of changing the controls to achieve remaining illness reduction goals.

(i) Should a disagreement arise between FDA and the Authority on the equivalency of a control as described in .04c, the Vv Subcommittee will be requested to provide guidance.

PUBLIC HEALTH SIGNIFICANCE: The purpose of the National Shellfish Sanitation Program is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state cooperation and uniformity of State Shellfish Programs. This includes protection of the public health by reducing the prevalence of food borne hazards. Complete elimination of illness is difficult to attain but public health programs should be designed to provide the greatest level of public health protection possible. The vision of public health officials must focus on maximizing protection with the most practical public health measures available. This plan is designed to assure a significant reduction in *Vibrio vulnificus* septicemia illnesses through a combination of consumer education, processing incentives and, if necessary, mandatory harvesting or processing controls.

COST INFORMATION: Unknown.

Action by 2001 Vibrio vulnificus Subcommittee

Recommended the following changes to Issue 00-201 at the July 22, 2001 subcommittee meeting:

TEXT OF PROPOSAL:

Modify Model Ordinance Chapter II. By adding Section @. 04:

@. 04 *Vibrio vulnificus* Risk Management for Oysters.

(A) For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement *a Vibrio vulnificus* management plan.

(B) The Source State's *Vibrio vulnificus* management plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction program. ~~The Plan shall include, at a minimum, the ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses.~~ The goal of the *Vibrio vulnificus* Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, Texas, from the consumption of commercially harvested raw or undercooked oysters by 40 percent, for years 2005 and 2006 (average) and by 60 percent for years 2007 and 2008 (average) from the average illness rate for the years 1995 - 1999 of 0.306/million. The list

of states (California, Florida, Louisiana, Texas) used to calculate rate reduction may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The illness rate shall be calculated as the number of illnesses per unit of population. The goal may be reevaluated prior to the year 2006 and adjusted in the event that new science, data or information becomes available.

(C) The Source States' *Vibrio vulnificus* management plan **shall include, at a minimum:**

(1) The ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses;

(2) A process to collected standardized information for each *Vibrio vulnificus* illness: including underlying medical conditions; knowledge of disease status; prior counseling on avoidance of high risk foods, including raw oysters; existence of consumer advisories at point of purchase or consumption; and, if possible, whether consumer was aware and understood the advisories;

(3) A standardized process for tracking products implicated in *Vibrio vulnificus* illnesses;

(4) Identification and preparation for achieving a goal of post-harvest treatment capacity of 25 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a Source State by the end of the third year (December 31, 2004). The percentage of post harvest treatment will include the capacity of all operational plants and the capacity of plants under construction;

(5) Identification and preparation for implementation of required post harvest treatment capacity of 50% of all oysters intended for the raw, half-shell market during the months of May through September, harvested from a Source State, which shall be implemented should the 40 percent illness reduction goal not be achieved by December 31, 2006. The percentage of post harvest treatment will include the capacity of all operational plants and the capacity of plants under construction. In the alternative, the state may utilize the control measures, or equivalent control measures, listed in .04, (C), (6) (a), (b), (c), and (d) below for such periods of time which, in combination with post harvest treatment, will provide equivalent outcomes. This portion of the plan shall be completed no later than December 31, 2005; and

(6) Identification and preparation for implementation of one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent rate of illness reduction goal not be achieved collectively by 2008. The control measures identified in the plan shall be appropriate to the state and reflect that state's contribution to the number of Vv illnesses and the controls that have been implemented by each state. This portion of the plan shall be completed no later than December 2007. The temperature and month-of the-year parameters identified in the following controls may be adjusted by the ISSC Executive Board as recommended by the Vibrio Management Committee (VMC) on a state by state basis, as needed to achieve the established illness reduction goal. The adjustment to the State's plan can take into account the illness rate reduction that has occurred since the last review of the plan.

(a) Labeling all oysters, "For shucking by a certified dealer," when the Average Monthly Maximum Water Temperature exceeds 75°F;

(b) Subjecting all oysters intended for the raw, half-shell market to an Authority-approved post-harvest treatment that reduces the *Vibrio vulnificus* levels to 3MPN/g or less," when the Average Monthly Maximum Water Temperature exceeds 75°F;

(c) Closing shellfish growing areas for the purpose of harvest of oysters intended for the raw, half-shell market when the Average Monthly

Maximum Water Temperature exceeds 75°F;
(d) Labeling all oysters, "For shucking by a certified dealer," during the months of May through September, inclusive;
(e) Subjecting all oysters intended for the raw, half-shell market to a post-harvest treatment that is both approved by the Authority and reduces the *Vibrio vulnificus* levels to 3MPN/g or less during the months of May through September, inclusive;
(f) Closing shellfish growing areas for the purpose of harvesting oysters intended for the raw, half-shell market during the months of May through September, inclusive.

Modify the NSSP Guide for the Control of Molluscan Shellfish by adding the following Guidance Document (numbering to be determined at time of publication of the next revision.)

***Vibrio vulnificus* Management Guidance Document**

***Vibrio vulnificus* Management**

The voting delegates at the 1999 Annual Meeting in New Orleans created the Vibrio Management Committee (VMC). Subsequently, *Vibrio vulnificus* and *Vibrio parahaemolyticus* subcommittees have been charged to develop appropriate illness control measures for these two pathogens. The VMC provides guidance and oversight to the subcommittees. Subcommittee recommendations are reviewed by the VMC before submittal to Task Forces. At the 2001 annual meeting, Task Forces will review the VMC's recommendation of reducing the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia with the intention to submit the recommendation to the voting delegates. The goal is to reduce the rate of illness reported in California, Florida, Louisiana and Texas due to the consumption of commercially harvested raw or undercooked oysters ~~by 40 percent by the end of 2006 and by 60 percent by the end of 2008.~~ **by 40 percent, for years 2005 and 2006 (average) and by 60 percent for years 2007 and 2008 (average) from the average illness rate for the years 1995 - 1999 of 0.306/million.** The list of states may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The rate of illness shall be calculated as the number of illnesses adjusted for population. This adjustment will be performed in consultation with statisticians and epidemiologists from California, Florida, Louisiana and Texas and Federal agencies. The baseline data and all future data for measuring illness reduction shall be the reported illnesses in the California, Florida, Louisiana and Texas for the period 1995 to 1999, inclusive, as compiled by the Southeast Regional Office of the U.S. Food and Drug Administration. The data used for measuring goal attainment shall begin with 2002 data. For the purpose of maintaining an accurate count of the number of illnesses report by each state (California, Florida, Louisiana and Texas), the following will apply:

(a) Illness cases counted are those reported by California, Florida, Louisiana and Texas;
(b) Each illness case is recorded under the state that reports it;
(c) Each case is not counted more than once; and
(d) In the event more than one report per case is filed, the case is recorded under the state of diagnosis.

The formula for calculating the rate of illness is as follows:

$$\frac{\text{number of cases}}{\text{population}}$$

The V.v. subcommittee members will include, at a minimum, balanced representation from industry and state shellfish control authorities from *Vibrio vulnificus* Illness Source States California, Florida, Louisiana and Texas, FDA, NOAA, EPA, CDC, state epidemiologists; as

well as industry and shellfish control representatives from other regions. *Vibrio vulnificus* Illness Source States are those states reporting two (2) or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state. Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met.

Recognizing the increasing importance and roles for the, the Committee leadership will be expanded and structured in a similar manner as stated in the ISSC By-Laws for Task Forces (reference: ISSC By-Law, Article I Task Forces). The VMC Chair shall alternately be selected from a state shellfish control authority and from industry. The Board Chairman, with approval of the Board, shall appoint a VMC Chair and Vice-Chair. If the VMC Chair represents a state shellfish control authority, the Vice-Chair shall be an industry representative. At the end of the VMC Chair's term of office, the Vice Chair will become Chairman and a new Vice Chair will be appointed who represents the same segment of the Conference as the outgoing VMC Chair. A VMC Chair and Vice Chair should be appointed before October 1, 2001 in order to be consistent with plans for annual VMC meetings and with the effective date of *Vibrio vulnificus* Risk Management Plans. Likewise, the term of office shall be for (2) years.

The VMC will meet at least annually to develop and approve annual VMC work plans for *Vibrio vulnificus* illness reduction and review progress. A series of work plans, each covering a one-year period shall be adopted. The first work plan and progress review period will cover a seventeen-month period from August 1, 2001 to December 31, 2003 followed subsequently by annual work plans. Work plans will include goals, tasks, performance measures and assessment methods to track and achieve progress towards the illness reduction goals. The work plans will be developed by the VMC and approved by the VMC membership. The chair of the VMC will deliver a written annual progress report, including a summary of the previous year's progress made in the education program, to the ISSC March executive board meeting. The report shall be made available to the general membership. The annual_work plan structure, outlined below, provides adaptive management and assures consistent progress towards the illness reduction goals. If annual assessment of progress towards achieving the illness rate reduction goals show inadequate progress the VMC shall incorporate actions into current and subsequent work plans to assure success in achieving those goals. In addition, if annual review shows inadequate progress the VMC will develop issues for deliberation at the 2005 biennial meeting to consider actions such as:

- increased educational efforts,
- limited harvest restriction,
- reduction in time from harvest to refrigeration,
- phased-in post-harvest treatment requirements, or
- other equivalent controls.

Work plans developed by the VMC shall include the following elements and shall define the administrative procedures and resources necessary for accomplishment (i.e. establishment and maintenance):

(a) An ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* infection. The Education Program's objectives will be 1) to increase the target audience's awareness that eating raw, untreated oysters can be life-threatening to them, and; 2) to change the at-risk group's oyster-eating behavior, i.e., to reduce or stop eating raw, untreated oysters. The ISSC Vibrio Management Committee and the *Vibrio vulnificus* Education Subcommittee will evaluate Year 2001 survey results and compare them with the Year 2003 or 2004 survey results determine the effectiveness in meeting the two objectives of the *Vv* education effort: (1) Show 40% increase in awareness of risk from Vv;

and (2) Show 15% increase in at-risk consumers no longer eating raw oysters while minimizing impacts to non-at-risk consumer raw oyster consumption.

(i) The Consumer Education Program will focus educational efforts **in** California, Florida, Louisiana and Texas. The Education Program will make educational materials available to additional states upon request.

(ii) Educational approaches will emphasize partnerships with health and advocacy organizations, and include dissemination of printed materials, posting materials on the Internet, broadcast of television spots, press releases, and other measures deemed effective such as the USDA Physician Notification Program.

(iii) Survey assessments at the state level shall be used as a means of assessing the baseline knowledge and effectiveness of educational interventions.

(b) Administration of a survey to determine the current *Vibrio vulnificus* disease reporting and education in each state.

(c) Creation of a working group to work cooperatively with local, state, and federal agencies and programs to assist in the collection of environmental and epidemiological data to further expand on the current information available. A coordinator may be utilized to facilitate the activities of this working group to develop standardized collection of environmental and epidemiological information from harvest to consumer.

(d) Industry-implemented post-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock which may include: time-temperature, post harvest treatment (i.e. hydrostatic pressure, cool pasteurization, IQF, and irradiation--pending approval), rapid chilling and other emerging technologies.

(e) Pursuit of ISSC options such as industry education and communication; FDA label incentives; PHT specific growing area classifications; targeted time/temperature assessment by FDA during annual shellfish program evaluations; assistance, as necessary, for the further study and possible implementation of dockside icing to investigate its effects on shelf life and variations in the effectiveness of the method as a result of seasonal and regional differences and incentives to add refrigeration capacity to harvest vessels. The goal will be to provide incentives necessary to post-harvest treat ~~20~~ **25** percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a Source State by the end of the third year (December 31, 2004). The assessment will include the capacity of all operational plants and the capacity of plants under construction. Should the ~~20~~ **25** percent goal not be accomplished, the VMC will investigate and report their findings as to why the goal was not reached.

(f) Development by the VMC of a list of issues relating to public health, various technologies~~,~~ including Post-harvest treatments; marketability; shelf -life and similar matters that lend themselves to investigation. The VMC will work with FDA, NOAA, CDC, EPA, the shellfish industry and other entities as appropriate to obtain or facilitate the investigation of the issues listed and take the results into account as it develops plans or recommended Issues for the ISSC.

(g) Provision for a VMC compilation and review of the data on rates of illness, which will be made available to the ISSC at the ISSC Biennial meeting

following the year in which the data was gathered. In the event that the data is not available at the time of the meeting, the VMC shall meet and review the data when it becomes available and issue a compilation report, which will be made available to the entire ISSC membership. In the event there is no Biennial meeting scheduled for a certain year, the VMC shall meet and review the data when it becomes available and issue a compilation report which will be made available to the entire membership.

Provision for a VMC evaluation of the effectiveness of reduction efforts, which will be conducted at the end of the fifth year (December 31, 2006). The evaluation will determine whether the 40 percent, 5-year goal to reduce the rate of illness or education/consumer intervention or post harvest controls performance measures set forth in prior work plans have been achieved. Should the VMC evaluation indicate the 40 percent, 5 year goal has not been accomplished, the committee will identify additional harvest controls in the 2007 - 2008 work plan to assure achievement of the 60 percent reduction in the rate of illness goal by the close of the seventh year. In addition, the VMC will evaluate the requirements in Section 04.C. with the possibility of changing the controls to achieve remaining illness reduction goals.

Should a disagreement arise between FDA and the Authority on the equivalency of a control as described in .04~~e~~**(C)**, the V.v. Subcommittee will be requested to provide guidance.

The *Vibrio vulnificus* Subcommittee further recommended the following:

1) **Request the Executive Board request FDA to meet with the Irradiation petition submitter to establish a timetable under which FDA will review the petition.**

2) **Request the Executive Board request FDA and the state of California seek additional funding to increase the education of at-risk consumers in California, particularly in southern California,**

3) **Recommended that the Chairman appoint a committee to develop further guidance language for implementation of .04 (C) (1)-(5).**

4) **Recommended adoption of an effective date of October 1, 2001, and further recommended an expedited review by FDA.**

Action by 2001 Vibrio Management Committee

Recommended adoption of the *V. vulnificus* Subcommittee Report recommendations.

Action by 2001 Task Force II

Recommended adoption of 2001 Vibrio Management Committee Report recommendations.

The Task Force further recommended the Executive Board Chairman appoint an appropriate committee which shall develop a threshold for adoption of *Vibrio vulnificus* management plans (.04)(A), and for development of an exit strategy for source states.

Action by 2001 General Assembly

Adopted recommendation of 2001 Task Force II.

Action by USFDA

Concurred with Conference action.

This issue was referred back to the ISSC V*ibrio vulnificus* Subcommittee following its marginal defeat at the 2000 ISSC. While FDA was disappointed that the 2000 Conference

voted to refer Issue 00-201 back to committee, we believe the dedicated efforts of the *Vibrio vulnificus* Subcommittee over the ensuing year resulted in ISSC adoption of a stronger and more workable plan to reduce *Vibrio vulnificus* illnesses associated with raw shellfish consumption. Issue 00-201 was designed to reduce *Vibrio vulnificus* septicemia illnesses through post harvest treatment (PHT) processing, consumer education, and, if necessary, mandatory harvesting and/or processing controls. FDA looks forward to working with states as they develop and implement *Vibrio vulnificus* management plans. We also look forward to our continued participation on the ISSC *Vibrio* Management Committee (VMC), *Vibrio vulnificus* Subcommittee, and *Vibrio vulnificus* Education Subcommittee to implement measures (including data collection, data analysis, and development of annual work plans by the VMC) set forth in the "*Vibrio vulnificus* Management Guidance Document" which was adopted as part of Issue 00-201.

During review of Issue 00-201, FDA noted that adopted in the third sentence of Chapter II. @. 04(C)(5) did not include alternatives (e) and (f) of 04(C)(6) should the 40% illness reduction goal not be achieved. It is our understanding that alternatives (e) and (f), which appear to have been inadvertently omitted, will be considered at the January meeting of the ISSC Executive Board for inclusion as alternatives in 04(C)(5).

Action by 2003 Vibrio vulnificus Subcommittee

Recommended that the baseline illness reduction rate of 1995 – 99 of 0.306 per million be modified in Chapter II @ 04 B to 0.303 per million to reflect the elimination of 1 case from the database.

Action by 2003 Vibrio Management Committee

Recommended adoption of Vv Subcommittee recommendation on Proposal 00-201.

Action By 2003 Task Force II

Recommended adoption of Vibrio Management Committee recommendation on Proposal 00-201.

Action By 2003 General Assembly

Adopted recommendations of 2003 Task Force II.

Action By USFDA

Concurred with Conference Action.

Action by 2005 *Vv* Subcommittee

Recommended the Vibrio Management Committee communicate to the Executive Board that the Conference has made significant progress toward achieving the 40% illness reduction goal as reflected in the 2004 rates compared to the baseline in the core states. Additionally, FDA has found all states required to implement Vv Management Plan are in compliance with the Model Ordinance. It should be noted that this is not an indication for a reduction in current efforts.

Action by 2005 Vibrio Management Committee

Recommended adoption of the Vv Subcommittee recommendation on Proposal 00-201. Additionally, the VMC adopted the following motion:

In the three (3) Gulf Core States the illness rate reduction was 32% from their baseline. In all four Core States the reduction was 47%. Likely factors that contributed to the illness reduction include increased voluntary post harvest processing, education of at-risk individuals and California's action to ban non-post harvest processed oysters. It is recommended that the Conference continue to pursue additional methods to measure success or failure of the Risk Management Plan in both the Core States and nationally.

Action by 2005 Task Force II

Recommended adoption of the Vibrio Management Committee recommendations on Proposal 00-201.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force II.

Action by USFDA

With reservation, FDA concurs with action taken on Proposal 00-201. Although FDA recognizes that a 47% reduction in *Vibrio vulnificus (Vv)* illnesses has been achieved in the Core reporting states, the Agency believes that this reduction is primarily the result of California's ban on non-post harvest processed Gulf oysters. At the 2005 Conference FDA proposed that California be removed from the list of Core states and that one or more additional states with consistent *Vv* illness reporting records be substituted. The *Vv* Subcommittee did not concur with FDA's recommendation and retained California as a Core state for measuring the success of the *Vv* Action Plan. FDA maintains the position that California should be removed as a Core reporting state and that illness reduction rates that include California provide a false indication of success relative to the *Vv* Action Plan illness reduction goals. FDA requests that the ISSC Executive Board direct the Vibrio Management Committee (VMC), during its March meeting, to reconsider the decision of the *Vv* Subcommittee to retain California as a Core reporting state.

Action by 2007 Vibrio Management Committee

Recommended that the Vibrio Management Committee continue to monitor the activities of Proposal 00-201.

Action by 2007 Task Force II

Recommended adoption of the Vibrio Management Committee recommendation on Proposal 00-201.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007
Concurred with Conference action with the following comments and recommendations for ISSC consideration.

At the 2007 Biennial Meeting, Dr. Alvin Rainosek advised the Conference that current efforts under the *Vibrio vulnificus* Management Plan are not likely to achieve the ISSC's 60% illness reduction goal by the end of 2008. FDA strongly encourages source states and the shellfish industry to begin preparing for the implementation of controls outlined in NSSP Model Ordinance Chapter II @ .04 and intended to ensure a 60% illness reduction in years subsequent to 2008. FDA anticipates that source states will be prepared to implement these controls at the conclusion of 2008 should the 60% reduction goal not be met. FDA also anticipates that implementation of those controls, should they be needed, will achieve a 60% illness reduction by the end of 2009 as determined by the average number of illnesses for the years 2008 and 2009 combined.

Proposal Subject Depuration

Specific NSSP Guide Reference NSSP Guide Model Ordinance Chapter XV. Depuration .03 Other Model Ordinance Requirements L. Process Verification (1) (b) and (2)

Text of Proposal/ Requested Action MODIFY Chapter XV.02L (1) and XV.03L (2):

.03 Other Model Ordinance Requirements

L. Process Verification:

(1) Perform process verification....

(a)

(b) Determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each ~~restricted~~ harvest area used...

(2) Conditional Protocol Verification. If the depuration performance indices for a specific growing area fail to meet the Critical Limits for the Indices of Depuration Plant Performance, or if a new ~~restricted~~ growing area is used as a source of shellfish for depuration, or if a new depuration process has generated less than 10 process batches of data, the process is considered to be unverified and the dealer shall adhere to the following conditional protocols: ...

Public Health Significance By definition, a Depuration Processor (DP) "receives shellstock from growing areas in the approved or conditionally approved, restricted, or conditionally restricted classification and submits such shellstock to an approved depuration process." All areas submitted to the depuration plant for processing should be included for Process Verification, not just restricted areas as stated in the current section.

Cost Information (if available) None

Action by 2001 Task Force I Recommended referral of Issue 01-206 to an appropriate committee as determined by the Committee Chairman.

Action by 2001 General Assembly Adopted recommendation of 2001Task Force II.

Action by USFDA Concurs with Conference action.

Action by 2003 Depuration Wet Storage Committee Recommended no action on Proposal 01-206. Rationale: The proposal is adequately addressed in the Model Ordinance in Chapter XV .02 L (1) and XV.03 L (2).

Action by 2003 Task Force I Recommended referral of Proposal 01-206 to appropriate committee as determined by the Conference Chairman.

Action by 2003 General Assembly Adopted recommendations of 2003 Task Force II.

Action by USFDA Concurred with Conference Action.

Action by 2005 PHP Committee Recommended referral of Proposal 01-206 to the appropriate committee as determined by the Conference Chairman.

The discussions of the committee/workgroup should include a review of the Chapter XV requirements for consistency with validation and verification requirements for *Vv/Vp* reduction and make recommendations to the Post Harvest Processing Committee for achieving NSSP consistency in validation/verification.

Action by 2005 Task Force II

Recommended adoption of the Post Harvest Processing Committee on Proposal 01-206.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force II.

Action by USFDA

Concurred with Conference action.

Action by 2007 Post Harvest Processing Committee

Recommended adoption of Proposal 01-206 as amended.

M. Process Verification.

The Dealer shall continually:

(1) **Routine Verification**. Perform process verification on a continuous basis according to the following protocol:

(a) Following completion of a minimum of 44 hours of depuration, collect and assay at least one end-product sample;

(i) from each lot of restricted shellstock to be depurated in the depuration unit.

(ii) **weekly from each lot of approved shellfish to be depurated in the depuration unit.**

(b) Determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each harvest area used.

(c) Compare daily, or as a results become available, the depuration performance indices with the following Critical Limits for the Indices of Depuration Plant Performance.

Limits for Verification of Depuration Plant Performance
Fecal coliforms per 100 grams

Species	Geometric Mean	90th Percentile
Soft Clams *(Mya arenaria)*	50	130
Hard Clams *(Mercenaria mercenaria*)	20	70
Oysters	20	70
Manilla Clams	20	70
Mussels	20	70

(d) If the depuration performance indices for a specific species from a specific growing area are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance, then the process is considered verified for that species from that growing area.

(e) For the purpose of making calculations, fecal coliform counts that signify the upper or lower limit of sensitivity of the test (MPN or ETCP) shall be increased or decreased by one significant figure. Thus, <9.0 becomes 8.9, <17 becomes 16 and >248 becomes 250. Individual plates which are too numerous to count (TNTC) are considered to have >100 colonies per plate. A sample containing "TNTC" plates is collectively rendered as having a count of 10,000.

Conditional Protocol Verification. If the depuration performance indices for a specific growing area fail to meet the Critical Limits for the Indices of Depuration Plant Performance, or if a new **restricted** growing area is used as a source of shellfish for depuration, or if a new depuration process has generated less than 10 process batches of data, the process is considered to be unverified and the dealer shall adhere to the following conditional protocols:…

Action by 2007 Task Force II Recommended adoption of the Post Harvest Processing Committee recommendation on Proposal 01-206.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force II.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject Post Harvest Processing

Specific NSSP Guide Reference NSSP Guide Model Ordinance Chapter X. Section .09

Text of Proposal/ Requested Action Move the contents of existing Chapter X, section .09 to a new Chapter XVI and rewrite as follows:

CHAPTER XVI

POST HARVEST PROCESSING

.01 Post-Harvest Processing.

(A) If a dealer elects to use a process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concern in shellfish, the dealer shall:

(1) Have a HACCP plan approved by the Authority for the process that ensures that the target pathogen(s) are at safe levels for the at risk population in product that has been subjected to the process.

(a) For processes that target *Vibrio vulnificus*, the level of *Vibrio vulnificus* in product that has been subjected to the process shall be non-detectable (<3 MPN/gram), to be determined by use of the *Vibrio vulnificus* FDA approved EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th Edition, 1992.

(b) For processes that target *Vibrio parahaemolyticus*, the level of *Vibrio parahaemolyticus* in product that has been subjected to the process shall be non-detectable (<1 CFU/0.1 gram).

(c) For processes that target other pathogens, the level of those pathogens in product that has been subjected to the process shall be below the appropriate FDA action level, or, in the absence of such a level, below the appropriate level as determined by the ISSC.

(d) The ability of the process to reliably achieve the appropriate reduction in the target pathogen(s) shall be validated by a study approved by the Authority, with the concurrence of FDA.

(e) The HACCP plan shall include:

(i) Process controls to ensure that the end point criteria are met for every lot; and,

(ii) A sampling program to periodically verify that the end point criteria are met.

(2) Package and label all shellfish in accordance with all requirements of this Ordinance. This includes labeling all shellfish which have been subjected to the process but which are not frozen in accordance with applicable shellfish tagging and labeling requirements in Chapter X.05 and X.06.

(3) Keep records in accordance with Chapter X.07.

(B) A dealer who meets the requirements of this section may label product that has been subjected to the reduction process as:

(1) "Processed for added safety," if the process reduces the levels of all pathogens of public health concern to safe levels for the at risk population;

(2) "Processed to reduce [name of target pathogen(s)] to non-detectable levels," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or

(3) "Processed to reduce [name of target pathogen(s)] to non-detectable levels for added safety," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or

(4) A term that describes the type of process applied (e.g. "pasteurized,"

"individually quick frozen," "pressure treated") may be substituted for the word "processed" in the options contained in (B)(1)-(3).

(C) For the purposes of refrigeration, if the end product is dead, the product shall be treated as shucked product. If the end product is live, the product shall be treated as shellstock.

Eliminate Chapter X, section .10, "Processed Products with Labeling Claims for Safety."

Public Health Significance

Protection of at-risk consumers and added incentives for post-harvest labeling.

Cost Information (if available)

None

Action By 2001 Task Force I

1. Recommended adoption of Issue 01-224 as submitted.
2. Recommended that an appropriate committee be established by the Conference Chairman with the following instructions: consider the establishment of a new PHT dealer classification and any other relevant topics.
3. Recommended an effective date of October 1, 2001 and request expedited FDA approval.
4. Recommended that FDA identify in the ICSSL those firms that have been identified by the SSCA as having an approved post harvest treatment process.

Note: Recommendation number four (4) on Issue 01-224 may be divided and debated separately.

Action By 2001 General Assembly

Adopted recommendations 1-3 of 2001 Task Force II. Referred recommendation 4 to appropriate committee as determined by Conference Chairman.

Action By USFDA

Concurs with Conference action.

FDA concurs with Conference action to adopt Issue 01-224 even though an important aspect of it was referred to committee for consideration at the next meeting. Issue 01-224 specifically outlined four recommendations for adoption, however only three were adopted. The forth, recommendation number 4, which was referred to an appropriate committee, would have provided for identification, in the Interstate Certified Shellfish Shippers List (ICSSL), of firms having an approved post harvest treatment process. FDA considers the ability to identify such firms in the shippers list as an important component of a comprehensive NSSP PHT program. We firmly believe that such a measure provides an important incentive to processors who currently use or who are considering installation of, PHT processes to reduce the presence of specific pathogens.

Action By 2003 Post-Harvest Processing Committee

Recommended adoption of the following recommendations to address recommendation#4 as indicated in Action by 2001 Task Force II.

1. A PHT designation should be defined and included in the ICSSL. The PHT definition should be as follows: PHT designates a certified dealer with the capability to apply a validated process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concerns in shellfish.
2. It is recommended that an ISSC committee address how to distinguish PHT products beyond current Model Ordinance pathogen reduction statements.
3. The PHT designation in the ICSSL should be accompanied by a change in the title of chapter XVI of the Model Ordinance from the current title "Post Harvest Processing" to Post Harvest Treatments.

Action By 2003 Task Force I

Recommended adoption of Post-Harvest Processing Committee recommendation on Proposal 01-224 as amended:

1. ~~A PHT designation should be defined and included in the ICSSL. The PHT definition should be as follows: PHT designates a certified dealer with the capability to apply a validated process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concerns in shellfish.~~
2. It is recommended that an ISSC committee address how to distinguish PHT products beyond current Model Ordinance pathogen reduction statements.
3. ~~The PHT designation in the ICSSL should be accompanied by a~~ Change ~~in~~ the title of chapter XVI of the Model Ordinance from the current title "Post Harvest Processing" to Post Harvest Treatments.

Action By 2003 General Assembly

Adopted recommendation of 2003 Task Force II.

Action By USFDA

Concurred with Conference action with the exception of **"no action"** on Post Harvest Processing Committee recommendation number one. FDA requests that Post Processing Committee recommendation number one be referred back to the Conference for deliberation by an appropriate committee.

Recommendation number one called for the establishment of a Post Harvest Treatment (PHT) designation for use in the Interstate Certified Shippers List (ICSSL). Such designation would identify dealers who utilize a validated process to reduce target pathogens in shellfish to safe levels. Recommendation number one also defined the PHY designation in a manner consistent with Model Ordinance requirements for PHT processing. FDA considers the ability to identify shellfish dealers that have a validated process for reducing target pathogens to safe levels an important component of a comprehensive NSSP program for PHT. We remain committed to the premise that ICSSL identification of PHT processors provides incentive to processors who currently employ or who are considering installation of PHT processes to improve shellfish safety.

Action By ISSC Executive Board

Concurred with the USFDA. Post Harvest Processing Committee recommendation number one will be referred back to the Conference for deliberation by an appropriate committee.

Action by 2005 Post Harvest Processing Committee

Recommended a PHP designation should be defined and included in the ICSSL. The PHP definition should be as follows: PHP designates a certified dealer with the capability to apply a validated process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concerns in shellfish.

Action by 2005 Task Force II

1. Recommended adoption of the Post Harvesting Processing Committee recommendation on Proposal 01-224 as amended:

   PHP designation should be defined and included in the ICSSL. The PHP definition should be as follows: PHP designates a certified dealer with the capability to apply a validated post harvest process to reduce the level(s) of hazards not addressed by controls in the 2003 NSSP Guide for the Control of Molluscan Shellfish Chapters XI through XIV.

2. Recommended the Post Harvest Processing Committee address inconsistencies between the definition of post harvest processing currently found in the Model Ordinance and the PHP designation definition in the ICSSL as stated above.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force II.

Action by USFDA

Concurred with Conference action.

Action by 2007 Post Harvest Processing Committee

Recommended adoption of Proposal 01-224 as amended.

1. Change the definition of Post Harvest Processing in Chapter I and other places in the Model Ordinance to:
   "Post Harvest Processing means any process which has been validated using NSSP validation procedures which reduces the levels of pathogenic hazards to below the appropriate FDA action level or in the absence of such a level, below the appropriate level as determined by the ISSC."
2. Add a new definition to Chapter I:
   "Post Harvest Processor means a designation given to a shellfish dealer that has incorporated a post harvest process."
3. Replace the current PHP designation in the ICSSL with the definition in Recommendation 2.

Action by 2007 Task Force II

Recommended adoption of Post Harvest Processing Committee recommendation on Proposal 01-224.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007
Concurred with Conference action.

Proposal Subject Identification of Wet Stored Shellstock

Specific NSSP Guide Reference NSSP Guide Model Ordinance Chapter X. General Requirements for Dealers @ .05 Shellstock Identification B. Tags (2) (c) (e) (g)

Text of Proposal/ Requested Action

.05 Shellstock Identification

B Tags

1) Tags……

2) The dealer's tag … below:

(a) The dealer's name …..;

(b) The dealer's certification …;

(c) The original shellstock shipper's …;

(d) The date of harvest; or if **wet stored** or depurated, the date of **wet storage** or depuration processing;

(e) ~~(f)~~The most precise identification of the harvest location as is practicable including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If growing areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number).

(f) If **wet stored in artificial bodies of water** or depurated, the **wet storage lot number of** depuration cycle number or lot number;

(g) When shellstock is placed in wet storage in state: (the statement "THIS PRODUCT WAS WET STORED FROM (DATE) TO (DATE)"

(~~g~~) **(h)** When the shellstock has been ….

~~(h)~~ **(i)** The following statement…..

~~(i)~~ **(j)** All shellstock…….

Public Health Significance Product wet stored in state is not identified as wet stored. Wet storage in artificial bodies of water is closer to depuration than wet storage using approved or conditionally approved waters so the tagging criteria should be similar.

Cost Information (if available) Not known.

Action by 2003 Task Force II Recommended referral of Proposal 03-203 to the appropriate committee as determined by the Conference Chairman.

Action by 2003 General Assembly Adopted recommendation of 2003 Task Force II.

Action by USFDA Concurred with Conference Action.

Action by 2005 PHP Committee Recommended adoption of Proposal 03-203 except for paragraph (g). The current language in the Model Ordinance should be retained for (g) rather than the proposed paragraph (g).

Action by 2005 Task Force II Recommended referral of Proposal 03-203 to appropriate committee as determined by the Conference Chairman, with the following instructions: At a minimum, resolve product identity concerns relative to date of removal from a growing area.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Traceability/PHP Committees Recommended adoption of Proposal 03-203 as amended.

Add language to Chapter X @ .05B.(1)(c)

(iv) The ~~date of~~ harvest date; or if depurated, the date of depuration processing, **or if wet stored, the harvest date is the date removed from wet storage.**

(v) If **wet stored** or depurated the **wet storage** or depuration cycle or lot number **The wet storage lot number shall begin with the letter "w"**.

~~(VII) When the shellstock has been transported across state lines and placed in wet storage in a dealer's operation, the statement: THIS PRODUCT IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE:'~~

Add language to Chapter X @ .08 B. 2.

(c) Trace the wet storage history of the shellstock including, original harvest site, original harvest date, wet storage site(s) and dates.

Action by 2007 Task Force II Recommended adoption of Traceability Committee and Post Harvest Processing Committee recommendation on Proposal 03-203 as amended.

Add language to Chapter X @ .05B.(1)(c)

(iv) The harvest date; or if depurated, the date of depuration processing, or if wet stored, the **original** harvest date**, and the final harvest date which** is the date removed from wet storage.

(v) If wet stored or depurated the wet storage or depuration cycle or lot number. The wet storage lot number shall begin with the letter "w".

Add language to Chapter X @ .08 B. 2.

(d) Trace the wet storage history of the shellstock including, original harvest site, original harvest date, wet storage site(s) and dates.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force II.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject Identification of Wet Stored Shellstock

Specific NSSP Guide Reference NSSP Guide Model Ordinance Chapter X. General Requirements for Dealers @ .05 Shellstock Identification B. Tags (2)

Text of Proposal/ Requested Action

.05 B. (2) The dealers tag…
- (a) The dealer's name…
- (b) The dealer's certification…
- (c) The original shellstock …
- (d) The date of harvest…
- (e) If depurated …
- (f) The most precise…
- (g) **When the shellstock has been transported from the original area and wet stored in another approved growing area within the same state for at least two weeks, the dealer will:**
  - **(i) use the date shellstock was harvested from the last growing area as the harvest date;**
  - **(ii) identify the last growing area as the harvest location.**
- ~~(g)~~ **(h)** When the shellstock has been transported across state lines…
- ~~(h)~~ **(i)** The type and quantity …
- ~~(i)~~ **(j)** The following statement…
- ~~(j)~~ **(k)** All shellstock intended…

Public Health Significance There is no guidance in the Model Ordinance on tagging shellstock that is moved from one growing area to another within the same state. After 2 weeks in a growing area, the shellstock would have the characteristics of the new growing area and the product should be tagged appropriately. This will facilitate product recall and trace backs in the event of human illnesses.

Cost Information (if available) None

Action by 2003 Task Force II Recommended referral of Proposal 03-204 to the appropriate committee as determined by the Conference Chairman.

Action by 2003 General Assembly Adopted recommendation of 2003 Task Force II.

Action by USFDA Concurred with Conference Action.

Action by 2005 Post Harvest Processing Committee Recommended adoption of Proposal 03-204 with the following change to (g):

(i) use the date shellstock was harvested from the ~~last~~ most recent growing area as the harvest date;

(ii) identify the ~~last~~ most recent growing area as the harvest location.

Action by 2005 Task Force II Recommended referral of Proposal 03-205 to appropriate committee as determined by the Conference Chairman.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Traceability/PHP Committees	Recommended no action on Proposal 03-204. Rationale – No scientific information has been provided to support the suggestion that shellstock harvested and wet stored for a specified period of time in a site other than the original harvest site takes on the characteristics of the wet storage area.
Action by 2007 Task Force II	Recommends referral of Proposal 03-204 back to the Post Harvest Processing Committee with direction to address confusion over whether activity is wet storage, relay, or transplanting under aquaculture and to secure whatever science is available relative to length of time in growing area to take on new characteristics of that growing area.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject Validation/Verification Process for PHT Product

Specific NSSP Guide Reference None Referenced

Text of Proposal/ Requested Action

VALIDATION/VERIFICATION INTERIM GUIDANCE:

Validation (level 1) – used for the initial validation of a process.

- Data on ten processed samples obtained on each of three processing days (total of 30 samples) are required.
- All samples used on a processing day must come from the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of 100,000 per gram or greater as described below for initial load testing. (If some lower initial levels are used the process will only be validated for those maximum initial levels.)
- Samples should be distributed throughout the processing day. A sample will consist of a composite of 10 to 12 oysters processed at one time.
- The zero hour level may be achieved through naturally occurring Vibrio levels in shellfish and, where not practical, by time/temperature abuse. **(Inoculated pack samples may be used as appropriate.)**
- For Vibrio parahaemolyticus, the 03:K6 serotype shall be used for the initial load through an inoculation process.
- Analytical methodology to determine Vibrio levels should be the official methods previously endorsed by the ISSC.
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with 0.1 g of shellfish per tube.
- The numerical value of the endpoint criteria should represent the lowest sensitivity of the MPN method, which is less than 3 per gram.
- For the process to be validated, no more than three samples out of 30 may fail. Failure is indicated by more than two out of five MPN tubes in any sample being positive. If any one sample has all five MPN tubes positive, the validation process will fail.

Validation (level 2) – used when a validated process is changed or when verification sampling indicates a failure in the process

- Data on ten processed samples obtained throughout a processing day are required.
- All samples used on a processing day must come form the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of 100,000 per gram or greater as described below in initial load testing.
- A sample will consist of a composite of 10 to 12 oysters processed at one time.
- **The zero hour level may be achieved through naturally occurring vibrio levels in shellfish and, where not practical, by time/temperature abuse.** (Inoculated pack samples may be used as appropriate).
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with 0.1 g of shellfish per tube.
- For level 2 validation, no more than one sample out of ten may fail. Failure is indicated by more than two out of five MPN tubes in any sample being positive. If any one sample has all five MPN tubes positive, the validation process will fail.

Initial Load Testing

Initial level of vibrios in shellfish for each lot of shellfish used in validation shall be 100,000 MPN per gram or greater based on the adjusted geometric mean (AGM) of the MPNs/g of four samples where the AGM is given by:

AGM = the geometric mean of the 4 MPNs/g multiplied by an adjustment factor of 1.3

Note: If 4 samples from a lot of shellfish with a true density of 100,000 cells per gram are examined by the MPN procedure, the probability of the geometric mean of the MPNs showing 100,000 or greater is about 50%. In an attempt to improve the probability of samples being accepted when the true density is 100,000/g an adjustment factor of 1.3 was selected based upon statistical analysis provided by Dr. Bob Blodgett.

Verification – Used to verify that a previously validated process is working properly.

- Process verification by microbiological testing should be done monthly
- The number of samples/sub samples for verification and the pass/fail criteria for the verification process will be determined by the validation/verification workgroup following evaluation of statistical data to be supplied by Dr. Bob Blodgett.
- The dealer in conjunction with the SSCA shall annually evaluate the previous 12 months of data and the HACCP plan.
- The dealer may elect, with SSCA concurrence, to conduct quarterly sampling if the previous 12 verification samples pass.

See Attachment

Public Health Significance

None Submitted

Cost Information (if available)

None Submitted

Action by 2003 Vibrio vulnificus Subcommittee

Recommended that amended Proposal 03-212 (below) be substituted for Proposal 03-212. This recommendation includes a recommendation from the Post-Harvest Vv Levels Workgroup. The workgroup recommended the <3 MPN level for Post-harvest labeling be changed to 30 MPN. The 30 MPN will become the non-detect level. Post-harvest treatment labeling claims can be made for non-detect at 30 MPN. Additionally, it is recommended that the Executive Board be given the authority to increase the level up to a level no higher than 100 upon recommendation by the Vv Subcommittee.

Additionally, recommended modification of Model Ordinance Chapter XVI.A. (1)(a) to change the non-detect level from <3 MPN/gram to <30 MPN/gram.

VALIDATION/VERIFICATION INTERIM GUIDANCE:

Process Validation ~~(level 1)~~ – used for the initial validation of a process **or when there has been a change to a previous validation process.**

- Data on ten processed samples obtained on each of three processing days (total of 30 samples) are required.
- All samples used on a processing day must come from the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of 100,000 per gram or greater as described below for initial load testing. (If some lower initial levels are used the process will only be validated for those maximum initial levels.)
- Samples should be distributed throughout the processing day. A sample will consist of a composite of 10 to 12 oysters processed at one time.
- The zero hour level may be achieved through naturally occurring Vibrio levels in shellfish and, where not practical, by time/temperature abuse. **(Inoculated pack samples may be used as appropriate.)**
- ~~For Vibrio parahaemolyticus, the 03:K6 serotype shall be used for the initial load through an inoculation process.~~
- Analytical methodology to determine Vibrio levels should be the official methods previously endorsed by the ISSC.
- Microbiological testing for processed samples will be by a single dilution five-tube

MPN, inoculating with 0.01 g of shellfish per tube.
- The numerical value of the endpoint criteria should represent the lowest sensitivity of the MPN method, which is less than 30 per gram.
- For the process to be validated, no more than three samples out of 30 may fail. Failure is indicated by more than two out of five MPN tubes in any sample being positive. If any one sample has all five MPN tubes positive, the validation process will fail.

Equipment Validation – used to ensure that each unit of equipment will deliver the validated process. May be accomplished using either of two methods:
- The process described under "Revalidation," below;
- A physical test of the equipment (e.g., thermal distribution study) that is designed to ensure that, when properly operated, it will consistently deliver the validated process.

Re~~V~~validation ~~(level 2)~~ – used when ~~a validated process is changed or when~~ verification sampling indicates a failure in the process

- Data on ten processed samples obtained throughout a processing day are required.
- All samples used on a processing day must come form the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of 100,000 per gram or greater as described below in initial load testing.
- A sample will consist of a composite of 10 to 12 oysters processed at one time.
- **The zero hour level may be achieved through naturally occurring vibrio levels in shellfish and, where not practical, by time/temperature abuse.** (Inoculated pack samples may be used as appropriate).
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with 0.01 g of shellfish per tube.
- The numerical value of the endpoint criteria should represent the lowest sensitivity of the MPN method, which is less than 30 per gram.
- For ~~level 2~~ revalidation, no more than one sample out of ten may fail. Failure is indicated by more than two out of five MPN tubes in any sample being positive. If any one sample has all five MPN tubes positive, ~~the~~ revalidation ~~process~~ will fail.

Initial Load Testing

Initial level of vibrios in shellfish for each lot of shellfish used in validation shall be 100,000 MPN per gram or greater based on the adjusted geometric mean (AGM) of the MPNs/g of four samples where the AGM is given by:

AGM = the geometric mean of the 4 MPNs/g multiplied by an adjustment factor of 1.3

Note: If 4 samples from a lot of shellfish with a true density of 100,000 cells per gram are examined by the MPN procedure, the probability of the geometric mean of the MPNs showing 100,000 or greater is about 50%. In an attempt to improve the probability of samples being accepted when the true density is 100,000/g an adjustment factor of 1.3 was selected based upon statistical analysis provided by Dr. Bob Blodgett.

Verification – Used to verify that a previously validated process is working properly.
- Process verification by microbiological testing should be done monthly
- The number of samples/sub samples for verification and the pass/fail criteria for the verification process will be determined by the validation/verification workgroup following evaluation of statistical data to be supplied by Dr. Bob Blodgett.
- The dealer in conjunction with the SSCA shall annually evaluate the previous 12 months of data and the HACCP plan.
- The dealer may elect, with SSCA concurrence, to conduct quarterly sampling if the

previous 12 verification samples pass.

Action by 2003 Vibrio Management Committee

Recommended adoption of the Vv Subcommittee recommendations on Proposal 03-212.

Action by 2003 Task Force II

Recommended adoption of Vibrio Management Committee recommendations on Proposal 03-212.

Additionally, Task Force II recommended that Model Ordinance Chapter XVI (A)(1)(b) be amended as follows:

(A)(1)(b) For processes that target *Vibrio parahaemolyticus* (the 03:K6 serotype shall be used for validation), the level of *Vibrio parahaemolyticus* in product that has been subjected to the process shall be non-detectable (<1 CFU/0.1 gram).

Action by 2003 General Assembly

Adopted recommendations of 2003 Task Force II.

Action by USFDA

Concurred with Conference action.

Action by 2005 Vibrio Management Committee

Recommended the PHP Workgroup continue to work on a revised approach and when completed, that it be considered by the Executive Board as an interim measure. Executive Board approval should be considered at its next scheduled meeting in March 2006 or sooner if the new approach can be completed well in advance of its next meeting in March.

Action by 2005 Task Force II

Recommended adoption of the Vibrio Management Committee recommendation on Proposal 03-212.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force II.

Action by USFDA

Concurred with Conference action.

Action by Executive Board

The ISSC Executive Board adopted a revised approach with interim approval. The revised approach was submitted for consideration as Proposal 07-208.

Action by 2007 Validation/ Verification Workgroup

Recommended Task Force II take no action on Proposal 03-212 if Proposal 07-209 is adopted.

Action by 2007 Task Force II

Recommended no action on Proposal 03-212. Rationale – addressed in Proposal 07-209.

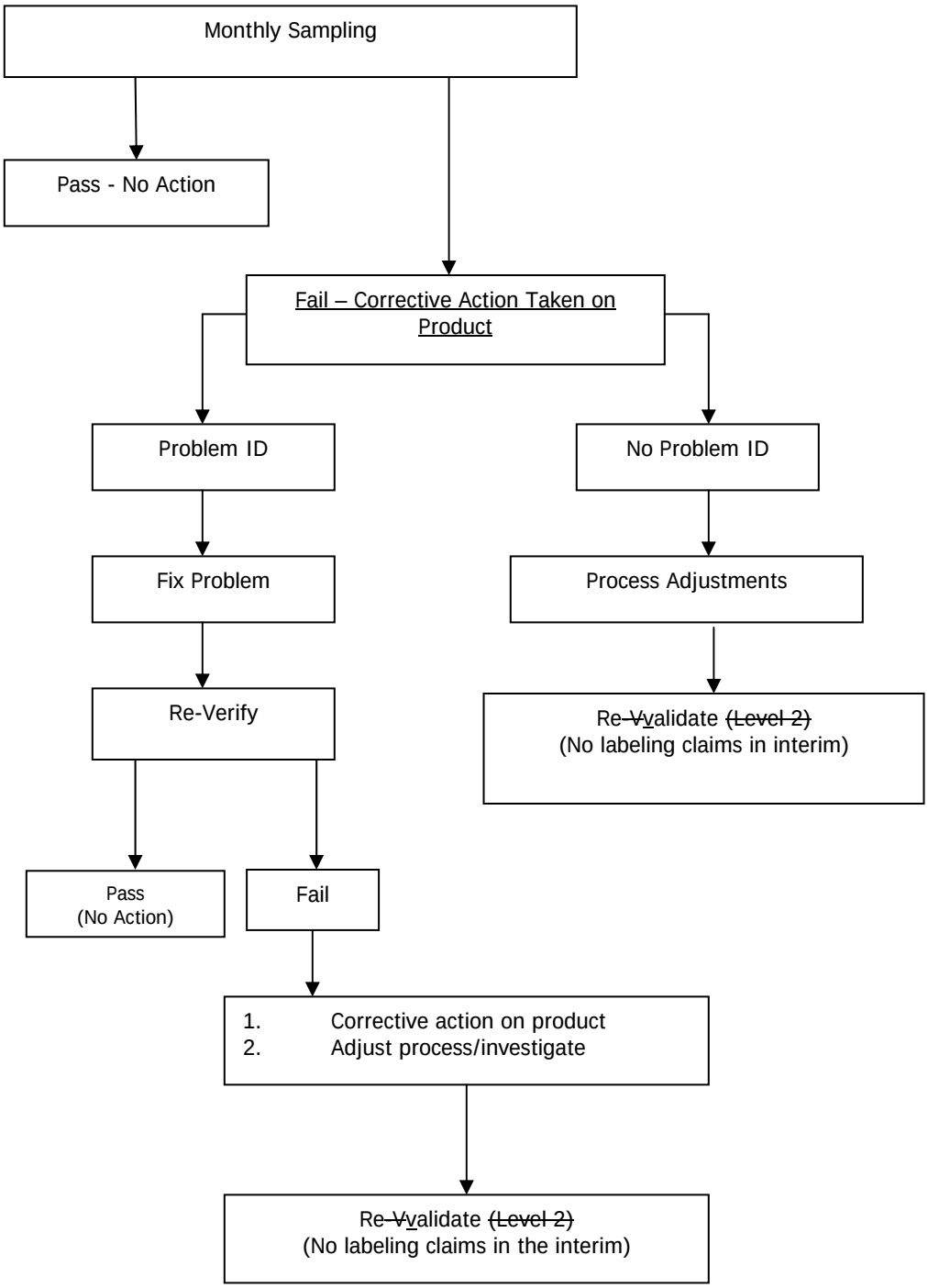
Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007
Concurred with Conference action.

Verification Sampling Protocol Decision Tree



Proposal Subject Post Harvest Processing

Specific NSSP Guide Reference: Model Ordinance Chapter I. Definitions
Model Ordinance Chapter IX. Transportation
Model Ordinance Chapter X. General Requirements for Dealers
Model Ordinance Chapter XVI. Post Harvest Treatment

Text of Proposal/ Requested Action

During its March 2004 meeting the ISSC Executive Board was made aware that changes were needed to address confusion associated with the handling and labeling of post harvest processed shellfish. A committee was appointed and recommendations developed for Board consideration at the August 2004 Executive Board meeting. The Board approved the following interim changes to the NSSP Model Ordinance. Included in the Model Ordinance changes adopted by the Executive Board is language in *Chapter X. General Requirements for Dealers .05 Shellstock Identification B. Tags*, which allows for inclusion of language, associated with USDA requirements for Country of Origin Labeling (COOL). The new Model Ordinance language does not require Country of Origin labeling but does allow dealers to include this information on tags and labels.

CHAPTER I. DEFINITIONS

Post Harvest Processing means processing of shellfish for the purpose of added safety or quality that involve hazards not addressed by controls in NSSP Model Ordinance Chapters XI. through XIV.

Raw means shellfish that have not been thermally processed:
(a) to an internal temperature of 145°F or greater for 15 seconds (or equivalent); or
(b) altering the organoleptic characteristics.

Shellfish means all species of:
(a) Oysters, clams or mussels, whether:
(i) Shucked or in the shell;
(ii) Raw, including post harvest processed;
~~(ii)~~**(iii)** Frozen or unfrozen;
~~(iii)~~**(iv)** Whole or in part; and
(b) Scallops in any form, except when the final product form is the adductor muscle only.

CHAPTER IX. TRANSPORTATION

Requirements for the Authority
@ .02 Shipment Acceptability
A. Shipments are properly identified with tags **and/or labels** and shipping documents;
B. Shellstock is alive…
C. Shucked **or post harvest processed** shellfish **are** ~~is~~ cooled to a temperature of 45° Fahrenheit (7.2° Centigrade) or less; and
D. The time-temperature…
E. All other conditions…

CHAPTER X. GENERAL REQUIREMENTS FOR DEALERS

.05 Shellstock Identification
B. Tags
(5) The statement "Keep Refrigerated" or an equivalent statement must be included on the tag.
(6) Country of origin information (USDA 2004) may be included on

the dealer tag.

.06 Shucked Shellfish Labeling
A. Shellfish Labeling
(5) The dealer shall assure that:
(a) The shucker-packer's or repacker's certification number is on the label of each package of fresh or frozen shellfish;
(b) The statement "Keep Refrigerated" or an equivalent statement appears on the label;
(c) Packages containing less than 64 fluid ounces have:
(i) A "SELL BY DATE" which is a reasonable subsequent shelf-life or the words "BEST IF USED BY" followed by a date when the product would be expected to reach the end of its shelf-life; and
(ii) The date as a month and day of the month.
(d) Packages containing 64 fluid ounces or more have on the lid and sidewall or bottom the "DATE SHUCKED" indicated as the number of the day of the year or the month and day of the month.

.07 Post Harvest Process Labeling
A. If a dealer elects to post harvest process shellfish and the final product form is live, the dealer shall label in accordance with Chapter X. . 05.
B. If a dealer elects to post harvest process shellfish and the final product form is not live, the dealer shall label in accordance with Chapter X. .06 and include the following, or equivalent statement: These shellfish have been post harvest processed.

NOTE: The Consumer Advisory shall be required for both A and B.

.08 Shipping Documents and Records.

.09 Wet Storage in Artificial Bodies of Water.

CHAPTER XVI. POST HARVEST **PROCESSING** ~~TREATMENT~~

All References in Chapter XVI. to post harvest treatment will be changed to post harvest processing.

Public Health Significance: None submitted

Cost Information (if available): Although these changes have immediate effective dates, the Executive Board recognizes the financial impact associated with tagging and labeling changes. The Executive Board requests states to establish reasonable implementation schedules to allow the shellfish industry to incorporate these changes into their tagging and labeling programs.

Action by 2005 PHP Committee The PHP Committee reviewed Proposal 05-200 and acknowledged implementation concerns associated with Chapter X. .07 and directed a workgroup to propose language to address the concerns to Task Force II.

Action by 2005 Task Force II Amended Proposal 05-200 by substituting the following language submitted by the PHP Workgroup to replace Chapter X. .07.

Chapter X. .07 Processed Shellstock Labeling

A. The dealer shall label all processed shellstock with tags meeting the requirements of § .05 B. (1).

B. Processed Shellstock Tags

(1) The dealer tag on processed shellstock shall contain the following indelible, legible information in the order specified below:

(a) The dealer's name and address;
(b) The dealer's certification number as assigned by the Authority;
(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required;
(d) A "SELL BY DATE" which is a reasonable subsequent shelf-life or the words "BEST IF USED BY" followed by a date when the product would be expected to reach the end of its shelf-life. The date shall include, month, day and year;
(e) If depurated, the depuration cycle number or lot number;
(f) The most precise identification of the harvest location as is practicable including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If the Authority has not indexed growing areas, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number).
(g) When the shellstock has been transported across state lines and placed in wet storage in a dealer's operation, the statement: "THIS PRODUCT IS A PRODUCT OF (NAME AND STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)";
(h) The type and quantity of processed shellstock; and
(i) The following statement in bold capitalized type on each tag: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."
(j) All processed shellstock intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-602.11 of the 1999 Food Code, or an equivalent statement, shall be included on all shellstock: "RETAILERS, INFORM YOUR CUSTOMERS" "Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."
(k) The statement "Keep Refrigerated" or an equivalent statement must be included on the tag.

(2) If the processed shellstock is removed from the original container, the tag on the new container shall meet the requirements in §.07B.

(3) Country of origin information (USDA 2004) may be included on the shucker-packer or reshipper tag.

Additionally, the Task Force added the following definition to Proposal 05-200:

Chapter I - Definitions

(80) Processed shellstock means shellstock that has been Post Harvest Processed with a validated or non-validated process which results in a frozen or unfrozen end product which is no longer alive, and that is sold in the whole or half shell.

Task Force II recommended that Proposal 05-200, as amended by the PHP Workgroup, be referred to the appropriate committee as determined by the Conference Chairman for further deliberation and Proposal 05-200 as amended remain interim pending further Conference action.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force II.

Action by USFDA

FDA concurs with action by the Conference to refer Proposal 05-200 to an appropriate committee for further deliberation. However, FDA does not concur with interim adoption of Proposal 05-200 language, as amended by Task Force II, pending further Conference action. FDA finds that the interim language needs clarification prior to inclusion in the NSSP Model Ordinance. Task Force II, in its decision to refer this Proposal back to committee, recognized the need for clarification relative to the "post harvest processing" and "processed shellstock" definitions and the potential confusion associated with labeling of such products. The concept of PHP has been expanded from its original intent, which focused on processing to reduce Vibrio levels to non-detect, to include other processes that do not necessarily achieve pathogen reduction of public health significance. As a result the ISSC is continuing to examine how the Model Ordinance can best address this broader approach to PHP and its associated labeling requirements. Until the ISSC has completed its deliberations on Proposal 05-200 it is in the best interest of industry and regulatory authorities not to include Proposal 05-200 interim language in the NSSP Model Ordinance at this time.

Action by 2007 Post Harvest Processing Committee

Recommended adoption of Proposal 05-200 as amended.

1. Change the title of Chapter X.07 from Processed Shellstock Labeling to : In-shell Product or Post Harvest Processed In-Shell Product Labeling. Replace all references to processed shellstock in the language adopted by the Conference in 2005 with "in shell product"

2. Add a definition for "in shell product" to Chapter I (Definitions):

   "In Shell Product means non-living, processed shellfish with one or both shells present."

3. The Conference should appoint a work group to review Chapters VII. (Wet Storage in Approved and Conditionally Approved Growing Areas), XV. (Depuration), and XVI. (Post Harvest Processing) to determine if requirements are consistent for the risks involved with each process.

4. A transition period of up to 12 months should be allowed to allow dealers to utilize their current inventory of shellfish and supplies before the new labeling requirements must be met.

Action by 2007 Task Force II

Recommended adoption of the Post Harvest Processing Committee recommendation on Proposal 05-200.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007
Concurred with Conference action.

Proposal Subject	Validation/Verification of PHP
Specific NSSP Guide Reference	Guidance Documents, Chapter IV.04 Validation/Verification Interim Guidance
Text of Proposal/ Requested Action	The validation/verification workgroup has identified a need for guidance in the evaluation of PHPs that are validated using initial loads other than the currently recommended 100,000/gram adjusted geometric mean. Alternative approaches to the validation/verification protocol for PHP should be considered One possible approach is the use of a log reduction criteria rather than a specific initial level and end point criteria. If this is determined to be a feasible approach, the workgroup will present a specific alternative protocol for validation and verification of PHPs to the Conference. The protocol will include guidance to be used by FDA and State Regulators in evaluating PHP validations.
Public Health Significance	Many food commodities are regulated based upon a specified log reduction of a particular pathogen. This log reduction approach could be applied to *V. vulnificus* and *V. parahaemolyticus* levels to achieve an appropriate level of public health protection in PHP shellfish.
Cost Information (if available)	None
Action by 2005 Task Force II	Recommended referral of Proposal 05-204 to the Validation/Verification Workgroup with instructions to continue reviewing alternative validation approaches using initial loads other than 100,000 per gram. Appropriate approaches should be reported to the Executive Board for interim approval.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force II.
Action by USFDA	Concurred with Conference action.
Action by Executive Board	The ISSC Executive Board adopted a revised approach with interim approval. The revised approach was submitted for consideration as Proposal 07-208.
Action by 2007 Validation/ Verification Workgroup	Recommended to Task Force II no action if Proposal 07-209 is adopted.
Action by 2007 Task Force II	Recommended no action on Proposal 05-204. Rationale – addressed in Proposal 07-209.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject Wet Storage

Specific NSSP Guide Reference NSSP Guide Model Ordinance, Definitions; Chapter I@.02 E; Chapter VII; Chapter VIII@.01 C: Chapter X.05 B, .08 B, and .09 C.

Text of Proposal/ Requested Action Modify current Model Ordinance Wet Storage Definition (106); Chapter 1@.02E; move Wet Storage requirements found under .08 and .09 of Chapter X and incorporate it into Chapter VII (Wet Storage); modify language in Chapter VII by removing, editing, and adding to existing language, as follows:

MODEL ORDINANCE

Definitions.

B. Definition of Terms.

(106) Wet storage means the storage, by a dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally approved classification, **either loose or** in containers or floats in natural bodies of water, or in tanks containing natural or synthetic seawater **at any permitted land-based activity or facility**.

I. SHELLFISH SANITATION PROGRAM

@.02 Dealer Certification.

E. Interstate Certified Shellfish Shippers List (ICSSL).

(1) When the Authority certifies a person to become a dealer, the Authority shall notify the FDA for the purpose of having the dealer listed in the ICSSL. **The Authority shall include any permit designation to be included in the ICSSL.** The notice shall be in the format of FDA Form 3038.

Designations			
Certification		Permit	
SP -	Shucker Packer	PHP -	Post Harvest Processing
RP -	Repacker	AQ -	Aquaculture
SS -	Shellstock Shipper	WS -	Wet Storage
RS -	Reshipper		
DP -	Depuration		

(2) The Authority shall notify the FDA for the purpose of having the dealer removed from the ICSSL whenever a dealer's certificate **or permit** is:
(a) Suspended; or
(b) Revoked.

VII. WET STORAGE ~~IN APPROVED AND CONDITIONALLY APPROVED GROWING AREAS~~

Table of Contents

Requirements for the Authority.

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

.01 General.

A. The Authority shall permit all wet storage activities to ensure that all wet storage activities are conducted by certified NSSP shellfish firms.

B. The Authority shall approve and maintain the following records while the wet storage activity continues:
(1) Construction and remodeling plans for any permitted wet storage facility;
(2) Wet storage operational plans;
(3) Wet storage permits; and
(4) Inspection documentation.

C. The Authority shall inspect wet storage activities at the following frequency:
(1) Activities in offshore natural bodies of water at least annually;
(2) Activities at land-based sites with flow-through systems at least every six months; and
(3) Activities at land-based sites with recirculating systems at least quarterly.

D. The Authority shall immediately notify (within 24 hours) all wet storage permit holders affected by a change in growing area classification or status.

E. Shellstock that has been removed from the original harvest area shall not be placed in wet storage more than one time prior to shucking, packing, PHP or consumption.

F. Reshippers shall not engage in wet storage activities.

Requirements for the Dealer.

.01 Source of Shellstock.

A. ~~The dealer~~ **Dealers** shall wet store shellstock harvested only from areas classified as approved, or conditionally approved in the open status~~, or taken from a certified depuration facility following successful completion of the depuration process~~.

B. Shellstock shall be harvested, identified and shipped to the wet storage ~~operation~~ **activity** in accordance with the requirements of Chapters VIII and IX.

.02 General.

A. Wet storage may be used to store, condition, remove sand or to add salt to shellstock. **Wet storage shall be deemed a processing activity.**

B. Wet storage of depurated product shall occur only within the facility in which it was depurated. **The shellstock shall:**
(1) Be packed and labeled according to the requirements in Chapter XV; and
(2) Include the dates of wet storage on the labels or tags.

C. Wet storage shall be practiced only by a dealer in strict compliance with the provisions in the written approval for the wet storage activity given by the Authority.
D. While awaiting placement in a wet storage ~~operation~~ **activity**, shellstock shall be protected from physical, chemical or thermal conditions which may compromise shellstock survival, quality or activity during wet storage.

E. Conditions and water quality during wet storage shall be sufficient to minimize the potential for compromising the sanitary quality of the shellstock during storage.

~~F. For the purpose of certification, each wet storage site or operation shall be evaluated annually. The evaluation shall include an inspection of the near shore storage site and floats,~~

~~or the wet storage operation.~~
~~G. Shellstock from a wet storage operation shall be harvested, identified and shipped according to the requirements of Chapters VIII, IX and X.~~

F. Shellstock from a wet storage ~~operation~~ activity shall be harvested, handled, identified, processed and shipped according to the requirements of Chapters VIII, IX and X.

G. The harvest date of shellstock that were held in wet storage shall remain the date the shellstock was removed from the original harvest area and this information shall be provided on shellstock tags.

~~H. When the product from wet storage was depurated prior to wet storage, the shellstock shall:~~
~~(1) Be packed and labeled according to the requirements in Chapter XV.; and~~
~~(2) Include the dates of wet storage on the labels or tags.~~

~~I~~ **H**. The wet storage operator shall keep complete and accurate records to enable a lot of shellstock to be traced back to the **original harvest location and** wet storage location**, and include the dates the shellstock were held in wet storage.** The records shall be maintained for ~~at least~~ **a minimum of one year**.
~~(1) 90 days from the date of removal of the shellstock from wet storage; and or~~
~~(2) 120 days from the date of removal of the shellstock from wet storage where the state of origin labeling is changed under §G.2.~~

I. Unless the dealer is in the Authority's commingling plan under Chapter I .01F different lots of shellfish shall not be commingled during wet storage. If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

.03 Wet Storage Sites **in Natural Bodies of Water (Offshore)**.

A. ~~Nearshore~~ **Natural bodies of water~~s~~** used for wet storage ~~in containers and floats~~ shall meet the requirements for classification as approved or conditionally approved while shellstock is being held in storage. Areas classified as conditionally approved may be used only when in the open status. When an area classified as conditionally approved is placed in a status other than its open status, any shellstock in wet storage in that area shall be:
(1) Subjected to relaying or depuration prior to human consumption; or
(2) Held in the wet storage site until the area is returned to the open status.

B. ~~The near shore~~ ~~s~~Site evaluation**s of natural bodies of water** shall include:
(1) The sanitary survey of the ~~near shore~~ storage site, with special consideration of potential intermittent sources of pollution;
(2) The location of ~~near shore~~ storage sites and/**or** floats; ~~and~~
(3) The examination of the construction of shellstock containers, if used, to ensure the free flow of water to all shellstock~~.~~**; and**
(4) A review of the operation's plan and operating procedures for an offshore activity as submitted by the dealer.

~~C. Different lots of shellfish shall not be commingled during wet storage. If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.~~

[Sections below are moved from Chapter X to Chapter VII]

~~.09~~ **.04** Wet Storage in Artificial Bodies of Water **(Land-based)**.

A. General.

(1) If the dealer chooses to practice wet storage in artificial bodies of water, the dealer shall meet the requirements of Chapter VII.01 and .02.

(2) For the purpose of permitting, each wet storage site or ~~operation~~ **activity** shall be evaluated ~~annually~~ **in accordance with @.01.B**. The evaluation shall include **a review of** the ~~operation's~~ plan and operating procedures for conducting a~~n onshore~~ **land-based wet storage** activity as submitted by the dealer.

(3) Prior to commencing construction, all plans for construction or remodeling of ~~onshore~~ wet storage facilities ~~or operations~~ shall be reviewed and authorized by the Authority.

(4) The wet storage facility ~~or operation~~ evaluation shall include a review of:
(a) The purpose of the wet storage activity, such as holding, conditioning or increasing the salt content of shellstock;
(b) Any species specific physiological factors that may affect design criteria; and
(c) The plan giving the design of the ~~onshore~~ **land-based wet** storage facility, source and quantity of **process** water to be used for wet storage, and details of any **process** water treatment **(disinfection)** system.

B. Operation Specifications.

(1) General. Each ~~onshore~~ **land-based** wet storage ~~operation~~ **activity** shall meet the following design, construction, and operating requirements.
(a) Effective barriers shall be provided to prevent entry of birds, animals, and vermin into the area.
(b) Storage tanks and related plumbing shall be fabricated of safe material and shall be easily cleanable. This requirement shall include:
(i) Tanks constructed so as to be easily accessible for cleaning and inspection, self-draining and fabricated from nontoxic, corrosion resistant materials; and
(ii) Plumbing designed and installed so that it can be cleaned and sanitized on a regular schedule, as specified in the operating procedures.
(c) Storage tank design, dimensions, and construction are such that adequate clearance between shellstock and the tank bottom shall be maintained.
(d) Shellstock containers, if used, shall be designed and constructed so that the containers allow the free flow of water to all shellstock within a container.

(2) Buildings. When a building is used for the wet storage ~~operation~~ **activity**:
(a) Floors, walls, and ceilings shall be constructed in compliance with the applicable provisions of Chapter XI; and
(b) Lighting, plumbing, water and sewage disposal systems shall be installed in compliance with applicable provisions of Chapter XI.

(3) Outdoor Tank Operation. When the wet storage ~~operation~~ **activity** is outdoors or in a structure other than a building, tank covers shall be used. Tank covers shall:
(a) Prevent entry of birds, animals or vermin; and
(b) Remain closed while the system is in operation except for periods of tank loading and unloading, or cleaning.

C. ~~Water Supply~~ **Wet Storage Source Water**

(1) General.

(a) Except for wells, the quality of the surface source water prior to treatment shall meet, at a

minimum, the bacteriological standards for the restricted classification **and water classified as Prohibited or Conditionally Restricted when in the Closed Status shall not be used as source water**.

(b) Any well used as source water for wet storage shall meet the requirements of Chapter XI.02 **(with the exception of the salt content in salt water wells)**.

(c) Except when the source of the water is a growing area in the approved classification, a water supply sampling schedule shall be included in the dealer's operating procedures and water shall be tested according to the schedule.

(d) Results of water samples and other tests to determine the suitability of the **source** water supply shall be maintained for at least 2 years.

(e) Disinfection or other water treatment such as the addition of salt cannot leave residues unless they are Generally Recognized as Safe (GRAS) and do not interfere with the shellstock's survival, quality or activity during wet storage.

(f) Disinfected **process** water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multi-tube MPN test per 100 ml. for potable water and follow the protocol of the Decision Tree (IV. Guidance Documents Chapter III.06, **or shall have no viable bacteria as measured weekly by the absence of turbidity (growth) in 100 ml of the disinfected process water cultured in a nonselective bacterial culture broth medium listed in *Standard Methods for the Examination of Water and Wastewater*, APHA, for 24 hours at 35°C**.

(g) When the laboratory analysis of a single sample of disinfected **process** water entering the wet storage tanks shows any positive result for the coliform group **or any positive result for viable bacteria**, daily sampling shall be immediately instituted until the problem is identified and eliminated.

(h) When the problem that is causing disinfected **process** water to show positive results for the coliform group **or the presence of viable bacteria** is eliminated, the effectiveness of the correction shall be ~~shown~~ **verified** on the first operating day following correction through the ~~immediate~~ collection, ~~within~~ **over** a 24 hour period, of a set of three samples of disinfected **process** water ~~and one sample of the source water prior to disinfection~~.

(i) For water that is disinfected by ultra-violet treatment, turbidity shall not exceed 20 nephelometric turbidity units (NTUs) measured in accordance with *Standard Methods for the Examination of Water and Wastewater*, APHA.

(j) The disinfection unit(s) for the **process** water supply shall be cleaned and serviced as frequently as necessary to assure effective water treatment.

(2) Continuous Flow-through System.

(a) If the system is of continuous flow-through design, water from a growing area classified as:
(i) Approved may be used, without disinfection, in wet storage tanks provided that the near shore water source used for supplying the system meets the approved classification bacteriological criteria at all times that shellstock are being held in wet storage; or
(ii) Conditionally Approved in the Closed Status, Restricted or Conditionally Restricted in the Open Status may be used if the source water is continuously subjected to disinfection and it is sampled **and analyzed** daily following disinfection.

(b) When a source classified as Conditionally Approved in the Closed Status, Restricted or Conditionally Restricted in the Open Status is used, a study shall be required to demonstrate

that the disinfection system ~~will~~ **can** consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall:
(i) Include five sets of three samples from each disinfection unit collected for five consecutive days at the outlet from the disinfection unit or at the inlet to at least one of the wet storage tanks served by the disinfection system;
(ii) Include one sample daily for five consecutive days from the source water prior to disinfection;
(iii) Use NSSP recognized methods to analyze the samples ~~to~~ **if determining** ~~determine~~ coliform levels;
(iv) Require all samples of disinfected water to be negative for the coliform group; and
(v) Be repeated if any sample of disinfected **process** water during the study is positive for the coliform group **or viable bacteria**.

(c) Once sanctioned for use, the water system shall be sampled daily to demonstrate that the disinfected water is negative for the coliform group **or free of detectable viable bacteria**.

(d) When other than approved water is located between the intake of a flow-through wet storage system and the land-based facility then the Authority may require periodic verification of the system's integrity to ensure that the other than approved water does not infiltrate into the intake pipe.

(3) Recirculating Water System.

(a) A study shall be required to demonstrate that ~~the~~ disinfection ~~system~~ for the recirculating system ~~will~~ **can** consistently produce water that tests negative for the coliform group **or viable bacteria** under normal operating conditions. The study shall meet the requirements in §C.(2)(b) above.

(b) Once sanctioned for use, the recirculating **process** water system shall be sampled weekly to demonstrate that the disinfected water is negative for the coliform group **or viable bacteria**.

(c) When make-up water of more than 10 percent of the **process** water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected ~~within~~ **over** a 24 hour period to reaffirm the ability of the system to produce **process** water free from the coliform group or viable bacteria.

(d) When ultra-violet treatment is used as the water disinfectant, each time a bulb change is required either to replace a burned out bulb or for servicing, new ultraviolet bulbs shall be installed and old bulbs discarded**, and the weekly disinfected process water sample shall be collected and analyzed**.

D. Shellstock Handling.

(1) Shellstock shall be thoroughly washed with water from a source authorized by the Authority and culled prior to wet storage in tanks. ~~Due to the adverse effects of culling on mussel physiology, culling of mussels may be done after wet storage,~~ **Any deviation to this requirement is** subject to permission from the Authority.

(2) Unless the dealer is in the Authority's commingling plan under Chapter I@.01F., different lots of shellstock shall not be commingled during wet storage in tanks. If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.
(3) Bivalve mollusks shall not be mixed with other species in the same tank. Where multiple tank systems use a common water supply system for bivalve mollusks and other species, wet storage **process** water shall be effectively disinfected prior to entering tanks containing the

bivalve mollusks.

VIII. CONTROL OF SHELLFISH HARVESTING.

@.01 Control of Shellstock Growing Areas.

C. Licensing of Harvesting.

(3) A license to harvest shall not allow a harvester to engage in shellstock packing **or engage in independent wet storage activities** as defined in this Ordinance unless the harvester is a ~~shellstock shipper or packs for a dealer.~~ **certified shellfish dealer and has a Wet Storage Permit issued by the Authority.**

X. GENERAL REQUIREMENTS FOR DEALERS

.05 Shellstock Identification.

B. Tags.
(1) The dealers' tags shall:
(a) Be durable, waterproof and sanctioned by the Authority prior to use; and
(b) Be at least 2 5/8 inches by 5 1/4 inches (6.7 x 13.3 cm) in size.

(2) The dealer's tag shall contain the following indelible, legible information in the order specified below:
(a) The dealer's name and address;
(b) The dealer's certification number as assigned by the Authority
(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required;
(d) The date of harvest; or if depurated, the date of depuration processing;
(e) If depurated, the depuration cycle number or lot number;
(f) The most precise identification of the harvest location as is practicable including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If the Authority has not indexed growing areas, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number)~~.~~
(g) When the shellstock has been ~~transported across state lines and~~ placed in wet storage in a dealer's operation, the statement: "THIS ~~PRODUCT~~ IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)";
(h) The type and quantity of shellstock; and
(i) The following statement in bold capitalized type on each tag:
"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."
(j) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-602.11 of the 1999 Food Code, or an equivalent statement, shall be included on all shellstock:
"RETAILERS, INFORM YOUR CUSTOMERS"
"Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

.08 Shipping Documents and Records.

B. Transaction and Shipping Records.
(1) Each dealer shall have a business address at which transaction records are maintained.
(2) Each dealer shall maintain accurate and legible transaction records that are sufficient to:
(a) Document that the shellfish are from a source authorized under this Ordinance;
(b) Permit a container of shellfish to be traced back to the specific incoming lot of shucked

shellfish from which it was taken;
(c) Permit a lot (or commingled lots as per Chapter I.@.01.F.) of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of harvest, **date and location of wet storage, if applicable,** and if possible, the harvester or group of harvesters.

~~.09 Wet Storage in Artificial Bodies of Water.~~ *[Delete Section .09 in its entirety from Chapter X.]*

Public Health Significance

This proposal would take all of the Wet Storage requirements currently found under Chapter X .09 and incorporate them into Chapter VII. This movement places all of the wet storage requirements under a single chapter of the Model Ordinance. The rationale for this reorganization is to simplify the utility of the Model Ordinance when determining which criteria would be applicable for wet storage activities. Under the Model Ordinance's Definition of Terms for "Wet Storage" (106) recommends adding the word "loose" and adding "permitted land-based activity or facility." By adding the word "loose" the definition includes a wet storage activity that does occur, however, the current definition only refers to wet storage in containers or floats. Adding "at any land-based activity or facility" simply differentiates this form of wet storage from off-shore wet storage. In Chapter I the words, "Authority shall include any permit designations" including "Wet Storage (WS)" in the ICSSL were added to ensure that particular certified dealers are permitted to conduct wet storage activity only after being evaluated for meeting the specific Model Ordinance guidelines. Wet storage is intended only to enable dealers to maintain shellstock temporarily in a healthy, viable, safe condition until sold.

The word, "activity" was substituted for "operation" in most places throughout the proposed changes, since wet storage qualifies as a post-harvest processing activity.

Existing paragraph F under Ch VII .02 (General) was removed and new paragraph F was added. This existing F requires annual inspection and specifies what must be inspected. These requirements have been moved to @.01 "Requirements for the Authority" since the Authority is responsible for inspections. Also the inspection frequency is now broken down to include various inspection frequencies based on the type of wet storage activity and the variables and risk associated with each. New paragraph F keeps some original language from the existing MO paragraph G regarding compliance for the wet storage operation with Chapters VII, IX and X.

New paragraph G states unambiguously that the original date of harvest and the original harvest area remain described on tags for shellstock that have been wet stored. Wet storage is nothing more than a means to temporarily store and in minor ways perhaps process shellfish, not create a new identity.

New paragraph I reinforces the provisions of new paragraph G with new words added. It is proposed with the addition of language to ensure that wet storage operators will keep complete and accurate records to enable each lot of shellfish stored to be traced to the original harvest location. In addition, the record retention required of the wet storage operator is extended from the original language to 1 year, to be consistent with other record keeping requirements in the current MO, for HACCP, and to reflect possible further raw, frozen storage before consumption.

All references to Near-shore were changed to Off-Shore to differentiate the Land-based wet storage activity from Off-shore wet storage activity, for clarification purposes.

Current .04 C Water Supply was renamed "Wet Storage Source Water."

In .04 C (1) , C (2), and C (3), an alternative to fecal coliform testing has been added, one which provides equivalent or even better assurance of disinfection and should reduce costs to operators. Suitable disinfection of process water can be readily measured as the absence of

viable bacteria in 100 ml.

Section 2 "Continuous Flow-through System" the Proposal recommends addition of a new paragraph (d) which allows the Authority to require the wet storage operator periodic verification of the piping system integrity if said piping system runs through water which is classified as Other than Approved. This would provide additional assurance that the failure of the piping has not allowed contaminated water to enter a wet storage system.

In Chapter VIII under Section @.01 "Control of Shellstock Growing Areas" C. "Licensing of Harvesting" the proposal recommends adding to the original language that the licensed harvester cannot engage in independent wet storage activities unless they have a Wet Storage Permit issued by the Authority. This is consistent with the requirements of the MO regarding harvester's limitations. The purpose for this change was to provide traceability to the original harvest location regardless if the product was harvested in-state or transported from another state's harvest waters.

In Chapter X under Section .08 "Shipping Documents and Records" "B" "Transaction and Shipping Records" (c) a requirement was added for shellstock taken from wet storage that provides records to allow a lot of shellstock to be traced to the date and location of wet storage activity. This will provide consistency with the other requirements relating to this Section of the MO regarding record keeping.

Cost Information (if available): Passage of this issue would add no additional costs to a State's program. There are no additional expenses to industry either, since new requirements for the wet storage facility or laboratory analyses are not made.

Action by 2005 Task Force II Recommended referral of Proposal 05-205 to appropriate Committee as determined by the Conference Chairman with a recommendation by Task Force II that a workgroup under the appropriate Committee be established to address this proposal before the 2007 Biennial Meeting.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Post Harvest Processing Committee and Wet Storage Workgroup Recommended adoption of Proposal 05-205 as amended.

Modify current Model Ordinance Wet Storage Definition (106); Chapter 1@.02E; move Wet Storage requirements found under .08 and .09 of Chapter X and incorporate it into Chapter VII (Wet Storage); modify language in Chapter VII by removing, editing, and adding to existing language, as follows:

MODEL ORDINANCE

Definitions.

B. Definition of Terms.

(106) Wet storage means the storage, by a dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally approved classification, either loose or in containers or floats in natural bodies of water, or in tanks containing natural or synthetic seawater at any permitted land-based activity or facility.

I. SHELLFISH SANITATION PROGRAM

@.02 Dealer Certification.

E. Interstate Certified Shellfish Shippers List (ICSSL).

(1) When the Authority certifies a person to become a dealer, the Authority shall notify the FDA for the purpose of having the dealer listed in the ICSSL. The Authority shall include any permit designation to be included in the ICSSL. The notice shall be in the format of FDA Form 3038.

Designations			
Certification		Permit	
SP -	Shucker Packer	PHP -	Post Harvest Processing
RP -	Repacker	AQ -	Aquaculture
SS -	Shellstock Shipper	WS -	Wet Storage
RS -	Reshipper		
DP -	Depuration		

(2) The Authority shall notify the FDA for the purpose of having the dealer removed from the ICSSL whenever a dealer's certificate or permit is:
(a) Suspended; or
(b) Revoked.

VII. WET STORAGE

Table of Contents

Requirements for the Authority.

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

.01 General.

A. The Authority shall permit all wet storage activities to ensure that all wet storage activities are conducted by certified NSSP shellfish firms.

B. The Authority shall approve and maintain the following records while the wet storage activity continues:
(1) Construction and remodeling plans for any permitted wet storage facility;
(2) Wet storage operational plans;
(3) Wet storage permits; and
(4) Inspection documentation.

C. The Authority shall inspect wet storage activities at the following frequency:
(1) Activities in offshore natural bodies of water at least annually;
(2) Activities at land-based sites with flow-through systems at least every six months; and
(3) Activities at land-based sites with recirculating systems at least quarterly.

D. The Authority shall immediately notify (within 24 hours) all wet storage permit holders affected by a change in growing area classification or status.

~~E. Shellstock that has been removed from the original harvest area shall not be placed in wet storage more than one time prior to shucking, packing, PHP or consumption.~~

~~F.~~E. Reshippers shall not engage in wet storage activities.

Requirements for the Dealer.

.01 Source of Shellstock.

A. Dealers shall wet store shellstock harvested only from areas classified as approved, or conditionally approved in the open status.

B. Shellstock shall be harvested, identified and shipped to the wet storage activity in accordance with the requirements of Chapters VIII and IX.

.02 General.

A. Wet storage may be used to store, condition, remove sand or to add salt to shellstock. Wet storage shall be deemed a processing activity.
B. Wet storage of depurated product shall occur only within the facility in which it was depurated. The shellstock shall~~: (1) B~~**b**e packed and labeled according to the requirements in Chapter XV.~~; and~~
~~(2) Include the dates of wet storage on the labels or tags.~~

C. Wet storage shall be practiced only by a dealer in strict compliance with the provisions in the written approval for the wet storage activity given by the Authority.

D. While awaiting placement in a wet storage activity, shellstock shall be protected from physical, chemical or thermal conditions which may compromise shellstock survival, quality or activity during wet storage.

E. Conditions and water quality during wet storage shall be sufficient to minimize the potential for compromising the sanitary quality of the shellstock during storage.

F. Shellstock from a wet storage ~~operation~~ activity shall be harvested, handled, identified, processed and shipped according to the requirements of Chapters VIII, IX and X.

~~G. The harvest date of shellstock that were held in wet storage shall remain the date the shellstock was removed from the original harvest area and this information shall be provided on shellstock tags.~~

G~~H~~**.** The wet storage operator shall keep complete and accurate records to enable a lot of shellstock to be traced back to the original harvest location and wet storage location, and include the dates the shellstock were held in wet storage. The records shall be maintained for a minimum of one year.

H~~I~~. Unless the dealer is in the Authority's commingling plan under Chapter I .01F different lots of shellfish shall not be commingled during wet storage. If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

.03 Wet Storage Sites in Natural Bodies of Water (Offshore).

A. Natural bodies of water used for wet storage shall meet the requirements for classification as approved or conditionally approved while shellstock is being held in storage. Areas classified as conditionally approved may be used only when in the open status. When an area classified as conditionally approved is placed in a status other than its open status, any shellstock in wet storage in that area shall be:
(1) Subjected to relaying or depuration prior to human consumption; or
(2) Held in the wet storage site until the area is returned to the open status.

B. Site evaluations of natural bodies of water shall include:

(1) The sanitary survey of the storage site, with special consideration of potential intermittent sources of pollution;
(2) The location of storage sites and/or floats;
(3) The examination of the construction of shellstock containers, if used, to ensure the free flow of water to all shellstock; and
(4) A review of the operation's plan and operating procedures for an offshore activity as submitted by the dealer.

[Sections below are moved from Chapter X to Chapter VII]

.04 Wet Storage in Artificial Bodies of Water (Land-based).

A. General.

(1) If the dealer chooses to practice wet storage in artificial bodies of water, the dealer shall meet the requirements of Chapter VII.01 and .02.

(2) For the purpose of permitting, each wet storage site or activity shall be evaluated in accordance with @.01.B. The evaluation shall include a review of the plan and operating procedures for conducting land-based wet storage activity as submitted by the dealer.

(3) Prior to commencing construction, all plans for construction or remodeling of wet storage facilities shall be reviewed and authorized by the Authority.

(4) The wet storage facility evaluation shall include a review of:
(a) The purpose of the wet storage activity, such as holding, conditioning or increasing the salt content of shellstock;
(b) Any species specific physiological factors that may affect design criteria; and
(c) The plan giving the design of the land-based wet storage facility, source and quantity of process water to be used for wet storage, and details of any process water treatment (disinfection) system.

B. Operation Specifications.

(1) General. Each land-based wet storage activity shall meet the following design, construction, and operating requirements.
(a) Effective barriers shall be provided to prevent entry of birds, animals, and vermin into the area.
(b) Storage tanks and related plumbing shall be fabricated of safe material and shall be easily cleanable. This requirement shall include:
(i) Tanks constructed so as to be easily accessible for cleaning and inspection, self-draining and fabricated from nontoxic, corrosion resistant materials; and
(ii) Plumbing designed and installed so that it can be cleaned and sanitized on a regular schedule, as specified in the operating procedures.
(c) Storage tank design, dimensions, and construction are such that adequate clearance between shellstock and the tank bottom shall be maintained.
(d) Shellstock containers, if used, shall be designed and constructed so that the containers allow the free flow of water to all shellstock within a container.

(2) Buildings. When a building is used for the wet storage activity:
(a) Floors, walls, and ceilings shall be constructed in compliance with the applicable provisions of Chapter XI; and
(b) Lighting, plumbing, water and sewage disposal systems shall be installed in compliance with applicable provisions of Chapter XI.

(3) Outdoor Tank Operation. When the wet storage activity is outdoors or in a structure other than a building, tank covers shall be used. Tank covers shall:

(a) Prevent entry of birds, animals or vermin; and
(b) Remain closed while the system is in operation except for periods of tank loading and unloading, or cleaning.

C. Wet Storage Source Water

(1) General.

(a) Except for wells, the quality of the surface source water prior to treatment shall meet, at a minimum, the bacteriological standards for the restricted classification and water classified as Prohibited or Conditionally Restricted when in the Closed Status shall not be used as source water.

(b) Any well used as source water for wet storage shall meet the requirements of Chapter XI.02 (with the exception of the salt content in salt water wells).

(c) Except when the source of the water is a growing area in the approved classification, a water supply sampling schedule shall be included in the dealer's operating procedures and water shall be tested according to the schedule.

(d) Results of water samples and other tests to determine the suitability of the source water supply shall be maintained for at least 2 years.

(e) Disinfection or other water treatment such as the addition of salt cannot leave residues unless they are Generally Recognized as Safe (GRAS) and do not interfere with the shellstock's survival, quality or activity during wet storage.

(f) Disinfected process water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multi-tube MPN test per 100 ml. for potable water and acceptable for use with marine water and follow the protocol of the Decision Tree (IV. Guidance Documents Chapter III.06~~. or shall have no viable bacteria as measured weekly by the absence of turbidity (growth) in 100 ml of the disinfected process water cultured in a nonselective bacterial culture broth medium listed in *Standard Methods for the Examination of Water and Wastewater*, APHA, for 24 hours at 35°C.~~

(g) When the laboratory analysis of a single sample of disinfected process water entering the wet storage tanks shows any positive result for the coliform group ~~or any positive result from viable bacteria,~~ daily sampling shall be immediately instituted until the problem is identified and eliminated.

(h) When the problem that is causing disinfected process water to show positive results for the coliform group ~~or the presence of viable bacteria~~ is eliminated, the effectiveness of the correction shall be verified on the first operating day following correction through the collection, over a 24 hour period, of a set of three samples of disinfected process water.

(i) For water that is disinfected by ultra-violet treatment, turbidity shall not exceed 20 nephelometric turbidity units (NTUs) measured in accordance with *Standard Methods for the Examination of Water and Wastewater*, APHA.

(j) The disinfection unit(s) for the process water supply shall be cleaned and serviced as frequently as necessary to assure effective water treatment.

(2) Continuous Flow-through System.

(a) If the system is of continuous flow-through design, water from a growing area classified as:
(i) Approved may be used, without disinfection, in wet storage tanks provided that the near

shore water source used for supplying the system meets the approved classification bacteriological criteria at all times that shellstock are being held in wet storage; or
(ii) Conditionally Approved in the Closed Status, Restricted or Conditionally Restricted in the Open Status may be used if the source water is continuously subjected to disinfection and it is sampled and analyzed daily following disinfection.

(b) When a source classified as Conditionally Approved in the Closed Status, Restricted or Conditionally Restricted in the Open Status is used, a study shall be required to demonstrate that the disinfection system can consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall:
(i) Include five sets of three samples from each disinfection unit collected for five consecutive days at the outlet from the disinfection unit or at the inlet to at least one of the wet storage tanks served by the disinfection system;
(ii) Include one sample daily for five consecutive days from the source water prior to disinfection;
(iii) Use NSSP recognized methods to analyze the samples if determining coliform levels;
(iv) Require all samples of disinfected water to be negative for the coliform group; and
(v) Be repeated if any sample of disinfected process water during the study is positive for the coliform group. ~~or viable bacteria~~.

(c) Once sanctioned for use, the water system shall be sampled daily to demonstrate that the disinfected water is negative for the coliform group ~~or free of detectable viable bacteria~~.

(d) When other than approved water is located between the intake of a flow-through wet storage system and the land-based facility then the Authority may require periodic verification of the system's integrity to ensure that the other than approved water does not infiltrate into the intake pipe.

(3) Recirculating Water System.

(a) A study shall be required to demonstrate that disinfection for the recirculating system can consistently produce water that tests negative for the coliform group ~~or viable bacteria~~ under normal operating conditions. The study shall meet the requirements in §C.(2)(b) above.

(b) Once sanctioned for use, the recirculating process water system shall be sampled weekly to demonstrate that the disinfected water is negative for the coliform group ~~or viable bacteria~~.

(c) When make-up water of more than 10 percent of the process water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected over a 24 hour period to reaffirm the ability of the system to produce process water free from the coliform group ~~or viable bacteria~~.

(d) When ultra-violet treatment is used as the water disinfectant, each time a bulb change is required either to replace a burned out bulb or for servicing, new ultraviolet bulbs shall be installed and old bulbs discarded, and the weekly disinfected process water sample shall be collected and analyzed.

D. Shellstock Handling.

(1) Shellstock shall be thoroughly washed with water from a source authorized by the Authority and culled prior to wet storage in tanks. Any deviation to this requirement is subject to permission from the Authority.

(2) Unless the dealer is in the Authority's commingling plan under Chapter I@.01F., different lots of shellstock shall not be commingled during wet storage in tanks. If more than one lot of

shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.
(3) Bivalve mollusks shall not be mixed with other species in the same tank. Where multiple tank systems use a common water supply system for bivalve mollusks and other species, wet storage process water shall be effectively disinfected prior to entering tanks containing the bivalve mollusks.

VIII. CONTROL OF SHELLFISH HARVESTING.

@.01 Control of Shellstock Growing Areas.

C. Licensing of Harvesting.

(3) A license to harvest shall not allow a harvester to engage in shellstock packing or engage in independent wet storage activities as defined in this Ordinance unless the harvester is a certified shellfish dealer and has a Wet Storage Permit issued by the Authority.

X. GENERAL REQUIREMENTS FOR DEALERS

.05 Shellstock Identification.

B. Tags.
(1) The dealers' tags shall:
(a) Be durable, waterproof and sanctioned by the Authority prior to use; and
(b) Be at least 2 5/8 inches by 5 1/4 inches (6.7 x 13.3 cm) in size.

(2) The dealer's tag shall contain the following indelible, legible information in the order specified below:
(a) The dealer's name and address;
(b) The dealer's certification number as assigned by the Authority
(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required;
(d) The date of harvest; or if depurated, the date of depuration processing;
(e) If depurated, the depuration cycle number or lot number;
(f) The most precise identification of the harvest location as is practicable including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If the Authority has not indexed growing areas, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number)~~.~~
(g) ~~When the shellstock has been placed in wet storage in a dealer's operation, the statement: "THIS IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)";~~ The type and quantity of shellstock; and
(h) The following statement in bold capitalized type on each tag:
"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."
(i) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-602.11 of the 1999 Food Code, or an equivalent statement, shall be included on all shellstock:
"RETAILERS, INFORM YOUR CUSTOMERS"
"Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

.08 Shipping Documents and Records.

B. Transaction and Shipping Records.
(1) Each dealer shall have a business address at which transaction records are maintained.

(2) Each dealer shall maintain accurate and legible transaction records that are sufficient to:
(a) Document that the shellfish are from a source authorized under this Ordinance;
(b) Permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken;
(c) Permit a lot (or commingled lots as per Chapter I.@.01.F.) of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of harvest, date and location of wet storage, if applicable, and if possible, the harvester or group of harvesters.

[Delete Section .09 in its entirety from Chapter X.]

Action by 2007 Task Force II

Recommended adoption of Post Harvesting Processing Committee recommendation on Proposal 05-205 as amended

Modify current Model Ordinance Wet Storage Definition (106); Chapter 1@.02E; move Wet Storage requirements found under .08 and .09 of Chapter X and incorporate it into Chapter VII (Wet Storage); modify language in Chapter VII by removing, editing, and adding to existing language, as follows:

MODEL ORDINANCE

Definitions.

B. Definition of Terms.

(106) Wet storage means the storage, by a dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally approved classification, ~~either loose or~~ in containers or floats in natural bodies of water, or in tanks containing natural or synthetic seawater at any permitted land-based activity or facility.

I. SHELLFISH SANITATION PROGRAM

@.02 Dealer Certification.

E. Interstate Certified Shellfish Shippers List (ICSSL).

(1) When the Authority certifies a person to become a dealer, the Authority shall notify the FDA for the purpose of having the dealer listed in the ICSSL. The Authority shall include any permit designation to be included in the ICSSL. The notice shall be in the format of FDA Form 3038.

Designations			
Certification		Permit	
SP -	Shucker Packer	PHP -	Post Harvest Processing
RP -	Repacker	AQ -	Aquaculture
SS -	Shellstock Shipper	WS -	Wet Storage
RS -	Reshipper		
DP -	Depuration		

(2) The Authority shall notify the FDA for the purpose of having the dealer removed from the ICSSL whenever a dealer's certificate or permit is:
(a) Suspended; or
(b) Revoked.

VII. WET STORAGE

Table of Contents

Requirements for the Authority.

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

.01 General.

A. The Authority shall permit all wet storage activities to ensure that all wet storage activities are conducted by certified NSSP shellfish firms.

B. The Authority shall approve and maintain the following records while the wet storage activity continues:
(1) Construction and remodeling plans for any permitted wet storage facility;
(2) Wet storage operational plans;
(3) Wet storage permits; and
(4) Inspection documentation.

C. The Authority shall inspect wet storage activities at the following frequency:
(1) Activities in offshore natural bodies of water at least annually;
(2) Activities at land-based sites with flow-through systems at least every six months; and
(3) Activities at land-based sites with recirculating systems ~~at least quarterly~~ **semi-annually**.

D. The Authority shall immediately notify (within 24 hours) all wet storage permit holders affected by a change in growing area classification or status.

E. Reshippers shall not engage in wet storage activities.

Requirements for the Dealer.

.01 Source of Shellstock.

A. Dealers shall wet store shellstock harvested only from areas classified as approved, or conditionally approved in the open status.

B. Shellstock shall be harvested, identified and shipped to the wet storage activity in accordance with the requirements of Chapters VIII and IX.

.02 General.

A. Wet storage may be used to store, condition, remove sand or to add salt to shellstock. Wet storage shall be deemed a processing activity.

B. Wet storage of depurated product shall occur only within the facility in which it was depurated. The shellstock shall be packed and labeled according to the requirements in Chapter XV

C. Wet storage shall be practiced only by a dealer in strict compliance with the provisions in the written approval for the wet storage activity given by the Authority.

D. While awaiting placement in a wet storage activity, shellstock shall be protected from physical, chemical or thermal conditions which may compromise shellstock survival, quality or activity during wet storage.

E. Conditions and water quality during wet storage shall be sufficient to minimize the potential for compromising the sanitary quality of the shellstock during storage.

F. Shellstock from a wet storage activity shall be harvested, handled, identified, processed and shipped according to the requirements of Chapters VIII, IX and X.

G. The wet storage operator shall keep complete and accurate records to enable a lot of shellstock to be traced back to the original harvest location and wet storage location, and include the dates the shellstock were held in wet storage. The records shall be maintained for a minimum of one year.

H. Unless the dealer is in the Authority's commingling plan under Chapter I .01F different lots of shellfish shall not be commingled during wet storage. If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

.03 Wet Storage Sites in Natural Bodies of Water (Offshore).

A. Natural bodies of waters used for wet storage shall meet the requirements for classification as approved or conditionally approved while shellstock is being held in storage. Areas classified as conditionally approved may be used only when in the open status. When an area classified as conditionally approved is placed in a status other than its open status, any shellstock in wet storage in that area shall be:
(1) Subjected to relaying or depuration prior to human consumption; or
(2) Held in the wet storage site until the area is returned to the open status.

B. Site evaluations of natural bodies of water shall include:
(1) The sanitary survey of the storage site, with special consideration of potential intermittent sources of pollution;
(2) The location of storage sites and/or floats;
(3) The examination of the construction of shellstock containers, if used, to ensure the free flow of water to all shellstock; and
(4) A review of the operation's plan and operating procedures for an offshore activity as submitted by the dealer.

[Sections below are moved from Chapter X to Chapter VII]

.04 Wet Storage in Artificial Bodies of Water (Land-based).

A. General.

(1) If the dealer chooses to practice wet storage in artificial bodies of water, the dealer shall meet the requirements of Chapter VII.01 and .02.

(2) For the purpose of permitting, each wet storage site or activity shall be evaluated in accordance with @.01.B. The evaluation shall include a review of the plan and operating procedures for conducting land-based wet storage activity as submitted by the dealer.

(3) Prior to commencing construction, all plans for construction or remodeling of wet storage facilities shall be reviewed and authorized by the Authority.

(4) The wet storage facility evaluation shall include a review of:
(a) The purpose of the wet storage activity, such as holding, conditioning or increasing the salt content of shellstock;
(b) Any species specific physiological factors that may affect design criteria; and
(c) The plan giving the design of the land-based wet storage facility, source and quantity of process water to be used for wet storage, and details of any process water treatment (disinfection) system.

B. Operation Specifications.

(1) General. Each land-based wet storage activity shall meet the following design, construction, and operating requirements.
(a) Effective barriers shall be provided to prevent entry of birds, animals, and vermin into the area.
(b) Storage tanks and related plumbing shall be fabricated of safe material and shall be easily cleanable. This requirement shall include:
(i) Tanks constructed so as to be easily accessible for cleaning and inspection, self-draining and fabricated from nontoxic, corrosion resistant materials; and
(ii) Plumbing designed and installed so that it can be cleaned and sanitized on a regular schedule, as specified in the operating procedures.
(c) Storage tank design, dimensions, and construction are such that adequate clearance between shellstock and the tank bottom shall be maintained.
(d) Shellstock containers, if used, shall be designed and constructed so that the containers allow the free flow of water to all shellstock within a container.

(2) Buildings. When a building is used for the wet storage activity:
(a) Floors, walls, and ceilings shall be constructed in compliance with the applicable provisions of Chapter XI; and
(b) Lighting, plumbing, water and sewage disposal systems shall be installed in compliance with applicable provisions of Chapter XI.

(3) Outdoor Tank Operation. When the wet storage activity is outdoors or in a structure other than a building, tank covers shall be used. Tank covers shall:
(a) Prevent entry of birds, animals or vermin; and
(b) Remain closed while the system is in operation except for periods of tank loading and unloading, or cleaning.

C. Wet Storage Source Water

(1) General.

(a) Except for wells, the quality of the surface source water prior to treatment shall meet, at a minimum, the bacteriological standards for the restricted classification and water classified as Prohibited or Conditionally Restricted when in the Closed Status shall not be used as source water.

(b) Any well used as source water for wet storage shall meet the requirements of Chapter XI.02 (with the exception of the salt content in salt water wells).

(c) Except when the source of the water is a growing area in the approved classification, a water supply sampling schedule shall be included in the dealer's operating procedures and water shall be tested according to the schedule.

(d) Results of water samples and other tests to determine the suitability of the source water supply shall be maintained for at least 2 years.

(e) Disinfection or other water treatment such as the addition of salt cannot leave residues unless they are Generally Recognized as Safe (GRAS) and do not interfere with the shellstock's survival, quality or activity during wet storage.

(f) Disinfected process water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multi-tube MPN test per 100 ml. for potable water and acceptable for use with marine water and follow the protocol of the Decision Tree (IV. Guidance Documents Chapter III.06.)

(g) When the laboratory analysis of a single sample of disinfected process water entering the wet storage tanks shows any positive result for the coliform group daily sampling shall be immediately instituted until the problem is identified and eliminated.

(h) When the problem that is causing disinfected process water to show positive results for the coliform group is eliminated, the effectiveness of the correction shall be verified on the first operating day following correction through the collection, over a 24 hour period, of a set of three samples of disinfected process water.

(i) For water that is disinfected by ultra-violet treatment, turbidity shall not exceed 20 nephelometric turbidity units (NTUs) measured in accordance with *Standard Methods for the Examination of Water and Wastewater*, APHA.

(j) The disinfection unit(s) for the process water supply shall be cleaned and serviced as frequently as necessary to assure effective water treatment.

(2) Continuous Flow-through System.

(a) If the system is of continuous flow-through design, water from a growing area classified as:
(i) Approved may be used, without disinfection, in wet storage tanks provided that the near shore water source used for supplying the system meets the approved classification bacteriological criteria at all times that shellstock are being held in wet storage; or
(ii) Conditionally Approved in the Closed Status, Restricted or Conditionally Restricted in the Open Status may be used if the source water is continuously subjected to disinfection and it is sampled and analyzed daily following disinfection.

(b) When a source classified as Conditionally Approved in the Closed Status, Restricted or Conditionally Restricted in the Open Status is used, a study shall be required to demonstrate that the disinfection system can consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall:
(i) Include five sets of three samples from each disinfection unit collected for five consecutive days at the outlet from the disinfection unit or at the inlet to at least one of the wet storage tanks served by the disinfection system;
(ii) Include one sample daily for five consecutive days from the source water prior to disinfection;
(iii) Use NSSP recognized methods to analyze the samples if determining coliform levels;
(iv) Require all samples of disinfected water to be negative for the coliform group; and
(v) Be repeated if any sample of disinfected process water during the study is positive for the coliform group.

(c) Once sanctioned for use, the water system shall be sampled daily to demonstrate that the disinfected water is negative for the coliform group.

(d) When other than approved water is located between the intake of a flow-through wet storage system and the land-based facility then the Authority may require periodic verification of the system's integrity to ensure that the other than approved water does not infiltrate into the intake pipe.

(3) Recirculating Water System.

(a) A study shall be required to demonstrate that disinfection for the recirculating system can consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall meet the requirements in §C.(2)(b) above.

(b) Once sanctioned for use, the recirculating process water system shall be sampled weekly

to demonstrate that the disinfected water is negative for the coliform group

(c) When make-up water of more than 10 percent of the process water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected over a 24 hour period to reaffirm the ability of the system to produce process water free from the coliform group or viable bacteria.

(d) When ultra-violet treatment is used as the water disinfectant, each time a bulb change is required either to replace a burned out bulb or for servicing, new ultraviolet bulbs shall be installed and old bulbs discarded, and the weekly disinfected process water sample shall be collected and analyzed.

D. Shellstock Handling.

(1) Shellstock shall be thoroughly washed with water from a source authorized by the Authority and culled prior to wet storage in tanks. Any deviation to this requirement is subject to permission from the Authority.

(2) Unless the dealer is in the Authority's commingling plan under Chapter I@.01F., different lots of shellstock shall not be commingled during wet storage in tanks. If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

(3) Bivalve mollusks shall not be mixed with other species in the same tank. Where multiple tank systems use a common water supply system for bivalve mollusks and other species, wet storage process water shall be effectively disinfected prior to entering tanks containing the bivalve mollusks.

VIII. CONTROL OF SHELLFISH HARVESTING.

@.01 Control of Shellstock Growing Areas.

C. Licensing of Harvesting.

(3) A license to harvest shall not allow a harvester to engage in shellstock packing or engage in independent wet storage activities as defined in this Ordinance unless the harvester is a certified shellfish dealer and has a Wet Storage Permit issued by the Authority.

X. GENERAL REQUIREMENTS FOR DEALERS

.05 Shellstock Identification.

B. Tags.
(1) The dealers' tags shall:
(a) Be durable, waterproof and sanctioned by the Authority prior to use; and
(b) Be at least 2 5/8 inches by 5 1/4 inches (6.7 x 13.3 cm) in size.

(2) The dealer's tag shall contain the following indelible, legible information in the order specified below:
(a) The dealer's name and address;
(b) The dealer's certification number as assigned by the Authority
(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required;
(d) The date of harvest; or if depurated, the date of depuration processing;
(e) If depurated, the depuration cycle number or lot number;
(f) The most precise identification of the harvest location as is practicable including the

initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If the Authority has not indexed growing areas, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number).
(g) The type and quantity of shellstock; and
(h) The following statement in bold capitalized type on each tag:
"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."
(i) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-602.11 of the 1999 Food Code, or an equivalent statement, shall be included on all shellstock:
"RETAILERS, INFORM YOUR CUSTOMERS"
"Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

.08 Shipping Documents and Records.

B. Transaction and Shipping Records.
(1) Each dealer shall have a business address at which transaction records are maintained.
(2) Each dealer shall maintain accurate and legible transaction records that are sufficient to:
(a) Document that the shellfish are from a source authorized under this Ordinance;
(b) Permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken;
(c) Permit a lot (or commingled lots as per Chapter I.@.01.F.) of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of harvest, date and location of wet storage, if applicable, and if possible, the harvester or group of harvesters.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force II.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject Plant Sanitation

Specific NSSP Guide Reference
NSSP Guide Model Ordinance
Chapter X. General Requirements for Dealers
.05 Shellstock Identification. (B) (2) (i) - amended
.06 Shucked Shellfish Labeling (A) (5) (e) – new

Text of Proposal/ Requested Action
Amend Chapter X .05 (B)(2)(i) to read:

The following statement in bold capitalized type on each tag **or label**: "THIS TAG **OR LABEL** IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."

Add new item (e) requirement to Chapter X .06 (A) (5) that reads:

(e) **The following statement "WHEN SHUCKED SHELLFISH ARE CONSUMED RAW, THIS LABEL IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS" appears on the label.**

Public Health Significance
Changes in the packaging, use, and consumption patterns of shellstock and shucked shellfish at the retail and consumer levels, while making it even more important to retain tag or label information relative to shellfish trace back, are also making it more difficult for retailers to retain the required trace back records.

Because shucked shellfish, both frozen and fresh, are being consumed raw and because retailers receive consumer sized bags of shellstock (each with a tag inside the bag) in bulk containers (such as cardboard boxes) with a label on the container, current NSSP requirements do not accommodate easy records retention at retail. In order to meet the 90 day tag retention requirement of the NSSP, the retailer would have to cut into each consumer sized bag to remove the tag. This gives consumers and/or inspectors the appearance of tampering or commingling and discourages retention by retailers. An allowance for retailers to retain the bulk container label would eliminate this problem while maintaining product trace back information. For shucked shellfish, on the other hand, there is no NSSP requirement for label retention when it is served for raw consumption. A requirement for shucked product labels would provide necessary trace back information for product consumed raw.

Retailers need simpler, user friendly ways of retaining shellfish trace back information consistent with current retail practices. Requiring retention messages on tags and labels addresses this need. This NSSP change will be reinforced through a Proposal to amend the FDA Food Code at the 2006 Conference for Food Protection to be consistent with this NSSP change.

Cost Information (if available): N/A

Action by 2005 Task Force II Recommended Proposal 05-206 be referred to appropriate committee as determined by the Conference Chairman.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Traceability Committee Recommended no action on Proposal 05-206.

Action by 2007 Task Force II	Recommended no action recommendation of Traceability Committee. Rationale – Requirement is impractical to implement and the current Model Food Code does not require retention of the label.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject Plant Sanitation

Specific NSSP Guide Reference: 2003 Model Ordinance Chapter XI.01

Text of Proposal/ Requested Action Modify Chapter XI. 01. (Critical Control Points) to make minor editorial changes and to add a new temperature requirement at receiving.

01. Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall shuck and pack only shellstock which is:
(1) Obtained from a licensed harvester who has:
(a) Harvested the shellstock from an approved or conditionally approved area in the open status as indicated by the tag; and **[C]**
(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or **[C]**
(2) Obtained from a **certified** dealer who has:
(a) Transported the shellstock iced, or in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature [C]; and
(b) Identified the shellstock with a tag on each container or transaction record with each bulk shipment. **[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:
(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**
(2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be;
(a) Iced; or **[C]**
(b) Placed and stored in a storage area or conveyance maintained at 45 ° F~~arenheit~~ (7.2 °C~~entigrade~~) or less; and **[C]**
(c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B (1) or §B (2) for more than 2 hours at points of transfer such as loading docks. **[C]**

C. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:
(1) For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2 ° C~~entigrade~~) or less within three hours of shucking. **[C]**
(2) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45°F (7.2 ° C~~entigrade~~) or less within four hours of removal from refrigeration. **[C]**
(3) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to 45 ° F~~arenheit~~ (7.2 ° C~~entigrade~~) or less within two hours after the heat shock process. **[C]**
(4) When heat shock shellstock are cooled and held under refrigeration for later shucking, the heat shocked shellstock shall be cooled to an internal temperature of 45° F~~arenheit~~ (7.2° C~~entigrade~~) within two hours from time of heat shock. **[C]**

D. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked and packed shellfish in covered containers at an ambient temperature of 45 ° F~~arenheit~~ (7.2 ° C~~entigrade~~) or less or covered with ice.

[C]

Public Health Significance:

Pathogens found in waters from which molluscan shellfish are harvested can cause illness or death in consumers with immune disorders or conditions. Pathogens, such as *Vibrio vulnificus, Vibrio parahaemolyticus,* and *Vibrio cholerae* non 01, are naturally occurring. *V. vulnificus* illness is associated with the consumption of raw oysters harvested from the Gulf of Mexico during the warm weather months. *V. parahaemolyticus* and *V. cholerae* non 01 illness is associated with the consumption of raw oysters harvested during the warm weather months from the Atlantic, Pacific, and Gulf of Mexico regions of the U.S., and similar climates world-wide. Some of these bacterial pathogens may be present in low numbers at the time that molluscan shellfish are harvested, and may increase to levels that are more hazardous if they are exposed to time/temperature abuse.

"Pathogens from the harvest area" should be considered a significant hazard at any harvesting, shipping, receiving, and processing steps where a preventive measure is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level. To minimize the risk of illness from the consumption of molluscan shellfish containing these pathogens, shellfish dealers must identify the receiving step as a critical control point for this hazard.

Pathogenic organisms can survive in shellfish for a considerable length of time after harvesting and bacterial pathogens may multiply in the absence of adequate refrigeration. Adequate temperature control is critical to product safety. The NSSP MO sets forth temperature requirements for shipping shellfish (Chapter IX). However, there is no a requirements for dealers to monitor temperature at receiving (dealer to dealer shipping). Adding temperature control at receiving will close the gap that exists now between the shipping and receiving steps.

Cost Information (if available):

None

Action by 2005 Task Force II

Recommended referral of Proposal 05-209 to appropriate Committee as determined by the Conference Chairman.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force II.

Action by USFDA

Concurred with Conference action.

Action by 2007 Time/Temperature Committee

Recommended adoption of Proposal 05-209 as amended.

Chapter XI. Shucking and Packing

Requirements for Dealers

01. Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall shuck and pack only shellstock which is:

(1) Obtained from a licensed harvester who has:

(a) Harvested the shellstock from an approved or conditionally approved area in the open status as indicated by the tag; and **[C]**

(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or **[C]**

(2) Obtained from a ~~certified~~ dealer who has:

(a) **Shipped** ~~Transported~~ the shellstock iced, or in a conveyance ~~maintained~~ at or below 45°F (7.2°C) ambient air temperature **or**

50° F (10° C) internal temperature or less; **[C]** and

(b) Identified the shellstock with a tag on each container or transaction record with each bulk shipment. **[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**

(2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be;

(a) Iced; or **[C]**

(b) Placed and stored in a storage area or conveyance maintained at 45° F (7.2°C) or less; and **[C]**

(c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B (1) or §B (2) for more than 2 hours at points of transfer such as loading docks. **[C]**

C. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within three hours of shucking. **[C]**

(2) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45°F (7.2° C) or less within four hours of removal from refrigeration. **[C]**

(3) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to 45° F (7.2° C) or less within two hours after the heat shock process. **[C]**

(4) When heat shock shellstock are cooled and held under refrigeration for later shucking, the heat shocked shellstock shall be cooled to an internal temperature of 45° F (7.2° C) within two hours from time of heat shock. **[C]**

D. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked and packed shellfish in covered containers at an ambient temperature of 45° F (7.2° C) or less or covered with ice. **[C]**

Action by 2007 Task Force II

Recommended tabling Proposals 05-209, 05-215, 05-217, and 05-219 and sent to a workgroup comprised of Chris Nelson, Steve Fleetwood, MaryAnn Guichard, Austin Doctor, Teddy Busick, Sandy Shepherd, Erin Butler, Miles Motes and AJ Erskine.

Action by 2007 Task Force II Workgroup

Recommended adoption of Proposal 05-209 as amended.

Chapter XI. Shucking and Packing

Requirements for Dealers

01. Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall shuck and pack only shellstock which is:

(1) Obtained from a licensed harvester who has:

(a) Harvested the shellstock from an approved or conditionally approved area in the open status as indicated by the tag; and **[C]**

(b) Identified the shellstock with a tag on each container or transaction

record on each bulk shipment; or **[C]**

(2) Obtained from a dealer who has:

(a) Shipped the shellstock iced, or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 50° F internal temperature or less **or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50° F (10° C) or less;** **[C]** and

(b) Identified the shellstock with a tag on each container or transaction record with each bulk shipment. **[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**

(2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be;

(a) Iced; or **[C]**

(b) Placed and stored in a storage area or conveyance maintained at 45° F (7.2°C) or less; and **[C]**

(c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B (1) or §B (2) for more than 2 hours at points of transfer such as loading docks. **[C]**

C. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within three hours of shucking. **[C]**

(2) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45°F (7.2° C) or less within four hours of removal from refrigeration. **[C]**

(3) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to 45° F (7.2° C) or less within two hours after the heat shock process. **[C]**

(4) When heat shock shellstock are cooled and held under refrigeration for later shucking, the heat shocked shellstock shall be cooled to an internal temperature of 45° F (7.2° C) within two hours from time of heat shock. **[C]**

D. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked and packed shellfish in covered containers at an ambient temperature of 45° F (7.2° C) or less or covered with ice. **[C]**

Action by 2007 Task Force II

Recommended adoption of Task Force II Workgroup recommendation on Proposal 05-209 as amended.

Chapter XI. Shucking and Packing

Requirements for Dealers

01. Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall shuck and pack only shellstock which is:

(1) Obtained from a licensed harvester who has:

(a) Harvested the shellstock from an approved or conditionally

approved area in the open status as indicated by the tag; and **[C]**

(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or **[C]**

(2) Obtained from a dealer **other than the original harvester** who has:

(a) Shipped the shellstock **adequately** iced; or in a conveyance at or below 45° F (7.2° C) ambient air temperature**;** or 50° F (10° C) internal temperature or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50° F (10° C) or less; **[C]**; and

(b) Identified the shellstock with a tag on each container or transaction record with each bulk shipment. **[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**

(2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be;

(a) Iced; or **[C]**

(b) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less; and **[C]**

(c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B (1) or §B (2) for more than 2 hours at points of transfer such as loading docks. **[C]**

C. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within three hours of shucking. **[C]**

(2) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45°F (7.2° C) or less within four hours of removal from refrigeration. **[C]**

(3) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to 45° F (7.2° C) or less within two hours after the heat shock process. **[C]**

(4) When heat shock shellstock are cooled and held under refrigeration for later shucking, the heat shocked shellstock shall be cooled to an internal temperature of 45° F (7.2° C) within two hours from time of heat shock. **[C]**

D. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked and packed shellfish in covered containers at an ambient temperature of 45° F (7.2° C) or less or covered with ice. **[C]**

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force II.

Action by USFDA December 20, 2007
Concurred with Conference action with the following comments and recommendations for ISSC consideration.

Action by the ISSC to identify receiving temperature as a critical limit at receiving represents an important addition to the public health safety measures of the NSSP. Under HACCP, assuring proper receiving temperatures has long been recognized as a necessary food safety control measure. Adoption of these proposals establishes consistency between NSSP safety

controls for molluscan shellfish and safety controls for other seafood. Section 01. A (2) (a) of Proposals 05-209 and 05-217 and Section 01. A (1) (a) of Proposal 05-219 states that shellstock shall be obtained from a dealer who has **"Shipped the shellstock adequately iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 50°F (10°C) internal temperature or less; *or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less;* [C]."** FDA points out that ***or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less"*** shall not be interpreted to mean that the refrigeration unit of the conveyance need not be turned on and operating. In those situations where the shellstock has recently been placed in the conveyance whereby the conveyance may not yet have achieved the required ambient temperature, this provision provides assurance that the shellstock is at least in a operating temperature controlled environment capable to maintaining the shellstock at an internal temperature at 50°F.

Proposal Subject Plant Sanitation

Specific NSSP Guide Reference Model Ordinance Chapter XI Shucking and Packing, Sections .02 & .03

Text of Proposal/ Requested Action Modify the organization of sanitation requirements of Chapter XI. Shucking and Packing Sections .02 and .03 to make them consistent with the interpretation and implementation of Title 21 of the Code of Federal Regulations (CFR) Part 123 Seafood HACCP Regulation by putting related items together.

Public Health Significance: This proposal attempts to reorganize the NSSP MO plant sanitation requirements in Chapter XI. Shucking and Packing, Sections .02 and .03 to:

1. Make them consistent with manner in which the sanitation requirements of the Seafood HACCP regulation, Title 21 Code of Federal Regulations (CFR) Part 123) are implemented; and
2. Consolidate similar items together.

In order to accommodate this reorganization there are instances in this proposal where editing and some minor word deletions or additions were made for coherency.

There is also one update regarding the NSSP construction guide.

Hopefully this will serve to eliminate some of the confusion that exists over how to interpret and implement the requirements between Seafood HAACP and NSSP.

This proposal provides revisions for Chapter XI that simply reorganize and reformat the written requirements already contained in this chapter. The revisions do not add or delete any requirements.

FDA will incorporate changes adopted by the ISSC in the FDA Standardization Field Guide and NSSP Standardized Shellfish Processing Plant Inspection Form. Copies of these revised documents then will be provided to each state.

Cost Information (if available): None

Action by 2005 Task Force II Recommended referral of Proposal 05-210 to appropriate Committee as determined by the Conference Chairman, with a recommendation by Task Force II that a workgroup be established to address this proposal in advance of the 2007 Biennial Meeting.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Plant Sanitation Committee Recommended adoption of Proposal 05-210 as amended.

The Committee recommended:

1. Not deleting Chapter XI. .02 B. 1. h. (ii).
2. Adopting the recommended change as submitted
   Chapter XI. .03 B. (5)

(5) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials ~~and tank construction shall be such that it:~~

(i) Is easily accessible for ~~cleaning~~ and inspection; [K]

(ii) Is self-draining; and [K]

(iii) Meets the requirements for food contact surfaces

Action by 2007 Task Force II

Recommended adoption of Plant Sanitation Committee recommendation on Proposal 05-210.

NOTE: The Chairman of the Plant Sanitation Committee has advised the Executive Board Chair, the Executive Director, and the Task Force II Chair of an error that was reported to Task Force II. The Voting Delegates in the closing General Assembly will be provided with an opportunity to correct the error.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II as editorially amended to be correct.

The error on Proposal 05-210 was discussed in the Closing General Assembly and corrected as follows:

Recommended adoption of Proposal 05-210 as amended.

The Committee recommended:

1. Not deleting Chapter XI. .02 B. 1. h. (ii). Is self-draining; and [K]

2. Delete Chapter XI. .03 B. (5)

~~**(5) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:**~~

~~**(i) Is easily accessible for cleaning and inspection; [K]**~~

~~**(ii) Is self-draining; and [K]**~~

~~**(iii) Meets the requirements for food contact surfaces**~~

Action by USFDA

December 20, 2007
Concurred with Conference action.

XI. SHUCKING AND PACKING

Requirements for Dealers.

.02 Sanitation.

A. Safety of Water for Processing and Ice Production.

(1) Water Supply.

(a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations. **[C]**

(b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: **[K]**

(i) Prior to use of the water supply; **[C]**

(ii) Every six months while the water supply is in use; and **[K]**

(iii) After the water supply has been repaired and disinfected.**[S$^{C/K}$]**

[*(c) was moved to Protection from Adulterants 02.E (6)]*

~~(c) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations.~~ **~~[K]~~**

(2) Ice Production. Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall~~:(a) B~~be made on-site from potable water in a commercial ice machine; ~~or~~ **[C]**

[*(b) was moved to Protection from Adulterants 02. E 4 (c)]*

~~(b) Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency~~ **[C]**

(3) Shellstock Washing.

(a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock. **[C]**

(b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:

(i) Obtain approval for the construction or remodeling of the system from the Authority. **[K]**

(ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and **[C]**

(iii) Test bacteriological water quality daily; **[$S^{C/K}$]**

(c) The dealer may use ultra-violet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed 20 nephelometric turbidity units (NTUs) measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*. **[K]**

(4) Plumbing and Related Facilities.

(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

(i) Prevent contamination of water supplies; **[C]**

(ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. **[C]** The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. **[K]**

[Portions of (b) pertaining to food contact surfaces were moved to Condition and Cleanliness, of Food Contact Surfaces 02.B (1) (h)and the portions of (b) pertaining to plumbing were moved to Plumbing and Related facilities .03 B (5)]

~~(b) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:~~

~~(i) Is easily accessible for cleaning and inspection; **[K]**~~

~~(ii) Is self-draining; and **[K]**~~

~~(iii) Meets the requirements for food contact surfaces. **[K]**~~

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guides [UPDATE]* ~~(August 1993)~~,**(available in the Guidance Document section of the NSSP Guide for the Control of Molluscan Shellfish),** U.S. Department of Health and Human Services. **[K]**

(b) The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are:

(i) Constructed in a manner and with materials that can be cleaned, and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products;**[K]**

(ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and **[K]**

(iii) Fabricated from food grade materials. **[K]**

(c) The dealer shall assure that all joints on food contact surfaces

(i) Have smooth easily cleanable surfaces~~;~~ and **[K]**

(ii) Are welded-**[K]**

(d) Shucking blocks shall be provided which are:
- (i) Easily cleanable; **[K]**
- (ii) Fabricated from safe material; **[K]**
- (iii) Solid, one piece construction; and **[K]**
- (iv) Easily removed from the shucking bench, unless the block is an integral part of the bench. **[K]**

(e) The dealer shall provide a temperature measuring device accurate to +/- 2° Fahrenheit for use in monitoring product temperatures. **[K]**

(f) All equipment used in heat shock processing shall meet the requirements of Chapter XI.02.B.(1) (a), (b), and (c). **[K]**

(g) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02.B.(1)(a), (b), and (c). **[K]**

[*Moved portions of (h) which pertain to food contact surfaces from Safety of Water 02.A(4)(b) Some editing was also done to fit this heading and the portions of (b) pertaining to plumbing were moved to Plumbing and Related facilities .03 B (5)]*

(h) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:
- **(i) Is easily accessible for cleaning and inspection; [K]**
- ~~(ii) Is self-draining; [K]~~
- **(ii) Meets the requirements for food contact surfaces [K]**

(2) Cleaning and sanitizing of food contact surfaces.

(a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall:
- (i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant; **[K]**
- (ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; **[K]**

[*Moved (iii) to Proper labeling, Storage and Use of Toxic Compounds .02F(2)(d)]*

- ~~(iii) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use; and~~
- ~~(iv)~~(iii) Wash and rinse equipment and utensils at the end of each day. **[K]**

Moved (b) to Construction and Cleaning Non Food Contact Surfaces 03(E) (5)]

~~(b) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. **[O]**~~

(~~c~~)(b) Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling. **[K]**

(~~d~~)(c) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded. **[K]**

(~~e~~)(d) Shucked shellfish shall be packed in clean covered containers and stored in a manner which assures their protection from contamination. **[K]**

(~~f~~)(e) If used, the finger cots or gloves shall be:
- (i) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; **[O]**
- (ii) Sanitized at least twice daily; **[K]**
- (iii) Cleaned more often, if necessary **[K]**;

(iv) Properly stored until used; and **[K]**
(v) Maintained in a clean, intact, and sanitary condition. **[K]**

C. Prevention of Cross Contamination.
(1) Protection of shellfish.
(a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. **[$S^{C/K}$]**
(b) Shucked shellfish shall be protected from contamination. **[$S^{C/K}$]**
(c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. **[K]**
(d) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. **[$S^{K/0}$]**

[*Moved (2) from Plants and Grounds 03 A (4)(a)(b)]*

(2) Separation of operations.
(a) Facilities for shucking and packing activities shall be separated by use of:
(i) Separate rooms; [K]
(ii) Partitions; or [K]
(iii) Sufficient spacing. [K]
(b) Manufacturing activities which could result in the contamination of the shellfish shall be separated by adequate barriers. [K]

~~(2)~~**(3)** Employee practices.
(a) Where the same employee works in both the shucking and packing activities, the employee shall wash his hands thoroughly after entering. **[K]**
(b) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:
(i) Before starting work; **[K]**
(ii) After each absence from the work station; **[K]**
(iii) After each work interruption; and **[K]**
(iv) Any time when their hands may have become soiled or contaminated. **[K]**

[Moved (c) from .03 J(1),(2),(3),(4),(5)(i)(ii)(iii)(iv) . Personnel]

(c) Any employee handling shucked shellfish shall be required to:
(i) Wear effective hair restraints; [O]
(ii) Remove any hand jewelry that cannot be sanitized or secured; [O]
(iii) Wear finger cots or gloves if jewelry cannot be removed; and [O]
(iv) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. [O]
(v) In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
a. Store clothing or other personal belongings; [O]
b. Eat or drink; [K]
c. Spit; and [K]
d. Use tobacco in any form. [K]

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.
(1) Handwashing facilities with warm water at a minimum temperature of 110 ^{o}F (43^{o}C), dispensed from a hot and cold mixing or combination faucet, shall be provided. **[$S^{K/O}$]**

[Moved (2) (a)(b)(c), (3) and (4) (a)(b)(c)(d) from .03 B (1)(a)(b)(c),(2),(3) (a)(b)(c)(d) Plumbing and Related Facilities; Moved (2) (d) from .03 B (4)(b) Plumbing and Related Facilities]

(2) Handwashing facilities shall be provided which are:
(a) Convenient to work areas; [O]

(b) Separate from the three compartment sinks used for cleaning equipment and utensils; [K]

(c) Directly plumbed to an approved sewage disposal system, and [$S^{O/K}$]

(d) Adequate in number and size for the number of employees, and located where supervisors can observe employee use; [K]

(3) The dealer shall provide at least one handsink in the packing room. [O]

(4) The dealer shall provide at each handwashing facility:

(a) Supply of hand cleansing soap or detergent; [K]

(b) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]

(c) Easily cleanable waste receptacle; and [O]

(d) Handwashing signs in a language understood by the employees; [O]

~~(2)~~(5) Sewage **[C]** and liquid disposable wastes shall be properly removed from the facility **[K]**

[Moved (6) (a) from .03 A (5) Plants and Grounds and edited for coherence]

(6) The dealer shall provide:

(a) Toilet room doors that are tight fitting, self closing, and do not open directly into a processing area; [K]

~~(3)~~ (b) An adequate number of conveniently located, toilets**[K]** ~~shall be provided;[K]~~

~~(4)~~ (c) ~~The dealer shall provide e~~Each toilet facility with an adequate supply of toilet paper **[K]** in a suitable holder. **[$S^{K/O}$]**.

E. Protection from Adulterants.

(1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing. **[K]**

(2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. **[O]**

(3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. **[K]**

(4) Protection of ice used in shellfish processing.

(a) Any ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. **[$S^{C/K}$]**

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[$S^{C/K}$]**

[Moved (c) from Safety of Water .02 A. (2) (b)]

(c) Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall ~~C~~come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]

(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[$S^{K/C}$]**

[Moved (6) from Safety of Water…. .02 A. (1) (c)]

(6) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations. [K]

[Moved (7) from Plants and Grounds…. .03 A. (1) (c)]

(7) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed. [O]

F. Proper Labeling, Storage and Use of Toxic Compounds.
(1) Storage of toxic compounds.
(a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. **[K]**
(b) Each of the following categories of toxic substances shall be stored separately:
(i) Insecticides and rodenticides/; **[K]**
(ii) Detergents, sanitizers, and related cleaning agents; and **[K]**
(iii) Caustic acids, polishes, and other chemicals. **[K]**
(c) The dealer shall not store toxic substances above shellfish or food contact surfaces. **[K]**
(2) Use and labeling of toxic compounds.
(a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. **[K]**
(b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. **[K]**
(c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions. **[K]**

[Moved (d) from Condition and Cleanliness of Food Contact Surfaces .02 B. (2) (a) (iii)]

(d) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use [K]

G. Control of Employees with Adverse Health Conditions.
(1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*. **[K]**
(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

[Moved the underlined part of the section below from .03 A (1) (b) Plants and Grounds;-edited to fit in this section; and moved the portion of the section pertaining to unauthorized persons to .03 Supervision (4) (c)]]

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. ~~**[K]**~~**. Animals** ~~or unauthorized persons~~ **shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]**

.03 Other Model Ordinance Requirements.

A. Plants and Grounds.
(1) General.
(a) The physical facilities shall be maintained in good repair. **[O]**

[Moved portion of (b)pertaining to animals to 02 H Exclusion of Pests and portion of (b) pertaining to unauthorized persons to .03 H (4) (c) Supervision]

~~(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored.~~ **~~[K]~~**

[Moved (c) to 02 E (7) Protection from Adulterants]

~~(c) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed.~~ **~~[O]~~**

(2) Flooding:

(a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. **[C]**

(b) If facilities are flooded:

(i) Shellfish processing, shucking or repacking activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. **[C]**

(ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use. **[C]**

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. **[$S^{C/K}$]**

[Moved (4) from .03 D (1) (a)(b)(c) Insect and Vermin Control]

(4) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in the facility.

(a) Tight fitting, self closing doors: [K]

(b) Screening of not less than 15 mesh per inch; [K] and

(c) Controlled air current. [K].

[Moved (4) (a) and (b) to .02 C (2) (a)(i)(ii)(iii) and (b) Prevention of Cross Contamination]

~~(4) Separation of operations.~~

~~(a) Facilities for shucking and packing activities shall be separated by use of~~

~~(i) Separate rooms;~~ **~~[K]~~**

~~(ii) Partitions; or~~ **~~[K]~~**

~~(iii) Sufficient spacing.~~ **~~[K]~~**

~~(b) Manufacturing activities which could result in the contamination of the shellfish shall be separated by adequate barriers.~~ **~~[K]~~**

[Moved (5) to .02 D (6) (a) Maintenance of Hand Washing Hand Sanitizing and Toilet Facilities]

~~(5) The dealer shall provide toilet room doors which are tightfitting, self closing, and do not open directly into a processing area. [K]~~

(~~6~~)(5) Plant Interior.

(a) Sanitary conditions shall be maintained through out the facility. **[O]**

(b) All dry area floors shall be hard, smooth, easily cleanable; and **[O]**

(c) All wet area floors used in areas to store shellstock, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:

(i) Are graded to provide adequate drainage; **[O]**

(ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; **[O]**

(iii) Have sealed junctions between floors and walls to render them impervious to water; and **[O]**

(d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials **[O]**.

(~~7~~)(6) Grounds. Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

(a) Rodent attraction and harborage; and **[O]**

(b) Inadequate drainage. **[O]**

B. Plumbing and Related Facilities.

[Moved (1)(a)(b)(c),(2),(3)(a)(b)(c)(d) to .02 D (2) (a)(b)(c)(d), (3), (4) (a)(b)(c)(d) Maintenance of Hand Washing Hand Sanitizing and Toilet Facilities]

~~(1) Handwashing facilities shall be provided which are:~~

~~(a) Convenient to work areas; **[O]**~~

~~(b) Separate from the three compartment sinks used for cleaning equipment and utensils; and **[K]**~~

~~(c) Directly plumbed to an approved sewage disposal system. **[S$^{O/K}$]**~~

~~(2) The dealer shall provide at least one handsink in the packing room. **[O]**~~

~~(3) The dealer shall provide at each handwashing facility:~~

~~(a) A supply of hand cleansing soap or detergent; **[K]**~~

~~(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**~~

~~(c) An easily cleanable waste receptacle; and **[O]**~~

~~(d) Handwashing signs in a language understood by the employees; **[O]**~~

~~(4)~~**(1)** All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes~~:(a)~~ cold and warm water at all sinks; ~~and~~ **[K]**

[Moved b to .02 C (2) D(2) Maintenance of Hand Washing Hand Sanitizing and Toilet Facilities]

~~(b) Handwashing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use; **[K]**~~

~~(5)~~**(2)** Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:

(a) Used in shellstock storage; **[K]**

(b) Used for food holding units **[K]** (e.g. refrigeration units);

(c) Cleaned by hosing, flooding, or similar methods **[K]**; and

(d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. **[K]**

(~~6~~)**(3)** A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[S$^{C/K}$]**

~~(7)~~**(4)** Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. **[K]**

[Moved (5) from .02 A (4)(b) Safety of Water; Edited out non plumbing portions and moved them to .02B (1)(h) Condition & Cleanliness of Food Contact Surfaces]

(5) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials ~~and tank construction shall be such that it:~~

(i) Is easily accessible for ~~cleaning~~ and inspection; [K]

(ii) Is self-draining; and [K]

~~(iii) Meets the requirements for food contact surfaces~~

C. Utilities.

(1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. **[$S^{C/K}$]**

(2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[$S^{C/K}$]**

[*Moved (D) to .03 A (4) (a)(b)(c) Plants and Grounds*]

~~D. Insect and Vermin Control.~~

~~(1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:~~

~~(a) Tight fitting, self-closing doors; **[K]**~~

~~(b) Screening of not less than 15 mesh per inch; **[K]** and~~

~~(c) Controlled air current. **[K]**~~

~~E.~~ D. Disposal of Other Wastes.

(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. **[O]**

(2) Shell and other non-edible materials shall be promptly and effectively removed from the shucking bench or table. **[O]**

(3) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; and **[O]**

[Sections .02 F and .02 G were combined to make new section "E" thus some slight editing for coherency]

~~F~~ E. Equipment**, Condition,** ~~and~~ **Cleaning, Maintenance, and** Construction **of** Non-Food Contact Surfaces.

(1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced. **[O]**

(2) The dealer shall use easily cleanable, corrosion-resistant impervious materials, free from cracks to construct:

(a) Shucking benches and contiguous walls; and **[O]**

(b) Stands or stalls and stools for shucker. **[O]**

(c) Any non-food contact surfaces in shellfish storage or handling areas. **[O]**

(3) Shucking benches shall drain completely and rapidly, and shall drain away from any shellfish on the benches. **[O]**

~~G. Cleaning Non-food Contact Surfaces.~~

~~(1)~~(4) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces. **[K]**

~~(2)~~(5) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. **[O]**

~~H~~. F. Shellfish Storage and Handling. The dealer shall:

(1) Assure that shellstock is:

(i) Reasonably free of sediment **[O]**; and

(ii) Culled; **[K]**

(2) Assure shucking buckets are completely empty at the packing room so that no overage is returned to the shucker; **[K]**

(3) Inspect incoming shipments and shall reject dead or inadequately protected shellstock; **[K]**

(4) Not allow the use of dip buckets for hand or knife rinsing; **[K]**

(5) Not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source; **[K]**

(6) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161§130. **[K]**

(7) Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room; **[K]**

(8) Conduct packing activities so as to conform to applicable food additive regulations; **[K]**

(9) Store packaged shellfish, if they are to be frozen, at an ambient temperature of 0°F~~ahrenheit~~ (-17.8°C~~entigrade~~) or less; and frozen solid within twelve hours following the initiation of freezing. **[S$^{K/0}$]**

(10) Not commingle shellstock during shucking unless the dealer is included in the Authority's commingling plan.**[K]**

~~I.~~G. Heat Shock. A dealer may elect to use heat shock to prepare shellstock for shucking.

(1) The dealer shall:

(a) Post the schedule for the heat shock process in a conspicuous location; and **[K]**

(b) Make sure all responsible persons are familiar with the requirements. **[K]**

(c) Cool all hot dipped shellstock immediately after the heat shock process **[K]**. This cooling shall be accomplished by:

(i) Dipping in a ice bath; or **[K]**

(ii) Use of flowing potable water. **[K]**

(2) If a heat shock tank is used, and the water is maintained at or above 140°F degrees the dealer shall completely drain and flush the tank at the end of each day's operation so that all the mud and debris which have accumulated in the dip tank are eliminated. If the temperatures are maintained below 140°F degrees, the dealer shall completely drain and flush the tank at three hour intervals. **[K]**

[Moved J (1), (2), (3), (4), (5) (i)(ii)(iii)(iv) items to 02. C (3) (i),(ii),(iii,)(iv),(v) (a)(b)(c)(d) Prevention of Cross Contamination]

~~J. Personnel. Any employee handling shucked shellfish shall be required to:~~

~~(1) Wear effective hair restraints; **[O]**~~

~~(2) Remove any hand jewelry that cannot be sanitized or secured; **[O]**~~

~~(3) Wear finger cots or gloves if jewelry cannot be removed; **[O]**~~

~~(4) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. **[O]**~~

~~(5) In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:~~

~~(i) Store clothing or other personal belongings; **[O]**~~

~~(ii) Eat or drink; **[K]**~~

~~(iii) Spit; and **[K]**~~

~~(iv) Use tobacco in any form. **[K]**~~

~~K.~~ H. Supervision.

(1) A reliable, competent individual shall be designated to supervise general plant management and activities; **[K]**

(2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. **[K]**

(3) All supervisors shall be:

(a) Trained in proper food handling techniques and food protection principles; and **[K]**

(b) Knowledgeable of personal hygiene and sanitary practices **[K]**

(4) The dealer shall require:

(a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. **[K]**

(b) Supervisors to assure that proper sanitary practices are implemented, including:

(i) Plant and equipment clean-up; **[K]**

(ii) Rapid product handling; and **[K]**

(iii) Shellfish protection from contamination. **[K]**

[Moved (c) from .03 A (1) (b) Plants and Grounds and edited to make appropriate for this section by adding "Supervisors shall not allow" and deleted the words "animal" "or", and the phrase "shall not be allowed"; Animal aspects moved to 02 H Exclusion of Pests]

(c) **Supervisors shall not allow** ~~Animals or~~ **unauthorized persons** ~~shall not be allowed~~ **in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]**

~~(e)~~(d) Employees

(i) To be trained in proper food handling and personal hygiene practices, and **[K]**

(ii) To report any symptoms of illness to their supervisor. **K]**

Proposal Subject Hand Washing Facilities

Specific NSSP Guide Reference Model Ordinance Chapter XI,XII,XIII,XIV Section .03 B. Plumbing

Text of Proposal/ Requested Action

B. Plumbing and Related Facilities.

(1) Hand washing facilities shall be provided which are:

(a) **Located in each facility in which shellstock is processed [K];**

~~(a)~~ **(b)** Convenient, **and readily accessible** to work-areas **so that employees are able to return to their work areas without recontaminating their hands after washing them [O]**

~~(b)~~ **(c)** Separate from the three compartment sinks used for cleaning equipment and utensils **[K]**; and

~~(c)~~ **(e)** Directly plumbed to an approved sewage disposal system.**[$S^{O/K}$]**

Public Health Significance

A wide range of communicable diseases and infections may be transmitted by infected employees to consumers through food. The fecal oral route pathogens often transmitted by food contaminated by infected persons are Norovirus (NoV), hepatitis A virus, Salmonella Typhii, and Shigella species. These pathogens are listed by the Centers for Disease Prevention and Control (CDC) in List 1, "Pathogens Often Transmitted by Food contaminated by Infected Persons", as published on a yearly basis in the Federal Register. These pathogens are all extremely infectious through the fecal oral route and difficult to control in an infected person. They all have an extremely low infectious dose (as low as 10-100 virus particles with NoV) and are shed in the stool in high numbers (as high as 1,000,000 viral particles per gram of feces with NoV) during peak infectivity [3,4,5,6].

When discussing hand decontamination, it is important to have an understanding of the factors that influence microbial contamination levels on the hands. The skin itself has inherent properties that provide protection from microbial contamination. Factors such as skin acidity, skin lipids (acid mantle), moisture, salt concentration, microbial antagonism, climate, and exposure to contaminants all play a role in determining the microbes on the hands at any time.

There are two types of microorganisms on the skin, known as "transients" and "residents". The resident bacteria live in deeper layers of the skin and are not removed during a basic hand washing. The transient microorganisms are found on the outer most layer of the skin and consist of viruses, protozoa, and bacteria accumulated from touching contaminated environmental surfaces. When the hands are exposed to heavy continuous environmental exposure, transient bacteria can become residents. The transient microorganisms are reduced or removed with a proper hand washing procedure.

The greatest concentration of microbes on the hands, exist around and under the fingernails. The area under the fingernails, known as the "subungal space", has by far the largest concentration of microbes on the hand and this is also the most difficult area of the hand to decontaminate [1].

Prevention of transmission of viruses and oocysts depends on preventing fecal contamination, and subsequent ingestion of fecal contamination. Infected employees who handle food for others, or who casually contact food that is later consumed by others, may spread bacterial, viral and protozoan disease [2].

Hand washing was accurately described by Reybrouck, in 1986, as "removing superficial desquamated skin scales, sweat and sebaceous secretions by the action of a detergent (e.g. soap) and water, and with them a variable proportion of the transient bacteria are also removed". Hand washing consists of three independent procedures, which are all important

in removing transient microorganisms. These procedures consist of: lathering and scrubbing the hands under running warm water; rinsing the hands under warm running water; and finally drying the hands with an approved drying method. Every stage in hand washing is important and has an additive effect in transient microbial reduction[7].

Friction and water have been found to play the most important role in removing transient microbes during hand washing. This is why the amount of time spent scrubbing the hands is critical in proper hand washing. It takes more than just the use of soap and running water to remove the transient pathogens that may be present. It is the abrasive action obtained by vigorously rubbing the surfaces being cleaned that loosens the transient microorganisms on the hands.

Hands are probably the most common vehicle for the transmission of pathogens to foods in an establishment. Hands can become soiled with a variety of contaminants during routine operations. Some employees are unlikely to wash their hands unless properly equipped hand washing facilities are accessible in the immediate work area. Facilities which are improperly located may be blocked by portable equipment or stacked full of soiled utensils and other items, rendering the facility unavailable for regular employee use. Nothing must block the approach to a hand washing facility thereby discouraging its use, and the facility must be kept clean and well stocked with soap and sanitary towels to encourage frequent use.

The Model Ordinance plant requirements are based on Title 21 of the Code of Federal Regulations (CFR) Part 110 Food Good Manufacturing Practices and Part 123 Seafood HACCP Regulation. States interpret this portion of the model ordinance differently. Some states use a distance rule, some states allow restroom sinks in other buildings on the same property of a facility where employees would recontaminate their hands going through doors to get from the hand sink to work the product, some states do not require hand washing sinks in the processing area at all.; This proposal would increase uniformity, and provide public health in encouraging employees to wash their hands when soiled as a sink would be provided which in is in the area in which they work.

Reference List:

1. Aly, R., Maibach, H. I., Shinefield, H.R., and Strauss, W. G., 1972. Survival of Pathogenic Microorganisms on Human Skin. J. Investigative Dermatology, Vol. 58, No. 4, pp. 205-210.
2. Cliver, D.O., 1985. Vehicular transmission of hepatitis A. Public Health Review. 13: p.235-292.
3. Caul, E.O. 1994. Small round-structured viruses' transmission and hospital control. Lancet. 343: 1240. 1242.
4. Koopmans, M., C.-H von Bonsdorff, J., Vinje, D., de Medicine and S. Monroe. 2002. Foodborne viruses. FEMS Microbiology Reviews 26: 187-205.
5. Lodder, WJ, Vinje J., van De Heide R, de Roda Husman AM, Leenen EJ, Koopmans, MP. 1999. Molecular detection of Norwalk-like caliciviruses in sewage. Appl. Environ. Microbiol. 65: 5624-5627.
6. Moe, C., Sobsey, M., Stewart, P. and Crawford-Brown, D. 1999. Estimating the risk of human calicivirus infection from drinking water. Proc. 1st Int. Workshop on Human Caliciviruses, Atlanta, GA. Pp.4-6.
7. Reybrouck,, 1986. Handwashing and hand disinfection. J. Hosp. Infect. 8: 5-23.

Cost Information (if available) None

Action by 2005 Task Force II Recommended referral of Proposal 05-212-C to appropriate Committee as determined by the Conference Chairman.

Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force II.
Action by USFDA	FDA concurs with referral of Proposal 05-212-C to an appropriate committee. However, the Summary of Actions does not accurately reflect the Proposal language as submitted. To ensure that the Conference deliberates the Proposal as originally submitted the words "*Land based*" need to be inserted in front of the word "*facility*" in B.(1)(a).
Action by 2007 Plant Sanitation Committee	Recommended no action on Proposal 05-212-C. Rationale – the proposal is adequately addressed in the Model Ordinance.
Action by 2007 Task Force II	Recommended adoption of Plant Sanitation Committee recommendation of no action on Proposal 05-212-C.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Bibliography List:

1. Aly, R., Maibach, H. I., Shinefield, H.R., and Strauss, W. G., 1972. Survival of Pathogenic Microorganisms on Human Skin. J. Investigative Dermatology, Vol. 58, No. 4, pp. 205-210.
2. Ansari, S. A., Springthorpe, V. S., Sattar, S. A., Tostowaryk, W., and Wells, G. A.,1991. Comparison of cloth, paper, and warm air drying in eliminating viruses and bacteria from washed hands. Am. J. Infect. Cont., Vol.19. No. 5. pp.243-249.
3. Ansari, S. A, Sattar, S. A., S., V. S., Wells, G. A. and Tostowaryk, W., 1989. In Vivo Protocol for Testing Efficacy of Hand-Washing Agents against Viruses and Bacteria: Experiments with Rotavirus and *Escherichia coli*. Appl. Environ. Microbiol., Vol. 55, No. 12. pp. 3113-3118.
4. Ansari, S. A., Sattar, S. A., Springthorpe, V. S., Wells, G. A., and Tostowaryk, W., 1988. Rotavirus Survival on Human Hands and Transfer of Infectious Virus to Animate and Nonpourous Inanimate Surfaces, J. Clin. Microbiol., Vol. 26, No.8. pp.1513-1518.
5. Atmar, R.L., Estes, M., Jan. 2001. Diagnosis of Noncultivatable Gastroenteritis Viruses, the Human Caliciviruses. Clinical Microbiology Reviews. P.15-37.
6. Ayliffe, G.A.J., Babb, J.R., Davies, J.G., and Lilly, H.A., 1988. Hand disinfection: a comparison of various agents in laboratory and ward studies. J. Hosp. Infect., Vol. 11, pp.226-243.
7. Ayliffe, G.A.J., Babb, J.R., and Quoraishi, A.H., 1978. A test for 'hygienic' hand disinfection. J. Clin. Path., Vol. 31, pp.923-928.
8. Baquero, F., Patron, C., Canton, R., and Ferrer, M.M., 1991. Laboratory and in-vitro testing of skin antiseptics: a prediction for in-vivo activity? J. Hosp. Infect. Vol. 18 (Supplement B) pp. 5-11.
9. Bean, N.H., Goulding, J.S., Frederick, J.A., Angulo, J., 1996; Surveillance for foodborne-disease outbreaks – United States, 1988-1992. MMWR, Vol. 45 (SS-5); pp. 1-55.
10. Bellamy, K., Alcock, R., Babb, J.R., Davies, J.G., and Ayliffe, G.A.J. 1993. A test for the assessment of 'hygienic' hand disinfection using rotavirus. J. Hosp. Infect., Vol. 24, pp.201-210.
11. Bidawid, S., Farber, J.M., Sattar, S.A., and Hayward, S., 2000. Heat Inactivation of Hepatitis A Virus in Dairy Foods. J. Food Protect., Vol. 63, No. 4, p. 522-528.
12. Casewell, M., Phillips, I., 1977. Hands as route of transmission for *Klebsiella* species. Brit. Med. J. Vol. 2, No.19. pp.1315-1317.
13. Center For Disease Control And Prevention, 2000, in Hepatitis A Slide Series, in: http://www.cdc.gov.ncidod/diseases/hepatitis/slideset/hep00008.htm.
14. Cliver, D. O., and Kostenbader, K. D., 1984. Disinfection of virus on hands for prevention of food-borne disease. Intern. J. Food Microbiol., Vol. 1, pp.75-87.
15. Cliver, D.O., 1985. Vehicular transmission of hepatitis A. Public Health Review. 13: p.235-292.
16. Cliver, D.O., Nov. 1995, Detection and control of foodborne viruses. Trends in Food Science & Technology. V. 6, p.353-358.
17. Crisley, F. D., and Foter, M. J., 1965. The Use of Antimicrobial Soaps and Detergents for Hand Washing in Food Service Establishments. J. Milk Food Tech. Vol. 28. pp.278-284.
18. Caul, E.O. 1994. Small round-structured viruses transmission and hospital control. Lancet. 343: 1240. 1242.
19. De Wit, J.C. 1985. The importance of hand hygiene in contamination of foods. Netherlands Society for Microbiology, section for food microbiology meeting at Ede on 24 May, 1984. Antonie von Leeuwenhoek, Vol. 51, pp. 523-527.
20. De Wit, J.C. and Kampelmacher E.H., 1988. Some Aspects of Bacterial Contamination of Hands of Workers in Food Service Establishments. Zentralbl Bakteriol Mikrobiol Hyg. 186(1): 45-54.
21. De Wit, J. C.and Rombouts F.M.,1992, Faecal micro-organisms on the hands of carriers: Escherichia coli as model for Salmonella. Zentralbl Hyg Umweltmed, 193(3): 230-6.
22. Eckert, D.G., Ehrenkranz, N.J., Alfonso, B.C. 1989. Indications for alcohol or bland soap in removal of aerobic gram-negative skin bacteria: assessment by a novel method. Infect. Control Hosp. Epidemiol., Vol. 10, pp. 306-311.
23. Eggers, H. J. 1990. Experiments on Antiviral Activity of Hand Disinfectants. Some Theoretical and Practical Considerations. Zbl. Bakt. Vol.273, pp.36-51.
24. Ehrenkranz, N.J., 1992. Bland soap handwash or hand antisepsis? The pressing need for clarity. Infect. Control Hosp. Epidemiol., Vol. 13, No. 5, pp.299-301.
25. Ehrenkranz, N.J., Alfonso, B., 1991. Failure of bland soap handwash to prevent hand transfer of patient bacteria to urethral catheters. Infect. Control Hosp. Epidemiol. Vol. 12, No. 11, pp. 654-662.
26. Fendler, E.J., Dolan, M.J., and Williams, R.A., 1998. Handwashing and gloving for food protection part I: Examination of the evidence. Dairy, Food and Environ. San., Vol.18, No.12, pp.814-823.

27. Fendler, E.J., Dolan, M.J., and Williams, R.A., 1998. Handwashing and gloving for food protection Part II. Effectiveness. Dairy, Food and Environ San. Vol.18, No.12. pp.824-829.
28. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 2000. Hepatitis A virus, in Bad Bug Book, Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, in http://cfsan.fda.gov/~mow/
29. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 2000. Norwalk A virus, in Bad Bug Book, Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, in http://cfsan.fda.gov/~mow/.
30. Gobetti, J.P., Cerminaro, M., and Shipman, Jr., C., 1986. Hand asepsis: the efficacy of different soaps in the removal of bacteria from sterile, gloved hands. JADA, Vol. 113, pp. 291-292.
31. Goldmann, D.A., 1991. The role of barrier precautions in infection control. J. Hosp. Infect., Vol. 18, (Supplement A), pp. 515-523.
32. Goldmann, D.A., and Larson, E. 1992. Handwashing and nosocomial infections. New Eng. J. Med., Vol. 327, No.2. pp. 120-122.
33. Grim, D. 2000. Vice President, Quality Assurance and Food Safety, Marriott International, Washington D.C., Personal Communication.
34. Hilgren, J., 1998. Sharing Our Food With Strangers. Infect. Control Today, (May), pp.12-20.
35. Kaferstein, F.K., Motarjemi, Y., and Bettcher, D.W. 1997. Foodborne disease control: A transnational challenge, Emerg. Infect. Dis., Vol. 3, No. 4, pp. 503-511.
36. Kerr, K.G., Birkenhead, D., Seale, K. Major, J., and Hawkey, P.M., 1993. Prevalence of Listeria spp. on the hands of food workers. J. Food Protect. 56 (6): p. 525-527.
37. Khan, M.U., 1982. Interruption of shigellosis by hand washing, Trans. Royal Soc. Trop. Med. Hyg., Vol. 76, No. 2, 1982.
38. Kjolen H., and Andersen, B. M., 1992. Handwashing and disinfection of heavily contaminated hands – effective or ineffective? J. Hosp. Infect., Vol. 21, pp.61-71.
39. Koff, R.S., May 30, 1998. Hepatitis A. The Lancet; v. 341: p.1643-1649.
40. Koopmans, M., C.-H von Bonsdorff, J., Vinje, D., de Medicine and S. Monroe. 2002. Foodborne viruses. FEMS Microbiology Reviews 26: 187-205.
41. Larson, E.L., 1995. APIC Guideline for handwashing and hand antisepsis in health care settings, American J. Infect. Control, Vol. 23, No. 4, pp. 251-269.
42. Lilly, H.A, Lowbury, E.J.L. 1978. Transient skin flora. Their removal by cleansing or disinfection in relation to their mode of deposition. J. Clin. Path. Vol. 31, pp. 919-922.
43. Lodder, WJ, Vinje J., van De Heide R, de Roda Husman AM, Leenen EJ, Koopmans, MP. 1999. Molecular detection of Norwalk-like caliciviruses in sewage. Appl. Environ. Microbiol. 65: 5624-5627.
44. Manthriratna, G.A. 1989. Efficacy of handwashing as an aid in the control of Rotavirus and Giardia transmission. Thesis. University of Arizona.
45. Mbithi, J.N., Springthorpe, S., and Sattar, S., 1993. Comparative in vivo efficiencies of hand-washing agents against Hepatitis A virus (HM-175) and Poliovirus Type 1 (Sabin). Applied Environ Microbiol. Vol.59, No.10, pp.3463-3469.
46. Mead, P.S., Slutsker, L., Dietz, V., McCraig, L.F., Bresee, J.S., Shapiro, C., Griffin, P.M., Tauxe, R.V., 1999. Food-related illness and death in the United States. Emerg. Infect. Dis. Vol. 5, No.5, pp.38, in: http://www.cdc.gov/ncidod/EID/vol5no5/mead.htm.
47. Michels, M., Caulum, L., Grimek, R., Lowell, M., Russell, Mary Jo, 1998. When is sick too sick to work? Infect. Control Today, May, pp. 94-97.
48. Miller, M.L., James-Davis, L.A., Milanesi, L.E., 1994. A field study evaluating the effectiveness of different hand soaps and sanitizers. Dairy, Food and Environ. San. Vol.14, No.3., pp.155-160.
49. Moe, C., Sobsey, M., Stewart, P. and Crawford-Brown, D. 1999. Estimating the risk of human calicivirus infection from drinking water. Proc. 1st Int. Workshop on Human Caliciviruses, Atlanta, GA. Pp.4-6.
50. Montville, R., Chen, Y., and Schaffner, D., 2001. Glove barriers to bacterial cross-contamination between hands to food. J Food Protection. 64 (6): p. 845-849.
51. Newsom, S.W.B., and Rowland, C., 1989. Application of the hygienic hand-disinfection test to the gloved hand. J. Hosp. Infect. Vol.14, pp.245-247.
52. Ojajarvi, J. 1980. Effectiveness of hand washing and disinfection methods in removing transient bacteria after patient nursing. J. Hyg.Vol.85, pp. 193-203.
53. Olsen, R.J., Lynch, P., et. al., 1993. Examination Gloves as Barriers to Hand Contamination in Clinical Practice. JAMA, Vol. 270, No. 3,

54. Pacini, D.L., Brady, M.T., Budde, C.T., Connell, M.J., Hamparian, V.V., and Hughes, J.H. 1987. Nosocomial Rotoviral diarrhea: pattern of spread on wards in a children's hospital. J. Med. Virol. Vol. 23, pp. 359-366.
55. Paulson, D.S., 1993. Variability evaluation of two handwash modalities employed in the food processing industry. Dairy, Food and Environ. San., Vol.13, No. 6, pp. 332-335.
56. Paulson, D.S., 1994. A comparative evaluation of different hand cleansers. Dairy, Food and Environ San. Vol.14, No.9, pp.524-528.
57. Paulson, D.S., Riccardi, C., Beausoleil, C.M., Fendler, E.J., Dolan, M.J., Dunkerton, L.V., and Williams, R.A. 1999. Efficacy Evaluation of Four Hand Cleansing Regimens for Food Handlers. Dairy, Food and Environ. San..Vol.19, No. 10. pp. 680-684.
58. Perloff, R.M., 1993. The Dynamics of Persuasion. General Communication Theory and Methodology. Lawrence Erlbaum Associates, Inc., Pub., Hillsdale, New Jersey. 411pp.
59. Pether, J.V.S., and Gilbert, R.J., 1971. The survival of salmonellas on finger-tips and transfer of the organism to foods. J. Hyg. Vol. 69, pp. 673-681.
60. Restaino, L. and Wind, C.E., 1990. Antimicrobial effectiveness of hand washing for food establishments. Dairy, Food and Environ. San. Vol.10, No.3, pp.136-141.
61. Reybrouck,, 1986. Handwashing and hand disinfection. J. Hosp. Infect. 8: 5-23.
62. Ritter, M.A., French, M.L.V., and Eitzen, H., Nov. 1976. Evaluation of microbial contamination of surgical gloves during actual use, Clinical Orthopaedics and Related Research. 117: p. 303-306.
63. Ross, M., and Guzewich, J., 1999. Evaluation of risks related to microbiological contamination of ready-to-eat food by food preparation workers and the effectiveness of interventions to minimize those risks. FDA White Paper, FDA, CFSAN, in: http://cfsan.fda.gov/~ear/.
64. Rose, J.B., and Slifko, T.R., 1999. Giardia, Cryptosporidium, and Cyclospora and their impact on foods: a review. J. Food Protect. Vol. 62., No. 9, pp. 1059-1070.
65. Rotter, M.L., Koller, W., 1991. An European test for the evaluation of the efficacy of procedures for the antiseptic handwash? Hyg. Med., Vol. 16, pp.4-12.
66. Sattar, S.A., and Springthorpe, V.S., 1996. Environmental spread and germicide control of viruses in hospitals. Infect Control & Steril.Tech, Vol.2, no.7, pp.30-36.
67. Schurmann, W., and Eggers, H.J., 1985. An experimental study on the epidemiology of enteroviruses: water and soap washing of poliovirus 1 – contaminated hands, its effectiveness and kinetics. Med. Microbiol. Immunol. Vol.174, pp.221-236.
68. Schurmann, W., and Eggers, H. J., 1983. Antiviral activity of an alcoholic hand disinfectant. Comparison of the in vitro suspension test with in vivo experiments on hands, and on individual fingertips. Antivir. Research, Vol. 3, pp. 25-41.
69. Schwab, K.J., Neill, F.H., Fankhauser, R.L., Daniels, N.A., Monroe, S.S., Bergmire-Sweat, D.A., Estes, M.K., and Atmar, R., Jan. 2000. Development of Methods to Detect "Norwalk-Like Viruses" (NLVs) and Hepatitis A Virus in Delicatessen Foods: Application to a Food-Borne NLV Outbreak. Applied and Environmental Microbiology. V.66, No.1, pp.213-218.
70. Sheena, A.Z., and Stiles, M.E. 1983. Immediate and residual (Substantive) efficacy of germicidal hand wash agents. J. Food Protect., Vol.46, No. 7, pp.629-632.
71. Smith, J.L., 1993. Cryptosporidium and Giardia as agents of foodborne disease. J. Food Protection. Vol. 56: 451-461.
72. Springthorpe, S., and Sattar, S. 1996. Handwashing product and technique comparisons. Infect. Control & Steriliz. Technol. pp. 19-22.
73. Springthorpe, S., Grenier, J.L., Lloyd-Evans, N., and Sattar, S. 1986. Chemical disinfection of human rotaviruses: efficacy of commercially-available products in suspension tests. J. Hyg., Vol. 97, pp. 139-161.
74. Sprunt, Katherine, Redman, Winifred, and Leidy, Grace, 1973. Antibacterial Effectiveness of Routine Hand Washing. Pediatrics, Vol.52, No.2, pp.264-271.
75. Steere, A.C., and Mallison, G.F., 1976. Handwashing and Semmelweiss. Ann. Intern. Med., Vol. 85, p. 398.
76. Steere, A.C., and Mallison, G.F. 1975. Handwashing Practices for the Prevention of Nosocomial Infections. Annals Int. Med. Vol. 83, pp. 683-690.
77. Taylor, A.K. 2000. Food Protection: New Developments in Handwashing, Dairy, Food Env. San., Vol. 20, No.2, pp. 114-119.
78. Walter, C.W., 1976. Handwashing and Semmelweiss, Annals Intern. Med., Vol. 85, No. 3, p.398.
79. Wolff, M.H., Schmitt. J., Rahaus, M., and Konig, A., 2001. Hepatitis A virus: a test method for virucidal activity. Journal of Hospital Infection. 48 (Supplement A): S18-S22.
80. Zimakoff, J., February, 1993. Glove use and handwashing frequency in ICU's. The Hospital Infection Society. P.63-67.

Proposal Subject Employee Health

Specific NSSP Guide Reference NSSP Guide Model Ordinance Chapters XI, XII, XIII, XIV, XV
.02 G. Control of Employees with Adverse Health Conditions

Text of Proposal/ Requested Action Add new language as follows to Chapters XI, XII, XIII, XIV, XV

.02 Sanitation.

G. Control of Employees with Adverse Health Conditions.

(1) The dealer **and the ~~person-in-charge~~ supervisor** shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The **pathogens causing** diseases which are transmissible from food workers through food are those determined by the U.S. Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the **Federal Register**. **These include: [K]**
(a) Norovirus,
(b) Hepatitis A virus,
(c) *Shigella* spp.,
(d) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
(e) *Salmonella typhi*;

(2) The dealer and ~~person-in-charge~~ supervisor shall ensure that all employees immediately report to the dealer and/or the ~~person-in-charge~~ information about their health and activities as they relate to diseases that are transmissible through food. All employees shall report the information in a manner that allows the dealer and/or ~~person-in-charge~~ supervisor to reduce the risk of shellfish-borne disease transmission, including providing necessary additional information, such as the date of onset of symptoms of an illness, or of a diagnosis without symptoms, or if the employee: [K]

(a) Has any of the following symptoms:
(i) Vomiting,
(ii) Diarrhea,
(iii) Jaundice,
(iv) Sore throat with fever, or
(v) A lesion containing pus such as a boil or infected wound that is open or draining on any part of the body, or
(b) Has an illness diagnosed by a health practitioner due to:
(i) Norovirus,
(ii) Hepatitis A virus,
(iii) Shigella spp.,
(iv) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
(v) *Salmonella typhi*;
(c) Had a previous illness, diagnosed by a health practitioner, within the past 3 months due to Salmonella typhi, without having received antibiotic therapy, as determined by a health practitioner;
(d) Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared

by a person who is infected or ill with:

(i) Norovirus within the past 24 hours of the last exposure;

(ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* or *Shigella* spp. within the past 3 days of the last exposure;

(iii) *Salmonella typhi* within the past 14 days of the last exposure;

(iv) Hepatitis A virus within the past 30 days of the last exposure; or

(e) Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual that works or attends a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:

(i) Norovirus within the past 24 hours of the last exposure;

(ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella* spp. within the past 3 days of the last exposure;

(iii) *Salmonella typhi* within the past 14 days of the last exposure; or

(iv) Hepatitis A virus within the past 30 days of the last exposure.

(3) If an employee with an infected wound **protects the lesion by** ~~keeps~~ **keeping** it covered with a proper bandage, ~~an~~ **a dry, durable, tight-fitting** impermeable barrier, and a single-use glove for a hand lesion, the dealer **and/or** ~~**person-in-charge**~~ supervisor may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

(4) The dealer ~~**and/or person-in-charge**~~ **supervisor shall notify the State Shellfish Control Authority and Health Department when *notified by* an employee *of a diagnosis or exhibits symptoms of hepatitis,*** ~~**is jaundiced, otherwise symptomatic, or diagnosed with hepatitis,**~~ **and shall ensure that the employee is excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces or that may transmit the illness to other employees. [K]**

(5) The dealer and/or ~~**person-in-charge**~~ **supervisor may reinstate an excluded employee under one or more of the following conditions: [K]**

(a) The employee is recovered from Norovirus illness and more than 24 hours have passed since the employee became completely asymptomatic, or the employee provides the dealer or ~~**person-in-charge**~~ **supervisor with written medical documentation from a health practitioner stating that the employee is free of a Norovirus infection with one of the following:**

(i) Test results show two consecutive negative stool samples taken at least 24 hours apart; or

(ii) Otherwise determined by the health practitioner to be free of a Norovirus infection.

(b) The employee diagnosed with an infection from Norovirus is now completely asymptomatic, and the employee provides written medical documentation from a health practitioner stating that the employee is free from Norovirus infection with one of the following:

(i) Test results show two consecutive negative stool samples taken at least 24 hours apart; or

(ii) Otherwise determined by the health practitioner to be free of a

Norovirus infection.

(c) The employee diagnosed with an infection from Norovirus is completely asymptomatic and without medical documentation, and more than 24 hours have passed since the employee became completely asymptomatic, or the employee never developed symptoms and more than 24 hours have passed since the employee was diagnosed.

(d) Except when diagnosed with an infection from Norovirus, hepatitis A virus, *Salmonella typhi*, *Shigella* spp., or Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, and when the employee was excluded because of symptoms of vomiting and/or diarrhea, the employee is asymptomatic for at least 24 hours or provides the dealer and/or ~~person-in-charge~~ supervisor with written medical documentation stating the symptom is from a noninfectious condition.

(e) When the employee is symptomatic with jaundice or is diagnosed with an infection from hepatitis A virus, one of the following conditions is met:

- **(i) the employee has been jaundiced for more than 7 calendar days;**
- **(ii) documentation of test results from a medical practitioner is provided that show falling liver enzymes in at least two consecutive blood tests; or**
- **(iii) documentation is provided from a health practitioner otherwise determining the employee to be free of a hepatitis A virus infection.**

(f) When excluded because of a diagnosis or a previous reported infection of *Salmonella typhi*, the employee provides written medical documentation from a health practitioner stating that the employee is free from *S. typhi* infection;

(g) When diagnosed with an infection from *Shigella* spp. and completely asymptomatic, and one of the following conditions is met:

- **(i) The employee provides to the dealer or ~~person-in-charge~~ supervisor written medical documentation from a health practitioner stating that the employee is free of a *Shigella* spp. infection based on test results from 2 consecutive stool specimens taken at least 48 hours after discontinuance of antibiotics and taken at least 24 hours apart report negative findings for *Shigella* spp.;**
- **(ii) Without medical documentation if all symptoms of vomiting and/or diarrhea have resolved and more than 7 calendar days have passed since the employee became completely asymptomatic, or if the employee never developed symptoms and more than 7 calendar days have passed since the diagnosis.**

(h) The employee of the dealer that was excluded because of a diagnosis of infection from Enterohemorrhagic or Shiga Toxin- producing *Escherichia coli*, the employee is completely asymptomatic and one of the following conditions is met:

- **(i) The employee provides written medical documentation from a health practitioner stating that the employee is free of an infection from Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli* based on test results showing 2 consecutive negative results for Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, from stool specimens occurring at least 24 hours apart, and not earlier**

than 48 hours after discontinuance of antibiotics;

(ii) Without medical documentation if the asymptomatic employee was excluded or restricted after symptoms of vomiting or diarrhea have resolved, and more than 7 calendar days have passed since the employee became asymptomatic, or the asymptomatic employee was excluded or restricted without ever developing symptoms, and more than 7 calendar days have passed since the employee was diagnosed.

(i) For an employee of the dealer that was excluded because an illness exhibiting acute sore throat with fever symptoms, the employee provides written medical documentation from a health practitioner stating that the employee meets one of the following conditions:

(i) Employee has received antibiotic therapy for *Streptococcus pyogenes* infection, as determined by a health practitioner, for more than 24 hours;

(ii) Employee has at least one negative throat specimen culture to *Streptococcus pyogenes* infection; or

(iii) Employee is otherwise determined by a health practitioner to be free of a *Streptococcus pyogenes* infection;

(J) For an employee of the dealer that was excluded because of an unprotected infected wound, cut, or pustular boil, restriction may be removed when the infected wound, cut, or pustular boil is properly covered with one of the following:

(i) A dry, durable, tight-fitting, impermeable bandage and a single-use glove is worn over the impermeable cover on the hand, finger or wrist;

(ii) A dry, durable, tight-fitting, impermeable bandage is worn over the wound on the arm; or

(iii) A dry, durable, tight-fitting, impermeable bandage, is worn over the wound on other parts of the body.

(k) For an employee of the dealer that was excluded because of exposure to a known foodborne pathogen, restriction may be removed as follows:

(i) If exposed to Norovirus, one of the following conditions is met:

1. More than 24 hours have passed since the last day the employee was potentially exposed, or

2. More than 24 hours have passed since the employee's household contact became asymptomatic;

(ii) If exposed to Shigella spp., or Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, one of the following conditions are met:

1. More than 3 calendar days have passed since the last day the employee was potentially exposed, or

2. More than 3 calendar days have passed since the employee's household contact became asymptomatic;

(iii) If exposed to *S. typhi*, one of the following conditions are met:

1. More than 14 calendar days have passed since the last day the employee was potentially exposed, or

2. More than 14 calendar days have passed since the employee's household contact became asymptomatic;

(iv) If exposed to hepatitis A virus, one of the following

conditions are met:

1. **More than 30 calendar days have passed since the last day the employee was potentially exposed, or**
2. **More than 30 calendar days have passed since the employee's household contact became jaundiced.**

Public Health Significance: Current provisions in the Model Ordinance covering employee health do not provide any specific information about the transmissible foodborne diseases of concern, the pathogens that cause these, the associated symptoms upon which reasonable judgments depend, and the actions expected of shellfish dealers and plant managers. This proposal adds specific language to enable reasonable determinations, decisions, and actions to protect shellfish from pathogens and enable the reinstatement of excluded employees. It more clearly and reasonably defines the requirements of the NSSP and provides consistency with the actions expected of other food dealers and vendors by CDC, FDA, and State health authorities, and follows the information prescribed in other cooperative program guidance documents, the 2005 Food Code and the Grade A Pasteurized Milk Ordinance.

Cost Information (if available): The added guidance does not attach an additional cost for dealers beyond that intended from previous requirements.

Action by 2005 Task Force II Recommended referral of Proposal 05-213-C to appropriate Committee as determined by the Conference Chairman.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Plant Sanitation Committee Recommended adoption of Proposal 05-213-C as amended.

That throughout the proposal "Supervisor" be substituted for "Person-in-charge."

Section G. (2) be modified by deleting "The Dealer and Person-In-Charge shall ensure that" and begin with "All employees" shall…..

That section G. (4) be modified to read as follows:

> "The dealer shall notify the State Shellfish Control Authority and Health Department when *notified* by an employee *of a diagnosis or exhibits symptoms of hepatitis*, and shall ensure that the employee is excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces or that may transmit the illness to other employees."

That Section 5 is added to the Guidance Documents to obtain specifics and details on reinstatement for employees recovering from the illness conditions listed.

Action by 2007 Task Force II Recommended adoption of Plant Sanitation Committee recommendation on Proposal 05-213-C and further recommends

(1) That .02 G. (5) be incorporated into the Guidance Documents; and
(2) That the Executive Board request FDA assistance in obtaining health education material.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force II.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject Plant Sanitation

Specific NSSP Guide Reference 2003 Model Ordinance Chapter XII Section .01

Text of Proposal/ Requested Action Modify Chapter XII.01 (Critical Control Points) to make minor editorial changes and to add a new temperature requirement at receiving.

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:
(1) Originated from a **certified** dealer; ~~and~~ **who has**
~~(2)~~ **(a) Transported the shellfish iced, or in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature; [C] and**
(b) I~~i~~dentified **the shellfish** with a label as outlined in Chapter X.06. **[C]**

B. Processing Critical Control Point - Critical Limits. The dealer shall ensure that repacked shucked shellfish do not exceed an internal temperature of 45° F~~ahrenheit~~ (7.2° C~~entigrade~~) for more than 2 hours. **[C]**

C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store repacked shellfish in covered containers at an ambient temperature of 45 ° F~~ahrenheit~~ (7.2 ° C~~entigrade~~) or less or covered in ice. **[C]**

Public Health Significance Pathogens found in waters from which molluscan shellfish are harvested can cause illness or death in consumers with immune disorders or conditions. Pathogens, such as *Vibrio vulnificus, Vibrio parahaemolyticus,* and *Vibrio cholerae* non 01, are naturally occurring. *V. vulnificus* illness is associated with the consumption of raw oysters harvested from the Gulf of Mexico during the warm weather months. *V. parahaemolyticus* and *V. cholerae* non 01 illness is associated with the consumption of raw oysters harvested during the warm weather months from the Atlantic, Pacific, and Gulf of Mexico regions of the U.S., and similar climates world-wide. Some of these bacterial pathogens may be present in low numbers at the time that molluscan shellfish are harvested, and may increase to levels that are more hazardous if they are exposed to time/temperature abuse.

"Pathogens from the harvest area" should be considered a significant hazard at any harvesting, shipping, receiving, and processing steps where a preventive measure is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level. To minimize the risk of illness from the consumption of molluscan shellfish containing these pathogens, shellfish dealers must identify the receiving step as a critical control point for this hazard.

Pathogenic organisms can survive in shellfish for a considerable length of time after harvesting and bacterial pathogens may multiply in the absence of adequate refrigeration. Adequate temperature control is critical to product safety. The NSSP MO sets forth temperature requirements for shipping shellfish (Chapter IX). However, there is no a requirements for dealers to monitor temperature at receiving (dealer to dealer shipping). Adding temperature control at receiving will close the gap that exists now between the shipping and receiving steps.

Cost Information (if available) None

Action by 2005 Task Force II Recommended referral of Proposal 05-215 to appropriate Committee as determined by the Conference Chairman.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Time/Temperature Committee Recommended adoption of Proposal 05-215 as amended.

Chapter XII. Repacking of Shucked Shellfish

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:
(1) Originated from a ~~certified~~ dealer; who has
(a) **Shipped** ~~Transported~~ the shellfish iced, or in a conveyance ~~maintained~~ at or below 45°F (7.2°C) ambient air temperature; **[C]** and
(b) **I**~~i~~dentified the shellfish with a label as outlined in Chapter X.06. **[C]**

B. Processing Critical Control Point - Critical Limits. The dealer shall ensure that repacked shucked shellfish do not exceed an internal temperature of 45° F (7.2° C) for more than 2 hours. **[C]**

C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store repacked shellfish in covered containers at an ambient temperature of 45° F (7.2°) or less or covered in ice. **[C]**

Action by 2007 Task Force II Recommended tabling Proposals 05-209, 05-215, 05-217, and 05-219 and sent to a workgroup comprised of Chris Nelson, Steve Fleetwood, MaryAnn Guichard, Austin Doctor, Teddy Busick, Sandy Shepherd, Erin Butler, Miles Motes and AJ Erskine.

Action by 2007 Task Force II Workgroup Recommended adoption of Time/Temperature Committee recommendation on Proposal 05-215.

Action by 2007 Task Force II Recommended adoption of the Task Force II Workgroup recommendation on Proposal 05-215.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force II.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject	Plant Sanitation
Specific NSSP Guide Reference	Model Ordinance Chapter XII. Repacking of Shucked Shellfish Sections .02 Sanitation and .03 Other Model Ordinance Requirements
Text of Proposal/ Requested Action	Modify the organization of sanitation requirements of Chapter XII, Sections .02 and .03 to make them consistent with the interpretation and implementation of Title 21 of the Code of Federal Regulations (CFR) Part 123 Seafood HACCP Regulation by putting related items together.
Public Health Significance:	This proposal attempts to reorganize the NSSP MO plant sanitation requirements in sections .02 and .03 to: 1) Make them consistent with manner in which the sanitation requirements of the Seafood HACCP regulation, Title 21 Code of Federal Regulations (CFR) Part 123) are implemented and 2) Consolidate similar items together. In order to accommodate this reorganization there are instances in this proposal where minor editing, deletions, or additions were made for coherency. There is also one update regarding the NSSP construction guide. Hopefully this proposed revision will serve to eliminate some of the confusion that exists over how to interpret and implement the requirements between Seafood HAACP and NSSP. This proposal provides revisions for Chapters XII that simply reorganize and reformat the written requirements already contained in this chapter. The revisions do not add or delete any requirements. FDA will incorporate changes adopted by the ISSC in the FDA Standardization Field Guide and NSSP Standardized Shellfish Processing Plant Inspection Form. Copies of these revised documents then will be provided to each state.
Cost Information (if available):	None
Action by 2005 Task Force II	Recommended referral of Proposal 05-216 to appropriate Committee as determined by the Conference Chairman, with a recommendation by Task Force II that a workgroup be established to address this proposal in advance of the 2007 Biennial Meeting.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force II.
Action by USFDA	Concurred with Conference action.
Action by 2007 Plant Sanitation Committee	Recommended adoption of Proposal 05-216 as submitted.
Action by 2007 Task Force II	Recommended adoption of Plant Sanitation Committee recommendation on Proposal 05-216.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.

Action by December 20, 2007
USFDA Concurred with Conference action.

XII. REPACKING OF SHUCKED SHELLFISH

.02 Sanitation.

A. Safety of Water for Processing and Ice Production.
(1) Water Supply.
(a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations. **[C]**
(b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: **[K]**
(i) Prior to use of the water supply; **[C]**
(ii) Every six months while the water supply is in use; and **[K]**
(iii) After the water supply has been repaired and disinfected. **[$S^{C/K}$]**

[*(c) was moved to Protection from Adulterants 02.E (5)]*

~~(c) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations.~~ **~~[K]~~**

[(a) section was moved up or incorporated into section 2 and the (a) was deleted as the (b) section was transferred as noted below]
(2) Ice Production. Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall~~:~~ ~~B~~be made on-site from potable water in a commercial ice machine; or **[C]**
~~(a) Be made on-site from potable water in a commercial ice machine; or~~ **~~[C]~~**

[*(b) was moved to Protection from Adulterants 02.E*]

~~(b) Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency.~~ **~~[C]~~**
(3) Plumbing and Related Facilities.
(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
(i) Prevent contamination of water supplies; **[C]**
(ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. **[C]** The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. **[K]**

B. Condition and Cleanliness of Food Contact Surfaces.
(1) Equipment and utensil construction for food contact surfaces.
(a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guides* [*UPDATE*] ~~(August 1993)~~,**available in the Guidance Document section of the NSSP Guide for the Control of Molluscan Shellfish)**, U.S. Department of Health and Human Services. **[K]**
(b) The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are:

(i) Constructed in a manner and with materials that can be cleaned, and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products;**[K]**

(ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and **[K]**

(iii) Fabricated from food grade materials. **[K]**

(c) The dealer shall assure that all joints on food contact surfaces

(i) Have smooth easily cleanable surfaces~~;~~ and **[K]**

(ii) Are welded-**[K]**

(d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02.B.(1) (a), (b), and (c). **[K]**

(e) The dealer shall provide a temperature measuring device accurate to +/- 2° Fahrenheit for use in monitoring product temperatures.

(2) Cleaning and Sanitizing of Food Contact Surfaces.

(a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall:

(i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant; **[K]**

(ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; **[K]**

[*Moved (iii) to Proper Labeling, Storage and Use of Toxic Compounds 02 F (d)]*

~~(iii) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use; and~~

(~~iv~~)**(iii)** Wash and rinse equipment and utensils at the end of each day. **[K]**

(~~v~~)**(iv)** Wash and rinse equipment and utensils at the end of each day. **[K]**

(b) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded. **[K]**

(c) Shucked shellfish shall be packed in clean covered containers:

(i) Fabricated from food grade materials; and [K]

(ii) Stored in a manner which assures their protection from contamination. **[K]**

(d) If used, the finger cots or gloves shall be:

(i) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; **[O]**

(ii) Sanitized at least twice daily; **[K]**

(iii) Cleaned more often, if necessary **[K]**;

(iv) Properly stored until used; and **[K]**

(v) Maintained in a clean, intact, and sanitary condition. **[K]**

C. Prevention of Cross Contamination.

(1) Protection of shellfish.

(a) Shucked shellfish shall be protected from contamination. **[$S^{C/K}$]**

(b) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. **[$S^{K/0}$]**

(2) Employee practices

(a) The dealer shall assure that all employees working in direct contact with shellfish processing activities or food contact surfaces maintain a high level of personal hygiene and cleanliness. **[K]**

(b) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:

(i) Before starting work; **[K]**

(ii) After each absence from the work station; **[K]**
(iii) After each work interruption; and **[K]**
(iv) Any time when their hands may have become soiled or contaminated. **[K]**

[Moved (c)(i),(ii)(iii),(iv) (v)(a)(b)(c)(d) from .03 J (1,)(2),(3),(4), and (5)(i)(ii)(iii)(iv) Personnel]

(c) Any employee handling shucked shellfish shall be required to:
(i) Wear effective hair restraints; [O]
(ii) Remove any hand jewelry that cannot be sanitized or secured; [O]
(iii) Wear finger cots or gloves if jewelry cannot be removed [O]
(iv) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. [O]
(v) In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
a. Store clothing or other personal belongings; [O]
b. Eat or drink; [K]
c. Spit; and[K]
d. Use tobacco in any form. [K]

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.
(1) Handwashing facilities with warm water at a minimum temperature of 110 ^{o}F (43^{o}C) dispensed from a hot and cold mixing or combination faucet shall be provided. **[$S^{K/O}$]**

[Moved (a)(i)(ii)(iv),(b), and (c) (i)(ii)(iii)(iv) from .03 B (1)(a)(b)(c),(2), 3(a)(b)(c)(d) Plumbing and Related Facilities and moved (a)(iii) from 03 B (4)(d)

(a) Handwashing facilities shall be provided which are:
(i) Convenient to work areas; [O]
(ii) Separate from the three compartment sinks used for cleaning equipment and utensils; [K]
(iii) Directly plumbed to an approved sewage disposal system, and [$S^{O/K}$]
(iv) Adequate in number and size for the number of employees, and located where supervisors can observe employee use; [K]
(b) The dealer shall provide at least one handsink in the packing room. [O]
(c) The dealer shall provide at each handwashing facility:
(i) Supply of hand cleansing soap or detergent; [K]
(ii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
(iii) Easily cleanable waste receptacle; and [O]
(iv) Handwashing signs in a language understood by the employees; [O]

(2) Sewage **[C]**and liquid disposable wastes **[K]** shall be properly removed from the facility.

[*Moved (3) from 03 A. (5) Plants and Grounds and made editorial changes to make it coherent*]

(3) **The dealer shall provide:** ~~toilet room doors that are tight fitting, self closing, and do not open directly into a processing area. [K]~~
(a) Toilet room doors that are tight fitting, self closing, and do not open directly into a processing area.[K]
~~(3)~~ **(b)** An adequate number of conveniently located, toilets ~~shall be provided.~~**[K]**
~~(4)~~ **(c)** ~~The dealer shall provide each toilet facility with a~~An adequate supply of toilet paper at each toilet facility**[K]** in a suitable holder, and **[$S^{K/O}$]**.

E. Protection from Adulterants.
(1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing. **[K]**

(2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. **[O]**

(3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. **[K]**

(4) Protection of ice used in shellfish processing.

(a) Any ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. **[$S^{C/K}$]**

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[$S^{C/K}$]**

[Moved (c) from Safety of Water…. .02 A. (2) (b)]

(c) Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall Ccome from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]

(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[$S^{K/C}$]**

[Moved (6) from Safety of Water .02 A. (1) (c)]

(6) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations. [K]

F. Proper Labeling, Storage and Use of Toxic Compounds.

(1) Storage of toxic compounds.

(a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. **[K]**

(b) Each of the following categories of toxic substances shall be stored separately:

(i) Insecticides and rodenticides; **[K]**

(ii) Detergents, sanitizers, and related cleaning agents; and **[K]**

(iii) Caustic acids, polishes, and other chemicals. **[K]**

(c) The dealer shall not store toxic substances above shellfish or food contact surfaces. **[K]**

(2) Use and labeling of toxic compounds.

(a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. **[K]**

(b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. **[K]**

(c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions. **[K]**

[Moved (d) from Condition and Cleanliness of Food Contact Surfaces .02 B. (2) (a) (iii)]

(d) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use [K]

G. Control of Employees with Adverse Health Conditions.

(1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in

compliance with the Americans with Disabilities Act, and published in the *Federal Register.* **[K]**

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

[Moved the underlined part of the section below from .03 A (1) (b) Plants and Grounds;-edited to fit in this section; and moved the portion of the section pertaining to unauthorized persons to .03 Supervision (4) (c)]]

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities ~~**[K]**~~**. Animals** ~~or unauthorized persons~~ **shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]**

.03 Other Model Ordinance Requirements.

A. Plants and Grounds.

(1) General.

(a) The physical facilities shall be maintained in good repair. **[O]**

[Moved the portion of (b)pertaining to animals to 02 H Exclusion of Pests and the portion of (b) pertaining to unauthorized persons to .03 H (4) (c) Supervision]

~~(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. **[K]**~~

[Moved (c) to 02 E (7) Protection from Adulterants]

~~(c) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed. **[O]**~~

(2) Flooding:

(a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. **[C]**

(b) If facilities are flooded:

(i) Shellfish processing, shucking or repacking activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. **[C]**

(ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use. **[C]**

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. **[$S^{C/K}$]**

[Moved (4) to .02 D (3)(a) Maintenance of Hand Washing Hand Sanitizing and Toilet Facilities]

~~(4) The dealer shall provide toilet room doors which are tight fitting, self closing, and do not open directly into a processing area. [K]~~

[Moved (4) (a)(b)(c) from .03 D (1)(a)(b)(c) Insect and Vermin Control]

(4) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in the facility.

(a) Tight fitting, self closing doors: [K]

(b) Screening of not less than 15 mesh per inch; [K] and

(c) Controlled air current. [K].

(5) Plant Interior.
- (a) Sanitary conditions shall be maintained throughout the facility. **[O]**
- (b) All dry area floors shall be hard, smooth, easily cleanable; and **[O]**
- (c) All wet area floors used in areas to store shellstock, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:
  - (i) Are graded to provide adequate drainage; **[O]**
  - (ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; **[O]**
  - (iii) Have sealed junctions between floors and walls to render them impervious to water; and **[O]**
- (d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials **[O]**.

(6) Grounds - around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:
- (a) Rodent attraction and harborage; and **[O]**
- (b) Inadequate drainage. **[O]**

B. Plumbing and Related Facilities.

[Moved (1) (a)(b)(c), (2),(3)(a)(b)(c)(d) to D (2) (a)(i)(ii)(iii),(b), and (c) (i)(ii)(iii)(iv) Maintenance of Hand Washing Hand Sanitizing and Toilet Facilities]

~~(1) Handwashing facilities shall be provided which are:~~
- ~~(a) Convenient to work areas; **[O]**~~
- ~~(b) Separate from the three compartment sinks used for cleaning equipment and utensils; and **[K]**~~
- ~~(c) Directly plumbed to an approved sewage disposal system. **[S$^{O/K}$]**~~

~~(2) The dealer shall provide at least one handsink in the packing room. **[O]**~~

~~(3) The dealer shall provide at each handwashing facility:~~
- ~~(a) A supply of hand cleansing soap or detergent; **[K]**~~
- ~~(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**~~
- ~~(c) An easily cleanable waste receptacle; and **[O]**~~
- ~~(d) Handwashing signs in a language understood by the employees; **[O]**~~

~~(4)~~ **(1)** All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes cold and warm water at all sinks; ~~and~~ **[K]**

[Moved deletion to .02 D (1)(a)(iv) Maintenance of Hand Washing Hand Sanitizing and Toilet Facilities]

- ~~(b) Handwashing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use; **[K]**~~

~~(5)~~**(2)** Adequate floor drainage, including backflow prevention such as air gaps, shall be provided where floors are:
- (a) Used in shellstock storage; **[K]**
- (b) Used for food holding units **[K]** (e.g. refrigeration units);
- (c) Cleaned by hosing, flooding, or similar methods **[K]**; and
- (d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. **[K]**

~~(6)~~**(3)** A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[S$^{C/K}$]**

~~(7)~~**(4)** Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. **[K]**

C. Utilities.

(1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. **[$S^{C/K}$]**

(2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[$S^{C/K}$]**

[*Moved D. (1) (a)(b)(c) to .03 A (4) (a)(b)(c) Plants and Grounds*]

~~D. Insect and Vermin Control.~~

~~(1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:~~

~~(a) Tight fitting, self-closing doors; **[K]**~~

~~(b) Screening of not less than 15 mesh per inch; **[K]** and~~

~~(c) Controlled air current. **[K]**~~

~~E.~~ D. Disposal of Other Wastes.

(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. **[O]**

(2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; ~~and~~ **[O]**

[*Sections .02 F and .02 G were combined thus some coherence editing]*

~~F.~~**E. Equipment, Condition,** ~~Construction, and~~ **Cleaning, Maintenance, and Construction of Non-food Contact Surfaces**

(1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced; and **[O]**

(2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellfish storage or handling areas. **[O]**

~~G. Cleaning Non-food Contact Surfaces.~~

~~(1)~~**(3)** Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and **non** food contact surfaces. **[K]**

~~(2)~~**(4)** All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. **[O]**

~~H.~~ **F.** Shellfish Storage and Handling.

(1) The dealer shall:

(a) Not commingle shellfish from different lots; **[K]**

(b) Repack shucked shellfish meats only into containers labeled with the authorized certification number; **[K]**

(c) Not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source. **[K]**

(d) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161§130. **[K]**

(e) Thoroughly drain, clean as necessary, and repack shucked shellfish meats promptly; **[K]**

(f) Conduct repacking activities so as to conform to applicable food additive regulations; **[K]**

(g) Store packaged shellfish, if they are to be frozen, at an ambient temperature of 32 ^{o}F(0 ^{o}C) or less and frozen solid within twelve hours following the initiation of freezing. [$S^{K/O}$]

~~I.~~ **G.** Heat Shock. N/A

[03 J (1,)(2),(3),(4), and (5)(i)(ii)(iii)(iv) Personnel was moved to 02. C (2) (c) (i)(ii)(iii)(iv) and (v)(a)(b)(c)(d)Prevention of Cross Contamination]

~~J.~~ ~~Personnel. Any employee handling shucked shellfish shall be required to:~~

~~(1) Wear effective hair restraints; **[O]**~~
~~(2) Remove any hand jewelry that cannot be sanitized or secured; **[O]**~~
~~(3) Wear finger cots or gloves if jewelry cannot be removed; **[O]**~~
~~(4) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. **[O]**~~
~~(5) In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:~~
~~(i) Store clothing or other personal belongings; **[O]**~~
~~(ii) Eat or drink; **[K]**~~
~~(iii) Spit; and **[K]**~~
~~(iv) Use tobacco in any form. **[K]**~~

~~K.~~ **H.** Supervision.

(1) A reliable, competent individual shall be designated to supervise general plant management and activities; **[K]**

(2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. **[K]**

(3) All supervisors shall be:
(a) Trained in proper food handling techniques and food protection principles; and **[K]**
(b) Knowledgeable of personal hygiene and sanitary practices. **[K]**

(4) The dealer shall require:
(a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. **[K]**
(b) Supervisors to assure that proper sanitary practices are implemented, including:
(i) Plant and equipment clean-up **[K]**
(ii) Rapid product handling; and **[K]**
(iii) Shellfish protection from contamination. **[K]**

*[Moved (c) from .03 A (1) (b) Plants and Grounds and edited to make appropriate in this section i.e. added "Supervisors to not allow" and deleted the phrases "animals or", and "*shall not be allowed"*]*

(c) **Supervisors to not allow ~~Animals or~~ unauthorized persons ~~shall not be allowed~~ in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]**

~~(c)~~**(d)** Employees
(i) to be trained in proper food handling and personal hygiene practices, and **[K]**
(ii) to report any symptoms of illness to their supervisor. **[K]**

Proposal Subject Plant Sanitation

Specific NSSP Guide Reference NSSP Guide Model Ordinance Chapter XIII. Shellstock Shipping
.01 Critical Control Points

Text of Proposal/ Requested Action Modify Chapter XIII .01 to make minor editorial changes and to add a new temperature requirement at receiving.

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall ship or repack only shellstock that is:
(1) Obtained from a licensed harvester who has:
(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and **[C]**
(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or **[C]**
(2) Obtained from a **certified** dealer who has:
(a) Transported the shellstock iced, or in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature [C]; and
(b) Identified the shellstock with a tag on each container**[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:
(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**
(2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
(a) Iced; or **[C]**
(b) Placed in a storage area or conveyance maintained at 45° F~~ahrenheit~~ (7.2° C~~entigrade~~) or less; and **[C]**
(c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B (1) or §B (2) for more than 2 hours at points of transfer such as loading docks. **[C]**

Public Health Significance Pathogens found in waters from which molluscan shellfish are harvested can cause illness or death in consumers with immune disorders or conditions. Pathogens, such as *Vibrio vulnificus, Vibrio parahaemolyticus,* and *Vibrio cholerae* non 01, are naturally occurring. *V. vulnificus* illness is associated with the consumption of raw oysters harvested from the Gulf of Mexico during the warm weather months. *V. parahaemolyticus* and *V. cholerae* non 01 illness is associated with the consumption of raw oysters harvested during the warm weather months from the Atlantic, Pacific, and Gulf of Mexico regions of the U.S., and similar climates world-wide. Some of these bacterial pathogens may be present in low numbers at the time that molluscan shellfish are harvested, and may increase to levels that are more hazardous if they are exposed to time/temperature abuse.

"Pathogens from the harvest area" should be considered a significant hazard at any harvesting, shipping, receiving, and processing steps where a preventive measure is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level. To minimize the risk of illness from the consumption of molluscan shellfish containing these pathogens, shellfish dealers must identify the receiving step as a critical control point for this hazard.

Pathogenic organisms can survive in shellfish for a considerable length of time after harvesting and bacterial pathogens may multiply in the absence of adequate refrigeration. Adequate temperature control is critical to product safety. The NSSP MO sets forth

temperature requirements for shipping shellfish (Chapter IX). However, there is no a requirements for dealers to monitor temperature at receiving (dealer to dealer shipping). Adding temperature control at receiving will close the gap that exists now between the shipping and receiving steps.

Cost Information (if available) None

Action by 2005 Task Force II Recommended referral of Proposal 05-217 to appropriate committee as determined by the Conference Chairman.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Time/Temperature Committee Recommended adoption of Proposal 05-217 as amended.

Chapter XIII. Shellstock Shipping

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall ship or repack only shellstock that is:
(1) Obtained from a licensed harvester who has:
(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and **[C]**
(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or **[C]**
(2) Obtained from a ~~certified~~ dealer who has:
(a) **Shipped** ~~Transported~~ the shellstock iced, or in a conveyance ~~maintained~~ at or below 45°F (7.2°C) ambient air temperature **or 50° F (10° C) internal temperature or less;** **[C]** and
(b) Identified the shellstock with a tag on each container. **[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:
(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**
(2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
(a) Iced; or **[C]**
(b) Placed in a storage area or conveyance maintained at 45° F (7.2° C) or less; and **[C]**
(c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B (1) or §B (2) for more than 2 hours at points of transfer such as loading docks. **[C]**

Action by 2007 Task Force II Recommended tabling Proposals 05-209, 05-215, 05-217, and 05-219 and sent to a working group comprised of Chris Nelson, Steve Fleetwood, MaryAnn Guichard, Austin Doctor, Teddy Busick, Sandy Shepherd, Erin Butler, Miles Motes and AJ Erskine.

Action by 2007 Task Force II Workgroup

Recommended adoption of Proposal 05-217 as amended.

Chapter XIII. Shellstock Shipping

01. Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall ship or repack only shellstock that is:
(1) Obtained from a licensed harvester who has:
(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and **[C]**
(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or **[C]**
(2) Obtained from a dealer who has:
(a) Shipped the shellstock iced, or in a conveyance at or below 45°F (7.2°C) ambient air temperature or 50° F (10° C) internal temperature or less; **or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50° F (10°) or less [C];** and
(b) Identified the shellstock with a tag on each container**[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:
(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**
(2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
(a) Iced; or **[C]**
(b) Placed in a storage area or conveyance maintained at 45° F (7.2° C) or less; and **[C]**
(c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B (1) or §B (2) for more than 2 hours at points of transfer such as loading docks. **[C]**

Action by 2007 Task Force II

Recommended adoption of the Task Force II Workgroup recommendation on Proposal 05-217 as amended.

Chapter XIII. Shellstock Shipping

01. Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall ship or repack only shellstock that is:
(1) Obtained from a licensed harvester who has:
(a) Harvested the shellstock from an Approved or Conditionally approved area in the open status as indicated by the tag; and **[C]**
(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or **[C]**
(2) Obtained from a dealer **other than the original harvester** who has:
(a) Shipped the shellstock **adequately** iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature**;** or 50° F (10° C) internal temperature or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50° F (10° C) or less; **[C]** and
(b) Identified the shellstock with a tag on each container. **[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:
   (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**
   (2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be;
      (a) Iced; or **[C]**
      (b) Placed and stored in a storage area or conveyance maintained at 45° F (7.2 °C) or less; and **[C]**
      (c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B (1) or §B (2) for more than 2 hours at points of transfer such as loading docks. **[C]**

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007
Concurred with Conference action with the following comments and recommendations for ISSC consideration.

Action by the ISSC to identify receiving temperature as a critical limit at receiving represents an important addition to the public health safety measures of the NSSP. Under HACCP, assuring proper receiving temperatures has long been recognized as a necessary food safety control measure. Adoption of these proposals establishes consistency between NSSP safety controls for molluscan shellfish and safety controls for other seafood. Section 01. A (2) (a) of Proposals 05-209 and 05-217 and Section 01. A (1) (a) of Proposal 05-219 states that shellstock shall be obtained from a dealer who has **"Shipped the shellstock adequately iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 50°F (10°C) internal temperature or less; *or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less;* [C]."** FDA points out that ***or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less"*** shall not be interpreted to mean that the refrigeration unit of the conveyance need not be turned on and operating. In those situations where the shellstock has recently been placed in the conveyance whereby the conveyance may not yet have achieved the required ambient temperature, this provision provides assurance that the shellstock is at least in a operating temperature controlled environment capable to maintaining the shellstock at an internal temperature at 50°F.

Proposal Subject Plant Sanitation

Specific NSSP Guide Reference NSSP Guide Model Ordinance Chapter XIII Shellstock Shipping Sections .02 Sanitation & .03 Other Model Ordinance Requirements

Text of Proposal/ Requested Action Modify the organization of sanitation requirements of Chapter XIII, Sections .02 and .03 to make them consistent with the interpretation and implementation of Title 21 of the Code of Federal Regulations (CFR) Part 123 Seafood HACCP Regulation by putting related items together.

Public Health Significance This proposal attempts to reorganize the NSSP MO plant sanitation requirements in Chapter XIII, sections .02 and .03 to:

3) Make them consistent with manner in which the sanitation requirements of the Seafood HACCP regulation, Title 21 Code of Federal Regulations (CFR) Part 123) are implemented and
4) Consolidate similar items together.

In order to accommodate this reorganization there are instances in this proposal where editing and minor deletions or additions were made for coherency.

There is also one update regarding the NSSP construction guide.

Hopefully this will serve to eliminate some of the confusion that exists over how to interpret and implement the requirements between Seafood HAACP and NSSP.

This proposal provides revisions for Chapters XIII that simply reorganize and reformat the written requirements already contained in this chapter. The revisions do not add or delete any requirements.

FDA will incorporate changes adopted by the ISSC in the FDA Standardization Field Guide and NSSP Standardized Shellfish Processing Plant Inspection Form. Copies of these revised documents then will be provided to each state.

Cost Information (if available) None

Action by 2005 Task Force II Recommended referral of Proposal 05-218 to an appropriate Committee as determined by the Conference Chairman, with a recommendation by Task Force II that a workgroup be established to address this proposal in advance of the 2007 Biennial Meeting.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Plant Sanitation Committee Recommended adoption of Proposal 05-218 as amended.

The Committee recommended:

1. Not deleting Chapter XIII. .02 B. 1. e. (ii).

2. Adopting the recommended change as submitted
   Chapter XIII. .03 B. (5)
   (5) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials ~~and tank construction shall be such that it:~~
   (i) Is easily accessible for ~~cleaning~~ and inspection; [K]

(ii) Is self-draining; and [K]
(iii) Meets the requirements for food contact surfaces

Action by 2007 Task Force II

Recommended adoption of Plant Sanitation Committee recommendation on Proposal 05-218. NOTE: The Chairman of the Plant Sanitation Committee has advised the Executive Board Chair, the Executive Director, and the Task Force II Chair of an error that was reported to Task Force II. The Voting Delegates in the closing General Assembly will be provided with an opportunity to correct the error.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II as editorially amended to be correct and consistent with other language in the NSSP Guide.

The error on Proposal 05-218 was discussed in the Closing General Assembly and corrected as follows:

Recommended adoption of Proposal 05-210 as amended.

The Committee recommended:

1. Not deleting Chapter XIII. .02 B. 1. e. (ii). Is self-draining; and [K]

2. Delete Chapter XIII. .03 B. (5)
   ~~(5) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:~~
   ~~(i) Is easily accessible for cleaning and inspection; [K]~~
   ~~(ii) Is self-draining; and [K]~~
   ~~(iii) Meets the requirements for food contact surfaces~~

Action by USFDA

December 20, 2007
Concurred with Conference action.

XIII. SHELLSTOCK SHIPPING

Exceptions. Shellstock Shippers are not required to pack shellstock in a building that complies with Sections .02 and .03 of this chapter when the Authority has determined that a shellstock shipper's practices and conditions do not warrant requiring shellstock to be packed in a building.

.02 Sanitation.

A. Safety of Water for Processing and Ice Production.
(1) Water Supply.
(a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations. **[C]**
(b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: **[K]**
(i) Prior to use of the water supply; **[C]**
(ii) Every six months while the water supply is in use; and **[K]**
(iii) After the water supply has been repaired and disinfected. **[$S^{C/K}$]**

[*(c) was moved to Protection from Adulterants 02.E (7)]*

~~(c) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations.~~ **~~[K]~~**

(2) Ice Production. Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall: ~~(a)~~ ~~B~~be made on-site from potable water in a commercial ice machine; or **[C]**

~~(a) Bbe made on-site from potable water in a commercial ice machine; or **[C]**~~

[*(b) was moved to Protection from Adulterants 02.E (5)(c)and editorial was then made to (2) (a) above to move it to the body of section (2) as there is no longer a(2) (b) to go with the (2) (a)*]

~~(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. **[C]**~~

(3) Shellstock Washing.

(a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock. **[C]**

(b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:

(i) Obtain approval for the construction or remodeling of the system from the Authority. **[K]**

(ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and **[C]**

(iii) Test bacteriological water quality daily; **[$S^{C/K}$]**

(c) The dealer may use ultra-violet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed 20 nephelometric turbidity units (NTUs) measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*. **[K]**

(4) Plumbing and Related Facilities.

~~(a)~~ **The dealer shall** design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

~~(i)~~(a) Prevent contamination of water supplies; **[C]**

~~(ii)~~(b) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. **[C]**

~~(iii)~~(c) The dealer shall Install and maintain in good working order devices to protect against backflow and back siphonage. **[K]**

[(b) was moved to Condition and Cleanliness, of Food Contact Surfaces 02.B (1) (g); Edited section above as no (b) section to go with (a) section]

~~(b) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:~~

~~(i) Is easily accessible for cleaning and inspection; **[K]**~~

~~(ii) Is self-draining; and **[K]**~~

~~(iii) Meets the requirements for food contact surfaces. **[K]**~~

B. Condition, and Cleanliness, of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guides* ~~(August 1993)~~, *[Update]* **(available in the Guidance Document section of the NSSP Guide for the Control of Molluscan Shellfish),** U.S. Department of Health and Human Services. **[K]** (b) The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are:

(i) Constructed in a manner and with materials that can be cleaned, and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products;**[K]**

(ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and **[K]**

(iii) Fabricated from food grade materials. **[K]**

(c) The dealer shall assure that all joints on food contact surfaces

(i) Have smooth easily cleanable surfaces~~;~~ and **[K]**

(ii) Are welded-**[K]**

(d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02.B.(1) (a), (b), and (c). **[K]**

[*Moved portions of (e) which pertain to food contact surfaces from Safety of Water 02. A (4) (b; Some editing was also done to fit this heading and the portions of (b) pertaining to plumbing were moved to Plumbing and Related facilities .03 B (5)]*

(e) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials~~-~~and tank construction shall be such that it:

(i) Is easily accessible for cleaning and inspection; **[K]**

~~**(ii) Is self-draining; and [K]**~~

(ii) Meets the requirements for food contact surfaces [K]

(2) Cleaning and sanitizing of food contact surfaces.

(a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall:

(i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant; **[K]**

(ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated;**[K]**

[Moved (iii) to Proper labeling, Storage and Use of Toxic Compounds 02 F (d)]

~~(iii) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use; and~~

~~(iv~~**(iii)** Wash and rinse equipment and utensils at the end of each day. **[K]**

(b) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded. **[K]**

(3) If used, the finger cots or gloves shall be:

(a) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; **[O]**

(b) Cleaned more often, if necessary **[K]**;

(c) Properly stored until used; and **[K]**

(d) Maintained in a clean, intact, and sanitary condition. **[K]**

C. Prevention of Cross Contamination.

(1) Protection of shellfish.

(a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. **[$S^{C/K}$]**

(b) Shucked shellfish shall be protected from contamination. **[$S^{C/K}$]**

(c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. **[K]**

(d) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. **[$S^{K/0}$]**

(2) Employee practices.

(a) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:

(i) Before starting work; **[K]**
(ii) After each absence from the work station; **[K]**
(iii) After each work interruption; and **[K]**
(iv) Any time when their hands may have become soiled or contaminated. **[K]**

[Moved (b) (i)(ii)(iii) from .03 J. (1),(2),(3),(4) Personnel]

(b) In any area where shellfish are stored and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
(i) Store clothing or other personal belongings; [O[
(ii) Eat or drink; [K]
(iii) Spit; and[K]
(iv) Use tobacco in any form. [K]

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.
(1) Handwashing facilities with warm water at a minimum temperature of 110°F (43°C), dispensed from a hot and cold mixing or combination faucet, shall be provided. **[$S^{K/O}$]**

[*Moved (a) (i)(ii)(iii), and (b) (i)(ii)(iii)(iv) from .03 B (1) (a)(b)(c) and 2(b), 3 (a)(b)(c)(d) Plumbing and Related Facilities; (a)(iv) was moved from.03 B (2)(b) Plumbing and Related Facilities]*

(a) **Handwashing facilities shall be provided which are:**
(i) Convenient to work areas; [O]
(ii) Separate from the three compartment sinks used for cleaning equipment and utensils; [K]
(iii) Directly plumbed to an approved sewage disposal system, and [$S^{O/K}$]
(iv) Adequate in number and size for the number of employees, and located where supervisors can observe employee use; [K]
(b) The dealer shall provide at each handwashing facility:
(i) Supply of hand cleansing soap or detergent; [K]
(ii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
(iii) Easily cleanable waste receptacle; and [O]
(iv) Handwashing signs in a language understood by the employees; [O]
(2) Sewage **[K]** and liquid disposable wastes **[K]** shall be properly removed from the facility

[Moved (3)(a) from Plants and Grounds…. .03 A. (4) Some editing was done to (b) and (c) for coherence]

(3) The dealer shall provide
(a) Toilet room doors that are tight fitting, self closing, and do not open directly into a processing area. [K]
(b) **An** ~~A~~adequate number of conveniently located, toilets ~~shall be provided~~, **[K]**
(c) The dealer shall provide ~~e~~Each toilet facility with an adequate supply of toilet paper **[K]** in a suitable holder, and **[$S^{K/O}$]**.

E. Protection from Adulterants.
(1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing. **[K]**
(2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. **[O]**
(3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. **[K]**
(4) Shellstock shall be packed in clean containers. **[K]**

(5) Protection of ice used in shellfish processing.

(a) Any ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. **[S$^{C/K}$]**

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[S$^{C/K}$]**

[Moved (c) from Safety of Water. .02 A. (2) (b)]

(c) Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall ~~C~~come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]

(6) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[S$^{K/C}$]**

[Moved (7) from Safety of Water .02 A. (1) (c)]

(7) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations. [K]

F. Proper Labeling, Storage and Use of Toxic Compounds.

(1) Storage of toxic compounds.

(a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. **[K]**

(b) Each of the following categories of toxic substances shall be stored separately:

(i) Insecticides and rodenticides; **[K]**

(ii) Detergents, sanitizers, and related cleaning agents; and **[K]**

(iii) Caustic acids, polishes, and other chemicals. **[K]**

(c) The dealer shall not store toxic substances above shellfish or food contact surfaces. **[K]**

(2) Use and labeling of toxic compounds.

(a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. **[K]**

(b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. **[K]**

(c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions. **[K]**

[Moved (d) from Condition and Cleanliness of Food Contact Surfaces .02 B. (2) (a) (iii)]

(d) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use [K]

G. Control of Employees with Adverse Health Conditions.

(1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*. **[K]**

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

[Moved the underlined part of the section below from .03 A (1) (b) Plants and Grounds;-edited to fit in this section; and moved the portion of the section pertaining to unauthorized persons to .03 Supervision (4) (c)]

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. ~~**[K]**~~**. Animals ~~or unauthorized persons~~ shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]**

.03 Other Model Ordinance Requirements.

A. Plants and Grounds.

(1) ~~General.~~

~~(a)~~ The physical facilities shall be maintained in good repair. **[O]**

[Moved deletion to 02 E Prevention of Cross Contamination and 02H Exclusion of Pests]

~~(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. **[K]**~~

[Moved deletion to 02E (7) Protection from Adulterants]

~~(c)Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed. **[O]**~~

(2) Flooding:

(a) Facilities in which shellfish are stored, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. **[C]**

(b) If facilities are flooded:

(i) Shellfish processing, repacking or shipping activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. **[C]**

(ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use. **[C]**

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. [$S^{C/K}$]

[Moved (4) from .03 D Insect and Vermin Control]

(4) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in the facility.

(a) Tight fitting, self closing doors: [K]

(b) Screening of not less than 15 mesh per inch; [K] and

(c) Controlled air current. [K].

[Moved (4) to .02 (2) D (3)(a) Maintenance of Hand Washing Hand Sanitizing and Toilet Facilities]

~~(4) The dealer shall provide toilet room doors which are tight fitting, self closing, and do not open directly into a processing area. [K]~~

(5) Plant Interior.

(a) Sanitary conditions shall be maintained throughout the facility. **[O]**

(b) All dry area floors shall be hard, smooth, easily cleanable; and **[O]**

(c) All wet area floors used in areas to store shellstock, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:

(i) Are graded to provide adequate drainage; **[O]**

(ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; **[O]**

(iii) Have sealed junctions between floors and walls to render them impervious to water; and **[O]**

(d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials **[O]**.

(6) Grounds. Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

(a) Rodent attraction and harborage; and **[O]**

(b) Inadequate drainage. **[O]**

B. Plumbing and Related Facilities.

[Moved .03 B(1)(a)(b)(c), B(2)(b), and B(3)(a)(b)(c)(d) to .02 D (1)(a)(i)(ii)(iii), .02 D (1)(a)(iv), and .02 D (1)(b)(i)(ii)(iii)(iv)Maintenance of Hand Washing Hand Sanitizing and Toilet Facilities]

~~(1) Handwashing facilities shall be provided which are:~~

~~(a) Convenient to work areas; **[O]**~~

~~(b) Separate from the three compartment sinks used for cleaning equipment and utensils; and **[K]**~~

~~(c) Directly plumbed to an approved sewage disposal system. **[S$^{O/K}$]**~~

~~(2)~~**(1)** All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to and provide a water system that is adequate in quantity and under pressure, and include~~s~~

~~(a)~~ cold and warm water at all sinks; ~~and~~ **[K]**

~~(b) Handwashing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use; **[K]**~~

~~(3) Hand washing facilities: The dealer shall provide at each handwashing facility:~~

~~(a) A supply of hand cleansing soap or detergent; **[K]**~~

~~(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**~~

~~(c) An easily cleanable waste receptacle; and **[O]**~~

~~(d) Handwashing signs in a language understood by the employees; **[O]**~~

~~(4)~~**(2)** Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:

(a) Used in shellstock storage; **[K]**

(b) Used for food holding units **[K]** (e.g. refrigeration units);

(c) Cleaned by hosing, flooding, or similar methods **[K]**; and

(d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. **[K]**

~~(5)~~**(3)** A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[S$^{C/K}$]**

~~(6)~~**(4)** Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. **[K]**

[Moved(5)(i) from .02 A (4)(b)(i)(ii)(iii) Safety of Water and edited out non plumbing aspects and moved them to 02 B(1)(e) Condition & Cleanliness of Food Contact Surfaces]

(5) Shellstock washing storage tanks ~~and related~~ plumbing shall be: fabricated from safe materials ~~and tank construction shall be~~ **such that it**

~~(i) is easily accessible for cleaning and inspection; **[K]**~~

~~(ii) I~~**is self-draining;** ~~and~~ **[K]**

~~(iii) Meets the requirements for food contact surfaces~~

C. Utilities.

(1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. **[S$^{C/K}$]**

(2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[S$^{C/K}$]**

[*Moved D(1)(a)(b)(c) to .03 Plants and Grounds*]

~~D. Insect and Vermin Control.~~

~~(1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:~~

~~(a) Tight fitting, self closing doors; **[K]**~~

~~(b) Screening of not less than 15 mesh per inch; **[K]** and~~

~~(c) Controlled air current. **[K]**~~

~~E.~~ D. Disposal of Other Wastes.

(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. **[O]**

(2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; and **[O]**

[Sections .02 F and .02 G were combined thus some slight editing was done for coherency]

~~F.~~E. Equipment**, Condition, ~~and~~ Cleaning, Maintenance, and** Construction of Non-Food Contact Surfaces.

(1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced; and **[O]**

(2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellfish storage or handling areas. **[O]**

~~G. Cleaning Non-food Contact Surfaces.~~

~~(1)~~**(3)** Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces. **[K]**

~~(2)~~**(4)** All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. **[O]**

~~H.~~**F.** Shellfish Storage and Handling.

(1) The dealer shall:

(a) Assure that shellstock is:

(i) Alive; [K]

(ii) Reasonably free of sediment **[O]**; and

(iii) Culled; **[K]**

(b) The dealer shall not commingle shellstock during shucking unless the dealer is included in the Authority's commingling plan. **[K]**

(2) The dealer shall inspect incoming shipments and shall reject dead or inadequately protected shellstock; **[K]**

(3) A dealer whose activity consists of trucks or docking facilities only shall:

(a) Have a permanent business address at which records are maintained and inspections can be performed; and **[K]**

(b) Not repack shellstock. **[K]**

(4) A dealer who stores or repacks shellstock shall have:

(a) His own facility for proper storage or repacking of shellstock; or **[K]**

(b) Arrangements with a facility approved by the Authority for the storage or repacking of shellstock. **[K]**

~~I.~~ **G.** Heat Shock. – N/A

[03 J (1)(2)(3)(4) was moved to 02. C Prevention of Cross Contamination]

~~J. Personnel. In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:~~

~~(1) Store clothing or other personal belongings; **[O]**~~

~~(2) Eat or drink; **[K]**~~

~~(3) Spit; and **[K]**~~

~~(4) Use tobacco in any form. **[K]**~~

~~K.~~ **H.** Supervision.

(1) A reliable, competent individual shall be designated to supervise general plant management and activities; **[K]**

(2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. **[K]**

(3) All supervisors shall be:

(a) Trained in proper food handling techniques and food protection principles; and **[K]**

(b) Knowledgeable of personal hygiene and sanitary practices. **[K]**

(4) The dealer shall require:

(a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. **[K]**

(b) Supervisors to assure that proper sanitary practices are implemented, including:

(i) Plant and equipment clean-up; **[K]**

(ii) Rapid product handling; and **[K]**

(iii) Shellfish protection from contamination. **[K]**

[Moved (c) from .03 A (1) (b) Plants and Grounds and edited to make appropriate for this section by adding "Supervisors shall not allow" and deleted the words "animal" "or", and the phrase "shall not be allowed"]

(c) **Supervisors shall not allow** ~~Animals or~~ **unauthorized persons** ~~shall not be allowed~~ **in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]**

~~(c)~~ **(d)** Employees

(i) to be trained in proper food handling and personal hygiene practices, and **[K]**

(ii) to report any symptoms of illness to their supervisor. **K]**

Proposal Subject Plant Sanitation

Specific NSSP Guide Reference NSSP Guide Model Ordinance
Chapter XIV. Reshipping Section .01 Critical Control Points

Text of Proposal/ Requested Action Modify Chapter XIV .01 to make minor editorial changes and to add a new temperature requirement at receiving.

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall reship only shellfish which:
(1) Originated from a **certified** dealer; ~~and~~ **[C] who has:**
(a) Transported the shellstock iced, or in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature [C]; and
(b) Identified the shellstock with a tag outlined in Chapter X .05 or a label as outlined in Chapter X .06. [C]

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
(1) Iced; or **[C]**
(2) Placed in a storage area or conveyance maintained at 45 °F~~ahrenheit~~ (7.2 ° C~~entigrade~~) or less; and **[C]**
(3) Not permitted to remain without ice, mechanical refrigeration, or other approved means of refrigeration for more than 2 hours at points of transfer such as loading docks. **[C]**

C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked shellfish at an ambient temperature of 45 ° F~~ahrenheit~~ (7.2 ° C~~entigrade~~) or less. **[C]**

Public Health Significance Pathogens found in waters from which molluscan shellfish are harvested can cause illness or death in consumers with immune disorders or conditions. Pathogens, such as *Vibrio vulnificus, Vibrio parahaemolyticus,* and *Vibrio cholerae* non 01, are naturally occurring. *V. vulnificus* illness is associated with the consumption of raw oysters harvested from the Gulf of Mexico during the warm weather months. *V. parahaemolyticus* and *V. cholerae* non 01 illness is associated with the consumption of raw oysters harvested during the warm weather months from the Atlantic, Pacific, and Gulf of Mexico regions of the U.S., and similar climates world-wide. Some of these bacterial pathogens may be present in low numbers at the time that molluscan shellfish are harvested, and may increase to levels that are more hazardous if they are exposed to time/temperature abuse.

"Pathogens from the harvest area" should be considered a significant hazard at any harvesting, shipping, receiving, and processing steps where a preventive measure is adequate to reduce the likelihood of occurrence of the hazard to an acceptable level. To minimize the risk of illness from the consumption of molluscan shellfish containing these pathogens, shellfish dealers must identify the receiving step as a critical control point for this hazard.

Pathogenic organisms can survive in shellfish for a considerable length of time after harvesting and bacterial pathogens may multiply in the absence of adequate refrigeration. Adequate temperature control is critical to product safety. The NSSP MO sets forth temperature requirements for shipping shellfish (Chapter IX). However, there is no a requirements for dealers to monitor temperature at receiving (dealer to dealer shipping). Adding temperature control at receiving will close the gap that exists now between the shipping and receiving steps.

Cost Information (if available) None

Action by 2005 Task Force II Recommended referral of Proposal 05-219 to appropriate Committee as determined by the Conference Chairman.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Time/Temperature Committee Recommended adoption of Proposal 05-219 as amended.

Chapter XIV. Reshipping

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall reship only shellfish which:
(1) Originated from a ~~certified~~ dealer; **[C]** who has:
(a) **Shipped** ~~Transported~~ the shellstock iced, or in a conveyance ~~maintained~~ at or below 45°F (7.2°C) ambient air temperature **or 50° F (10° C) internal temperature or less; [C]** and**/or**
(b) **Shipped the shellfish iced or in a conveyance at or below 45°F (7.2°C) ambient air temperature;[C] and**
(c) Identified the shellstock with a tag outlined in Chapter X .05 or a **shellfish** label as outlined in Chapter X .06; **[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
(1) Iced; or **[C]**
(2) Placed in a storage area or conveyance maintained at 45°F (7.2° C) or less; and **[C]**
(3) Not permitted to remain without ice, mechanical refrigeration, or other approved means of refrigeration for more than 2 hours at points of transfer such as loading docks. **[C]**

C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked shellfish at an ambient temperature of 45° F (7.2° C) or less. **[C]**

Action by 2007 Task Force II Recommended tabling Proposals 05-209,05-217, 05-215, 05-219 and send to working group: Chris Nelson, Steve Fleetwood, MaryAnn Guichard, Austin Doctor, Teddy Busick, Sandy Shepherd, Erin Butler, Miles Motes and AJ Erskine.

Action by 2007 Task Force II Workgroup Recommended adoption of Proposal 05-219 as amended.

Chapter XIV. Reshipping

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall reship only shellfish which:
(1) Originated from a dealer; **[C]** who has:
(a) Shipped the shellstock iced, or in a conveyance at or below 45°F

(7.2°C) ambient air temperature or 50° F (10° C) internal temperature or less; **or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50° F (10° C) or less;** **[C]** and/or

(b) Shipped the shellfish iced or in a conveyance at or below 45°F (7.2°C) ambient air temperature; **[C]** and

(c) Identified the shellstock with a tag outlined in Chapter X .05 or a shellfish label as outlined in Chapter X.06. **[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:

(1) Iced; or **[C]**

(2) Placed in a storage area or conveyance maintained at 45°F (7.2° C) or less; and **[C]**

(3) Not permitted to remain without ice, mechanical refrigeration, or other approved means of refrigeration for more than 2 hours at points of transfer such as loading docks. **[C]**

C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked shellfish at an ambient temperature of 45° F (7.2° C) or less. **[C]**

Action by 2007 Task Force II

Recommended adoption of the Task Force II Workgroup recommendation on Proposal 05-219 as amended.

Chapter XIV. Reshipping

01. Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall reship only shellfish which:

(1) Originated from a dealer **other than the original harvester** **[C]** who has:

(a) Shipped the shellstock **adequately** iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature**;** or 50° F (10° C) internal temperature or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50° F (10° C) or less; **[C]**; and/or

(b) Shipped the shellfish iced or in a conveyance at or below 45°F (7.2°C) ambient air temperature; **[C]** and

(c) Identified the shellstock with a tag outlined in Chapter X .05 or a shellfish label as outlined in Chapter X .06. **[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:

(1) Iced; or **[C]**

(2) Placed in a storage area or conveyance maintained at 45°F (7.2° C) or less; and **[C]**

(3) Not permitted to remain without ice, mechanical refrigeration, or other approved means of refrigeration for more than 2 hours at points of transfer such as loading docks. **[C]**

C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked shellfish at an ambient temperature of 45° F (7.2° C) or less. **[C]**

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007

Concurred with Conference action with the following comments and recommendations for ISSC consideration.

Action by the ISSC to identify receiving temperature as a critical limit at receiving represents an important addition to the public health safety measures of the NSSP. Under HACCP, assuring proper receiving temperatures has long been recognized as a necessary food safety control measure. Adoption of these proposals establishes consistency between NSSP safety controls for molluscan shellfish and safety controls for other seafood. Section 01. A (2) (a) of Proposals 05-209 and 05-217 and Section 01. A (1) (a) of Proposal 05-219 states that shellstock shall be obtained from a dealer who has **"Shipped the shellstock adequately iced; or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 50°F (10°C) internal temperature or less; *or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less;* [C]."** FDA points out that ***or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less"*** shall not be interpreted to mean that the refrigeration unit of the conveyance need not be turned on and operating. In those situations where the shellstock has recently been placed in the conveyance whereby the conveyance may not yet have achieved the required ambient temperature, this provision provides assurance that the shellstock is at least in a operating temperature controlled environment capable to maintaining the shellstock at an internal temperature at 50°F.

Proposal Subject	Plant Sanitation
Specific NSSP Guide Reference	NSSP Model Ordinance Chapter XIV. Reshipping Sections .02 Sanitation & .03 Other Model Ordinance Requirements
Text of Proposal/ Requested Action	Modify the organization of sanitation requirements of Chapter XIV, Sections .02 and .03 to make them consistent with the interpretation and implementation of Title 21 of the Code of Federal Regulations (CFR) Part 123 Seafood HACCP Regulation by putting related items together.
Public Health Significance	This proposal attempts to reorganize the NSSP MO plant sanitation requirements in Chapter XI, sections .02 and .03 to: 5) Make them consistent with manner in which the sanitation requirements of the Seafood HACCP regulation, Title 21 Code of Federal Regulations (CFR) Part 123) are implemented and 6) Consolidate similar items together. In order to accommodate this reorganization there are instances in this proposal where editing and some minor deletions or additions were made for coherency. There is also one update regarding the NSSP construction guide. Hopefully this will serve to eliminate some of the confusion that exists over how to interpret and implement the requirements between Seafood HAACP and NSSP. This proposal provides revisions for Chapters XIV that simply reorganize and reformat the written requirements already contained in this chapter. The revisions do not add or delete any requirements. FDA will incorporate changes adopted by the ISSC in the FDA Standardization Field Guide and NSSP Standardized Shellfish Processing Plant Inspection Form. Copies of these revised documents then will be provided to each state.
Cost Information (if available)	None
Action by 2005 Task Force II	Recommended referral of Proposal 05-220 to an appropriate Committee as determined by the Conference Chairman, with a recommendation by Task Force II that a workgroup be established to address this proposal in advance of the 2007 Biennial Meeting.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force II.
Action by USFDA	Concurred with Conference action.
Action by 2007 Plant Sanitation Committee	Recommended adoption of Proposal 05-220 as submitted.
Action by 2007 Task Force II	Recommended adoption of Plant Sanitation Committee recommendation on Proposal 05-220.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Chapter XIV. Reshipping

Exceptions. Reshippers are not required to comply with the building requirements in Sections .02 and .03 of this chapter when the Authority has determined that a reshipper's practices and conditions do not warrant requiring a building.

.02 Sanitation.

A. Safety of Water for Processing and Ice Production.

(1) Water Supply.

(a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations. **[C]**

(b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: **[K]**

(i) Prior to use of the water supply; **[C]**

(ii) Every six months while the water supply is in use; and **[K]**

(iii) After the water supply has been repaired and disinfected. **[$S^{C/K}$]**

(2) Ice Production. Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:

(a) Be made on-site from potable water in a commercial ice machine; or **[C]**

[*(b) was moved to Protection from Adulterants 02.E]*

~~(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]~~

(3) Plumbing and Related Facilities.

(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

(i) Prevent contamination of water supplies; **[C]**

(ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. **[C]** The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. **[K]**

B. Condition, and Cleanliness of Food Contact Surfaces.

Equipment and utensil construction for food contact surfaces. All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02.B.(1) (a), (b), and (c). **[K]**

C. Prevention of Cross Contamination.

(1) Protection of shellfish.

(a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. **[$S^{C/K}$]**

(b) Shucked shellfish shall be protected from contamination. **[$S^{C/K}$]**

(c) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. **[$S^{K/0}$]**

(2) Employee practices.

(a) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:

(i) Before starting work; **[K]**

(ii) After each absence from the work station; **[K]**

(iii) After each work interruption; and **[K]**

(iv) Any time when their hands may have become soiled or contaminated. **[K]**

[Moved (b)(i)(ii)(iii)(iv) from ..03 J(1),(2),(3),(4) Personnel]

(b) In any area where shellfish are stored and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
(i) Store clothing or other personal belongings; [O]
(ii) Eat or drink; [K]
(iii) Spit; and[K]
(iv) Use tobacco in any form. [K]

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.
(1) Handwashing facilities with warm water at a minimum temperature of 110°F (43°C), dispensed from a hot and cold mixing or combination faucet, shall be provided. **[$S^{K/O}$]**

[Moved (a)(i)(ii)(iii), (a)(iv) and (b)(i)(ii)(iii(iv) from .03 B (1)(a)(b)(c), .03 B (2)(b) and .03 B (3)(a)(b)(c (d) Plumbing and Related Facilities]

(a) **Handwashing facilities shall be provided which are:**
(i) Convenient to work areas; [O]
(ii) Separate from the three compartment sinks used for cleaning equipment and utensils; [K]
(iii) Directly plumbed to an approved sewage disposal system, and [$S^{O/K}$]
(iv) Adequate in number and size for the number of employees, and located where supervisors can observe employee use. [K]
(b) The dealer shall provide at each handwashing facility:
(i) Supply of hand cleansing soap or detergent; [K]
(ii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
(iii) Easily cleanable waste receptacle; and [O]
(iv) Handwashing signs in a language understood by the employees; [O]
(2) Liquid disposable wastes shall be properly removed from the facility **[K**

[Moved (3) from Plants and Grounds .03 A. (4) and some editing was done for coherence]

(3) The dealer shall provide:
(a) Toilet room doors that are tight fitting, self closing, and do not open directly into a processing area; [K]
~~**(3)**~~ (b) An adequate number of conveniently located, toilets**[K]** ~~shall be provided;~~**[K]**
~~(4)~~ (c) ~~The dealer shall provide e~~Each toilet facility with an adequate supply of toilet paper **[K]** in a suitable holder. **[$S^{K/O}$]**.

E. Protection from Adulterants.
(1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing. **[K]**
(2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. **[O]**
(3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. **[K]**
(4) Protection of ice used in shellfish reshipping.
(a) Any ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. **[$S^{C/K}$]**
(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[$S^{C/K}$]**

[Moved (c) from Safety of Water .02 A. (2) (b)]

(c) Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall ~~C~~come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]

(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[$S^{K/C}$]**

F. Proper Labeling, Storage and Use of Toxic Compounds.

(1) Storage of toxic compounds.

(a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. **[K]**

(b) Each of the following categories of toxic substances shall be stored separately:

(i) Insecticides and rodenticides; **[K]**

(ii) Detergents, sanitizers, and related cleaning agents; and **[K]**

(iii) Caustic acids, polishes, and other chemicals. **[K]**

(c) The dealer shall not store toxic substances above shellfish or food contact surfaces. **[K]**

(2) Use and labeling of toxic compounds.

(a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. **[K]**

(b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. **[K]**

(c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions. **[K]**

G. Control of Employees with Adverse Health Conditions.

(1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register.* **[K]**

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

[Moved the underlined part of the section below from .03 A (1) (b) Plants and Grounds;-edited to fit in this section; and moved the portion of the section pertaining to unauthorized persons to .03 Supervision (4) (c)]

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. **~~[K]~~. Animals ~~or unauthorized persons~~ shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]**

.03 Other Model Ordinance Requirements.

A. Plants and Grounds.

(1) General.

(a)The physical facilities shall be maintained in good repair. **[O]**

(2) Flooding:

(a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. **[C]**

(b) If facilities are flooded:

(i) Shellfish processing, shucking or repacking activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. **[C]**

(ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use. **[C]**

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. [$S^{C/K}$]

[Moved(4)(a)(b)(c) from .03 D Insect and Vermin Control]

(4) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in the facility.

(a) Tight fitting, self closing doors: [K]

(b) Screening of not less than 15 mesh per inch; [K] and

(c) Controlled air current. [K].

[Moved (4) to .02 D (3)(a) Maintenance of Hand Washing Hand Sanitizing and Toilet Facilities]

~~(4) The dealer shall provide toilet room doors which are tightfitting, self closing, and do not open directly into a processing area. [K]~~

(5) Plant Interior.

(a) Sanitary conditions shall be maintained throughout the facility. **[O]**

(b) All dry area floors shall be hard, smooth, easily cleanable; and **[O]**

(c) All wet area floors used in areas to store shellstock, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:

(i) Are graded to provide adequate drainage; **[O]**

(ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; and **[O]**

(iii) Have sealed junctions between floors and walls to render them impervious to water.; and **[O]**

(d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials **[O]**.

(6) Grounds. Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

(a) Rodent attraction and harborage; and **[O]**

(b) Inadequate drainage. **[O]**

B. Plumbing and Related Facilities.

[Moved (1)(2)(3) to .02 D(1) (a)(i)(ii)(iii)and (b)(i)(ii)(iii)(iv) Maintenance of Hand Washing Hand Sanitizing and Toilet Facilities]

~~(1) Handwashing facilities shall be provided which are:~~

~~(a) Convenient to work areas; **[O]**~~

~~(b) Separate from the three compartment sinks used for cleaning equipment and utensils; and **[K]**~~

~~(c) Directly plumbed to an approved sewage disposal system. **[$S^{O/K}$]**~~

~~(2) The dealer shall provide at least one handsink in the packing room. **[O]**~~

~~(3) The dealer shall provide at each handwashing facility:~~

~~(a) A supply of hand cleansing soap or detergent; **[K]**~~

~~(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**~~

~~(c) An easily cleanable waste receptacle; and **[O]**~~

~~(d) Handwashing signs in a language understood by the employees; **[O]**~~

~~(4)~~**(1)** All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes~~:~~

~~(a) C~~**c**old and warm water at all sinks; ~~and~~ **[K]**

[Moved (b) to .02 D(1)(a)(iv) Maintenance of Hand Washing Hand Sanitizing and Toilet Facilities]

~~(b) Handwashing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use; **[K].**~~

~~(5)~~**(2)** Adequate floor drainage, including backflow preventers~~s~~ such as air gaps, shall be provided where floors are:

(a) Used in shellstock storage; **[K]**

(b) Used for food holding units ~~**[K]**~~ (e.g. refrigeration units); **[K]**

(c) Cleaned by hosing, flooding, or similar methods **[K]**; and

(d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. **[K]**

~~(5)~~**(3)** A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[$S^{C/K}$]**

~~(6)~~**(4)** Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. **[K]**

C. Utilities.

(1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. **[$S^{C/K}$]**

(2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[$S^{C/K}$]**

[*Moved D. to .03 Plants and Grounds*]

~~D~~. ~~Insect and Vermin Control.~~

~~(1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:~~

~~(a) Tight fitting, self-closing doors; **[K]**~~

~~(b) Screening of not less than 15 mesh per inch; **[K]** and~~

~~(c) Controlled air current. **[K]**~~

~~E~~.D. Disposal of Other Wastes.

(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. **[O]**

(2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; and **[O]**

[Sections .02 F and .02 G were combined thus some coherence editing]

~~F.~~E. Equipment**, Condition, ~~and~~ Cleaning, Maintenance, and** Construction **of** Non-Food Contact Surfaces.

(1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced; and **[O]**

(2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellfish storage or handling areas. **[O]**

~~G.~~ ~~Cleaning Non-food Contact Surfaces.~~

~~(1)~~**(3)** Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and **non** food contact surfaces. **[K]**

~~(2)~~**(4)** All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. **[O]**

~~H~~. **F.** Shellfish Storage and Handling.

(1) The dealer shall;

(a) Buy shellfish only from sources certified by the Authority or listed in the ICSSL; and **[K]**

(b) Add his name and certification number to the package. **[K]**

(2) The dealer shall not:

(a) Commingle, sort, or repack shellstock or shucked shellfish; or **[K]**
(b) Remove or alter any existing tag or label. **[K]**

(3) A dealer whose activity consists of trucks only shall:
(a) Have his own facility for the storage of shellfish; or **[K]**
(b) Have arrangements with a facility approved by the Authority for the storage of shellfish; and **[K]**
(c) Have a permanent business address at which records are maintained and inspections can be performed. **[K]**

~~I.~~ **G.** Heat Shock. – N/A

[J was moved to 02. C (2)*(b)(i)(ii)(iii)(iv)* Prevention of Cross Contamination]

~~J. Personnel. In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:~~
~~(k) Store clothing or other personal belongings; **[O]**~~
~~(ii) Eat or drink; **[K]**~~
~~(iii) Spit; and **[K]**~~
~~(iv) Use tobacco in any form. **[K]**~~

~~K.~~ **H.** Supervision.
(1) A reliable, competent individual shall be designated to supervise general plant management and activities; **[K]**
(2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. **[K]**
(3) All supervisors shall be:
(a) Trained in proper food handling techniques and food protection principles; and **[K]**
(b) Knowledgeable of personal hygiene and sanitary practices. **[K]**
(4) The dealer shall require:
(a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. **[K]**
(b) Supervisors to assure that proper sanitary practices are implemented, including:
(i) Plant and equipment clean-up; **[K]**
(ii) Rapid product handling; and **[K]**
(iii) Shellfish protection from contamination. **[K]**

[Moved (c) from .03 A (1) (b) Plants and Grounds and edited to make appropriate for this section by adding "Supervisors shall not allow" and deleted the words "animal" "or", and the phrase "shall not be allowed"; Animal aspects moved to 02 H Exclusion of Pests]

(c) **Supervisors to not allow** ~~Animals or~~ **unauthorized persons** ~~be~~ **in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]**
~~(c)~~**(d)** Employees
(i) to be trained in proper food handling and personal hygiene practices, and **[K]**
(ii) to report any symptoms of illness to their supervisor.[**K]**

Proposal Subject Oyster/Shellfish Gardening

Specific NSSP Guide Reference NSSP Guide Model Ordinance, Chapter VI. Shellfish Aquaculture

Text of Proposal/ Requested Action Modify Chapter VI of the Model Ordinance as per attached text.

Public Health Significance

Due to declining wild stocks of oysters in the Mid-Atlantic and South Atlantic States over the past several decades, alternative methods of growing oysters have been explored to replenish natural beds and to meet market demand for fresh oysters. One such method has been oyster/shellfish gardening where private individuals obtain seed oysters (often through programs managed by government agencies or non-profit organizations) and raise them in trays on private property or private leases until they are market size. Once they reach market size, they are either placed on oyster reefs to help restore natural beds, or in some states, they are used for consumption. The concept of oyster/shellfish gardening is growing rapidly in the Mid-Atlantic and South Atlantic States due to its ability to allow private individuals to participate in the restoration of oyster beds.

Public health concerns with oyster/shellfish gardening are due to the facts that, 1) locations chosen for oyster/shellfish gardening are often waters classified as Prohibited or Restricted; 2) persons involved are often not familiar with shellfish sanitation and; 3) persons involved are often elderly and may be more susceptible to illness from consumption of tainted shellfish. With oysters readily available from non-Approved waters and with a lack of knowledge of shellfish sanitation, we feel that the growth in popularity of oyster/shellfish gardening comes with an increasing risk of illness by an ill-informed consumer. In addition to the public health concerns, such an occurrence of illness could have economic impacts to the shellfish industry in general.

The requested action makes a distinction in the Model Ordinance between commercial aquaculture where product is being marketed and oyster/shellfish gardening where it is not being marketed. It would allow the NSSP to more adequately address these public health concerns through increased education of oyster/shellfish gardeners and improved accountability for product being grown in non-Approved waters. It does this through requiring that the Authority permit or register oyster/shellfish gardening activities.

Cost Information (if available) Negligible

PROPOSED ADDITION TO DEFINITIONS OF 2005 ISSC

Model Ordinance
B. Definition of Terms
( ) Float aquaculture means open water aquaculture where the shellfish product is suspended at the water surface using floats.

PROPOSED CHANGES TO CHAPTER VI. 2005 ISSC
Model Ordinance
VI. Shellfish Aquaculture
Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@.01 General.

A. The Authority shall recognize two types of aquaculture:
(1) Commercial – product cultivated for direct marketing.

(2) Oyster/shellfish gardening – product cultivated to enhance water quality or for owners own consumption and not for direct marketing.

B. The Authority shall maintain the following records while the aquaculture activity continues:

(1) Construction and remodeling plans for any permitted aquaculture facility;
(2) **Aquaculture** operational plans; and
(3) Aquaculture permits.

C. The Authority shall inspect **commercial** aquaculture systems at least every six months.

@.02 Seed Shellstock.

A. The Authority shall establish the submarket size for each species of shellfish in accordance with §.01B. and §.01C.

B. All sources of seed shall be sanctioned by the Authority.

@.03 Commercial Open Water and Land Based Aquaculture

A. Inspection. The Authority shall inspect land-based **and float aquaculture** sites at least every six months.

B. The Authority shall approve the written operational plan for any land based **or float** aquaculture facility prior to its implementation.

C. The Authority may not permit commercial aquaculture activities in areas that do not meet restricted, conditionally restricted, conditionally approved, or approved classification.D. Commercial float aquaculture sites, where the floats are attached to or near piers shall be inspected at least every year. This site evaluation by the Authority shall include:

(1) The survey of the commercial float aquaculture site, with special consideration of potential intermittent sources of pollution;
(2) The location of float; and
(3) The examination of the construction of shellstock containers to ensure the free flow of water to all shellstock.

@.04 Oyster/shellfish Gardening

A. The Authority shall permit or register oyster/shellfish gardening activities.

B. The Authority shall establish permit or registration conditions and determine classification of waters where oyster/shellfish gardening can take place prior to its implementation.

C. The Authority shall provide information to the oyster/shellfish gardener on the risk of consuming shellfish from private docks, piers, and oyster floats attached to piers or docks.

D. The Authority shall require that the oyster/shellfish gardener maintain records on the disposition of the shellfish product and provide these records to the Authority.

Requirements for the Harvester/Dealer

.01 Exceptions. The following activities are exempted from these requirements:

A. Hatcheries;

B. Nursery products which do not exceed 10 percent of the market weight; and

C. Nursery products which are 6 months or more growing time from market size.

.02 General.

A. **Commercial aquaculture** encompasses both monoculture and polyculture.

B. Any person who performs **commercial** aquaculture or operates an aquaculture facility to raise shellfish for human consumption shall obtain:

(1) A permit from the Authority for the activity or for construction and functioning of his facility;
(2) A harvester's license; and
(3) Certification as a dealer, where necessary.

C. Shellfish aquaculture shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the aquaculturist's written operational plan.

D. Prior to beginning his activity, an aquaculturist shall obtain the permission of the Authority for use of his site and **submit the following to the Authority for review and approval in accordance with @.01**:

1. Prior to beginning any activity, a detailed construction and operational plan describing the new facility location and activity.

2. For an existing permitted facility, a detailed construction plan describing the proposed remodeling, modifications, or otherwise permanent alteration of the facility prior to any work commencing.

3. An updated operational plan on an annual basis or whenever operational procedures change requiring the plan to be updated.

E. Water quality at any site used for **commercial** aquaculture shall meet the criteria for the approved, conditionally approved, restricted or conditionally restricted classification.

F. Shellfish cultured in any **commercial aquaculture** system meeting the criteria for the approved classification of a growing area throughout the culture period may be immediately marketed.

G. Any shellfish raised in **commercial** aquaculture shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:

(1) The closed status of the conditionally approved classification;
(2) The restricted classification; or
(3) The open status of the conditionally restricted classification.

H. Only drugs sanctioned by the FDA shall be used for shellfish treatment.

I. Harvesting, processing, storage, and shipping requirements for shellfish raised in **commercial** aquaculture shall be the same as the requirements for wild shellfish specified in Chapters V, VII, VIII, IX, X, XI, XII, XIII and XIV.

J. Complete and accurate records shall be maintained for at least two (2) years by the **commercial** aquaculturist and shall include the:

(1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved classification;
(2) Dates of transplanting and harvest; and
(3) Water source, its treatment method, if necessary, and its quality in land based systems.

.03 Seed Shellstock.

A. Seed may come from any growing area, or from any growing area in any classification, provided that:

(1) The source of the seed is sanctioned by the Authority.
(2) Seed from growing areas or growing areas in the restricted or prohibited classification have acceptable levels of poisonous or deleterious substances; and
(3) Seed from growing areas or growing areas in the prohibited classification are cultured for a minimum of 6 months.

.04 **Commercial** Open Water Aquaculture**.**

A. Any open water **commercial** aquaculture activity shall be in compliance when it meets the requirements of §**. 01,** §.02, and §.03, as appropriate.

.05 **Commercial** Land Based Aquaculture.

A. Operational Plan. Each land based aquaculture facility shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:

(1) A description of the design and activities of the culture facility;
(2) The specific site and boundaries in which shellfish culture activities will be conducted;

(3) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats which will be placed in the waters;
(4) The species of shellfish to be cultured and harvested;
(5) If appropriate, the source and species of other organisms to be cultured in any polyculture systems;
(6) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;
(7) A program of sanitation, maintenance, and supervision to prevent contamination of the final shellfish products;
(8) A description of the water source, including the details of any water treatment process or method, if necessary;
(9) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring. The bacterial indicator monitored shall be the same as used for monitoring growing areas;
(10) Collection of information on the microbial and chemical quality of shellfish harvested from the aquaculture site;
(11) Collection of data concerning the quality of food production (algae or other) used in the artificial harvest system;
(12) Maintenance of the required records; and
(13) How shellstock will be harvested, processed if applicable, and sold.

B. Water Systems.

(1) If the aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.
(2) Water used in land-based aquaculture incorporating a closed or recirculating system shall:
(a) Not contaminate shellfish with residues that are not Generally Recognized As Safe (GRAS);
(b) Come from a source meeting the restricted classification criteria at a minimum;
(c) Be maintained, at a minimum, at the bacteriological quality of the restricted classification; and
(d) Be measured at least five times per year.

(3) If the water in the closed or recirculating system meets the criteria for the conditionally approved classification, the operational plan, prior to shellstock harvest, shall require, at a minimum:
(a) Collection of three water samples from the tank at least three days apart over a 14 day period; and

(b) A fecal coliform of less than 14 MPN per 100 ml in each water sample from the holding tank.

C. Shellstock Quality.

(1) Shellstock cultured in any system meeting the criteria for the approved classification throughout the culture period may be used in direct marketing.
(2) If the water in a closed or recirculating system is classified as conditionally approved and in the open status, and if the water quality meets a fecal coliform level of less than 14 MPN per 100 ml in each sample collected in the 14 days prior to harvest, the shellstock may be used in direct marketing.
(3) Shellstock cultured in a closed or recirculating system which does not meet the requirements of §B.(1) or §B.(2) shall be relayed or depurated prior to direct marketing.

.06 **Commercial** Polyculture Systems.

A polyculture system shall:

A. Meet all requirements in §. 05 Land Based Systems;

B. Provide information concerning all sources of and species of all organisms to be cultivated, cultured, and harvested;

C. Include in its operational plan requirements to:

(1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious

substances that might be associated with polyculture activities; and

(2) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and

.07 Requirements for the Oyster/shellfish Gardener

A. Oyster/shellfish gardening shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the oyster/shellfish gardening activity.

B. Oyster/shellfish gardeners shall document that they understand the risks associated with consumption for shellfish grown from docks or private piers.

Oyster/shellfish gardeners shall keep accurate records on the fate or final destination of all oysters grown at their oyster garden site and provide these records to the Authority upon request

Action by 2005 Task Force II Proposal 05-221 was referred to Task Force I.

Action by 2005 Task Force I Recommended referral of Proposal 05-221 to an appropriate committee as determined by the Conference Chairman. Task Force I recommended consideration by the Growing Area Classification Committee, the Restoration Committee, and the Patrol Committee.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force I.

Action by USFDA Concurred with Conference action.

Action by 2007 Growing Area, Shellfish Restoration, and Patrol Committees Recommended adoption of Proposal 05-221 as substituted.

PROPOSED ADDITION TO DEFINITIONS OF 2005 ISSC

Model Ordinance
B. Definition of Terms
( ) Float aquaculture means open water aquaculture where the shellfish product is suspended at the water surface using floats.

"Shellfish Gardening (Non-commercial shellfish culture), to be generally distinguished from traditional shellfish culture, and be characterized by, though not limited, in definition, by the use of off-bottom culture / infrastructure, including; but not limited to suspension floats, and/or bags, and/or the use of docks, piers, and/or other rigid structures, to facilitate said culture – generally, though not limited to the purposes of enhancing water quality, or enhancing natural stocks and not for sale for consumption."

PROPOSED CHANGES TO CHAPTER VI. 2005 ISSC

Model Ordinance
VI. Shellfish Aquaculture
Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@.01 General.

A. The Authority ~~shall recognize~~may distinguish between two types of aquaculture:

(1) Commercial – product cultivated for direct marketing.

(2) ~~Oyster/s~~Shellfish gardening – product cultivated to enhance water

quality, ~~or for~~ or to improve shellfish resources, ~~owners own consumption~~ and not for sale for consumption~~direct marketing~~.

B. The Authority shall maintain the following records while the aquaculture activity continues:
(1) Construction and remodeling plans for any permitted aquaculture facility;
(2) **Aquaculture** operational plans; and
(3) Aquaculture permits.

C. The Authority shall inspect **~~commercial~~** aquaculture systems at least every six months.

@.02 Seed Shellstock.

A. The Authority shall establish the submarket size for each species of shellfish in accordance with §.01B.and §.01C.

B. All sources of seed shall be sanctioned by the Authority.

@.03 ~~Commercial~~ Open Water and Land Based Aquaculture

A. Inspection. The Authority shall inspect land-based **and float aquaculture** sites at least every six months.

B. The Authority shall approve the written operational plan for any land based **or float** aquaculture facility prior to its implementation. **~~aquaculture activities in areas that do not meet restricted, conditionally restricted, conditionally approved, or approved classification. commercialC. The Authority may not permit float aquaculture site, with special consideration of potential intermittent sources of pollution;~~**
~~(2) The location of float; and~~
~~(3) The examination of the construction of shellstock containers to ensure the free flow of water to all shellstock. commercial float aquaculture sites, where the floats are attached to or near piers shall be inspected at least every year. This site evaluation by the Authority shall include:~~
~~(1) The survey of the Commercial D.~~

@.04 ~~Oyster/s~~Shellfish Gardening

A. The Authority shall permit or register ~~oyster/~~shellfish gardening activities.

B. The Authority shall establish permit or registration conditions and determine classification of waters where ~~oyster/~~shellfish gardening can take place prior to its implementation.

C. The Authority shall provide information to the ~~oyster/~~shellfish gardener on the risk of consuming shellfish from private docks, piers, and ~~oyster~~shellfish floats attached to piers or docks and from waters not classified and open to harvest for direct consumption.

D. The Authority shall require that the ~~oyster/~~shellfish gardener maintain records on the disposition of the shellfish product and provide these records to the Authority.

E. The authority may not permit new shellfish gardening activities in areas that do not meet restricted, conditionally restricted, conditionally

approved or approved classification.

Requirements for the Harvester/Dealer

.01 Exceptions. The following activities are exempted from these requirements:

A. Hatcheries;
B. Nursery products which do not exceed 10 percent of the market weight; and
C. Nursery products which are 6 months or more growing time from market size.

.02 General.

A. ~~**Commercial**~~ **aquaculture** encompasses both monoculture and polyculture.
B. Any person who performs ~~**commercial**~~ aquaculture or operates an aquaculture facility to raise shellfish for human consumption shall obtain:

(1) A permit from the Authority for the activity or for construction and functioning of his facility;
(2) A harvester's license; and
(3) Certification as a dealer, where necessary.

C. Shellfish aquaculture shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the aquaculturist's written operational plan.

D. Prior to beginning his activity, an aquaculturist shall obtain the permission of the Authority for use of his site and ~~**submit the following to the Authority for review and approval in accordance with @.01:**~~

~~**1. Prior to beginning any activity, a detailed construction and operational plan describing the new facility location and activity.**~~

~~**2. For an existing permitted facility, a detailed construction plan describing the proposed remodeling, modifications, or otherwise permanent alteration of the facility prior to any work commencing.**~~

~~**3. An updated operational plan on an annual basis or whenever operational procedures change requiring the plan to be updated.**~~

E. Water quality at any site used for ~~**commercial**~~ aquaculture shall meet the criteria for the approved, conditionally approved, restricted or conditionally restricted classification.

F. Shellfish cultured in any ~~**commercial**~~ **aquaculture** system meeting the criteria for the approved classification of a growing area throughout the culture period may be immediately marketed.

G. Any shellfish raised in ~~**commercial**~~ aquaculture shall be subjected to relaying or depuration prior todirect marketing if the culture area or facility is located in or using water which is in:

(1) The closed status of the conditionally approved classification;
(2) The restricted classification; or
(3) The open status of the conditionally restricted classification.

H. Only drugs sanctioned by the FDA shall be used for shellfish treatment.

I. Harvesting, processing, storage, and shipping requirements for shellfish raised in

~~commercial~~ aquaculture shall be the same as the requirements for wild shellfish specified in Chapters V, VII, VIII, IX, X, XI, XII, XIII and XIV.

J. Complete and accurate records shall be maintained for at least two (2) years by the ~~commercial~~ aquaculturist and shall include the:

(1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved classification;
(2) Dates of transplanting and harvest; and
(3) Water source, its treatment method, if necessary, and its quality in land based systems.

.03 Seed Shellstock.

A. Seed may come from any growing area, or from any growing area in any classification, provided that:
(1) The source of the seed is sanctioned by the Authority.
(2) Seed from growing areas or growing areas in the restricted or prohibited classification have acceptable levels of poisonous or deleterious substances; and
(3) Seed from growing areas or growing areas in the prohibited classification are cultured for a minimum of 6 months.

.04 ~~Commercial~~ Open Water Aquaculture**.**

A. Any open water ~~commercial~~ aquaculture activity shall be in compliance when it meets the requirements of §**. 01,** §.02, and §.03, as appropriate.

.05 ~~Commercial~~ Land Based Aquaculture.

A. Operational Plan. Each land based aquaculture facility shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:
(1) A description of the design and activities of the culture facility;
(2) The specific site and boundaries in which shellfish culture activities will be conducted;
(3) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats which will be placed in the waters;
(4) The species of shellfish to be cultured and harvested;
(5) If appropriate, the source and species of other organisms to be cultured in any polyculture systems;
(6) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;
(7) A program of sanitation, maintenance, and supervision to prevent contamination of the final shellfish products;
(8) A description of the water source, including the details of any water treatment process or method, if necessary;
(9) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring. The bacterial indicator monitored shall be the same as used for monitoring growing areas;
(10) Collection of information on the microbial and chemical quality of shellfish harvested from the aquaculture site;
(11) Collection of data concerning the quality of food production (algae or other) used in the artificial harvest system;
(12) Maintenance of the required records; and
(13) How shellstock will be harvested, processed if applicable, and sold.

B. Water Systems.

(1) If the aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.

(2) Water used in land-based aquaculture incorporating a closed or recirculating system shall:

(a) Not contaminate shellfish with residues that are not Generally Recognized As Safe (GRAS);

(b) Come from a source meeting the restricted classification criteria at a minimum;

(c) Be maintained, at a minimum, at the bacteriological quality of the restricted classification; and

(d) Be measured at least five times per year.

(3) If the water in the closed or recirculating system meets the criteria for the conditionally approved classification, the operational plan, prior to shellstock harvest, shall require, at a minimum:

(a) Collection of three water samples from the tank at least three days apart over a 14 day period; and

(b) A fecal coliform of less than 14 MPN per 100 ml in each water sample from the holding tank.

C. Shellstock Quality.

(1) Shellstock cultured in any system meeting the criteria for the approved classification throughout the culture period may be used in direct marketing.

(2) If the water in a closed or recirculating system is classified as conditionally approved and in the open status, and if the water quality meets a fecal coliform level of less than 14 MPN per 100 ml in each sample collected in the 14 days prior to harvest, the shellstock may be used in direct marketing.

(3) Shellstock cultured in a closed or recirculating system which does not meet the requirements of §B.(1) or §B.(2) shall be relayed or depurated prior to direct marketing.

.06 ~~**Commercial**~~ Polyculture Systems.

A polyculture system shall:

A. Meet all requirements in §. 05 Land Based Systems;

B. Provide information concerning all sources of and species of all organisms to be cultivated, cultured, and harvested;

C. Include in its operational plan requirements to:

(1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and

(2) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and

.07 Requirements for the ~~Oyster/s~~Shellfish Gardener

A. ~~Oyster/s~~Shellfish gardening shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the oyster/shellfish gardening activity.

B. ~~Oyster/s~~Shellfish gardeners shall document that they understand the risks

associated with consumption for shellfish grown from docks or private piers.

~~Oyster/s~~Shellfish gardeners shall keep accurate records on the fate or final destination of all ~~oysters~~shellfish grown at their ~~oyster~~shellfish garden site and provide these records to the Authority upon request.

Action by 2007 Task Force II

Recommended adoption of Growing Area Classification Committee, Shellfish Restoration Committee, and Patrol Committee recommendations on Proposal 05-221, as amended.

PROPOSED ADDITION TO DEFINITIONS OF 2005 ISSC

Model Ordinance

B. Definition of Terms

Float aquaculture means open water aquaculture where the shellfish product is suspended at the water surface using floats.

~~"Shellfish Gardening (Non-commercial shellfish culture), to be generally distinguished from traditional shellfish culture, and be characterized by, though not limited, in definition, by the use of off-bottom culture / infrastructure, including; but not limited to suspension floats, and/or bags, and/or the use of docks, piers, and/or other rigid structures, to facilitate said culture -- generally, though not limited to the purposes of enhancing water quality, or enhancing natural stocks and not for sale for consumption."~~

Shellfish gardening is non-commercial shellfish culture for the purposes of enhancing water quality, or enhancing natural stocks and not for sale for consumption.

PROPOSED CHANGES TO CHAPTER VI. 2005 ISSC

Model Ordinance Chapter VI. Shellfish Aquaculture

Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this
section in regulation.]

@.01 General.

A. The Authority may distinguish between two types of aquaculture:
   (1) Commercial – product cultivated for direct marketing.
   (2) Shellfish gardening – product cultivated to enhance water quality, or to improve shellfish resources, and not for sale for consumption.

B. The Authority shall maintain the following records while the aquaculture activity continues:
   (1) Construction and remodeling plans for any permitted aquaculture facility;
   (2) Aquaculture operational plans; and
   (3) Aquaculture permits.

C. The Authority shall inspect **commercial** aquaculture systems at least every six months.

@.02 Seed Shellstock.

A. The Authority shall establish the submarket size for each species of shellfish in

accordance with §.01B. and §.01C.

B. All sources of seed shall be sanctioned by the Authority.

@.03 Open Water and Land Based Aquaculture

A. Inspection. The Authority shall inspect land-based and float aquaculture sites at least every six months.

B. The Authority shall approve the written operational plan for any land based or float aquaculture facility prior to its implementation.

@.04 Shellfish Gardening

If a state recognizes shellfish gardening the Authority

A. ~~The Authority~~ shall permit or register shellfish gardening activities.

B. ~~The Authority~~ shall establish permit or registration conditions and determine classification of waters where shellfish gardening can take place prior to its implementation.

C. ~~The Authority~~ shall provide information to the shellfish gardener on the risk of consuming shellfish from private docks, piers, and shellfish floats attached to piers or docks and from waters not classified and open to harvest for direct consumption.

D. ~~The Authority shall~~ **may** require that the shellfish gardener maintain records on the disposition of the shellfish product and provide these records to the Authority.

~~E. The authority may not permit new shellfish gardening activities in areas that do not meet restricted, conditionally restricted, conditionally approved or approved classification.~~

Requirements for the Harvester/Dealer

.01 Exceptions. The following activities are exempted from these requirements:

A. Hatcheries;
B. Nursery products which do not exceed 10 percent of the market weight; and
C. Nursery products which are 6 months or more growing time from market size.

.02 General.

A. Aquaculture encompasses both monoculture and polyculture.

B. Any person who performs aquaculture or operates an aquaculture facility to raise shellfish for human consumption shall obtain:

(1) A permit from the Authority for the activity or for construction and functioning of his facility;
(2) A harvester's license; and
(3) Certification as a dealer, where necessary.

C. Shellfish aquaculture shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the aquaculturist's written operational plan.

D. Prior to beginning his activity, an aquaculturist shall obtain the permission of the Authority for use of his site and

E. Water quality at any site used for aquaculture shall meet the criteria for the approved, conditionally approved, restricted or conditionally restricted classification.

F. Shellfish cultured in any **aquaculture** system meeting the criteria for the approved classification of a growing area throughout the culture period may be immediately marketed.

G. Any shellfish raised in aquaculture shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:
(1) The closed status of the conditionally approved classification;
(2) The restricted classification; or
(3) The open status of the conditionally restricted classification.

H. Only drugs sanctioned by the FDA shall be used for shellfish treatment.

I. Harvesting, processing, storage, and shipping requirements for shellfish raised in aquaculture shall be the same as the requirements for wild shellfish specified in Chapters V, VII, VIII, IX, X, XI, XII, XIII and XIV.

J. Complete and accurate records shall be maintained for at least two (2) years by the aquaculturist and shall include the:
(1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved classification;
(2) Dates of transplanting and harvest; and
(3) Water source, its treatment method, if necessary, and its quality in land based systems.

.03 Seed Shellstock.

A. Seed may come from any growing area, or from any growing area in any classification, provided that:
(1) The source of the seed is sanctioned by the Authority.
(2) Seed from growing areas or growing areas in the restricted or prohibited classification have acceptable levels of poisonous or deleterious substances; and
(3) Seed from growing areas or growing areas in the prohibited classification are cultured for a minimum of 6 months.

.04 Open Water Aquaculture**.**

A. Any open water aquaculture activity shall be in compliance when it meets the requirements of §. 01, §.02, and §.03, as appropriate.

.05 Land Based Aquaculture.

A. Operational Plan. Each land based aquaculture facility shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:
(1) A description of the design and activities of the culture facility;
(2) The specific site and boundaries in which shellfish culture activities will be conducted;
(3) The types and locations of any structures, including rafts, pens, cages,

nets, tanks, ponds, or floats which will be placed in the waters;

(4) The species of shellfish to be cultured and harvested;

(5) If appropriate, the source and species of other organisms to be cultured in any polyculture systems;

(6) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;

(7) A program of sanitation, maintenance, and supervision to prevent contamination of the final shellfish products;

(8) A description of the water source, including the details of any water treatment process or method, if necessary;

(9) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring. The bacterial indicator monitored shall be the same as used for monitoring growing areas;

(10) Collection of information on the microbial and chemical quality of shellfish harvested from the aquaculture site;

(11) Collection of data concerning the quality of food production (algae or other) used in the artificial harvest system;

(12) Maintenance of the required records; and

(13) How shellstock will be harvested, processed if applicable, and sold.

B. Water Systems.

(1) If the aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.

(2) Water used in land-based aquaculture incorporating a closed or recirculating system shall:

(a) Not contaminate shellfish with residues that are not Generally Recognized As Safe (GRAS);

(b) Come from a source meeting the restricted classification criteria at a minimum;

(c) Be maintained, at a minimum, at the bacteriological quality of the restricted classification; and

(d) Be measured at least five times per year.

(3) If the water in the closed or recirculating system meets the criteria for the conditionally approved classification, the operational plan, prior to shellstock harvest, shall require, at a minimum:

(a) Collection of three water samples from the tank at least three days apart over a 14 day period; and

(b) A fecal coliform of less than 14 MPN per 100 ml in each water sample from the holding tank.

C. Shellstock Quality.

(1) Shellstock cultured in any system meeting the criteria for the approved classification throughout the culture period may be used in direct marketing.

(2) If the water in a closed or recirculating system is classified as conditionally approved and in the open status, and if the water quality meets a fecal coliform level of less than 14 MPN per 100 ml in each sample collected in the 14 days prior to harvest, the shellstock may be used in direct marketing.

(3) Shellstock cultured in a closed or recirculating system which does not meet the requirements of §B.(1) or §B.(2) shall be relayed or depurated prior to direct marketing.

.06 Polyculture Systems.

A polyculture system shall:

A. Meet all requirements in §. 05 Land Based Systems;
B. Provide information concerning all sources of and species of all organisms to be cultivated, cultured, and harvested;
C. Include in its operational plan requirements to:
   (1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and
   (2) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and

.07 Requirements for the Shellfish Gardener

A. Shellfish gardening shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the oyster/shellfish gardening activity.
B. Shellfish gardeners shall document that they understand the risks associated with consumption for shellfish grown from docks or private piers.

   If required by the Authority, ~~S~~shellfish gardeners shall keep accurate records on the fate or final destination of all shellfish grown at their shellfish garden site and provide these records to the Authority upon request.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force II.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject Harvester Sanitation Requirements

Specific NSSP Guide Reference NSSP Guide Model Ordinance Chapter VIII.
02. Shellstock Harvesting and Handling.

Text of Proposal/ Requested Action Between Sections 02. A. Harvesters and 02. B. Vessels add a new section 02.B. Harvester Sanitation Requirements:

B. Harvester Sanitation Requirements.
(1) Harvesters shall institute practices to protect shellfish from contamination during harvest and transport due to:
(a) animals;
(b) birds;
(c) oil products;
(d) chemicals, including pesticides;
(e) unsafe water;
(f) soiled containers;
(g) fecal material;
(h) poor personal hygiene; and
(i) other environmental contaminants.

~~B.~~ **C.** Vessels.
~~C.~~ **D.** Disposal of Human Sewage from Vessels.
~~D.~~ **E.** Shellstock Washing.
~~E.~~ **F.** Shellstock Identification

Public Health Significance Chapter X.02 General Sanitation Requirements includes requirements for shellfish dealers to assure the safety of the water supply that will contact food or food contact surfaces, including ice; the condition and cleanliness of food contact surfaces, utensils and outer garments; the prevention of cross contamination from unsanitary objects or raw products to finished product; the protection of food, packaging material and food contact surfaces from adulteration; the maintenance of hand washing, hand sanitizing and toilet facilities; the proper labeling, storage and use of toxic compounds; the control of employee health conditions that could result in microbiological contamination; and the exclusion of pests from the food plant.

Chapter VIII.02.B. Vessels, currently includes similar general sanitary controls focused only on vessels. Chapter IX.01, Trucks or other Vehicles Used to transport Shellstock to the Original Dealer, and IX.04, Cargo Protection From Cross Contamination, provides similar general sanitary controls for harvesters who utilize vehicles. In order to maintain safe and wholesome products, shellfish must also be protected from unnecessary adulteration during harvesting activities as well as during transport by either a vessel or vehicle.

This new section in Chapter VIII lists potential sources of contamination that harvesters need to address during harvesting activities, which are similar to the current sanitation requirements for dealers.

Cost Information (if available) N/A

Action by 2005 Task Force II Recommended referral of Proposal 05-222 to appropriate Committee as determined by the Conference Chairman.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Harvester Sanitation Committee

Recommended that this proposal be substituted with new language that makes the distinction between "non-vessel" and "vessel" harvesting and handling concerns by inserting language that identifies this difference and provides for the same protective language as for "vessels" that the Authority can further interpret with guidance and compliance. This can be accomplished by creating a new section in Chapter VIII. .02

B. <u>Non-Vessel Harvesting</u>

<u>Harvesters shall assure shellstock are harvested, handled, and transported to prevent contamination, deterioration, and decomposition.</u>

Action by 2007 Task Force II

Recommended adoption of Proposal 05-222 as recommended by the Harvester Sanitation Committee.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007
Concurred with Conference action.

Proposal Subject Containers for Waste Disposal

Specific NSSP Guide Reference NSSP Model Ordinance Chapter VIII Control of Shellfish Harvesting, .02 Shellfish Harvesting and Handling, C. Disposal of Human Sewage from Vessels

Text of Proposal/ Requested Action

C. Disposal of Human Sewage from Vessels.

(1) Human sewage shall not be discharged overboard from a vessel used in the harvesting of shellstock, or from vessels which buy shellstock while the vessels are in growing areas.

(2) The Authority shall educate all licensed harvesters and shellstock dealers concerning the public health significance of discharging human sewage overboard.

~~(3) An approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.~~

(~~4~~**3**) **When provided,** ~~Portable~~ **portable** toilets shall:

(a) Be used only for the purpose intended;

(b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage;

(c) Be emptied only into a sewage disposal system;

(d) Be cleaned before being returned to the boat; and

(e) Not be cleaned in equipment used for washing or processing food.

(~~5~~**4**) ~~Use of other~~**Other** receptacles for sewage disposal may be ~~approved by the Authority~~ **used** if the receptacles are:

(a) Constructed of impervious, cleanable materials and have tight fitting lids; and

(b) Meet the requirements in §C.(~~4~~**3**).

Public Health Significance Vessel size and design differences can be considerable. What may be appropriate for outfitting vessels often varies substantially between harvest regions. Additionally, travel time and distance from shore facilities varies substantially from growing area to growing area. Mandating the provision of waste receptacles on all vessels is unrealistic (what type of receptacle is appropriate for use on kayaks?). Past legislative mandates were a foundation for pubic dissatisfaction and dissention and have resulted in guidance document and regulation amendment**.** Aggressive harvester education and encouragement of the use (where appropriate) of certified marine sanitation devices or other receptacles, combined with enforcement of existing prohibitions on discharge of human waste into harvest areas, will adequately address this perceived problem.

Cost Information (if available) N/A

Action by 2005 Task Force II Recommended referral of Proposal 05-223 to appropriate Committee as determined by the Conference Chairman with instruction to obtain input from patrol.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Harvester Sanitation and Patrol Committees Recommended adoption of Proposal 05-223 as amended.

C. Disposal of Human Sewage from Vessels.

(1) Human sewage shall not be discharged overboard from a vessel used in the harvesting of shellstock, or from vessels which buy shellstock while the vessels are in growing areas.

(2) The Authority shall educate all licensed harvesters and shellstock dealers concerning the public health significance of discharging human sewage

overboard.

(3) **As required by the Authority,** an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.

(4) Portable toilets shall:
   (a) Be used only for the purpose intended;
   (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage;
   (c) Be emptied only into a sewage disposal system;
   (d) Be cleaned before being returned to the boat; and
   (e) Not be cleaned in equipment used for washing or processing food.

(5) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are:
   (a) Constructed of impervious, cleanable materials and have tight fitting lids; and
   (b) Meet the requirements in §C. (3).

Action by 2007 Task Force II

Recommended adoption of Harvester Sanitation Committee recommendation of Proposal 05-223 as amended.

C. Disposal of Human Sewage from Vessels.

(1) Human sewage shall not be discharged overboard from a vessel used in the harvesting of shellstock, or from vessels which buy shellstock while the vessels are in growing areas.

(2) The Authority shall educate all licensed harvesters and shellstock dealers concerning the public health significance of discharging human sewage overboard.

(3) As required by the Authority, **in consultation with FDA,** an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.

(4) Portable toilets shall:
   (a) Be used only for the purpose intended;
   (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage;
   (c) Be emptied only into a sewage disposal system;
   (d) Be cleaned before being returned to the boat; and
   (e) Not be cleaned in equipment used for washing or processing food.

(5) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are:
   (a) Constructed of impervious, cleanable materials and have tight fitting lids; and
   (b) Meet the requirements in §C. (3).

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II

Action by USFDA

December 20, 2007
Concurred with Conference action.

Proposal Subject	Freight Forwarding
Specific NSSP Guide Reference	Model Ordinance Chapter IX. Transportation
Text of Proposal/ Requested Action	There are numerous freight forwarding operations in which shellstock is transferred or stored by a third party that is not a dealer, owner or consignee. There is little time/temperature control and no records to monitor the time/temperature to ensure that the product meets the NSSP. These operations do not own the product and in effect may store it for short or long periods of time with our without adequate refrigeration. These operations shall now be licensed and required to maintain only those records that reflect the time/temperature parameters in the NSSP and appropriate SSOP records that apply to a particular facility.
Public Health Significance	The results of time/temperature abuse may result in significant growth of pathogens.
Cost Information (if available)	None
Action by 2005 Task Force II	Recommended referral of Proposal 05-224 to appropriate Committee as determined by the Conference Chairman.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force II.
Action by USFDA	Concurred with Conference action.
Action by 2007 Time/Temperature Committee	Recommended no action on Proposal 05-224. Rationale - Outside the jurisdiction of ISSC.
Action by 2007 Task Force II	Recommended adoption of Committee's recommendation of no action on Proposal 05-224.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject Plant Sanitation

Specific NSSP Guide Reference Model Ordinance Chapters XI., XII., XIII., XIV., and XV.
Sections .03 Other Model Ordinance Requirements

Text of Proposal/ Requested Action Eliminate specific references to deficiencies found in the sections entitled "Other Model Ordinance Requirements" already covered in other sections of the 2003 NSSP Guide for the Control of Molluscan Shellfish.

The following references need to be deleted from Model Ordinance Chapters XI., XII., XIII., XIV., and XV. Of the 2003 NSSP Guide:

.03 A. (6) (c) and (d)	Covered in .02 C. Sanitation Requirements (SSOP)
.03 A. (7)	Covered in .02 H. Pest Control Program
.03 B. (1) and (2)	Covered in .02 D. SSOP
.03 B. (4)	Covered in .02 A. Sanitation Requirements (SSOP)
.03 D. and E.	Covered in .02 H. Pest Control
.03 F. and G.	Not a food safety issue and covered in SSOP
.03 J.	Plant Sanitation Program

Public Health Significance All of these deficiencies are covered through the HACCP and sanitation requirements already in place as well as in other sections of the 2003 NSSP Guide.

In addition, elimination of these deficiencies will help the State Health Authorities to better focus on the Critical Control Points and Sanitation requirements of the NSSP Model Ordinance.

Eliminating the above mentioned deficiencies contained in the sections entitled "Other Model Ordinance Requirements" located in sections entitled "Requirements for Dealers" of the 2003 NSSP Guide will not lessen public health protection.

Cost Information (if available) Significant cost savings could be realized by states not spending the time and effort to: (1) cite deficiencies; (2) to establish corrective action schedules; and (3) to follow up on deficiencies already covered through HACCP and sanitation requirements already in place and other sections of the 2003 NSSP Guide. Similar cost savings could be also realized by industry.

Action by 2005 Task Force II Recommended referral of Proposal 05-225 to appropriate Committee as determined by the Conference Chairman, with a recommendation that a workgroup be established to address this proposal in advance of the 2007 Biennial Meeting.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Plant Sanitation Committee Recommended no action on Proposal 05-225. Rationale - This proposal is adequately addressed by action on Proposals 05-210, 05-216, 05-218, and 05-220.

Action by 2007 Task Force II Recommended adoption of the Plant Sanitation Committee recommendation on Proposal 05-225.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force II.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject *Vibrio vulnificus* Risk Management Plan

Specific NSSP Guide Reference Model Ordinance Chapter II. Risk Assessment and Risk Management @ .04 Vibrio vulnificus Risk Management for Oysters

Text of Proposal/ Requested Action Modify Chapter II. @ .04 B. as follows:

B. The Source State's *Vibrio vulnificus* management plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction **and maintenance** program. The goal of the *Vibrio vulnificus* Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, Texas, from the consumption of commercially harvested raw or undercooked oysters by 40 percent, for years 2005 and 2006 (average) and by 60 percent for years 2007 and 2008 (average) from the average illness rate for the years 1995 -1999 of 0.306/million. The list of states (California, Florida, Louisiana, Texas) used to calculate rate reduction may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The illness rate shall be calculated as the number of illnesses per unit of population. The goal may be reevaluated prior to the year 2006 and adjusted in the event that new science, data, or information becomes available. **States' compliance with the Plan will require States to maintain a minimum of 60% reduction in years subsequent to 2008. Determination and compliance after 2008 will be based on two-year averages beginning in 2009.**

Public Health Significance: The illness reduction goals required of states implementing the Vibrio vulnificus Risk Management Plan, as adopted by the ISSC in 2001, should be maintained in years following 2008.

Cost Information (if available): Unavailable.

Action by 2005 Task Force II Recommended referral of Proposal 05-226 to appropriate committee as determined by the Conference Chairman.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.

Action by 2007 Vibrio Management Committee Recommended adoption of Proposal 05-226 as submitted.

Action by 2007 Task Force II Recommended adoption of Proposal 05-226 as amended by Task Force II.

Modify Chapter II. @ .04 B. as follows:

B. The Source State's *Vibrio vulnificus* management plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction ~~**and maintenance**~~ program. The goal of the *Vibrio vulnificus* Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, Texas, from the consumption of commercially harvested raw or undercooked oysters by 40 percent, for years 2005 and 2006 (average) and by 60 percent for years 2007 and 2008 (average) from the average

illness rate for the years 1995 -1999 of 0.306/million. The list of states (California, Florida, Louisiana, Texas) used to calculate rate reduction may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The illness rate shall be calculated as the number of illnesses per unit of population. The goal may be reevaluated prior to the year 2006 and adjusted in the event that new science, data, or information becomes available. States' compliance with the Plan will require States to maintain a minimum of 60% reduction in years subsequent to 2008. Determination and compliance after 2008 will be based on two-year averages beginning in 2009.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force II.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject	Labeling of Shucked Shellfish
Specific NSSP Guide Reference:	Model Ordinance Chapter XIV. Reshipping .03 Other Model Ordinance Requirements H. (1) (b)
Text of Proposal/ Requested Action	~~(b) Add his name and certification number to the package.~~
Public Health Significance:	Compliance with this requirement is difficult, if not impossible. To achieve compliance, it may be necessary to improperly handle or temperature abuse the shucked shellfish.
Cost Information (if available):	No cost impact.
Action by 2005 Task Force II	Recommended referral of Proposal 05-227 to appropriate committee as determined by the Conference Chairman.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force II.
Action by USFDA	Concurred with Conference action.
Action by 2007 Traceability Committee	Recommended adoption of Proposal 05-227 as amended. Add the following language to Chapter XIV at .03 H. (1) (b) Add his name and certification number to the package **of shellstock**..
Action by 2007 Task Force II	Recommended adoption of Traceability Committee recommendation on Proposal 05-227.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject Requirements to Conduct Product Recall

Specific NSSP Guide Reference NSSP Model Ordinance Chapter II. Risk Assessment and Risk Management
@.02 Presence of Human Pathogens in Shellfish Meats

Text of Proposal/ Requested Action

B. Growing Area Investigation
(1) The Authority shall…
(2) The Authority shall …
(3) When the Authority determines that the growing area is not properly classified **or that the growing area may be the source of the pathogens** the Authority shall take immediate action to:
(a) Change the existing classification to the correct classifications; or
(b) Close the growing area until the correct classification can be determined~~.~~**; and**
(c) Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulations Part 7.
(4) When the Authority determines that illegal harvesting is taking place, the Authority shall promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7 for all shellfish that may be falsely represented.

C. Distribution and Processing
(1) The Authority shall …
(2) The Authority shall …
(3) When the Authority determines that a problem exists in the distribution or processing of the shellfish, the Authority shall take immediate steps to correct the problem **and promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulation Part 7**.

Public Health Significance The Model Ordinance is not clear regarding the disposition of shellfish that have been harvested and then found positive for the presence of human pathogens. Failure to initiate recall procedures when human pathogens are known to be present in shellfish meats is inconsistent with the conservative public health approach of the NSSP and jeopardizes consumer health. Furthermore, while the Model Ordinance addresses a finding of no illegal harvesting (@.02 B. (2)), it is silent regarding what happens when illegal harvesting is determined. Adoption of the proposed language clarifies what action is to be taken when human pathogens are found present in shellfish meats.

Cost Information (if available) N/A

Action by 2007 Task Force II Recommended referral of Proposal 07-200 to an appropriate committee as determined by the Conference Chairman.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force II.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject Annual *Vp* Illness Data Reporting by States

Specific NSSP Guide Reference Model Ordinance Chapter II. Risk Assessment and Risk Management
@.01 Outbreaks of Shellfish-Related Illnesses

Text of Proposal/ Requested Action

It is currently a requirement that states self report *Vp* illnesses to the Conference annually. It was pointed out that at the time this requirement was adopted; *Vp* was only reportable by a few states. Now that the Conference of State and Territorial Epidemiologists (CSTE) has recommended that all states report Vibrio illnesses, conditions have changed such that it would be a redundant effort to have both CDC and the ISSC collect this information and maintain two databases.

The ISSC met with FDA and CDC and all parties have agreed to share information to accommodate ISSC needs. The ISSC Executive Board decided at its meeting in March of 2007 not to collect 2006 *Vp* illness data as required in Model Ordinance Chapter II. The Executive Board is also recommending deleting state reporting requirements from Chapter II.

J. The Authority shall assess annually *Vibrio 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 and 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~~.

Public Health Significance

Cost Information (if available)

Action by 2007 Task Force II Recommended adoption of Proposal 07-201 as submitted.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force II.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject *Vibrio parahaemolyticus (Vp)* Control Plan

Specific NSSP Guide Reference Model Ordinance Chapter II. Risk Assessment and Risk Management
Add New @ .05 *Vibrio parahaemolyticus (Vp)* Control Plan

Text of Proposal/ Requested Action

@ .05 *Vibrio parahaemolyticus* Control Plan.

The goal of the Control Plan is to reduce the likelihood of occurrence of *Vibrio parahaemolyticus* illness during periods that have been historically associated with predictable annual illnesses. The Plan is to be implemented as part of a comprehensive program which includes all the time and temperature requirements contained in the Model Ordinance.

A. Risk Evaluation.

Every State from which oysters are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this sections reasonably likely to occur shall mean that the risk constitutes a predictable annual occurrence)

(1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters harvested from the State to the area from which they are harvested; and

(2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and

(3) The water temperatures in the area; and

(4) The air temperatures in the area; and

(5) Salinity in the area; and

(6) Harvesting techniques in the area; and

(7) The quantity of harvest from the area and its uses i.e. shucking, halfshell, PHP.

B. Control Plan

(1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for that area.

(2) If a State has a shellfish growing area that is in approved or conditionally approved status at a time when average monthly daytime water temperatures* exceed those listed in (a), the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.

(a) The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:

(i) Waters bordering the Pacific Ocean 61°F*

(ii) Waters bordering the Gulf of Mexico 81°F*

(iii) Waters bordering the Atlantic Ocean 81°F*

(b) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.

(i) In conducting the evaluation, the State shall evaluate the factors listed in A. for the area during periods when the temperatures exceed those listed in B. (2) (a);

(ii) In concluding that the risk is not reasonably likely to

occur, the State shall consider how the factors listed in B. (2) (a) differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; and

(c) If a State has a shellfish growing area that was the source of oysters that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.

(3) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:

(a) Implement measures to reduce the risk of *Vibrio parahaemolyticus* illness, under the circumstances determined by A. and B. (2) and (3). The measures may include:

(i) Post harvest processing using a process that has been validated to ensure that levels of total *Vibrio parahaemolyticus* after processing do not exceed the average levels found in the area at times of the year when the State has determined that *Vibrio parahaemolyticus* illness is not reasonably likely to occur;

(ii) Closure of the area to oyster harvest;

(iii) Restricting oyster harvest to product that is labeled "For Cooking Only;"

(iv) Other measures (e.g., reduction in time from harvest to refrigeration) that based on appropriate scientific studies, are designed to ensure that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F do not exceed the average levels from the harvest water by more than 0.5 logarithms.

(v) Other measures that based on appropriate scientific studies, are designed to ensure that the risk of *Vibrio parahaemolyticus* illness is no longer reasonably likely to occur (e.g., sampling, based on a statistically valid sampling plan, that demonstrates the absence of tdh+ *Vibrio parahaemolyticus* in the shellfish growing area)

(b) When measures provided in B. (3) (a) (iv) are included in a State's *Vibrio parahaemolyticus* Control Plan, the State shall annually demonstrate the effectiveness of the Plan for each area under the circumstances determined by A. and B. (2) and (3), to ensure that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F do not exceed the average levels from the harvest water by more than 0.5 logarithms. Alternatively, the State may require that individual dealers perform such verification.

(c) Modify the Control Plan when verification shows the Plan is ineffective.

*** Further analysis is necessary to finalize these temperatures and definition is required for Average Water Temperature (e.g., tide status, source of data, time of day).**

Public Health Significance

Cost Information (if available)

Action by 2007 Vibrio Management Committee

@ .05 *Vibrio parahaemolyticus* Control Plan.

The goal of the Control Plan is to reduce the probability ~~likelihood~~ of occurrence of *Vibrio parahaemolyticus* illness during periods that have been historically associated with ~~predictable~~ annual illnesses. The Plan is to be implemented as part of a comprehensive program which includes all the time and temperature requirements contained in the Model Ordinance.

A. Risk Evaluation.

Every State from which oysters are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, ~~s~~ "reasonably likely to occur" shall mean that the risk constitutes an ~~predictable~~ annual occurrence)

(1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters commercially harvested from the State. ~~to the area from which they are harvested~~; and

(2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and

(3) The water temperatures in the area; and

(4) The air temperatures in the area; and

(5) Salinity in the area; and

(6) Harvesting techniques in the area; and

(7) The quantity of harvest from the area and its uses i.e. shucking, halfshell, PHP.

B. Control Plan

(3) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan ~~for that area~~.

(4) If a State has a shellfish growing area ~~that is in approved or conditionally approved status~~in which harvesting occurs ~~that is in approved or conditionally approved status~~ at a time when average monthly daytime water temperatures* exceed those listed ~~in (a~~below~~)~~, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan ~~for the area~~.

~~(a)~~ The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:

(i) Waters bordering the Pacific Ocean ~~61~~60°F*

(ii) Waters bordering the Gulf of Mexico and Atlantic Ocean (SC and south) 81°F*

(iii) Waters bordering the Atlantic Ocean (NJ to NC, inclusive) ~~81~~~~68~~~~8~~~~8~~168°F*

~~(b)~~ However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.

(a~~i~~) In conducting the evaluation, the State shall evaluate the factors listed in A. for the area during periods when the temperatures exceed those listed in ~~B. (2) (a)~~this section;

(b~~ii~~) In concluding that the risk is not reasonably likely to

occur, the State shall consider how the factors listed in A~~B. (2) (a)~~ differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; and

(3e) If a State has a shellfish growing area that was the source of oysters that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.

(43) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:

(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in (B~~b~~)(2) where they apply, or other triggers as determined by the risk evaluation.

(b~~a~~) Implement one or more control ~~-~~measures to reduce the risk of *Vibrio parahaemolyticus* illness~~, under the circumstances determined by A. and B. (2) and (3)~~ at times when it is reasonably likely to occur.. The control measures may include:

(i) Post harvest processing using a process that has been validated to ensure that levels of total *Vibrio parahaemolyticus* after processing do not exceed the average levels found in the area at times of the year when the State has determined that *Vibrio parahaemolyticus* illness is not reasonably likely to occur;

(ii) Clos~~ure~~ing ~~of~~ the area to oyster harvest;

(iii) Restricting oyster harvest to product that is labeled "For Cooking Only;"

(iv) ~~Other measures (e.g., r~~Reduction in~~~~Limiting time from harvest to refrigeration to no more than five hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;~~.~~

~~) that based on appropriate scientific studies, are designed to ensure that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F do not exceed the average levels from the harvest water by more than 0.5 logarithms.~~

(v) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F (internal temperature of the oysters) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the authority;

(vi) Other control measures that based on appropriate scientific studies, are designed to ensure that the risk of Vp illness is no longer reasonably likely to occur, as approved by the authority.~~Other measures that based on appropriate scientific studies, are designed to ensure that the risk of *Vibrio parahaemolyticus* illness is no longer reasonably likely to occur (e.g., sampling, based on a statistically valid sampling plan, that demonstrates the absence of tdh+ *Vibrio parahaemolyticus* in the shellfish growing area)~~

~~(b)~~(c) ~~When measures provided in B. (43) (ba) (iv) are included in a~~

~~**State's *Vibrio parahaemolyticus* Control Plan, the State shall annually demonstrate**~~ **Evaluate the effectiveness of the Plan** ~~**for each area under the circumstances determined by A. and B. (2) and (3), to ensure that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F do not exceed the average levels from the harvest water by more than 0.5 logarithms. Alternatively, the State may require that individual dealers perform such verification.**~~

(d) ~~**M**~~**Modify the Control Plan when** ~~**verification**~~ **the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.**~~.~~

(e) **Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.**

~~*** Further analysis is necessary to finalize these temperatures and definition is required for Average Water Temperature (e.g., tide status, source of data, time of day).**~~

Action by 2007 Task Forces I & II

Recommended adoption of Vibrio Management Committee recommendation on Proposal 07-202 as amended.

@ .05 *Vibrio parahaemolyticus* Control Plan.

The goal of the Control Plan is to reduce the probability of occurrence of *Vibrio parahaemolyticus* illness during periods that have been historically associated with annual illnesses. The Plan is to be implemented as part of a comprehensive program which includes all the time and temperature requirements contained in the Model Ordinance.

A. Risk Evaluation.

Every State from which oysters are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence)

(1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters commercially harvested from the State.; and
(2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and
(3) The water temperatures in the area; and
(4) The air temperatures in the area; and
(5) Salinity in the area; and
(6) Harvesting techniques in the area; and
(7) The quantity of harvest from the area and its uses i.e. shucking, halfshell, PHP.

B. Control Plan

(5) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan or.
(6) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures* exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan.

The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:

(i) Waters bordering the Pacific Ocean 60°F*
(ii) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south) 81°F*

However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.

(a) In conducting the evaluation, the State shall evaluate the factors listed in A. for the area during periods when the temperatures exceed those listed in this section;

(b) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in A differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or

(3) If a State has a shellfish growing area that was the source of oysters that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.

(4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:

(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in (B)(2) where they apply, or other triggers as determined by the risk evaluation.

(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include:

(i) Post harvest processing using a process that has been validated to ensure that levels of total *Vibrio parahaemolyticus* after processing do not exceed the average levels found in the area at times of the year when the State has determined that *Vibrio parahaemolyticus* illness is not reasonably likely to occur;

(ii) Closing the area to oyster harvest;

(iii) Restricting oyster harvest to product that is labeled "For Cooking Only;"

(iv) Limiting time from harvest to refrigeration to no more than five hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;

(v) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F (internal temperature of the oysters) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the authority;

(vi) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of Vp illness is no longer reasonably likely to occur, as approved by the authority.

(c) Evaluate the effectiveness of the Plan.

(d) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.

(e) Optional cost benefit analysis of the *Vibrio parahaemolyticus*

Control Plan.

C. Effective Date
To be effective six (6) months following FDA concurrence.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007
Concurred with Conference action with the following comments and recommendations for ISSC consideration.

FDA commends the ISSC for its proactive efforts in addressing *Vibrio parahaemolyticus* illnesses associated with consumption of raw oysters. FDA urges the Conference to advise states of the requirements of the *Vibrio parahaemolyticus* Control Plan as adopted in Proposal 07-202. These requirements will impact many areas of the country and timely communication between ISSC and the states will help them prepare for compliance in 2008. FDA requests that in those communications the ISSC emphasize that the *Vibrio parahaemolyticus* Control Plan focuses on harvest areas where a risk evaluation determines that the risk of illness from oyster consumption is **"reasonably likely to occur." "Reasonably likely to occur"** as defined in the Control Plan means **"the risk constitutes and annual occurrence"**. It is essential that states and industry understand that **"annual occurrence"** shall not be interpreted to mean the annual occurrence of confirmed illnesses but rather the annual occurrence of conditions that create an elevated risk of illness from oyster consumption. FDA also wishes to engage the Conference in a dialogue to discuss effective ways in which state programs could be evaluated for compliance with the requirements of Proposal 07-202.

Proposal Subject Disposal of Human Sewage from Vessels

Specific NSSP Guide Reference NSSP Model Ordinance Chapter VIII. Control of Shellfish Harvesting
Requirements for Harvesters .02 Shellstock Harvesting and Handling

Text of Proposal/ Requested Action

C. Disposal of Human Sewage from Vessels
(1) Harvesters…
(2) Vessels…
(3) An approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the **harvest** vessel to contain human sewage.

Also, the need to differentiate between a "Harvest Vessel" and that of a "Transport Vessel" inclusive of the need to define how the vessel is utilized and how it pertains to the need to have a requirement for the disposal of human waste.

Public Health Significance Not all vessels are suitable for marine sanitation devices (MSD) such as the canoes, punts, and skiffs used to transport the harvester and harvest of Soft-Shell Clams in the Northeast. These small vessels are only used during a tide cycle usually under 6 hours. There is a public health concern with the size of these smaller vessels such as a canoe capsizing and the sewage being dumped into the growing areas inadvertently. A more important public health concern with these small vessels is that currently the approved bucket serves no applicable use other than the potential for an additional harvest container when a harvester runs out of bags or other containers to transport product.

Cost Information (if available) None

Note: 2007 Biennial Meeting This proposal was not discussed by Task Force II. The Task Force did discuss Proposal 05-223 that addressed the intent of Proposal 07-203 which was to require harvest vessels to be provided with an approved marine sanitation device. The submitter was consulted and agreed that Proposal 07-203 was addressed by Task Force II consideration of Proposal 05-223 and no further action was required.

Action by 2007 General Assembly Adopted recommendation that no further action is needed on Proposal 07-203.
Rationale – This proposal was addressed in Task Force II action on Proposal 05-223.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject

Reduction of Time - Temperature Matrix Levels 2 & 3 for *Vibrio parahaemolyticus*

Specific NSSP Guide Reference

NSSP Model Ordinance, Chapter VIII. Control of Shellfish Harvesting, Requirements for Harvesters, .03 Shellstock Temperature Control, Option 2

Text of Proposal/ Requested Action

Reduce the time to temperature control for *Vibrio parahaemolyticus, Option 2.* The basis for this reduction in time of exposure is due to the *Vp* risk associated with consumption of raw shellfish from growing areas that have AMMAT temperatures at these levels. *Vp* numbers multiply faster as temperatures increase. The intent is to shorten the period from harvest to temperature control to further reduce the risk of *Vp* with raw oyster consumption.

Time-Temperature Matrix for *Vibrio parahaemolyticus*:

Action Level	Average Monthly Maximum Air Temperature	Maximum Hours from Harvest to Temperature Control
Level 1	<66 °F (18 °C)	36 hours
Level 2	66 °F - 80 °F (19 °C - 27 °C)	~~12~~ **10** hours
Level 3	≥81 °F (≥27 °C)	~~10~~ **8** hours

Public Health Significance

During the summer of 1997, the Pacific coast experienced a significant increase in the number of *Vibrio parahaemolyticus* (*Vp*) illnesses attributed to shellfish consumption. *Vp* was never found to exceed the NSSP action level in the growing waters associated with these illnesses. Recognizing the inadequacy of the NSSP action levels, the ISSC developed the current Interim Control Plan (ICP) for *Vp*.

Due to either low *Vp* levels in the water since or the stronger provisions in the ICP, or both, Vp related illnesses remained at low levels until the summer of 2006, Last year, the northwest experienced the highest number of *Vp* related illnesses in recorded history. Product recalls extended into many states and countries. The affected industry and regulatory control agencies are determined to prevent this from occurring again, and met extensively over the intervening period to discuss possible actions to accomplish this goal. It was acknowledged that stricter controls were needed and that time and temperature controls were key.

The ICP has retained its 'interim' status, acknowledging that the tighter controls resulting from the 1997 illnesses might yet have to be revisited. This Proposal is one component of a multi-pronged response to the 2006 *Vp* illnesses.

Vp numbers are known to multiply faster as temperatures increase. Shortening the period from harvest to temperature control should reduce the number of *Vp* in oysters when they reach temperature control.

While replacing all time values in this table with zeros would maximize the impact of this time-temperature control effort, practicality in the field has also been taken into consideration. These new time values are being proposed as significant reductions to the existing allowances, after extensive consultation with the industry, to ensure that compliance is possible, though in some cases, it may require considerable effort.

Acknowledging that a scientific basis is frequently the preferred method to arrive at numeric limits, we ask that you accept our proposed numbers, and give appropriate credit for the significant reduction they represent, and the practicality component that was also considered.

Cost Information (if available)

Specific cost information has not been calculated as it would vary significantly by operation and location. The west coast industry and regulatory agencies, tribal and non-tribal, have all been parties to this effort and generally believe that this is a workable part of a solution to this problem.

Substitute Proposal Submitted to 2007 Task Force II

Chapter VIII Control of Shellfish Harvesting – Requirements for Harvesters
.03 Shellstock Temperature Control

For Options 1, 2 and 3, wherever appropriate to accomplish the objective, change language so that in each Time - Temperature Matrix, the time begins once the first shellstock harvested is no longer submerged, i.e. when the shellstock is no longer able to take in and expel water, which naturally prevents internal logarithmic bacterial growth.

The following language is intended to reflect the changes being proposed:

OPTION 1

Introduction: " ... the Authority shall adopt the following ~~harvest~~ **exposure** time to temperature controls in the time - temperature matrix below ..."

Table: "Maximum Hours from ~~Harvest~~ Exposure to Temperature Control"

OPTION 2

Introduction: " ... the Authority shall adopt the following ~~harvest~~ **exposure** time to temperature controls in the time - temperature matrix below ..."

Table: "Maximum Hours from ~~Harvest~~ **Exposure** to Temperature Control"

OPTION 3

Table: "Maximum Hours from ~~Harvest~~ **Exposure** to Temperature Control"

Since it is NOT the intent of this Proposal to reduce the total allowable Time to Temperature Control, the Authority in any state, with the concurrence of FDA, may add the time that it typically takes to gather shellstock, to the currently allowable time to temperature control.

PUBLIC HEALTH SIGNIFICANCE:

On a nationwide level, for many years, numerous efforts have been undertaken to address the problem of *Vibrio* bacteria in shellstock. Two main approaches have been adopted 1. Time - Temperature Control, which seeks to limit bacterial growth within shellstock, and; 2. Post Harvest Processing, which seeks to eliminate bacteria once the process of harvesting has been completed. This proposal seeks to improve efforts in the first approach by standardizing the time when 'the clock starts ticking'.

Submerged, undisturbed shellstock typically filter large volumes of water to respire and feed. Food and bacterial concentrations within shellstock are therefore related to the levels of food and bacteria in the surrounding water. Once this process is interrupted, either naturally as the tide recedes, or artificially as shellstock are removed from the water as part of the harvest process, additional bacteria do not enter the shellstock and bacteria already within it, for the most part, do not leave. Unfortunately, the number of internal bacteria does not remain fixed. Bathed in a stable, nutrient-rich medium, bacteria multiply, at a rate that increases as temperature increases. This is the basis behind the 3 Time - Temperature Control Matrixes.

Ever since the matrixes were adopted, it has been accepted that if illnesses continue to occur, a reduction in the time to temperature control would reduce the number of illnesses. For the industry, a certain amount of time reduction was initially not too difficult to incorporate, and only involved improving efficiency. At some point however, efficiency can no longer be improved and any further reduction in time to temperature control becomes impossible. The result is either a shut-down of harvesting or operating outside the matrix. Neither is desirable.

With last year's *V. parahaemolyticus* outbreak on the west coast, there was much focus on the requirements in Option 2, and it became obvious that the time requirement was flawed.

One type of harvest consists of waiting until the tide has started to go out, collecting & placing shellstock in containers, and then removing the containers before the tide returns. The time between high tides is roughly 12 hours and shellstock high on the beach may be out of the water for 8-10 hours before those containers are removed from the beach. Since 'Harvest' is defined as 'the act of removing shellstock from growing areas and its placement on or in a manmade conveyance or other means of transport', the TIME component of the Time - Temperature Matrix, may not start until bacteria in some of the shellstock has been multiplying for 8-10 hours.

Assume that a company harvests as described above one day, and the next day, due to a rush, or small order, that same company has its harvesters follow the tide out collecting all needed shellstock as they become exposed. All collection on day 2 could be completed within an hour. Even if matrix requirements are met on both days, if *Vibrio* is in the water, it is not difficult to imagine shellstock from the 1st day resulting in illness and a subsequent questioning as to whether the matrix time requirements are inadequate. Total adherence to the Matrix, even though its specified times may be adequate to protect public health, could still result in illnesses, financial loss, loss of reputation and added regulatory scrutiny.

Another type of harvest consists of gathering submerged shellstock from the bottom. Here too, a long day of harvest with possibly a break before leaving the harvesting area, could result in much bacterial multiplication before the time component of the Matrix even starts.

The intent of this Proposal is:

- to start the clock ticking as soon as the first shellstock is no longer in the water and conditions for bacterial multiplication become favorable, and;
- NOT to shorten the currently allowed time to temperature control
  i.e. if gathering or collecting shellstock in a state currently takes 6 hours (for example), and the Authority acknowledges this, it would be appropriate, with FDA's concurrence, to add this time to the allowable time in the Matrix.

COST INFORMATION:

Additional cost is not anticipated.

Action by 2007 Task Force II

Recommended adoption of Proposal 07-204 as substituted by the submitter; and add to the NSSP Guide Model Ordinance Chapter II Risk Assessment and Risk Management as follows:

@ .05 The Time When Harvest Begins.

For the purposes of time to temperature control time begins once the first shellstock harvested is no longer submerged.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007
Concurred with Conference action.

Proposal Subject

Label all Packages of Fresh or Frozen Shucked Shellfish with a Consumer Advisory Statement Consistent with or Equivalent to Language used in Section 3-602.11 of the Current Food Code

Specific NSSP Guide Reference

NSSP Model Ordinance Chapter X. General Requirement for Dealers
06. Shucked Shellfish Labeling

Text of Proposal/ Requested Action

A. Shellfish Labeling
Add new subsection (11) to read:

(11) The dealer shall assure that each package of fresh or frozen shucked shellfish shall include a consumer advisory. The following statement, from Section 3-602.11 of the Current Food Code, or an equivalent statement, shall be included on all packages: "RETAILERS, INFORM YOUR CUSTOMERS" "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

Public Health Significance

Foodborne illnesses and deaths have occurred from consuming shucked product raw. Fresh & frozen shellfish are now marketed in a variety of product forms. We can no longer assume that shucked shellfish is going to be cooked prior to consumption. While these products may ultimately be cooked or partially cooked by the end consumer, this is not always the case. The consumer advisory is required for Post Harvest Processed Product so that "at risk" consumers will continue to be aware that raw or undercooked shellfish may increase their risk of foodborne illness. To require a consumer advisory on some product forms and exclude others does not reinforce the education message and policy statement that this conference has adopted.

Cost Information (if available)

Most processors are already including a consumer advisory on containers of shucked product. Those that are not should be allowed to use up current supplies of containers and transition to new containers that include a consumer advisory.

Action by 2007 Task Force II

Recommended adoption of Proposal 07-205 as amended.

A. Shellfish Labeling
Add new subsection (11) to read:

(11) The dealer shall assure that each package of fresh or frozen shucked shellfish shall include a consumer advisory. The following statement, from Section 3-6032.11 of the Current Food Code, or an equivalent statement, shall be included on all packages: ~~"RETAILERS, INFORM YOUR CUSTOMERS"~~ "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions." "A phase in period ending 12/31/2009 during which current supplies of containers and transition to new containers shall be allowed."

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007
Concurred with Conference action.

Proposal Subject Post Harvest Processing Reducing *Vv* and *Vp* Levels

Specific NSSP Guide Reference Model Ordinance XVI. Post Harvest Processing

Text of Proposal/ Requested Action Post-Harvest Processing

A. If a dealer elects to use a process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concern in shellfish, the dealer shall:

(1) Have a HACCP plan approved by the Authority for the process that ensures that the target pathogen(s) are at safe levels for the at risk population in product that has been subjected to the process.

(a) **The dealer must demonstrate that** the **process reduces the** level of *Vibrio vulnificus* in **the processed** product **to** non-detectable (<30 MPN/gram) **and the process achieves a minimum 3.52 log reduction,** to be determined by use of the *Vibrio vulnificus* FDA approved EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th Edition, 1992, or other method approved for NSSP use.

(b) **The dealer must demonstrate that the process reduces the level of *Vibrio parahaemolyticus* in the processed product to non-detectable (<30 MPN/gram) and the process achieves a minimum 3.52 log reduction.**

(c) For processes that target other pathogens **the dealer must demonstrate that** the level of those pathogens in **processed** product **has been reduced to levels** e below appropriate FDA action level, or, in the absence of such a level, below the appropriate level as determined by the ISSC.

(d) The ability of the process to reliably achieve the appropriate reduction in the target pathogen(s) shall be validated by a study **as outlined in Guidance Documents Chapter IV Naturally Occurring Pathogens, Section .04,** approved by the Authority, with the concurrence of FDA.

(e) The HACCP plan shall include:

(i) Process controls to ensure that the end point criteria are met for every lot; and,

(ii) A sampling program to periodically verify that the end point criteria are met

(2) Package and label all shellfish in accordance with all requirements of this Ordinance. This includes labeling all shellfish which have been subjected to the process but which are not frozen in accordance with applicable shellfish tagging and labeling requirements in Chapter X.05 and X.06.

(3) Keep records in accordance with Chapter X.07.

B. A dealer who meets the requirements of this section may label product that has been subjected to the reduction process as:

(1) Processed for added safety", if the process reduces the levels of all pathogens of public health concern to safe levels for the at risk population;

(2) Processed to reduce [name of target pathogen(s)] to non-detectable levels," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or

(3) Processed to reduce [name of target pathogen(s)] to non-detectable levels for added safety," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or

(4) A term that describes the type of process applied (e.g. "pasteurized,"

"individually quick frozen," "pressure treated") may be substituted for the word "processed" in the options contained in (B)(1)-(3).

C. For the purposes of refrigeration, if the product is dead, the product shall be treated as shucked product. If the product is live, the product shall be treated as shellstock.

Public Health Significance	N/A
Cost Information (if available)	N/A
Action by 2007 Task Force II	Recommended adoption of proposal 07-206 as submitted.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject

NSSP Standardized Shellfish Processing Plant Inspection Form
New Item (Written Recall Procedures)

Specific NSSP Guide Reference

Guidance Documents Chapter III. Harvesting, Handling, Processing, Distribution
.02 Shellfish Plant Standardization Procedures

Text of Proposal/ Requested Action

NSSP Standardized Shellfish Processing Plant Inspection Form

Add a new item number 31 called "Written Recall Procedures", criticality code "Key," to the NSSP Standardized Shellfish Processing Plant Inspection Form found in NSSP Guidance Documents Chapter III. 02. Associated with the addition of this new checklist item are needed changes to other sections of NSSP Guidance Documents Chapter III. 02. These include:

1. Under "EXIT CONFERENCE" - Table 1 - Additional MO Requirements (Items 17 - ~~30~~ **31**)

2. Under "Standardization Scoring" - "CANDIDATE SCORING" item (c) Other Model Ordinance Requirements (Items 17 - ~~30~~ **31**)

3. Under "ATTACHMENT 2" - "ADDITIONAL MODEL ORDINANCE REQUIREMENTS" add a new item: **31 Written Recall Procedures**

4. Under "ATTACHMENT 2" change the third bullet under "FIELD REQUIREMENT FOR THE SUCCESSFUIL COMPLETION OF STANDARDIZATION" to read Additional Model Ordinance inspection form items 17 - ~~30~~ **31**.

Public Health Significance

NSSP Model Ordinance Chapter X. General Requirements for Dealers 03. Other Model Ordinance Requirements B. Recalls (1) and (2) require that each shellfish dealer adopt written procedures for conducting recalls. Recent illness outbreaks and their associated recalls have revealed that not all processors have written recall procedures. Adding this item to the plant inspection checklist will help ensure compliance with this NSSP Model Ordinance requirement.

Note: Consideration should be given to other proposals (05-307 for example), revisions to the checklist, etc that may result in the need to update the references and numbers.

Cost Information (if available)

Action by 2007 Task Force II

Recommended adoption of Proposal 07-207 as amended.

Incorporate “Written Recall Procedures” into Line 30 of the Plant Inspection Form.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007
Concurred with Conference action.

NSSP Standardized Shellfish Processing Plant Inspection Form

Agency Name:							Date	
Type of Inspection	☐ Certification ☐ Pre-operational ☐ Routine ☐ Follow-up ☐ Standardization							
Dealer Name:					Certification Number			
Dealer Address:								
	Hazard Analysis Critical Control Point (HACCP)							
1.	**HACCP Plan** Yes ☐ No ☐ Required for Certification							
2.	**Plan Elements** Identified and Adequate	✔/✘ **NA**	Code			✔/✘ **NA**	Code	
	(a) Hazards		O	(e) Critical Control Points			K	
	(b) Records		O	(f) Monitoring			K	
	(c) Critical Limits		K	(g)Verification Procedures			O	
	(d) Name, Address, Signed and Dated		O	(h) Corrective Action if identified			K	
3.	HACCP Training	o Yes o No		**Code**	O			

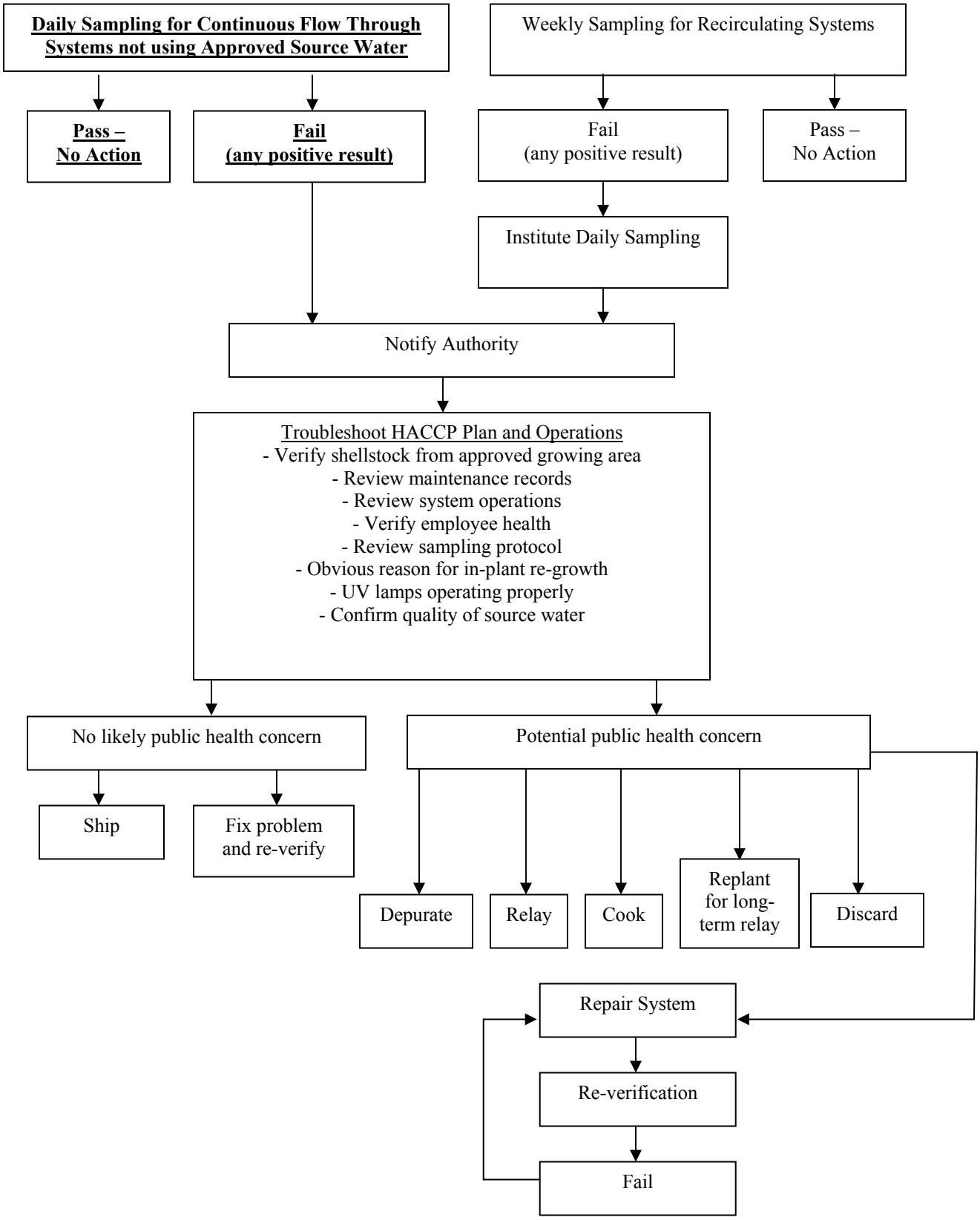
4.	Plan Implementation	**Corrective Actions (C)**		**Verification Procedures (K)**		**Monitoring Procedures (K)**		**Records Accurate/ Maintained (K)** **Records Format Signed/Dated Firm's Name (O)**	
		✔/✘	Code	✔/✘	Code	✔/✘	Code	✔/✘	Code
	(a) Receiving								
	(b) Shellstock Storage								
	(c) Processing								
	(d) Shucked Meat Storage								
	(e) Other Critical Limits								

5.	Approved Source Control Failure			C
6.	Time/Temperature Control Failure			C
7.	Other Critical Control Failure			C
	Sanitation Items	Citation	✔/✘	Code
8.	Safety of water for processing and ice production	.02A		
9.	Condition and cleanliness of food contact surfaces	.02B		
10.	Prevention of cross-contamination	.02C		
11.	Maintenance of hand-washing, hand sanitizing, and toilet facilities	.02D		
12.	Protection from adulterants	.02E		
13.	Proper labeling, storage, and use of toxic compounds	.02F		
14.	Control of employees with adverse health conditions	.02G		
15.	Exclusion of pests	.02H		
16.	Sanitation Monitoring and Records			K
	Additional Model Ordinance Requirements	Citation	✔/✘	Code
17.	Plants and Grounds	.03A		
18.	Plumbing and related facilities	.03B		
19.	Utilities	.03C		
20.	Insects and vermin control	.03D		
21.	Disposal of other waste	.03E		
22.	Equipment construction (non-food contact surfaces)	.03F		
23.	Cleaning non-food contact surfaces	.03G		
24.	Shellfish storage and handling	.03H		
25.	Heat shock	.03I		
26.	Personnel	.03J		
27.	Supervision	.03K		
28.	Transportation (To include only the person shipping)	IX.05		K
29.	Labeling and Tagging (Other than receiving)	X.05, .06		S (K/O)
30.	Shipping Documents and Records	X.07		K
31	**Written Recall Procedures**			**K**

Dealer's Signature	Inspector's Signature

Proposal Subject	Protocol for Addressing Positive Coliform Sample in an Artifical Wet Storage Water Body
Specific NSSP Guide Reference	Guidance Documents Chapter III. Harvesting, Handling, Processing, Distribution .06 Protocol for Addressing Positive Coliform Sample in an Artificial Wet Storage Water Body
Text of Proposal/ Requested Action	Revise flow diagram and associated 508 compliance language.
Public Health Significance	Model Ordinance Chapter X. 09.C. (2) requires daily sampling for continuous flow through systems not using source water from approved growing areas or conditionally approved growing areas in the open status and Model Ordinance Chapter X. 09. C. (3) requires weekly sampling for recirculating wet storage systems in order to demonstrate that the disinfected water is negative for the coliform group. The current flow diagram shows only the procedures to be followed when a positive coliform sample is found in a recirculating wet storage system. Therefore, the flow diagram should be revised to include procedures for both types of wet storage systems when a positive coliform sample is found. A suggested revision is attached, but consideration should also be given to decisions made regarding Proposal 05-205 which may alter the language associated with wet storage requirements. Additionally, text was added after the flow chart in the 2005 Revision of the NSSP Guide to the Control of Molluscan Shellfish to ensure compliance with requirements under Section 508 of the Rehabilitation Act, which requires Federal agencies to make their electronic and information technology accessible to people with disabilities. If the flow chart is revised, this language should then also be updated.
Cost Information (if available)	None
Action by 2007 Task Force II	Recommended adoption of Proposal 07-208 as submitted.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

NSSP Guidance Documents Chapter III. Harvesting, Handling, Processing, and Distribution
.06 Protocol for Addressing Positive Coliform Sample in an Artificial Wet Storage Water Body



Description: Flow chart showing the protocol for addressing positive coliform results in artificial wet storage water bodies.

Collect weekly water samples **for recirculating systems and daily samples for continuous flow through systems not using an approved water source**.

If the water sample is negative for coliforms **in either system**, no action is required.

If the water sample is positive for coliforms **in the recirculating system**, institute daily sampling.

~~notify t~~**T**he authority **should be notified of a failure in either system.** ~~, and t~~

Troubleshoot the HACCP Plan and operations by

(1) Verifying that shellstock is from an approved growing area,
(2) Reviewing maintenance records,
(3) Reviewing system operations,
(4) Verifying employee health,
(5) Reviewing the sampling protocol,
(6) Looking for an obvious reason for in-plant re-growth,
(7) Determining that UV lamps are operating properly, and
(8) Confirming the quality of the source water.

If no likely public health concern is found after troubleshooting, the product may be shipped and the problem causing the positive coliform result shall be fixed. Once fixed, re-verify through sampling that the system's water quality is acceptable.

If a potential public health concern is found after troubleshooting, the product may be depurated, relayed, cooked, replanted for long-term relay, or discarded and the problem causing the positive coliform result shall be repaired. Once repaired, re-verify through sampling that the system's water quality is acceptable. If the system fails after re-verification, attempts to repair the system must be made until the re-verification demonstrates acceptable water quality.

Proposal Subject Validation Verification Revision

Specific NSSP Guide Reference Guidance Documents Chapter IV @.04 Post Harvest Processing Validation/Verification Interim Guidance for *Vibrio vulnificus* and *Vibrio parahaemolyticus*

Text of Proposal/ Requested Action

.04 **Post Harvest Processing (PHP)** Validation/Verification Interim Guidance **for *Vibrio vulnificus* and *Vibrio parahaemolyticus***

A. Process Validation

Used for the initial validation of a process or when there has been a change to a previous validation process.

- Data on ten processed samples obtained on each of three processing days (total of 30 samples) are required.
- All samples used on a processing day must come from the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of ~~100,000~~ **10,000** per gram or greater as described below for initial load testing. ~~(If some lower initial levels are used the process will only be validated for those maximum initial levels.)~~
- Samples should be distributed throughout the processing day. A sample will consist of a composite of 10 to 12 oysters processed at one time.
- The zero hour level may be achieved through naturally occurring Vibrio levels in shellfish and, where not practical, by time/temperature abuse. (Inoculated pack samples may be used as appropriate.)
- Analytical methodology to determine Vibrio levels should be the official methods previously endorsed by the ISSC **as indicated in Model Ordinance Chapter XVI. Post Harvest Processing**.
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with **either** 0.01 g **or 0.1 g** of shellfish per tube **based upon the table below**.
- The numerical value of the endpoint criteria should ~~represent the lowest sensitivity of the MPN method, which is~~ **be** less than 30 per gram **and achieves a minimum 3.52 log reduction**.
- For the process to be validated, no more than three samples out of 30 may fail. **Depending upon the initial load, ~~F~~failure of a single sample** is ~~indicated by more than two out of five MPN tubes in any sample being positive. If any one sample has all five MPN tubes positive, the validation process will fail.~~ **determined according to the table below.**

AGM Interval	Grams Per Tube	Positive Tubes Allowed
59,995 or Greater	.01	2
37,174 – 59,994	.01	1
23,449 – 37,173	.1	4
12,785 – 23,448	.1	3
10,000 – 12,784	.1	2

For example, if the AGM equals 50,000, then use the second row because 37,174 ≤50,000 < 59,994. the second row tells to inoculate with .01 grams of the original oyster homogenate in each tube and the test fails if more than one of the five tubes is positive.

B. Equipment Validation

Used to ensure that each unit of equipment will deliver the validated process. May be accomplished using either of two methods:

- The process described under "Revalidation," below:
- A physical test of the equipment (e.g., thermal distribution study) that is designed to ensure that, when properly operated, it will consistently deliver the validated process.

C. Revalidation

Used when verification sampling indicates a failure in the process.

Option 1:

- Data on ten processed samples obtained throughout a processing day are required.
- All samples used on a processing day must come form the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of 100,000 per gram or greater as described below in initial load testing.
- A sample will consist of a composite of 10 to 12 oysters processed at one time.
- The zero hour level may be achieved through naturally occurring Vibrio levels in shellfish and, where not practical, by time/temperature abuse. (Inoculated pack samples may be used as appropriate).
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with 0.01 g of shellfish per tube.
- The numerical value of the endpoint criteria should represent the lowest sensitivity of the MPN method, which is less than 30 per gram.
- For revalidation, no more than one sample out of ten may fail. Failure is indicated by more than two out of five MPN tubes in any sample being positive. If any one sample has all five MPN tubes positive, revalidation will fail.

Option 2:

Repeat full validation when initial levels of 100,000 per gram can't be achieved.

D. Initial Load Testing

Initial level of vibrios in shellfish for each lot of shellfish used in validation shall be ~~100,000~~ 10,000 MPN per gram or greater based on the adjusted geometric mean (AGM) of the MPNs/g of four samples where the AGM is given by:

AGM = the geometric mean of the 4 MPNs/g multiplied by an adjustment factor of 1.3

Note: If 4 samples from a lot of shellfish with a true density of 100,000 cells per gram are examined by the MPN procedure, the probability of the geometric mean of the MPNs showing 100,000 or greater is about 50%. In an attempt to improve the probability of samples being accepted when the true density is 100,000/g an adjustment factor of 1.3 was selected based upon statistical analysis. ~~provided by Dr. Bob Blodgett.~~

E. Verification

Used to verify that a previously validated process is working properly.

- Process verification by microbiological testing should be done monthly
- The number of samples/sub samples for verification and the pass/fail criteria for the verification process will be determined by the validation/verification workgroup following evaluation of statistical data to be supplied by Dr. Bob Blodgett.
-
- The dealer in conjunction with the SSCA shall annually evaluate the previous 12 months of data and the HACCP plan.
- The dealer may elect, with SSCA concurrence, to conduct quarterly sampling if the previous 12 verification samples pass.

Public Health Significance N/A

Cost Information (if available) N/A

Action by 2007 Validation/Verification Workgroup Recommended adoption of Proposal 07-209 as substituted.

.04 **Post Harvest Processing (PHP)** Validation/Verification Interim Guidance **for *Vibrio vulnificus* and *Vibrio parahaemolyticus***

A. Process Validation

Used for the initial validation of a process or when there has been a change to a previous validation process.

- Data on ten processed samples obtained on each of three processing days (total of 30 samples) are required.
- All samples used on a processing day must come from the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of **10,000** per gram or greater as described below for initial load testing.
- Samples should be distributed throughout the processing day. A sample will consist of a composite of 10 to 12 oysters processed at one time.
- The zero hour level may be achieved through naturally occurring Vibrio levels in shellfish and, where not practical, by time/temperature abuse. (Inoculated pack samples may be used as appropriate.)
- Analytical methodology to determine Vibrio levels should be the official methods previously endorsed by the ISSC **as indicated in Model Ordinance Chapter XVI. Post Harvest Processing**.
- **Microbiological testing for initial levels will be by a 3 tube MPN using appropriate dilutions (10^{-1}- 10^{-6})**
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with **either** 0.01 g **or 0.1 g** of shellfish per tube **based upon the table below**.
- The numerical value of the endpoint criteria should be less than 30 per gram **and achieves a minimum 3.52 log reduction.**
- For the process to be validated, no more than three samples out of 30 may fail. **Depending upon the initial load, failure of a single sample** is **determined according to the table below.**

AGM Interval	Grams Per Tube	Positive Tubes Allowed
59,995 or Greater	.01	2
37,174 – 59,994	.01	1
23,449 – 37,173	.1	4
12,785 – 23,448	.1	3
10,000 – 12,784	.1	2

For example, if the AGM equals 50,000, then use the second row because 37,174 ≤50,000 < 59,994. the second row tells to inoculate with .01 grams of the original oyster homogenate in each tube and the test fails if more than one of the five tubes is positive.

B. Equipment Validation
Used to ensure that each **new or modified** unit of equipment will deliver the validated process. May be accomplished using ~~either of two methods:~~**the following:**

- ~~The process described under "Revalidation," below:~~
- A physical test of the equipment (e.g., thermal distribution study) that is designed to ensure that, when properly operated, it will consistently deliver the validated process.
- **The process needs to be verified according to section D. before labeling claims can be made.**

~~C.~~ ~~Revalidation~~

~~Used when verification sampling indicates a failure in the process.~~

~~**Option 1:**~~

- ~~Data on ten processed samples obtained throughout a processing day are required.~~
- ~~All samples used on a processing day must come form the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of 100,000 per gram or greater as described below in initial load testing.~~
- ~~A sample will consist of a composite of 10 to 12 oysters processed at one time.~~
- ~~The zero hour level may be achieved through naturally occurring Vibrio levels in shellfish and, where not practical, by time/temperature abuse. (Inoculated pack samples may be used as appropriate).~~
- ~~Microbiological testing for processed samples will be by a single dilution five tube MPN, inoculating with 0.01 g of shellfish per tube.~~
- ~~The numerical value of the endpoint criteria should represent the lowest sensitivity of the MPN method, which is less than 30 per gram.~~
- ~~For revalidation, no more than one sample out of ten may fail. Failure is indicated by more than two out of five MPN tubes in any sample being positive. If any one sample has all five MPN tubes positive, revalidation will fail.~~

~~**Option 2:**~~

~~**Repeat full validation when initial levels of 100,000 per gram can't be achieved.**~~

~~D~~C. Initial Load Testing

Initial level of vibrios in shellfish for each lot of shellfish used in validation shall be 10,000 MPN per gram or greater based on the adjusted geometric mean (AGM) of the MPNs/g of four samples where the AGM is given by:

AGM = the geometric mean of the 4 MPNs/g multiplied by an adjustment factor of 1.3

Note: If 4 samples from a lot of shellfish with a true density of 100,000 cells per gram are examined by the MPN procedure, the probability of the geometric mean of the MPNs showing 100,000 or greater is about 50%. In an attempt to improve the probability of samples being accepted when the true density is 100,000/g an adjustment factor of 1.3 was selected based upon statistical analysis.

~~E~~D. Verification

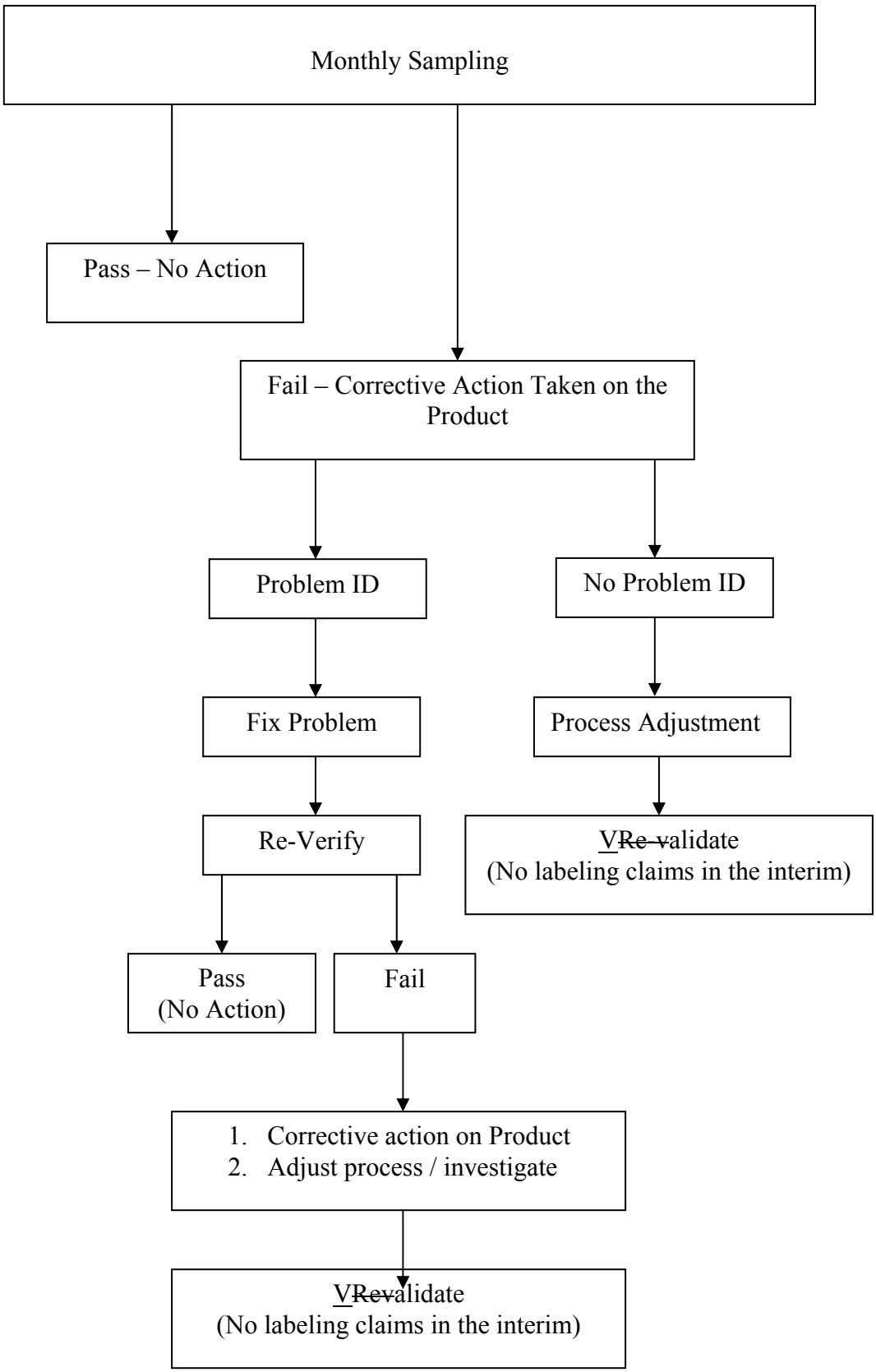
Used to verify that a previously validated process is working properly.

- Process verification by microbiological testing should be done monthly
- ~~The number of samples/sub samples for verification and the pass/fail criteria for the verification process will be determined by the validation/verification workgroup following evaluation of statistical data to be supplied by Dr. Bob Blodgett.~~
- ~~The dealer in conjunction with the SSCA shall annually evaluate the previous 12 months of data and the HACCP plan.~~
- ~~The dealer may elect, with SSCA concurrence, to conduct quarterly sampling if the previous 12 verification samples pass.~~ **The monthly sampling shall consist of 30 tubes from a minimum of three samples of 10 tubes each with an innoculum of 0.01 grams. Ideally, this would**

be done on three separate days of production, spread throughout the month, using a 10 tube MPN each day. If this is not feasible, the 30 tubes can consist of 3 samples from three consecutive days or 3 samples from a given day (from three separate lots if possible)

- **Each sample will consist of 10-12 oysters**
- **If more than 11 tubes of the 30 most recent 3-10 tube samples within any calendar month are positive, then the process fails for that month. In this case, corrective actions as outlined in the Verification Sampling Plan Decision Tree must be taken and verification must be repeated within one week of the analysis indicating verification failure. Labeling claims may not be used during this time.**
- **If all ten tubes are positive for any given sample, this is considered a verification failure and corrective actions must be taken immediately regardless of the result of the other samples for that month.**
- **If verification fails twice during a twelve month period, revalidation is required and product should not be labeled until revalidation occurs.**
- **The dealer in conjunction with the SSCA shall annually evaluate the previous 12 months of data and the HACCP plan.**

Verification Sampling Protocol Decision Tree



NOTE: When a monthly verification fails, the verification must be repeated within one week of failure.

Action by 2007 Task Force II

Recommended adoption of substitute Proposal 07-209 submitted by the Validation/Verification Workgroup as amended by Task Force II. The substitute included changing Monthly Sampling to Verification Sampling in the Verification Sampling Protocol Decision Tree.

.04 Post Harvest Processing (PHP) Validation/Verification Interim Guidance for *Vibrio vulnificus* and *Vibrio parahaemolyticus*

A. Process Validation

Used for the initial validation of a process or when there has been a change to a previous validation process.

- Data on ten processed samples obtained on each of three processing days (total of 30 samples) are required.
- All samples used on a processing day must come from the same lot of shellfish and be determined to have an adjusted geometric mean (AGM) MPN of 10,000 per gram or greater as described below for initial load testing.
- Samples should be distributed throughout the processing day. A sample will consist of a composite of 10 to 12 oysters processed at one time.
- The zero hour level may be achieved through naturally occurring Vibrio levels in shellfish and, where not practical, by time/temperature abuse. (Inoculated pack samples may be used as appropriate.)
- Analytical methodology to determine Vibrio levels should be the official methods previously endorsed by the ISSC as indicated in Model Ordinance Chapter XVI. Post Harvest Processing.
- Microbiological testing for initial levels will be by a 3 tube MPN using appropriate dilutions (10^{-1}- 10^{-6})
- Microbiological testing for processed samples will be by a single dilution five-tube MPN, inoculating with either 0.01 g or 0.1 g of shellfish per tube based upon the table below.
- The numerical value of the endpoint criteria should be less than 30 per gram and achieves a minimum 3.52 log reduction.
- For the process to be validated, no more than three samples out of 30 may fail. Depending upon the initial load, failure of a single sample is determined according to the table below.

AGM Interval	Grams Per Tube	Positive Tubes Allowed
59,995 or Greater	.01	2
37,174 – 59,994	.01	1
23,449 – 37,173	.1	4
12,785 – 23,448	.1	3
10,000 – 12,784	.1	2

For example, if the AGM equals 50,000, then use the second row because 37,174 ≤50,000 < 59,994. the second row tells to inoculate with .01 grams of the original oyster homogenate in each tube and the test fails if more than one of the five tubes is positive.

B. Equipment Validation

Used to ensure that each new or modified unit of equipment will deliver the validated process. May be accomplished using the following:

- A physical test of the equipment (e.g., thermal distribution study) that is designed to ensure that, when properly operated, it will consistently deliver the validated process.

- The process needs to be verified according to section D. before labeling claims can be made.

C. Initial Load Testing

Initial level of vibrios in shellfish for each lot of shellfish used in validation shall be 10,000 MPN per gram or greater based on the adjusted geometric mean (AGM) of the MPNs/g of four samples where the AGM is given by:

AGM = the geometric mean of the 4 MPNs/g multiplied by an adjustment factor of 1.3

Note: If 4 samples from a lot of shellfish with a true density of 100,000 cells per gram are examined by the MPN procedure, the probability of the geometric mean of the MPNs showing 100,000 or greater is about 50%. In an attempt to improve the probability of samples being accepted when the true density is 100,000/g an adjustment factor of 1.3 was selected based upon statistical analysis.

D. Verification

Used to verify that a previously validated process is working properly.

- Process verification by microbiological testing should be done monthly
- The monthly sampling shall consist of 30 tubes from a minimum of three samples of 10 tubes each with an innoculum of 0.01 grams. Ideally, this would be done on three separate days of production, spread throughout the month, using a 10 tube MPN each day. If this is not feasible, the 30 tubes can consist of 3 samples from three consecutive days or 3 samples from a given day (from three separate lots if possible)
- Each sample will consist of 10-12 oysters
- If more than 11 tubes of the 30 most recent 3-10 tube samples within any calendar month are positive, then the process fails for that month. In this case, corrective actions as outlined in the Verification Sampling Plan Decision Tree must be taken and verification must be repeated within one week of the analysis indicating verification failure. Labeling claims may not be used during this time.
- If all ten tubes are positive for any given sample, this is considered a verification failure and corrective actions must be taken immediately regardless of the result of the other samples for that month.
- If verification fails twice during a twelve month period, revalidation is required and product should not be labeled until revalidation occurs.
- The dealer in conjunction with the SSCA shall annually evaluate the previous 12 months of data and the HACCP plan.
- ~~(81)~~ The dealer may elect, with SSCA concurrence, to conduct quarterly sampling if the previous 12 verification samples pass.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force II.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject Maintenance of Identify of Origin on all Raw Molluscan Shellfish

Specific NSSP Guide Reference Chapter X. General Requirements for Dealers
.06 Shucked Shellfish Labeling

Text of Proposal/ Requested Action

(4) At a minimum the dealer shall label each individual package containing ~~fresh or frozen shucked~~ **raw** shellfish meat, **whether in the shell or removed there from, including fresh, frozen or that processed with any other procedure that has not been determined to be equivalent to cooking**, in a legible and indelible form in accordance with CFR 21, Part 101; Part 161, Subpart B (161.30, and 161.136) and the Federal Fair Packaging and Labeling Act.

(5) The dealer shall assure that:

(a) **The shucker-packer's or repacker's certification number ~~is on the label of each package of fresh or frozen shellfish~~** and the most precise identification of the harvest location as is practicable, including the initials of the state and the Authority's designation of the growing area, by indexing, administrative or geographic designation, is unambiguously indicated on the label of each package of raw shellfish, including post-harvest processed shellstock, shucked meats, and whole or parts of frozen shellfish, whether in the shell or removed there from.

Public Health Significance

Unlike the requirements for maintenance and unambiguous declaration of origin on containers of all raw/live shellstock that is processed, distributed and offered for sale in retail outlets and in food service establishments, there persists an exception that permits omission of a label designating the true harvest area for certain raw shellfish products. There is no specific requirement for declaration of the state and growing/harvest area location that would apply to shucked and other raw shellfish that have been subjected to some process that would not be considered biochemically (microbiologically) equivalent to cooking. In lieu of maintenance of harvest area origin, these products may be packed and distributed under the label designation and certification identifier of the entity that shucked, processed or repacked shellfish that it has received from a primary or secondary source in another geographic area. This is clearly a circumvention of the original intent of maintenance of identity of origin for raw shellfish products.

The "rationale" for such an exception has been based on the assumption that all shucked shellfish are cooked prior to consumption. It is quite evident that this is certainly not the case; many restaurants present to the table pre-shucked oysters or previously frozen oysters in the "half-shell mode"; some dealer's actually supply empty shells to restaurant buyers to facilitate such procedures.

Another argument is based on the declared impracticality and added burden that maintenance of identity of origin on the final product would impose on the processor. The perception - and consequent justification that the maintenance and declaration of origin on the final packaging of processed shellfish is impracticable and excessively burdensome is certainly not sustainable in light of the currently available technologies (vd. information on costs).

A third objection derives from the assumption that the origin of the product can eventually be traced via the records that the final processor/shipper is required to maintain. This argument is difficult to justify in light of the widely recognized utility of maintenance of true origin on all other raw shellfish – a long-standing policy of the NSSP. Indeed, when instances of shellfish related disease outbreaks occur, it is quite helpful to both local and regional health authorities to have immediate access to the least ambiguous information pertaining to the true origin of the suspect shellfish lots. There is a high probability of an erroneous origin for the suspect product being established and disseminated by local health authorities unfamiliar with the details of the NSSP requirements. This confusion of origin promulgated and fostered via the uncritical communication media, can result in misdirected and ineffective responses by both the consumer community and well-intentioned agencies involved in food

safety issues acting on defective information. Such dispersion of effort is counterproductive in such situations.

Though not directly a public health issue, it is propitious that a reputable industry, considering the litigious nature of current society, would make every effort to avoid the eventual accusations of "consumer fraud", which could be fabricated by so-called consumer interest groups that would not hesitate to use the obfuscation of product identity as a pretext in their hysteria-driven anti-industry campaigns.

The reputable retailer and thoughtful consumer have a legitimate expectation of truth in product identity. Maintenance of identity of origin has been a fundamental concept of the shellfish sanitation program since its inception; remedying the exception to this key component of the program is long overdue.

Cost Information (if available)

For small shucking and processing operations (up to a few hundred containers per day), label making machines are available for less than 300 dollars; there will be less than one hour of labor per process cycle to apply and prepare marked containers; this operation can be integrated with other container handling procedures associated with product packing. For larger operations that require practical labeling of large numbers of containers, a stand-alone, industrial quality ink-jet printer system can be obtained for less than 10,000 dollars, which can be amortized at a reasonable annual rate over an expected service life of 15 years. Most printers can be configured to apply identifying labels without operator attendance. Daily setup and routine maintenance is minimal.

Action by 2007 Task Force II

Recommended no action on Proposal 07-210. Rationale – Concerns regarding traceability and record keeping are already being addressed.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force II.

Action by USFDA

December 20, 2007
Concurred with Conference action.

Proposal Subject	Elimination of the Vv & Vp Subcommittee
Specific NSSP Guide Reference	NSSP Guide for the Control of Molluscan Shellfish Guidance Documents Chapter IV. Naturally Occurring Pathogens
Text of Proposal/ Requested Action	Add the following addendum to the end of the ***Vibrio vulnificus*** **Management Guidance Document** In 2006 the Executive Board directed the elimination of the Vv & Vp subcommittees. The VMC assumed all responsibilities of the subcommittees as outlined in the Vibrio vulnificus Management Guidance Document. Representation on the VMC Committee will be consistent with all guidance (VMC and Vv subcommittee) outlined in the Vibrio vulnificus Management Guidance Document.
Rationale	The subcommittees were eliminated to reduce redundancy and travel cost.
Cost Information (if available)	
Action by 2007 Task Force II	Recommended adoption of Proposal 07-211-L as submitted.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposed Specific Research Need/ Problem to be Addressed:	Provide a template for addressing the time/temperature issues at points in transportation that are for the most part unregulated.
How will addressing this research support/improve the mission/role of the ISSC/NSSP/Industry?	Based on routine regulatory work these operations do not own the product and are not a dealer in the traditional sense, they have no records to provide for time/ temperature monitoring and under many individual state laws are not required to have a shellfish permit.
Support need with literature citations as appropriate.	None submitted

Relative Priority Rank in Terms of Resolving Research Need:	Immediate	☒	Valuable	☒
	Required	☐	Other	☐
	Important	☐		

Estimated Cost:	Unknown
Proposed Sources of Funding/Support:	Routine surveillance of facilities to prepare data base. After analysis is completed then submit a specific proposal if data warrants need for action.
Time Frame Anticipated:	None submitted
Action by 2005 Task Force II	Recommended referral of Research Needs Proposal 05-RN-200 to the Executive Board.
Action by ISSC Executive Board August 2005	Referred Research Needs Proposal 05-RN-200 to the Time/Temperature Committee.
Action by USFDA	Concurred with Conference action.
Action by 2007 Time/Temperature Committee	Recommended no action on Proposal 05-RN-200. Rationale - The committee recognizes that there is little data on this subject and the proposal is outside the jurisdiction of ISSC.
Action by 2007 Task Force II	Recommended no action on 05-RN-200.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposed Specific Research Need/ Problem to be Addressed:	*Vibrio*, aerobic plate count, and PH analysis of severely temperature abused oysters from all regions of the country, including post harvest processed oysters from all regions of the country, because the ISSC has no control of time/temperature abused raw or post harvest processed shellstock at the retail level.
How will addressing this research support/improve the mission/role of the ISSC/NSSP/Industry?	This research would support the illness reduction goals and requirements set forth in the *Vibrio vulnificus Management* Plan because of the number of unknown harvest areas of shellstock implicated in *V.v.* illnesses and because *Vibrio*, aerobic plate counts, and PH in severely temperature abused PHT and unprocessed raw oysters from all regions are unknown. This research would also address the current ISSC and FDA raw consumption policy statements that do not address consumer safety of post harvest processed oysters in the Model Ordinance. This research would also give guidance to State public health regulators and shellfish control agencies addressed in Resolution 97-01 that would help the SSCA approval of PHT processes which are able to consistently and reliably reduce *Vibrio vulnificus* to non-detectable levels in raw molluscan shellfish. All of the above research requests would enable the voting delegates of the ISSC to make better decisions relating to the *Vibrio vulnificus Management* Plan.
Support need with literature citations as appropriate.	There is no research relating to the research requested above that's why there is a need.

Relative Priority Rank in Terms of Resolving Research Need:	Immediate	☒	Valuable	☐
	Required	☐	Other	☐
	Important	☐		

Estimated Cost:	Unknown
Proposed Sources of Funding/Support:	FDA or GMP or GSAFF or GOIP or ISSC
Time Frame Anticipated:	March 2006 ISSC Board meeting
Action by 2005 Task Force II	Recommended referral of Research Needs Proposal 05-RN-201 to the Executive Board.
Action by ISSC Executive Board August 2005	Referred Research Needs Proposal 05-RN-201 to the Vibrio Management Committee for referral to the *Vibrio vulnificus* Subcommittee assisted by the Research Guidance Committee.
Action by USFDA	Concurred with Conference action.
Action by 2006 Vibrio Management Committee	Recommended no action on Research Needs Proposal 05-RN-201 and directed the Executive Director to obtain a copy of a presentation on the same or similar subject and make this available to the submitter of the proposal. The Committee further directed that should the information not address the concerns of the submitter that the proposal will be reconsidered by the *Vv* Subcommittee at the 2007 Spring meeting.
Action by Executive Board October 2006	Recommended adoption of the Vibrio Management Committee recommendation on Research Needs Proposal 05-RN-201.
Action by 2007 Vibrio Management Committee	Recommended adoption of Research Needs Proposal 05-RN-201.

Action by 2007 Research Guidance Committee	Recommended that Research Needs Proposal 05-RN-201 be placed into consideration for funding when available and further recommended that this research need be given a high priority due to the issues with imports and human health impacts.
Action by 2007 Task Force II	Recommended adoption of Research Guidance Committee recommendation on Research Needs Proposal 05-RN-201.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposed Specific Research Need/ Problem to be Addressed:

New economic impacts study of requiring post-harvest processing of oysters.

How will addressing this research support/improve the mission/role of the ISSC/NSSP/Industry?

In 1999 and 2000, the ISSC contracted with Research Triangle Institute, (RTI), to develop an economic impacts study of requiring post-harvest processing, (PHP), of oysters intended for the raw half-shell and shucked markets. Since that time there is more information available that will give a better economic picture of the impact of such a requirement since California banned the sale of raw half-shell and shucked oysters harvested in the Gulf States April through October and new PHP facilities have opened and closed.

Support need with literature citations as appropriate.

Bauman Amendment, Letter from Congress to FDA July 11, 2000, RTI Economic Impacts of Requiring post-harvest treatment of oysters.

Bauman Amendment:

- Coastal Zone Management Act of 1972 to assist the States in enhancing and restoring the shellfish resources of the coastal zone, to establish the National Advisory Shellfish Committee.
- Shellfish Area Management Act - Directs the Secretary of Commerce, to establish a National Shellfish Advisory Committee.
- Directs the Committee to review all aspects of the shellfish industry, including the impact of Federal legislation affecting water quality on the industry and existing standards with respect to bacteria, pesticides, and toxic metals by which the wholesomeness of shellfish is determined. Directs the Committee to report the findings of such review to the Secretary and to Congress by June 30, 1977.
- Authorizes the Secretary to make grants to coastal States for the improvement of shell- fish resources. Requires Congressional review of all proposed Federal regulations affecting the shellfish industry with respect to interstate commerce.

Relative Priority Rank in Terms of Resolving Research Need:

Immediate	☒	Valuable	☐
Required	☐	Other	☐
Important	☐		

Estimated Cost: Unknown

Proposed Sources of Funding/Support: FDA or GMP or GSAFF or GOIP or ISSC

Time Frame Anticipated: August 2006 ISSC Board meeting

Action by 2005 Task Force II Recommended referral of Research Needs Proposal 05-RN-202 to the Executive Board.

Action by ISSC Executive Board August 2005 Referred Research Needs Proposal 05-RN-202 to the Vibrio Management Committee for referral to the *Vibrio vulnificus* Subcommittee assisted by the Research Guidance Committee.

Action by USFDA Concurred with Conference action.

Action by 2006 Vibrio Management Committee Recommended referral of Research Needs Proposal 05-RN-202 to the 2007 Research Guidance Committee for review and prioritization.

Action by 2007 Vibrio Management Committee	Recommended adoption of Research Needs Proposal 05-RN-202.
Action by 2007 Research Guidance Committee	Recommended that Research Needs Proposal 05-RN-202 be placed into consideration for funding when available and further recommended that this research need be given a high priority due to the issues with imports and human health impacts.
Action by 2007 Task Force II	Recommended adoption of Research Guidance Committee recommendation on Research Needs Proposal 05-RN-202.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposed Specific Research Need/ Problem to be Addressed:	Study the impact of CDHS requiring post-harvest treatment of oysters harvested in the Gulf States April through October. The research requests that an independent study analyze the number of lbs. of PHT and traditional shucked and shellstock oysters were sold April through October into California in 2001 and 2002 and the number of lbs. of shucked and shellstock PHT oysters were sold April through October into California during 2003 and 2004. The study would also research the number of oysters sold by certified dealers from the Gulf, Atlantic, Pacific coast States as well as importers of oysters into California prior to April 2003 and after April 2003 during April through October. The research will determine if there has been any impact, either positive and/or negative, to any certified dealers listed in the ICSSL. The SSCAs along with the FDA should conduct the study to assure that the information is kept confidential.
How will addressing this research support/improve the mission/role of the ISSC/NSSP/Industry?	On April 3, 2003 the California Department of Health Services, (CDHS), banned the sales of oysters harvested in the Gulf States, April through October that had not undergone a post harvest treatment approved by CDHS. This research will show which certified shellfish dealers have been positively or negatively impacted by the CDHS regulation banning the sale of unprocessed oysters harvested in the Gulf States April through October.
Support need with literature citations as appropriate	CDHS emergency regulation, the NSSP, ISSC Constitution and By-laws, ISSC May 1, 2003 memo to the Gulf Coast State Legislative Delegations and Staff
Relative Priority Rank in Terms of Resolving Research Need	Immediate ☒ Valuable ☐ Required ☐ Other ☐ Important ☐
Estimated Cost:	Unknown
Proposed Sources of Funding/Support:	FDA or GMP or GSAFF or GOIP or ISSC
Time Frame Anticipated:	August 2006 ISSC Board meeting
Action by 2005 Task Force II	Recommended referral of Research Needs Proposal 05-RN-203 to the Executive Board.
Action by ISSC Executive Board August 2005	Referred Research Needs Proposal 05-RN-203 to the Vibrio Management Committee for referral to the *Vibrio vulnificus* Subcommittee assisted by the Research Guidance Committee.
Action by USFDA	Concurred with Conference action.
Action by 2006 Vibrio Management Committee	Recommended referral of Research Needs Proposal 05-RN-203 to the 2007 Research Guidance Committee for review and prioritization.
Action by 2007 Vibrio Management Committee	Recommended adoption of Research Needs Proposal 05-RN-203.
Action by 2007 Research Guidance Committee	Recommended that Research Needs Proposal 05-RN-203 be placed into consideration for funding when available and further recommended that this research need be given a high priority due to the issues with imports and human health impacts.
Action by 2007 Task Force II	Recommended adoption of Research Guidance Committee recommendation on Research Needs Proposal 05-RN-203.

Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposed Specific Research Need/ Problem to be Addressed:	Determine thermal inactivation curve of acid phosphatase levels of imported shellfish species. Over the past several years State Food Programs have had to embargo/detain and destroy shipments of raw molluscan shellfish from non-MOU countries such as China, Vietnam, and Thailand. Much of this foreign shellfish is labeled as "cooked" or "pre-cooked", however sensory evaluations have revealed that this is actually a raw shellfish product. Viral illness outbreaks have been identified, traced to clams from China, and falsely labeled as "cooked". Currently the only "approved" methodology for determining whether shellfish is "cooked" or "raw" involves a subjective sensory evaluation, which can determine it a raw product or that some level of heat processing has been applied. Shellfish internal meats that are not heated to above 145 º F for 15 seconds are considered "raw" under the NSSP Model Ordinance, and must originate from a country having a FDA MOU. States are currently finding molluscan shellfish from non-MOU countries that is either, not labeled at all regarding "cooked", "raw", or misbranded. States have no approved laboratory procedure to determine the level of thermal processing applied to the shellfish meats, either in shell, half shell or frozen, and therefore, cannot take regulatory actions. The measuring of acid phosphatase levels has been utilized and approved for many years to determine milk pasteurization, and recently used to determine juice/cider pasteurization, and ground meat cooking to required temperature.
How will addressing this research support/improve the mission/role of the ISSC/NSSP/Industry?	Establish regulatory guidelines. The ISSC through the Laboratory Procedures Evaluation Committee has approved the process of calculating levels of acid phosphatase as a methodology to determine the level of heat processing applied to shellfish meats. This methodology could be used by States and FDA to determine its regulatory action when finding imported shellfish from non-MOU countries. Further, the 2005 ISSC Lab Procedures Evaluation Committee requested additional analyses using acid phosphatase methodology to determine the thermal inactivation curves for shellfish from non-MOU countries using both raw, partially cooked, and cooked procedures.
Support need with literature citations as appropriate	(See attached published paper by Dr. Cutter of Penn State Univ. regarding the evaluation of this acid phosphatase methodology.)
Relative Priority Rank in Terms of Resolving Research Need	Immediate ☒ Valuable ☐ Required ☐ Other ☐ Important ☐
Estimated Cost:	$650.00 Supplies & Reagents $300.00 Shellfish Samples $950.00 TOTAL
Proposed Sources of Funding/Support:	FDA / ISSC
Time Frame Anticipated:	Immediate. Time is of the essence since states have been anxiously awaiting final approval to this analytical test.
Action by 2006 Vibrio Management Committee	Recommended referral of Research Needs Proposal 07-RN-200 to the 2007 Research Guidance Committee for review and prioritization.
Action by 2007 Vibrio Management Committee	Recommended adoption of Research Needs Proposal 07-RN-200.

Action by 2007 Research Guidance Committee	Recommended that Research Needs Proposal 07-RN-200 be placed into consideration for funding when available and further recommended that this research need be given a high priority due to the issues with imports and human health impacts.
Action by 2007 Task Force II	Recommended adoption of Research Guidance Committee recommendation on Research Needs Proposal 07-RN-200.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force II.
Action by USFDA	December 20, 2007 Concurred with Conference action.

USE OF AN ACID PHOSPHATASE ASSAY TO DETECT DEVIATIONS IN THERMAL PROCESSING OF SEAFOOD

Catherine N. Cutter, Ph.D.* and Barbara J. Miller
Department of Food Science, 111 Borland Laboratory
Pennsylvania State University

ABSTRACT

Viral pathogens, including Hepatitis A virus (HAV) and Norwalk-like viruses (NLV), have been implicated in foodborne outbreaks associated with seafood consumption. In August 2000, imported clams were implicated in an outbreak of viral gastroenteritis in New York State. According to the manufacturer, the clams were packaged, thermally processed, labeled as "cooked," frozen, and shipped to the U.S. Upon receipt, organoleptic/sensory analyses of the thawed clams indicated that they were undercooked. Additional microbiological analyses also concurred with these findings (Kingsley et al., 2002). The purpose of the current study was to determine if acid phosphatase (ACP), a heat labile enzyme found in raw muscle tissue, could be assayed to assess adequate thermal processing of seafood. In the first set of experiments, raw seafood products (lobster, shrimp, oysters, crab) were thermally processed to an internal temperature ranging from 130 to 165°F (55 to75°C), and acid phosphatase levels determined using a commercial ACP assay. Precooked seafood products (crab, shrimp, and lobster) were obtained from retail establishments and evaluated for adequate thermal processing. Additional studies involved development of ACP curves for clams and ACP assays from steamed, canned, and thermally processed clams, including the implicated clams from the 2000 outbreak. The results from this study demonstrated that the ACP assay verified adequate thermal processing of several precooked seafood products (crab, shrimp, lobster), but the implicated clams exhibited higher levels of ACP, indicating they may have been undercooked. The information from this study may be of importance to seafood processors or regulatory agencies that are interested in identifying a rapid method to verify thermal processing of seafood.

INTRODUCTION

In 1996, U.S. aquaculture production equaled 227,000 metric tons. Products include baitfish, catfish, salmon, trout, clams, crawfish, mussels, oysters, fresh and saltwater shrimp, ornamental fish, alligators, algae, aquatic plants, tilapia, and hybrid striped bass (Garrett et al., 1997). In addition to production for the U.S., rainbow trout, Atlantic salmon, tilapia, catfish, freshwater crawfish, and live mussels also are exported around the world. Additionally, the U.S. also imports large volumes of aquaculture products, including tuna, lobster, molluscan

shellfish, shrimp, clams, and salmon, originating in 172 countries around the world (Garrett et al., 1997).

Most foodborne illnesses from aquaculture products are associated with toxic substances; however, numerous outbreaks have been linked to biological hazards such as parasites, bacteria, and viruses (Nilsson and Gram, 2002). More recent outbreaks have been linked to bacteria (*Clostridium* spp., *Vibrio* spp., *Salmonella* spp., *Shigella* spp., *Campylobacter* spp., *and Listeria monocytogenes*) or viruses (Norwalk-like, Hepatitis A and E, Rotavirus; Nilsson and Gram, 2002). In fact, the largest known outbreak associated with an aquaculture product occurred in 1988 (Halliday et al., 1991). In this outbreak, 300,000+ people (5% of population) in Shanghai, China, developed Hepatitis A after the consumption of the contaminated clams (Halliday et al., 1991).

During the summer of 2000, imported clams were implicated in an outbreak of Norwalk-like virus in the Northeastern United States. According to the manufacturer, the clams were harvested, vacuum packaged, "thermally processed," frozen, and shipped to the U.S. (Jack Welte, Pennsylvania Department of Agriculture, personal communication). The product was distributed throughout New Jersey, New York and Pennsylvania. An outbreak of Norwalk-like illness from a restaurant in Cortland, NY, was linked to the clams (Kingsley et al., 2002). In this outbreak, five cases of gastroenteritis were reported (Kingsley et al., 2002). Organoleptic/sensory analyses of the clams indicated that, although the product was packaged and labeled as "cooked," the physical appearance and texture was that of raw clams when thawed (Kingsley et al., 2002).

Following these findings, stocks of clams were embargoed by the New Jersey State Health Department, and health officials in other states were notified. Additional microbiological analyses of the embargoed clams demonstrated that the clams exhibited fecal coliform levels of > 5 $\log_{10}$ (300-fold higher than acceptable levels; Kingsley et al. 2002). Further analyses of the digestive tracts of the clams indicated that the clams appeared to be contaminated with Hepatitis A virus and Norwalk-like virus while in their native setting (Kingsley et al., 2002). It is important to note that, in this particular outbreak, health officials relied upon organoleptic/sensory observations and microbiological analyses to determine that the clams were undercooked.

Acid phosphatase (ACP) is a heat labile enzyme found in significant levels of raw muscle tissue. Decreased ACP activity correlates with increased thermal processing. The ACP assay uses a self-indicating substrate that, when acted upon by ACP, loses a phosphate radical and becomes a highly fluorescent compound (Davis, 1998). Several researchers have demonstrated that monitoring of ACP levels can be used to determine proper heat treatments of muscle foods such as poultry and ground beef patties (Davis and Townsend, 1994; Davis, 1998; Lyon et

al., 2001). However, very little information exists as to the use of ACP as a means of determining proper thermal processing of seafood and other aquaculture products.

The objectives of this study were to develop ACP curves by testing raw and cooked seafood to internal temperatures of 130 to 165°F (55 to 75°C) and to test commercially processed seafood products for deviations in thermal processing.

MATERIALS AND METHODS

Seafood

Lobster, shrimp, clams, and oysters, used for the ACP curves in this study, were purchased raw or pre-cooked (pasteurized or steamed 10 min) from local retail establishments, and transported to the laboratory within 1 h of purchase and kept at approximately 40° F (4°C) until needed. Crab was harvested from the Atlantic Ocean, flash-frozen, and shipped to the laboratory on ice for analyses. Crabs were stored at -4° F (-20°C) upon receipt and thawed for 24 h at 40° F (4°C) prior to use. Canned clams were purchased from a retail establishment. Additional cooked-in-bag (CIB) products (implicated clams from the outbreak), cooked mussels, and raw quahogs were shipped frozen to our laboratory from the New Jersey Department of Health.

Preparation of seafood for heat treatments

Raw seafood was put through a food grinder once (9.53 mm or 4.76 mm plates). After grinding, raw oysters were placed in a sieve for 1-2 minutes to allow for drainage of excess moisture. For each replication performed, five separate 16 X 100 mm glass test tubes were packed with 10 grams of the ground sample. Tubes were placed in a rack located in a heated water bath set approximately 2.0°F (0.5°C) above the target end point temperature (EPT). The internal temperature of the product was monitored using a thermocouple (Digisense, Cole-Parmer Instrument Co., Vernon Hill, IL) placed in the geometric center of each of the five samples. Shrimp were cooked to an internal temperature from 145°F to 165°F (63°C to 74°C); crab and lobster were cooked to an internal temperature from 140°F to 165°F (60°C to 74°C); oysters were cooked to an internal temperature of 140°F to 175°F (60°C to 79.5°C); and clams were cooked to an internal temperature of 130°F to 165°F (54.5°C to 74°C). Once each of the five samples reached the EPT, samples were removed from the water bath and cooled immediately in an ice water bath to 33°F to 37.5°F (1 – 2 °C). Sample tubes were refrigerated (40°F; 4°C) until needed for ACP analyses (within 24 hours). After chilling, a center plug (approximately 15 g) was removed from the test tubes, chopped with a sterile scalpel and mixed to ensure even distribution of the cooked product. ACP assays on heat-treated or precooked products were performed as described below.

ACP Assays

The procedures for processing raw and cooked samples for ACP assays are depicted in Figure 1. After thawing raw product or chilling cooked product, seafood samples were weighed to 0.8 g and added to a homogenizing tube. Sterile deionized water (1.6 ml; 1:3 ratio) was added to the sample. Using a homogenizer (Advanced Instruments, Norwood, MA) on the low setting, 2-3 short up and down strokes were applied to each sample for approximately 8-10 sec. The resulting homogenate was poured into a 35cc filter syringe with a 1µm filter (for clams, 0.45 µm filters were used) and filtered. Approximately 300 µl of the resulting extract was transferred into a disposable cuvette. Within 24 h, the resulting sample was refrigerated (40°F; 4°C) until assayed for ACP. Approximately 75 µl of filtrate sample was assayed using the fluorometer (Advanced Instruments). To avoid over-range results with raw oysters, 10-fold serial dilutions of the filtrate sample were made in sterile deionized water. ACP Fluorophos reagents were purchased and prepared according to manufacturer's instructions (Advanced Instruments). The Fluorometer ACM100 was programmed according to Standard Laboratory Procedures found in the Fluorometer User's Guide. The ACP Calibrator kit insert was followed for product calibration on the ACP Meat Channel.

ACP activity in the filtrate was measured after mixing the filtered extract with an acetate buffer (pH 5) containing a nonfluorescent aromatic monophosphoric ester substrate (Advanced Instruments; Davis, 1998). The rate of fluorophore formation was monitored during a 1 min incubation period 100°F (38°C) in the fluorometer, and ACP enzyme activity (U/kg sample) read and recorded from the fluorometer.

Calculations and analyses

Five replications of ACP assays were performed for each of the raw or cooked samples. Average ACP values were determined for each product and plotted against EPT.

RESULTS AND DISCUSSION

The resulting ACP analyses for raw and cooked oysters are depicted in Figure 2. Raw oysters (40°F; 4°C) exhibited average ACP levels of >60 U/kg. When oyster meat reached an endpoint temperature (EPT) of 145°F (63°C), average ACP levels decreased to >20 U/kg. Average ACP levels of <1 U/kg were not reached until the oyster meat reached an EPT of at least 155°F (68°C), indicating that the product was cooked.

At 40°F, raw lobster exhibited significantly lower average ACP levels (approximately 7 U/kg) than observed with oysters (Figure 3). Cooking to a minimum EPT of 140°F (60°C) reduced average ACP levels to <1 U/kg. Average ACP levels in raw shrimp were >9 U/kg, whereas after reaching an EPT

of 145°F (60°C), average ACP levels dropped to >1 U/kg (Figure 4). Raw crab also exhibited high levels of average ACP (>11 U/kg), but was demonstrated to be <1 U/kg after reaching an EPT of 160°F (71°C; Figure 5). In all instances, raw seafood had high levels of ACP, and cooking to at least 140°F reduced ACP levels significantly.

To further validate these findings, cooked and chilled seafood was purchased from local retail establishments and evaluated for ACP. Three samples of cooked crab, two samples of cooked shrimp, and two samples of cooked lobster were subjected to ACP analyses (Figure 6). In all instances, average ACP levels were <0.8 U/kg, indicating thermal processing of these seafood products.

Since clams were implicated in the 2000 outbreak, additional experiments were performed with raw and cooked clams. When assayed in this set of experiments, raw clams exhibited significantly lower average ACP levels (approximately 1.2 U/kg) than the other seafoods examined in this study (Figure 7). However, levels dropped to <0.5 U/kg when cooked to an EPT of at least 130°F (54°C).

Further validation studies were performed on raw quahogs, steamed clams, canned clams, cooked mussels, and clams cooked-in-bag (CIB; Brands A, B, C). In these analyses, raw quahogs exhibited average ACP levels of >3.5 U/kg (Figure 8). Steamed clams, canned clams, and cooked mussels exhibited average ACP levels of <0.5 U/kg, suggesting that thermal processing had occurred. Brand A CIB clams and 5 oz (142 g) Brand C CIB clams also exhibited average low ACP levels of <0.5 U/kg.

Brand B CIB clams, which were implicated in the 2000 clam outbreak, were found to have average ACP levels of >2 U/kg, indicating they may have been undercooked (Figure 8). Interestingly, a 16 oz (454 g) package of Brand C CIB clams also exhibited higher levels of average ACP than expected (>1.4 U/kg), thereby suggesting that these clams may have been undercooked as well.

It is important to note that, during the 2000 outbreak, health officials relied upon organoleptic/sensory observations and microbiological analyses to ascertain that the clams were undercooked (Kingsley et al., 2002; Jack Welte, personal communication). In the current study, similar observations were conducted with the cooked-in-bag (CIB) products of Brands A, B, and C. Clam shells from Brand A CIB and Brand C CIB 5 oz were found to be tightly packed and overlapping on one another. After opening the bag, most of the clams were separated or opened. The remaining clams could be opened by prying the shells apart by hand. Once opened, the adductor muscle appeared to be separated from the shell and the meat appeared to be light yellow in color.

Clams from Brand B CIB (implicated clams) and Brand C CIB 16 oz were also found to be tightly packed and overlapping on one another. However, after the

bag was opened, it was noted that very few of the clams had separated or opened. In order to process the meat from the clams for ACP analyses, a sterile screwdriver was needed to pry open most of the clam shells. Once open, the outside of the meat from most clams was found to be off white/gray in color. It was also noted that some of the adductor muscles did not appear to be separated completely from the shell. These observations, coupled with the ACP analyses and microbiological data (Kingsley et al., 2002), suggest that the implicated clams from the outbreak did not receive sufficient heat treatment.

Implicated clams from the 2000 outbreak were evaluated microbiologically and found to contain high levels of fecal coliforms (Kingsley et al., 2002). The presence of fecal coliforms, hepatitis virus, and Norwalk viruses in the digestive tracts of the clams, rather than on the surface, suggested that the clams were harvested from an area with high levels of fecal pollution (Kingsley et al., 2002). The high fecal coliform counts observed in the study corroborated the raw appearance of the clams (Kingsley et al., 2002). The authors also deduced that if the clams had been tested for fecal coliforms, the clams would not have been allowed to enter commerce (Kingsley et al., 2002). It is important to note that microbiological analyses used in outbreak investigations can take several hours to days to complete.

The current study has demonstrated that not only can ACP be detected rapidly in a variety of raw seafood products, including oysters, crab, shrimp, lobster, and clams, but the levels of the enzyme decrease during thermal processing. Our experiments with raw seafood also demonstrated that seafood products have varied ranges of ACP levels. Therefore, it is recommended that curves or a baseline ACP levels, be established for each and every product to be evaluated with the assay.

Our findings are similar to those of Lyon et al (2001) who measured ACP in consumer-style, griddle-cooked ground beef patties and Davis and Townsend (1994), who evaluated ACP levels in cooked poultry. In both of these studies, the authors were able to verify adequate thermal processing of the muscle foods through the use of ACP assays.

In the current study, the assays conducted on raw or thermally processed seafood were conducted with a commercial ACP system and took less than 20 min to complete; the assay itself takes approximately 5 minutes to complete. The loss of ACP at cooking temperatures >130°F (54°C) and under the conditions described in this study makes ACP a potential indicator of thermal processing. The use of an ACP assay to verify thermal processing could be of importance when developing and/or implementing a hazard analysis and critical control point (HACCP) system. To our knowledge, the current study is the first to report the use of ACP as an indicator of thermal processing in seafood.

Based on the current study, the use of ACP as an indicator of thermal processing could be useful to U.S. seafood importers, health inspectors, and/or state or federal regulators, who may rely upon visual inspection or questionable HACCP documentation for acceptance of seafood product(s) at points of entry.

ACKNOWLEDGEMENTS

The authors would like to thank Advanced Instruments (Norwood, MA) for training and for the use of the fluorometer. The authors also would like to thank Ken Micciche (Advanced Instruments) for his advice and guidance on the project and for his review of this manuscript. The authors also thank Phillips Foods, Inc. (Baltimore, MD), for the crabs and the members of the Susquehanna Conference of the Central Atlantic States Association (CASA) of Association of Food and Drug Officials for their input. Special thanks to Jack Welte (Pennsylvania Department of Agriculture) and Gary Wolf (formerly New Jersey Department of Health, now with FDA) for their input and encouragement on the project and manuscript and for sharing the implicated clams from the outbreak.

REFERENCES

Davis C. E. (1998) Fluorometric determination of acid phosphatase in cooked, boneless, nonbreaded broiler breast and thigh meat. *J. of AOAC International* 81: 887-906.

Davis C. E. and Townsend W. E. (1994) Rapid fluorometric analysis of acid phosphatase activity in cooked poultry meat. *J. Food Prot.* 57:1094-1097.

Garrett E.S., Jahncke M.L. and Lima dos Santos C.A.M. (1997) Public and animal health implications of aquaculture. Paper presented at the International Life Sciences Institute Conference on Emerging Foodborne Pathogens: Implications and Control, Alexandria, Va., USA, March 1997.

Halliday M.L., Kang L.Y., Zhou T.K., Hu, M.D., Pan Q.C., Fu T.Y., Huang Y.S. and Hu S.L. (1991) An epidemic of hepatitis A attributable to the ingestion of raw clams in Shanghai, *China. J. Infect. Dis.* 164:852-859.

Kingsley, D.H., Meade G.K. and Richards G.P. (2002) Detection of both Hepatitis A Virus and Norwalk-Like Virus in Imported Clams Associated with Food-Borne Illness. Appl. Environ. Microbiol. 68:3914-3918.

Lyon B.G., Davis C.E., Windham W.R. and Lyon C.E. (2001) Acid phosphatase activity and color changes in consumer-style griddle-cooked ground beef patties. *J. Food Prot.* 64:1199-1205.

Nilsson L., and Gram L. (2002). Improving the control of pathogens in fish products, pp. 54-84. *In* Safety and quality issues in fish processing, H. A. Bremmer (ed.), Boca Raton: FL *CRC Press.*

Figure 1. Protocol for analyzing thermally processed or raw seafood products

25 g of raw product was transferred into a test tube

↓

Using thermocouples, raw product was cooked to an internal temperature of 130°F to 175°F (55°C to 75°C) in heated water baths

↓

Cooked product was cooled in an ice water bath (15 min) and refrigerated

↓

The center plug was extracted (approximately 15 g)

↓

Cooked/Raw product was added to deionized, sterile water (1:3 ratio)

↓

Handheld homogenizer was used to blend

↓

Homogenized product was filtered to extract 300 µl

↓

75 µl of filtrate sample was mixed with 2 ml Fluorophos substrate

↓

Tube was inserted into a calibrated fluorometer and results were read after 1 min

Figure 2. ACP analyses for oysters at various cooking temperatures

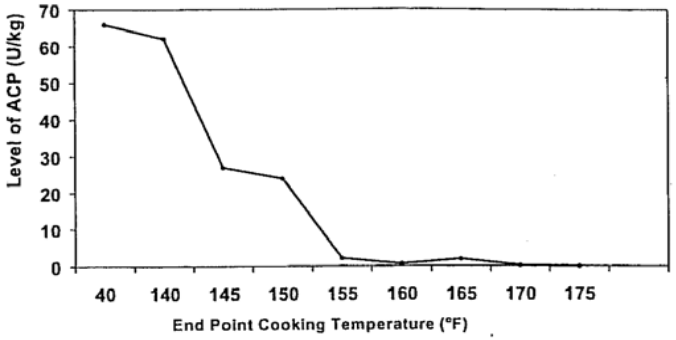


Figure 3. ACP analyses for lobster at various cooking temperatures

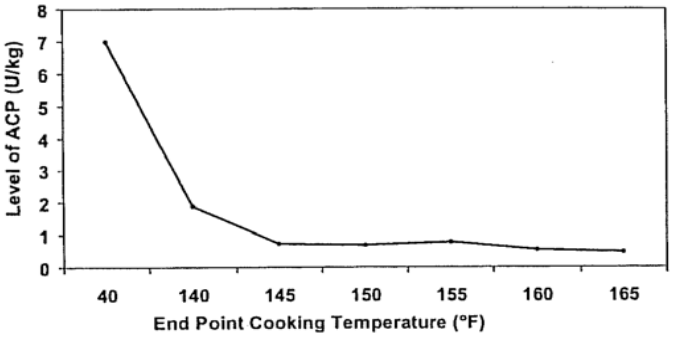


Figure 4. ACP analyses for shrimp at various cooking temperatures

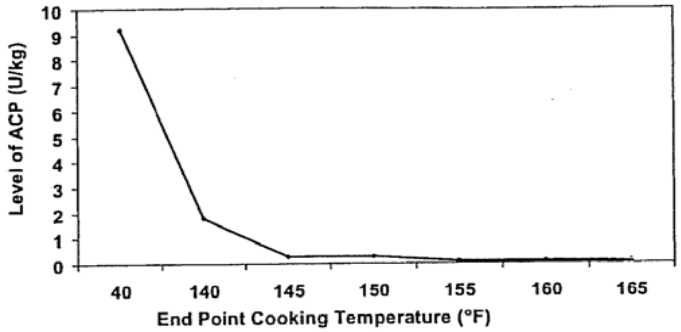


Figure 5. ACP analyses for crab at various cooking temperatures

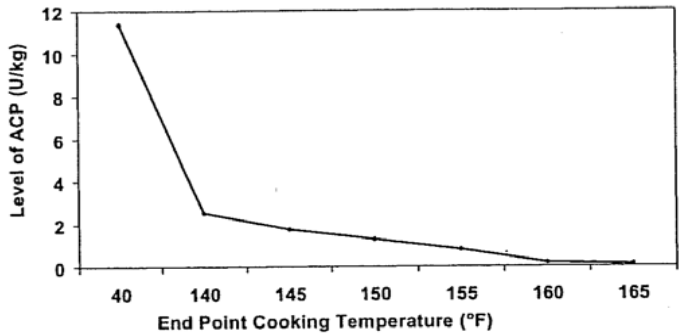


Figure 6. ACP analyses for purchased seafood (cooked and chilled)

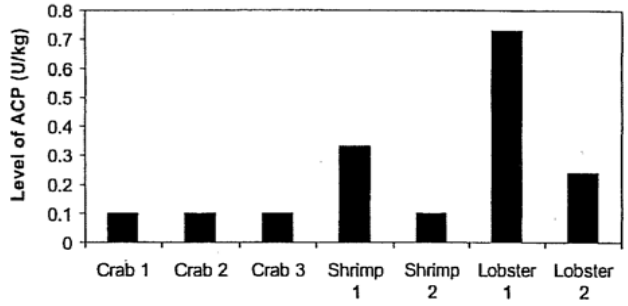


Figure 7. ACP analyses for clams at various cooking temperatures

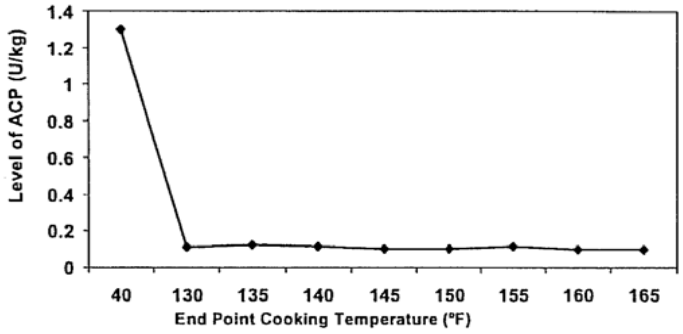
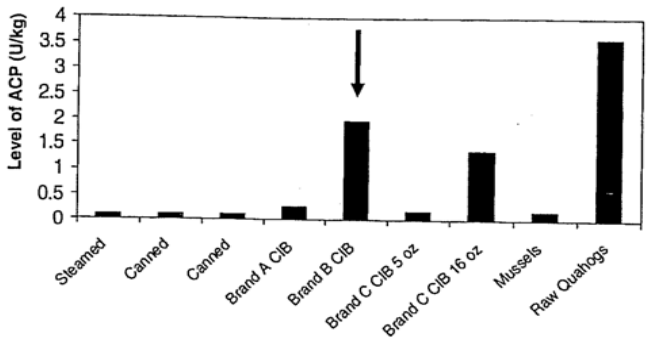


Figure 8. ACP analyses for a variety of clams



Note: Arrow indicates implicated clams in 2000 outbreak.

MAINTAINING A SAFE AND AFFORDABLE PRESCRIPTION DRUG SUPPLY FOR CONSUMERS IN AN ERA OF GLOBAL MARKETS AND INTERNET TRADING*

Mark B. McClellan, M.D., Ph.D.
Commissioner
Food and Drug Administration

Good evening, and thank you for your kind words. It's an honor to be here tonight, and to be able to pay tribute to someone who dedicated so much of his life to helping others improve their health.

I didn't know David Winston personally, but I certainly know his legacy, and I think his impact came on two levels. First, by what he was able to accomplish. For example, as president of the National Committee for Quality Health Care, he helped set some of the standards through which many people came to enjoy higher quality healthcare—perhaps not a glamorous achievement, but an essential one for identifying and encouraging best medical practices. And second, by the seriousness and effectiveness with which he approached health policy problems. He set an example for all of us in how to find solutions for difficult health care problems. President Reagan would later say of David that he was "the kind of person who made a tremendous contribution by working largely behind the scenes, but those who knew him were keenly aware of his central role."

Biomedical technology has advanced dramatically since then, and the details of the healthcare policy debates have changed along with medicine. But some of the most pressing healthcare problems remain the same as when David was working to advance the health of the public. The mark of good leadership is finding ways to achieve the often-competing goals in health policy, to get the best care to the most people to achieve the greatest improvements in public health. Even though we all want simple and fair solutions, it's not easy to get there. But real leadership like that which David Winston provided is more important today than ever.

And that brings me to my main topic. A lot of public attention has focused on drug importation recently. It's easy to understand why: people walking into a pharmacy and paying "list price" are facing much higher prices for brand-name drugs in the United States than in Canada, France, or any other country for that matter. Americans now pay about half of all costs of prescription drugs

**Speech before Fifth Annual David A. Winston Lecture National Press Club Washington, D.C. Remarks by Mark B McClellan, M.D., Ph.D. Commissioner, Food and Drug Administration*

Proposal Subject	Reciprocity and Uniformity
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Amend Procedure V and Add New Section
Text of Proposal/ Requested Action	Procedure 5 Section 1. The NSSP **and Model Ordinance** as adopted by the ISSC and the FDA, without footnotes except as the Conference may adopt, shall be used as the basic guidelines for the classification of shellfish growing waters and the basic sanitation guidelines in making shellfish sanitation certification inspections of interstate shellfish shippers. The Conference discourages the use of separate guidelines for intrastate shellfish shippers. Shellfish from any state participating in the ISSC ~~should~~ **shall** be accepted for sale in any other member state under the principles of reciprocity, provided the state's program is in compliance with the NSSP and **Model Ordinance**. Such states **that do not comply with the NSSP and Model Ordinance** shall **not** be indicated on the ICSSL. Reciprocity for the purpose of ISSC agreements shall mean that no action or requirements on the part of any regulatory authority will cause or require any action in excess of the requirements of the NSSP or the ISSC agreements. For the purpose of the NSSP and ISSC in total, the District of Columbia shall be considered as a state with all the rights, duties, responsibilities, and privileges of a state.
Public Health Significance	None
Cost Information (if available)	None
Action by 2003 Task Force III	Recommended postponing discussion on Proposal 03-302 until 8:30 AM on Wednesday, August 6, 2003. In the interim, there will be a working committee that will attempt to develop a proposal that addresses the concerns identified in the discussion. The committee will be made up of one industry and one regulatory representative from each ISSC region and one representative from each of the federal agencies. The representative from the region will be determined by the Task Force members and reported to the Chair as soon as possible.
Action by 2003 Task Force III Workgroup	Recommended the following language be substituted for the language in Proposal 03-302. Procedure V Section 1. Intent: The NSSP as adopted by the ISSC and the FDA, without footnotes except as the Conference may adopt, shall be used as the basic guidelines for the classification of shellfish growing waters and the basic sanitation guidelines in making shellfish sanitation certification inspections of interstate shellfish shippers. The Conference discourages the use of separate guidelines for intrastate shellfish shippers. Shellfish from any state participating in the ISSC should be accepted for sale in any other member state under the principles of reciprocity, provided the state's program is in compliance with the NSSP. Such states shall be indicated on the ICSSL. Circumstances under which a State may refuse to exercise reciprocity should be limited to newly emergent public health issues that are not being adequately addressed by the NSSP. Reciprocity for the purpose of ISSC agreements shall mean that no action or requirements on the part of any regulatory authority will cause or require any action in excess of the requirements of the NSSP or the ISSC agreements. For the purpose of the NSSP and ISSC in total, the District of Columbia shall be considered as a state with all the rights, duties, responsibilities, and privileges of a state.

Section 2. Notification and Consultation:

A state, prior to taking an action that may fail to meet the definition of "reciprocity," must first notify and consult with the Executive Board. Notification should be as far in advance as is reasonably possible in order to take into account the views of the ISSC in prior to a decision to take the action. The state should provide the rationale for the proposed action by describing, at a minimum:

- The potential effect on the public health within that state;
- The potential effect on the public health in other states;
- The potential economic impact on states;
- The necessity for the action within the proposed timeframe; and
- How the proposed actions are consistent with Procedure I requirements relating to uniformity and the importance of operating within a collective framework.

A state may also notify the ISSC Executive Board upon learning of another state's intention to take action that may violate Procedure V.

Action by 2003 Task Force III

Recommended adoption of the Work Group recommendations as amended.

Procedure V
Section 1. Intent:

The NSSP as adopted by the ISSC and the FDA, without footnotes except as the Conference may adopt, shall be used as the basic guidelines for the classification of shellfish growing waters and the basic sanitation guidelines in making shellfish sanitation certification inspections of interstate shellfish shippers. The Conference discourages the use of separate guidelines for intrastate shellfish shippers. Shellfish from any state participating in the ISSC should be accepted for sale in any other member state under the principles of reciprocity, provided the state's program is in compliance with the NSSP. Such states shall be indicated on the ICSSL. ~~Circumstances under which a State may refuse to exercise reciprocity should be limited to newly emergent public health issues that are not being adequately addressed by the NSSP.~~ Reciprocity for the purpose of ISSC agreements shall mean that no action or requirements on the part of any regulatory authority will cause or require any action in excess of the requirements of the NSSP or the ISSC agreements. For the purpose of the NSSP and ISSC in total, the District of Columbia shall be considered as a state with all the rights, duties, responsibilities, and privileges of a state.

Further recommended that the Executive Board establish a working group to determine the appropriate language to identify the circumstances under which reciprocity may not be honored.

Further recommended that the new Procedure V take effect immediately after adoption by the General Assembly.

Action by 2003 General Assembly

Adopted recommendations of Task Force III.

Action by USFDA

Concurred with Conference Action.

Action by 2005 Executive Board

The ISSC Executive Board did not take action on this proposal due to a pending Procedure V complaint.

Action by 2005 Task Force III

Recommended the Executive Board continue to pursue appropriate language to identify the circumstances under which reciprocity may not be honored.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force III that the Executive Board continue to pursue appropriate language to identify the circumstances under which reciprocity may not be honored.

Action by USFDA

Concurred with Conference action.

Action by 2007 Reciprocity Committee

Recommended modification of the ISSC Constitution, Bylaws, and Procedures by moving portions of Procedure V. and creating a new Procedure XVII. Additional language was added to the ISSC Constitution, Bylaws, and Procedures to amend Procedure V. and move deleted sections to a new Procedure XVII.

PROCEDURE V. GUIDELINES

The NSSP as adopted by the ISSC and the FDA, without footnotes except as the Conference may adopt, shall be used as the basic guidelines for the classification of shellfish growing waters and the basic sanitation guidelines in making shellfish sanitation certification inspections of interstate shellfish shippers. The Conference discourages the use of separate guidelines for intrastate shellfish shippers. Shellfish from any state participating in the ISSC should be accepted for sale in any other member state under the principles of reciprocity, provided the state's program is in compliance with the NSSP. Such states shall be indicated on the ICSSL. ~~Reciprocity for the purpose of ISSC agreements shall mean that no action or requirements on the part of any regulatory authority will cause or require any action in excess of the requirements of the NSSP or the ISSC agreements.~~ For the purpose of the NSSP and ISSC in total, the District of Columbia shall be considered as a state with all the rights, duties, responsibilities, and privileges of a state

~~**Section 1. Intent**~~

~~The NSSP as adopted by the ISSC and the FDA, without footnotes except as the Conference may adopt, shall be used as the basic guidelines for the classification of shellfish growing waters and the basic sanitation guidelines in making shellfish sanitation certification inspections of interstate shellfish shippers. The Conference discourages the use of separate guidelines for intrastate shellfish shippers. Shellfish from any state participating in the ISSC should be accepted for sale in any other member state under the principles of reciprocity, provided the state's program is in compliance with the NSSP. Such states shall be indicated on the ICSSL. Reciprocity for the purpose of ISSC agreements shall mean that no action or requirements on the part of any regulatory authority will cause or require any action in excess of the requirements of the NSSP or the ISSC agreements. For the purpose of the NSSP and ISSC in total, the District of Columbia shall be considered as a state with all the rights, duties, responsibilities, and privileges of a state.~~

~~**Notification and Consultation**~~

~~A state, prior to taking an action that may fail to meet the definition of "reciprocity," must first notify and consult with the Executive Board. Notification should be as far in advance as is reasonably possible in order to take into account the views of the ISSC prior to a decision to take the action. The state should provide the rationale for the proposed action by describing, at a minimum:~~

- ~~The potential effect on the public health within that state;~~
- ~~The potential effect on the public health in other states;~~
- ~~The potential economic impact on states;~~
- ~~The necessity for the action within the proposed timeframe; and~~
- ~~How the proposed actions are consistent with Procedure I requirements~~

~~relating to uniformity and the importance of operating within a collective framework.~~

~~A state may also notify the ISSC Executive Board upon learning of another state's intention to take action that may violate Procedure V.~~

~~**Section 3. Consideration**~~

~~If, after fully considering the state's rationale for the proposed actions, the Executive Board determines that the state's actions are unwarranted and contrary to the interests of the collective membership, the Executive Board shall so advise the state. If the State takes the proposed action after being so advised, or fails to follow Procedure V, the Executive Board will commence a formal Procedure V process.~~

~~**Section 4. Formal Procedure V. Process**~~

~~The process will include written notification to all states involved (initiating and affected states), to present findings on the scientific and public health issues raised, which support their respective views or actions on the issue, along with identification of the formal procedural process and timeline.~~

~~All affected states (initiating and affected states), shall present the following information to the ISSC EXECUTIVE BOARD:~~

- ~~Scientific and related public health issues;~~
- ~~Economic issues;~~
- ~~Other relevant issues;~~
- ~~Rationale why Procedure V has/has not been violated.~~
- ~~Alternative Actions for consideration.~~

~~The Executive Board determination will include Findings of Facts and Conclusions.~~

~~Section 5. Censure~~

~~If the state takes the proposed action after being so advised, or fails to follow Procedure V, the Executive Board may place the state under censure until such time as removed from the censure by the Executive Board and so inform the governor of that state in writing. A state under censure may attend all functions and otherwise exercise rights as a member of the ISSC, but may not vote, either in committees, task forces, or in the general assembly. The Executive Board reserves the right to take additional actions against the non-compliant State.~~

PROCEDURE XVII. RECIPROCITY

Reciprocity for the purpose of ISSC agreements shall mean that no action or requirements on the part of any regulatory authority will cause or require any action in excess of the requirements of the NSSP or the ISSC agreements. The intent of this procedure is to ensure that state actions do not unnecessarily restrict interstate shipment of shellfish conforming to the reciprocity of the NSSP. The ISSC recognizes that states should be allowed to appropriately respond to public health emergencies that could restrict interstate shipment of oysters. Chapter XVII. Section 1. Notification and Consultation provides adequate opportunity for communication between interested parties that could include state and federal regulatory agencies and the industry.

Section 1. Notification and Consultation

A state, prior to taking an action that may fail to meet the definition of "reciprocity," must first notify and consult with the Executive Board. Notification should be as far in advance as is reasonably possible in order to take into account the views of the ISSC prior to a decision to take the action. The state should provide the rationale for the proposed action by describing, at a minimum:

- The potential effect on the public health within that state;
- The potential effect on the public health in other states;

- The potential economic impact on states;
- The necessity for the action within the proposed timeframe; and
- How the proposed actions are consistent with Procedure I requirements relating to uniformity and the importance of operating within a collective framework.

A state may also notify the ISSC Executive Board upon learning of another state's intention to take action that may violate Procedure V.

Section 2. Consideration

If, after fully considering the state's rationale for the proposed actions, the Executive Board determines that the state's actions are unwarranted and contrary to the interests of the collective membership, the Executive Board shall so advise the state. If the State takes the proposed action after being so advised, or fails to follow Procedure V, the Executive Board will commence a formal Procedure V process.

Section 3. Formal Procedure V. Process

The process will include written notification to all states involved (initiating and affected states), to present findings on the scientific and public health issues raised, which support their respective views or actions on the issue, along with identification of the formal procedural process and timeline.

All affected states (initiating and affected states), shall present the following information to the ISSC EXECUTIVE BOARD:

- Scientific and related public health issues;
- Economic issues;
- Other relevant issues;
- Rationale why Procedure V has/has not been violated.
- Alternative Actions for consideration.

The Executive Board determination will include Findings of Facts and Conclusions.

Section 4. Censure

If the state takes the proposed action after being so advised, or fails to follow Procedure V, the Executive Board may place the state under censure until such time as removed from the censure by the Executive Board and so inform the governor of that state in writing. A state under censure may attend all functions and otherwise exercise rights as a member of the ISSC, but may not vote, either in committees, task forces, or in the general assembly. The Executive Board reserves the right to take additional actions against the non-compliant State.

Action by 2007 Task Force III

Recommended adoption of the Reciprocity Committee recommendation on Proposal 03-302.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force III.

Action by USFDA

December 20, 2007
Concurred with Conference action with the following comments and recommendations for ISSC consideration.

The word "oyster" at the end of sentence three in paragraph one of Procedure XVII should be changed to "shellfish." This is in keeping with use of the word "shellfish" elsewhere in Procedures XVII and Procedure XVII's intent to address all species of molluscan shellfish, not just oysters.

Proposal Subject	Change in ISSC Proposal Review
Specific NSSP Guide Reference	Constitution, Bylaws, and Procedures of the ISSC, Article III and Article IV
Text of Proposal/ Requested Action	Since the ISSC is now meeting every two years and since a majority of issues go to committees for further discussion, the time of a final result on these issues sent to committee may take a minimum of two years. In order to hasten the final decision process on an issued, a new process of issue review is described. The task forces would meet at the beginning of the ISSC meeting (Sunday morning) to consider only the newly submitted issues. If the task forces want further discussion and work performed on the issue, the issue would go to the appropriate committee for review at that ISSC meeting. (The chairman would already have determined to what committee each new issue would go.) The committees would not start their discussions until the task forces are completed with the new issues. The committee meetings occur the next day so that paperwork for the committees can be prepared. All committees not scheduled to meet will have to be placed on a stand-by position. If an issue has to go to a committee not schedule to meet, then that committee will be given a time to meet at the closing end of the time period scheduled for committee meetings. This is done in an attempt to minimize the problem of one person assigned to two committees meeting at the same time. The committees meet to discuss any old business (if applicable) and then the new issues. The committees' decisions on all issues then go back to the appropriate task force in the same manner as the current procedure. The task force does its work on the issue for the General Assembly.
Public Health Significance	Many ISSC issues that result in changes in the Model Ordinance have improved public health as one outcome. The faster such changes occur, the faster the improvement of safety to the consumer. In addition, from a laboratory perspective, this issue is especially important to laboratories since laboratory changes need to be immediately incorporated into laboratory quality assurance program. This will provide laboratory accuracy, precision and efficiency when generating public health data.
Cost Information (if available)	None
Action by 2003 Task Force III	Recommended referral of Proposal 03-306 to Executive Board to develop a procedure to facilitate discussions of proposals as outlined in Proposal 03-306.
Action by 2003 General Assembly	Adopted recommendation of Task Force III.
Action by USFDA	Concurred with Conference Action.
Action by 2005 Executive Board	Recommended no action on Proposal 03-306. Rationale – The present procedures are adequate to accomplish Conference discussion of proposals.
Action by 2005 Task Force III	Recommended referral of Proposal 03-306 to the Executive Board to consider ways to facilitate discussion of new proposals during Biennial Meetings.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force III to refer Proposal 03-306 to the Executive Board.
Action by USFDA	Concurred with Conference action.
Action by 2007 Executive Board	Recommended no action on Proposal 03-306. Rationale - Executive Board has taken steps to address the concerns outlined in Proposal 03-306.

Action by 2007 Task Force III	Recommended adoption of Executive Board recommendation on Proposal 03-306.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject	Executive Board Member Terms
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures, Article IV. Section 7.
Text of Proposal/ Requested Action	To accomplish the intent of the Constitution it is necessary to elect approximately ½ of the Board to four-year terms. After the 2005 election all Board members will be elected to four-year terms. In 2005 (odd or even) regions will be elected to four-year terms with the remaining elected to (two-year or four-year) terms. ISSC Constitution Article IV. Executive Board, Officers, Committees Section 7. Elected Board members shall serve ~~two~~ **four-year** terms. Terms of the elected Board members shall expire at the end of the voting General Assembly of the regular Biennial Conference meeting.
Public Health Significance	None
Cost Information (if available)	None
Action by 2005 Task Force III	Recommended adoption of Proposal 05-300 as submitted. In addition, requests the Executive Board to consider whether Board Officer terms should be addressed.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force III.
Action by ISSC Executive Board August 19, 2005	Recommended consideration of Proposal 05-300 at the March 2006 Executive Board meeting.
Action by USFDA	Concurred with Conference action.
Action by 2007 Executive Board	Recommends no further action on Proposal 05-300. Rationale – Conducting Board Officer elections every two years does not create concern for the Executive Board.
Action by 2007 Task Force III	Recommended adoption of Executive Board recommendation on Proposal 05-300.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject	Laboratory Method Acceptance into NSSP
Specific NSSP Guide Reference	Constitution By-Laws and Procedures of the ISSC
Text of Proposal/ Requested Action	The Laboratory Methods Review Committee must review laboratory methods that are to be accepted into the ISSC program. The Laboratory Methods Review Committee must follow Procedure XVI found in the Constitution By-Laws and Procedures of the Interstate Shellfish Sanitation Conference. If a public health emergency should arise, the Executive Committee shall approve new laboratory procedures. Such emergency action shall involve consultation with a quorum of the Laboratory Methods Review Committee. The Laboratory Methods Review Committee at the next ISSC Meeting will review new methods, accompanied by their validation and collaborative studies data, which were allowed by the emergency action. Such review can result in the method being accepted as a particular type method or denied acceptance. During this time period, the committee will evaluate and review a laboratory checklist for the method submitted by the method's author(s). Since not all methods listed in the *Bacteriological Analytical Manual* (BAM) are collaboratively tested and approved, methods that appear in the BAM cannot be accepted into the program based solely on the method's inclusion in the BAM. At the time of method submission, the submitter(s) must also include a draft laboratory checklist that is to be used during laboratory evaluation by Laboratory Evaluation Officers.
Public Health Significance	Laboratory methods detecting the direct or indirect presence of human pathogens must be proven to consistently work at various laboratories throughout the country and participating MOU countries. Detailed review of scientific data (preferably from collaborative studies) by the Laboratory Methods Review Committee must be done.
Cost Information (if available)	None
Action by 2005 Task Force III	Recommended referral of Proposal 05-303 to the Executive Board to investigate ISSC approaches to adopting laboratory methods for use in the NSSP.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force III.
Action by ISSC Executive Board August 19, 2005	Recommended appointment of a workgroup to determine what the role of the ISSC should be in adoption of laboratory methods. The workgroup is also directed to look at similar conferences' procedures regarding laboratory methods approval. The workgroup will report their findings to the Executive Board at the March 2006 meeting.
Action by USFDA	Concurred with Conference action.
Action by 2006 Laboratory Methods Validation Protocol Workgroup	Developed a protocol of Single Lab Validation for method approval within the NSSP and SOPs for *Vv* and *Vp* PCR Methods.
Action by Executive Board April 2006	Adopted as interim, the procedures developed by the Lab Methods Validation Protocol Workgroup.
Laboratory Methods Review Committee	Recommended adoption of the interim protocol.

Action by 2007 Task Force III	Recommended adoption of Single Lab Protocol which was adopted in 2006 as interim by the Executive Board.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Method Application and Single Lab Validation Checklist For Acceptance of a Method for Use in the NSSP

The purpose of single laboratory validation in the National Shellfish Sanitation Program (NSSP) is to ensure that the analytical method under consideration for adoption by the NSSP is fit for its intended use in the Program. A Checklist has been developed which explores and articulates the need for the method in the NSSP; provides an itemized list of method documentation requirements; and, sets forth the performance characteristics to be tested as part of the overall process of single laboratory validation. For ease in application, the performance characteristics listed under validation criteria on the Checklist have been defined and accompany the Checklist as part of the process of single laboratory validation. Further a generic protocol has been developed that provides the basic framework for integrating the requirements for the single laboratory validation of all analytical methods intended for adoption by the NSSP. Methods submitted to the Interstate Shellfish Sanitation Conference (ISSC) Laboratory Methods Review (LMR) Committee for acceptance will require, at a minimum, six (6) months for review from the date of submission.

Name of the New Method	
Name of the Method Developer	
Developer Contact Information	

Checklist	Y/N	Submitter Comments
A. Need for the New Method		
1. Clearly define the need for which the method has been developed.		
2. What is the intended purpose of the method?		
3. Is there an acknowledged need for this method in the NSSP?		
4. What type of method? i.e. chemical, molecular, culture, etc.		
B. Method Documentation		
1. Method documentation includes the following information:		
Method Title		
Method Scope		
References		
Principle		
Any Proprietary Aspects		
Equipment Required		
Reagents Required		
Sample Collection, Preservation and Storage Requirements		
Safety Requirements		
Clear and Easy to Follow Step-by-Step Procedure		
Quality Control Steps Specific for this		

Method		
C. Validation Criteria		
1. Accuracy / Trueness		
2. Measurement Uncertainty		
3. Precision Characteristics (repeatability and reproducibility)		
4. Recovery		
5. Specificity		
6. Working and Linear Ranges		
7. Limit of Detection		
8. Limit of Quantitation / Sensitivity		
9. Ruggedness		
10. Matrix Effects		
11. Comparability (if intended as a substitute for an established method accepted by the NSSP)		
D. Other Information		
1. Cost of the Method		
2. Special Technical Skills Required to Perform the Method		
3. Special Equipment Required and Associated Cost		
4. Abbreviations and Acronyms Defined		
5. Details of Turn Around Times (time involved to complete the method)		
6. Provide Brief Overview of the Quality Systems Used in the Lab		
Submitters Signature	Date:	
Submission of Validation Data and Draft Method to Committee	Date:	
Reviewing Members	Date:	
Accepted	Date:	
Recommendations for Further Work	Date:	
Comments:		

DEFINITIONS

1. Accuracy/Trueness - Closeness of agreement between a test result and the accepted reference value.
2. Analyte/measurand - The specific organism or chemical substance sought or determined in a sample.
3. Blank - Sample material containing no detectable level of the analyte or measurand of interest that is subjected to the analytical process and monitors contamination during analysis.

4. Comparability – The acceptability of a new or modified method as a substitute for an established method in the NSSP. Comparability must be demonstrated for each substrate or tissue type by season and geographic area if applicable.
5. Fit for purpose – The analytical method is appropriate to the purpose for which the results are likely to be used.
6. HORRAT value – HORRAT values give a measure of the acceptability of the precision characteristics of a method.[4]
7. Limit of Detection – the minimum concentration at which the analyte or measurand can be identified. Limit of detection is matrix and analyte/measurand dependent.[4]
8. Limit of Quantitation/Sensitivity – the minimum concentration of the analyte or measurand that can be quantified with an acceptable level of precision and accuracy under the conditions of the test.
9. Linear Range – the range within the working range where the results are proportional to the concentration of the analyte or measurand present in the sample.
10. Measurement Uncertainty – A single parameter (usually a standard deviation or confidence interval) expressing the possible range of values around the measured result within which the true value is expected to be with a stated degree of probability. It takes into account all recognized effects operating on the result including: overall precision of the complete method, the method and laboratory bias and matrix effects.
11. Matrix – The component or substrate of a test sample.
12. Method Validation – The process of verifying that a method is fit for purpose.[1]
13. Precision – the closeness of agreement between independent test results obtained under stipulated conditions.[1, 2] There are two components of precision:
    a. Repeatability – the measure of agreement of replicate tests carried out on the same sample in the same laboratory by the same analyst within short intervals of time.
    b. Reproducibility – the measure of agreement between tests carried out in different laboratories. In single laboratory validation studies reproducibility is the closeness of agreement between results obtained with the same method on replicate analytical portions with different analysts or with the same analyst on different days.
14. Quality System – The laboratory's quality system is the process by which the laboratory conducts its activities so as to provide data of known and documented quality with which to demonstrate regulatory compliance and for other decision-making purposes. This system includes a process by which appropriate analytical methods are selected, their capability is evaluated, and their performance is documented. The quality system shall be documented in the laboratory's quality manual.
15. Recovery – The fraction or percentage of an analyte or measurand recovered following sample analysis.
16. Ruggedness – the ability of a particular method to withstand relatively minor changes in analytical technique, reagents, or environmental factors likely to arise in different test environments.[4]
17. Specificity – the ability of a method to measure only what it is intended to measure.[1]
18. Working Range – the range of analyte or measurand concentration over which the method is applied.

REFERENCES:

1. Eurachem Guide, 1998. The Fitness for Purpose of Analytical Methods. A Laboratory Guide to Method Validation and Related Topics. LGC Ltd. Teddington, Middlesex, United Kingdom.
2. IUPAC Technical Report, 2002. Harmonized Guidelines for Single-Laboratory Validation of Methods of Analysis, Pure Appl. Chem., Vol. 74, (5): 835-855.
3. Joint FAO/IAEA Expert Consultation, 1999. Guidelines for Single-Laboratory Validation of Anilytical Methods for Trace-Level Concentrations of Organic Chemicals.
4. MAF Food Assurance Authority, 2002. A Guide for the Validation and Approval of New Marine Biotoxin Test Methods. Wellington, New Zealand.
5. National Environmental Laboratory Accreditation. , 2003. Standards. June 5.
6. EPA. 2004. EPA Microbiological Alternate Procedure Test Procedure (ATP) Protocol for Drinking Water, Ambient Water, and Wastewater Monitoring Methods: Guidance. U.S. Environmental Protection Agency (EPA), Office of Water Engineering and Analysis Division, 1200 Pennsylvania Avenue, NW, (4303T), Washington, DC 20460. April.

SINGLE LABORATORY VALIDATION (SLV) PROTOCOL
FOR SUBMISSIONTO THE INTERSTATE SHELLFISH SANITATION CONFERENCE (ISSC)

For Method Approval

Critical Information:

Applicants shall attach all procedures, with materials, methods, calibrations and interpretations of data with the request for review and potential approval by the ISSC. The ISSC also recommends that submitters include peer-reviewed articles of the procedure (or similar procedures from which the submitting procedure has been derived) published in technical journals with their submittals. Methods submitted to the ISSC LMR committee for acceptance will require, at a minimum, 6 months for review from the date of submission.

Note:
The applicant should provide all information and data identified above as well as the following material, if applicable:

Justification for New Method

- Name of the New Method.
- Specify the Type of Method (e.g., Chemical, Molecular, or Culture).
- Name of Method Developer.
- Developer Contact Information [e.g., Address and Phone Number(s)].
- Date of Submission.
- Purpose and Intended Use of the Method.
- Need for the New Method in the NSSP, Noting Any Relationships to Existing Methods.
- Method Limitations and Potential Indications of Cases Where the Method May Not Be Applicable to Specific Matrix Types.
- Other Comments.

Method Documentation

- Method Title.
- Method Scope.
- References.
- Principle.
- Analytes/Measurands.
- Proprietary Aspects.
- Equipment.
- Reagents.
- Media.
- Matrix or Matrices of Interest.
- Sample Collection, Preservation, Preparation, Storage, Cleanup, etc.
- Safety Requirements.
- Other Information (Cost of the Method, Special Technical Skills Required to Perform the Method, Special Equipment Required and Associated Cost, Abbreviations and Acronyms Defined and Details of Turn Around Times [Time Involved to Complete the Method]).
- Test Procedures, (Be Specific and Provide Easy-to-Follow Step-by-Step Procedures.).
- Quality Control (Provide Specific Steps.).
- Validation Criteria (Include Accuracy / Trueness, Measurement Uncertainty, Precision [Repeatability and Reproducibility], Recovery, Specificity, Working and Linear Ranges, Limit of Detection, Limit of Quantitation / Sensitivity, Ruggedness, Matrix Effects and Comparability (if intended as a substitute for an established method accepted by the NSSP).
- Data and Statistical Analyses Performed for Each Validation Criterion Tested (Be Specific and Provide Clear Easy-to-Follow Step-by-Step Procedures.).
- Calculations and Formulas Used for Each Validation Criterion Tested.
- Results for Each Validation Criterion Tested.
- Discussion of Each Validation Criterion Tested.
- Summary of Results.

Additional Requirement

If a laboratory method is found acceptable for use in the National Shellfish Sanitation Program and adopted by the Interstate Shellfish Sanitation Conference, the method submitter will draft a laboratory checklist that can be used to evaluate laboratories performing their procedure. The checklist will be submitted to the ISSC and reviewed by the Laboratory Quality Assurance Committee for Conference approval.

(For guidance: refer to the checklists in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2003, Guidance Documents, Chapter II – Growing Areas, .11 Evaluation of Laboratories by State Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.)

Single Laboratory Validation (SLV) Protocol
For Submission to the Interstate Shellfish Sanitation Conference (ISSC)
For Method Approval

Critical Information: Applicants shall attach all procedures, with materials, methods, calibrations and interpretations of data with the request for review and potential approval by the ISSC. The ISSC also recommends that submitters include peer-reviewed articles of the procedure (or similar procedures from which the submitting procedure has been derived) published in technical journals with their submittals. Methods submitted to the ISSC LMR committee for acceptance will require, at a minimum, 6 months for review from the date of submission.

Note: The applicant should provide all information and data identified above as well as the following material, if applicable:

Justification for New Method

- Name of the New Method.
- Specify the Type of Method (e.g., Chemical, Molecular, or Culture).
- Name of Method Developer.
- Developer Contact Information [e.g., Address and Phone Number(s)].
- Date of Submission.
- Purpose and Intended Use of the Method.
- Need for the New Method in the NSSP, Noting Any Relationships to Existing Methods.
- Method Limitations and Potential Indications of Cases Where the Method May Not Be Applicable to Specific Matrix Types.
- Other Comments.

Method Documentation

- Method Title.
- Method Scope.
- References.
- Principle.
- Analytes/Measurands.
- Proprietary Aspects.
- Equipment.
- Reagents.
- Media.
- Matrix or Matrices of Interest.
- Sample Collection, Preservation, Preparation, Storage, Cleanup, etc.
- Safety Requirements.
- Other Information (Cost of the Method, Special Technical Skills Required to Perform the Method, Special Equipment Required and Associated Cost, Abbreviations and Acronyms Defined and Details of Turn Around Times [Time Involved to Complete the Method]).
- Test Procedures, (Be Specific and Provide Easy-to-Follow Step-by-Step Procedures.).
- Quality Control (Provide Specific Steps.).
- Validation Criteria (Include Accuracy / Trueness, Measurement Uncertainty, Precision [Repeatability and Reproducibility], Recovery, Specificity, Working and Linear Ranges, Limit of Detection, Limit of Quantitation / Sensitivity, Ruggedness, Matrix Effects and Comparability (if intended as a substitute for an established method accepted by the NSSP).
- Data and Statistical Analyses Performed for Each Validation Criterion Tested (Be Specific and Provide Clear Easy-to-Follow Step-by-Step Procedures.).
- Calculations and Formulas Used for Each Validation Criterion Tested.
- Results for Each Validation Criterion Tested.
- Discussion of Each Validation Criterion Tested.
- Summary of Results.

Additional Requirement

If a laboratory method is found acceptable for use in the National Shellfish Sanitation Program and adopted by the Interstate Shellfish Sanitation Conference, the method submitter will draft a laboratory checklist that can be used to evaluate laboratories performing their procedure. The checklist will be submitted to the ISSC and reviewed by the Laboratory Quality Assurance Committee for Conference approval.

(For guidance: refer to the checklists in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2003, Guidance Documents, Chapter II – Growing Areas, .11 Evaluation of Laboratories by State Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.)

Summary Table for Validation Criteria Test and Data Handling

Validation Criteria	Test	Number of Tests	Statistical Test – Data Handling	Recommended Acceptable Criteria (if available)
1. **Accuracy/Trueness**	**1.& 2.** **For each shellfish of interest-** Spike with test analyte: Spiked sample Blank samples Range: Low, but detectable to 10^7 Run by QPCR & by plate	**1. & 2.** 20 samples 2 aliquots per sample: 1 spiked 1 blank Run by both plate and QPCR	**1.** Log transformation Avg QPCR MPN/Avg plate count X 100	
2. **Measurement Uncertainty**			**2.** Log transformation Find difference between plate and corresponding QPCR Find 95% confidence interval for differences	
3. **Precision**	**3. & 4.** **For each shellfish of interest:** Ten samples: Spike with three concentrations of analyte (low, medium & high). Analyze by plate method and QPCR	**3. & 4.** 10 Samples: 4 aliquots per sample Low, medium, high concentration + blank 2 replications of each concentration QPCR, 1 replication at each concentration plate method, 1 blank Run by plate and QPCR	**3.** Log transformation Nested ANOVA If F α0.05 is not significant, compare standard deviation of total over **a**ll concentrations to standard deviation of 3 tube decimal dilution (0.317) with one sided t test α0.05.	**3.** Calculated F < F α0.05 S_L < 0.317
4. **Recovery**			**4.** Log transformation Average QPCR replicates Subtract Avg QPCR from associated plate count Perform single ANOVA	**4.** Calculated F < F α0.05 If significant , use Tukey's HSD to compare recovery by concentration
5. **Specificity**	**5.** For each shellfish of interest: Spike with test organism (at low level)& interfering organism at moderate level Run by QPCR	**5.** 1 samples per interfering organism(io): 3 aliquots 1 spiked w analyte organism 1 spiked w analyte + io 1 blank Run: 5 replicates of spiked samples 1 repilcate of accompanying blank	**5.** Log transformation Specificity index (SI): SI = Analyte Spike / Analyte io Spike For SI > or < 1: Perform two sided t test	**5.** $[SI_{avg} - m_{0=1}] > u$

Validation Criteria	Test	Number of Tests	Statistical Test – Data Handling	Recommended Acceptable Criteria (if available)
6. **Linear Range**	**6, 7, & 8.** **For each shellfish of interest:** Each sample divide into 10 aliquots Spike with 9 concentrations 10^0,10^1… 10^8 Analyze by plate count and QPCR	**6, 7, & 8.** 5 Samples: 9 spike concentrations per sample: 2 replicates by QPCR 1 replicate by plate method	**6.** Plot Critical Threshold(Ct) verses Plate Counts (log transformed) Provide equation for the line Determine if linear relationship exists , compute correlation coefficient (Pearson's r)	**6.** Test r for significance
7. **Limit of Detection**			**7.** If linear, use y=mx+b Where: y = # cycles of PCR amplification Using slope and y-intercept from **6.** above, set y = to total number of PCR cycles and solve for x Take antilog of X	**7.** X = 1 If different from 1, determine if significantly different at 95% confidence interval.
8. **Limit of Quantitation/ Sensitivity**			**8.** If x = 1, LOQ based on 3 tube, 3 dilution ratio of 0.01, 0.001, 0.0001	
9. **Ruggedness**	**9.** **For each shellfish of interest:** Two aliquots Spike with analyte –range of concentrations Prepare two separate batches(or lots) of reagents Analyze by QPCR , 1 aliquot use set 1 reagents, second aliquot use set 2 reagents	**9.** 10 Samples Use set 1 and set 2 prepared reagents for all ten samples Samples should cover range of concentrations. Process samples over a period of days	**9.** Log transformation Perform two sided t-test at 95% Confidence interval	**9.** If $\lvert X_{A\,Avg} - X_{B\,Avg} \rvert < u$ Method sufficiently rugged

VALIDATION CRITERIA

1. Accuracy/Trueness is the closeness of agreement between test results and the accepted reference value. To determine method accuracy, the concentration of *Vibrio vulnificus* or *Vibrio parahaemolyticus* as measured by QPCR MPN is compared to a reference concentration.

2. Measurement Uncertainty is a single parameter (usually a standard deviation or confidence interval) expressing the possible range of values around the measured result within which the true value is expected to be with a stated degree of probability. It takes into account all recognized effects operating on the result including: overall precision of the complete method, the method and laboratory bias and matrix effects.

Procedure: For each shellfish type of interest use a minimum of 10-12 animals per sample. For each sample take two (2) aliquots of homogenate appropriately sized for your work and spike one(1) of the two (2) aliquots with a suitable concentration of either *Vibrio vulnificus* or *Vibrio parahaemolyticus* as appropriate. Do not spike the second aliquot. This is the sample blank. Determine the concentration of *Vibrio vulnificus* or *Vibrio parahaemolyticus* used to spike each sample by plating on appropriate agar. Process both aliquots of sample homogenate as usual to determine the QPCR MPN. Do twenty (20) samples for each shellfish tissue type of interest. **Use a range of concentrations (from low but detectable by QPCR MPN through 10^7) to spike sample homogenates**. Use samples from a variety of growing areas, the same growing area harvested on different days or from different process lots.

Data:

Sample	Plate count (CFU)	Sample blank, QPCR MPN	Spiked sample, QPCR MPN
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

DATA HANDLING

1. Accuracy/Trueness – Data handling
The accuracy/trueness of a method consists of two distinct components, the portion due to the method itself regardless of the laboratory performing it and the portion contributed by the laboratory's performance. In a single laboratory method validation, it is impossible to distinguish the contribution of each to the overall accuracy/trueness of the method. Consequently, what is being estimated is the accuracy/trueness of the method as implemented by the laboratory performing the analysis. Good accuracy/trueness suggests the appropriateness of the method and the laboratory's performance of it for the intended work. Poor accuracy/trueness on the other hand indicates the unsuitability of the method and/or the laboratory's performance of it for the intended work. Accuracy/trueness will be determined by calculating the closeness of agreement between the test results and an accepted reference value obtained by plate count.

Procedure: To determine the accuracy/trueness of the method as implemented by the laboratory over the range in concentrations important in post harvest processing operations or for implementation of the Interim Control Plan, the data is worked-up in the following manner.

1. If necessary use the sample blank to correct the QPCR MPN of the spiked sample for matrix effects.
2. Convert plate counts and QPCR MPNs to logs.
3. Calculate the average plate count of the data in logs.
4. Calculate the average QPCR MPN of the data in logs.
5. Divide the average QPCR MPN in logs by the average plate count in logs.

6. Multiply the quotient by 100. This provides an estimate in percent of the accuracy/trueness of the method as implemented by the laboratory over the range in concentrations of *Vibrio vulnificus* or *Vibrio parahaemolyticus* of importance in post harvest processing operations or for implementation of the Interim Control Plan.

2. Measurement uncertainty – Data handling
Measurement uncertainty can be determined by subtracting the QPCR MPN results for each sample from the accepted reference values for the samples as determined by the accompanying plate count and calculating the 95% confidence interval of these differences. The confidence interval of these differences represents the range in values within which the true measurement uncertainty lies. A narrow range in values indicates that the method as implemented by the laboratory produces reliable results. A wide range in values suggests that the method and/or the laboratory's implementation of it may not be suitable for the intended work.

Procedure: Use the log transformed data for both the plate count and the QPCR MPN results. Calculate the two-sided 95% confidence interval for the difference in log counts between the reference (plate count) and the QPCR MPN method.

1. Let $\alpha = .05$ and $1-\alpha = .95$ %, the confidence interval for the test.
2. Subtract the (corrected if necessary) log QPCR MPN for each sample tested from its accompanying log plate count value.
3. Calculate the average (X_{avg}) of these values. This is the average difference between the reference and test values.
4. Calculate the standard deviation (s) of these values. This is the standard deviation of the difference in counts between the reference and test method.
5. Look up $t = t_{1-\alpha/2}$ for n-1 degrees of freedom (n =19) in the Table of the distribution of *t*.
5. Calculate x_u and x_L:

$$x_u = X_{(avg)} + t(s/n^{0.5})$$
$$x_L = X_{(avg)} - t(s/n^{0.5})$$

6. Take the antilog of x_u and x_L.
7. The interval from x_L to x_u is the 95% confidence interval of the average difference between the reference and test method. This is the measurement uncertainty of the method as implemented.

VALIDATION CRITERIA

3. Precision is the closeness of agreement between independent test results obtained under stipulated conditions.

4. Recovery is the fraction or percentage of an analyte or measurand recovered following sample analysis.

Procedure: For each shellfish type of interest use a minimum of 10-12 animals per sample. For each sample take four (4) aliquots of homogenate appropriately sized for your work. Spike one of the four aliquots with a low (but detectable by QPCR MPN) concentration of either *Vibrio vulnificus* or *Vibrio parahaemolyticus as* appropriate. Spike the second aliquot of homogenate with a medium concentration of either organism as appropriate. Spike the third aliquot of homogenate with a high ($>10^6$) concentration of either organism as appropriate. Do not spike the fourth aliquot of homogenate. This is the sample blank. Determine the concentration of *Vibrio vulnificus* or *Vibrio parahaemolyticus* used to spike each aliquot by plating on appropriate agar. Process each aliquot including the sample blank as usual to determine the QPCR MPN. Do two (2) replicates for each of the three (3) spiked aliquots. Replicate analysis is unnecessary for the sample blank. Do only one sample blank per sample. Do ten (10) samples for each shellfish tissue type of interest. Use the same spiking levels for each of the ten (10) samples analyzed in this exercise (i.e. 10^1, 10^4 and 10^7). Use samples from a variety of growing areas, the same growing area harvested on different days or from different process lots.

Data:

Sample	Plate count (CFU)	Spiked Sample QPCR, MPN
1L		$1L_a$
		$1L_b$
1M		$1M_a$
		$1M_b$
1H		$1H_a$
		$1H_b$
1B		1B
2L		$2L_a$
		$2\ L_b$
2M		$2M_a$
		$2M_b$
2H		$2H_a$
		$2H_b$
2B		2B

"	"
"	"
"	"
"	"
10L	$10L_a$
	$10L_b$
10M	$10M_a$
	$10M_b$
10H	$10H_a$
	$10H_b$
10B	

L, M and H refer to low, medium and high concentrations respectively. L_a, L_b, M_a, M_b, H_a and H_b refer to the replicate determinations of the sample aliquots spiked with low (L), medium (M) and high (H) concentrations of either *Vibrio vulnificus* or *Vibrio parahaemolyticus*. B refers to the sample blank.

DATA HANDLING

3. Precision – Data handling

The MPN provides the means through which these real time PCR methods become quantitative for application in the NSSP. As an MPN, they are limited in their maximum level of precision to that achievable by the number of tubes and the dilution ratio employed. These Vibrio methods use a 3-tube, decimal dilution MPN and are limited to the maximum precision described by the equation $0.5487/n^{0.5}(D)$ where n is the number of tubes in each dilution and D is the log of the dilution ratio. In order for these real time PCR methods to be effective in monitoring post harvest processing operations or implementation of the Interim Control Plan, they cannot be significantly more variable than the 3-tube, decimal dilution MPN at their basis over the entire range of concentrations important for either operation.

Procedure: To determine the precision of the method as implemented by the laboratory over the range in concentrations important in post harvest processing operations or implementation of the Interim Control Plan, the data is manipulated in the following manner:

1. Calculate the precision of the 3-tube, decimal dilution MPN from the equation $0.5487/3^{0.5}(1) = 0.317$
2. If necessary use the sample blank to correct the QPCR MPNs of the spiked samples for matrix effects.
3. Convert plate counts and QPCR MPNs for the spiked samples to logs.
4. Perform a nested or hierarchical analysis of variance (ANOVA) with the following variance components:

Source of Variation	Degrees of freedom	Sum of Squares	Mean Square
Samples	9		
Concentrations in samples	20		
Determinations within concentrations	30		
Total	59		

5. Calculate the variance ratio (F) at the 95% confidence interval for the variance components, concentrations in samples/determinations within concentrations. If the variance ratio is significant this indicates that the precision of the method as implemented by the laboratory is not consistent over the range in concentrations important in post harvest processing operations or to implementation of the Interim Control Plan and may be unsuitable for the routine monitoring of such operations.

   If the variance ratio is not significant, compare the standard deviation (Mean Square$^{0.5}$) of the ANOVA variance component, total to the standard deviation for the 3-tube, decimal dilution MPN (0.317) by performing a one-sided t-test at the .05 significance level to determine if the variability of the QPCR MPN exceeds that of the 3-tube, decimal dilution MPN test.

Procedure: To determine if the variability of the QPCR MPN exceeds the variability of the 3-tube, decimal dilution MPN at the .05 significance level, the following procedure is used:

1. Let $\alpha = 0.05$, the significance level of the test.
2. Look up $A_{.05}$ for n -1 degrees of freedom from the Table of factors for calculating one-sided confidence limits for σ. n - 1 = the number of degrees of freedom for the ANOVA variance component, total.
3. Calculate the standard deviation s, s = (Mean Square)$^{0.5}$ of the ANOVA variance component, total.
4. Calculate s_L, $s_L = A_{.05}s$.
5. If $s_L > 0.317$, decide that the variability of the QPCR MPN exceeds the variability of the 3-tube, decimal dilution MPN test and that the method as implemented by the laboratory may be unsuitable for use in monitoring post harvest processing operations or the Interim Control Plan for *Vibrio parahaemolyticus*. If s_L

does not exceed 0.317 this indicates that the variability of the QPCR MPN is consistent with the variability of the MPN test used to make the real time PCR method quantitative and that the method as implemented by the laboratory may be of value in monitoring post harvest processing operations and the Interim Control Plan for *Vibrio parahaemolyticus*.

4. Recovery: Data handling
The recovery of *Vibrio vulnificus* or *Vibrio parahaemolyticus* as appropriate must be consistently good (≥95%) over the range of concentrations of importance in post harvest processing operations or to implementation of the Interim Control Plan to be of benefit in the intended work. To determine whether recovery by the method as implemented by the laboratory recovers consistently over the range in concentrations important in post harvest processing operations or to implementation of the Interim Control Plan, the data is manipulated in the following manner:

1. If necessary, use the sample blank to correct the QPCR MPNs of the spiked samples for matrix effects.
2. Convert plate counts and QPCR MPN data for the spiked samples to logs.
3. For each sample determine the average in logs of the replicate QPCR MPN counts at each concentration such that there is only one log value, the average of the two replicate counts at each concentration.
4. For each sample subtract the average QPCR MPN count in logs from its associated log plate count value at each concentration.
5. Perform a single classification analysis of variance (ANOVA) on the data formatted by sample concentration with the following variance components:

Source of variation	Degrees of freedom	Sum of Squares	Mean Square
Concentration	2		
Error	27		
Total	29		

6. Calculate the variance ratio (F) at the 95% confidence interval for the mean square for concentration divided by the mean square for error. If the variance ratio or F test is significant at the 95% confidence interval, Tukey's Honestly Significant Difference (HSD) may be used to compare recovery by concentration. A significant F test suggests that recovery of the method as implemented by the laboratory is not consistent over the range in concentrations important in post harvest processing operations or to implementation of the Interim Control Plan and may not be suitable for the work intended.

   If the variance ratio or F test is not significant at the 95% confidence interval, conclude that the recovery is consistent over the range in concentrations important in post harvest processing operations or to implementation of the Interim Control Plan and calculate the overall percent recovery of the method as implemented by the laboratory.

Procedure: To determine the percent recovery of the method as implemented by the laboratory, the data is manipulated in the following manner:

1. If necessary use the sample blank to correct the QPCR MPNs of the spiked samples for matrix effects.
2. Convert plate counts and QPCR MPN data for the spiked samples into logs.
3. Calculate the average plate count in logs by summing over concentrations and dividing by 30.
4. Calculate the average OPCR MPN in logs by summing over concentrations and replicates and dividing by 60.
5. Divide the average QPCR MPN in logs from step 4 by the average plate count in logs from step 3 and then multiply by 100. This is the percent recovery of the method as implemented by the laboratory and should be equal to or greater than 95% to be useful in post harvest processing operations or for implementation of the Interim Control Plan.

VALIDATION CRITERIA

5. Specificity is the ability of the method to measure only what it is intended to measure. To determine method specificity samples containing suspected interferences (i.e. interfering organisms) are analyzed in the presence of the analyte/measurand of interest (*Vibrio vulnificus*, *Vibrio parahaemolyticus*, etc).

Procedure: For each shellfish tissue type of interest use a minimum of 10-12 animals per sample. For each sample take three (3) aliquots of homogenate appropriately sized for your work and spike two (2) of the three (3) with a low but determinable level (by QPCR MPN) of *Vibrio vulnicus* or *Vibrio parahaemolyticus* as appropriate. Take one of these two (2) aliquots and spike it with a moderate to high level of a suspected interfering organism. Do not spike the third aliquot. This is the sample blank. Process each aliquot, the blank, the aliquot spiked with either *Vibrio vulnificus* or *Vibrio parahaemolyticus* and the aliquot spiked with *Vibrio vulnicus* or *Vibrio parahaemolyticus* plus the suspected interfering

organism as usual to determine the QPCR MPN. Do five (5) replicates for each aliquot excluding the sample blank. Do one sample blank per analysis. Repeat this process for all suspected interfering organisms.

Data:
Name of suspected interfering organism #1 _____

Sample blank, QPCR MPN _____

	Aliquot spiked with Vv or Vp, QPCR MPN	Aliquot spiked with Vv or Vp and interfering organism, QPCR MPN
Replicate 1		
2		
3		
4		
5		

Repeat for each suspected interfering organism tested.

DATA HANDLING

5. Specificity – Data handling
The **Specificity index** will be used to test the specificity of the method in the presence of suspected interfering organisms. The Specificity index (SI) is calculated as indicated below.

$$\text{Specificity index (SI)} = \frac{\text{Sample spiked with analyte}}{\text{Sample spiked with analyte and suspected interference}}$$

Samples spiked with analyte and analyte in the presence of suspected interferences may have to be corrected for matrix effects before determining the Specificity index (SI). A sample blank must accompany the analysis and is used for this purpose.

Rationale: The specificity index should equal one (1) in the absence of interferences. To test the significance of a specificity index other than one (1) for any suspected interfering organism, a two-sided t-test is used.

Procedure: For each suspected interfering organism calculate the Specificity index (SI) for each of the 5 replicates analyzed for each sample using the formula below.

$$\text{SI} = \frac{\text{Log QPCR MPN of sample spiked with analyte}}{\text{Log QPCR MPN of sample spiked with analyte and suspected interference}}$$

Perform the two-sided t-test to determine if the average specificity index (SI) obtained from the 5 replicates of each analysis differs from one (1).

1. Let the significance level, $\alpha = .05$
2. Look up $t_{1-\alpha/2}$ for n-1 degrees of freedom (n = 4) in the Table of the distribution of *t*.
3. Calculate the average Specificity index (SI_{avg}) from the data for each analysis.
4. Calculate the standard deviation (s).
5. Calculate u, $u = t_{1-\alpha/2}\, s/n^{0.5}$, n = # of replicates per analysis.
6. If $[SI_{avg} - m_o] > u$, where $m_o = 1$ decide that the average Specificity index (SI_{avg}) differs from one (1) and that the method may not be specific for the analyte (i.e. *Vibrio vulnificus* or *Vibrio parahaemolyticus*)

Repeat this analysis for all interfering organisms tested.

Data Summary:
Interfering organism #1_____ SI_{avg} _____ Significant difference from 1 _____
Interfering organism #2_____ SI_{avg} _____ Significant difference from 1 _____
Interfering organism #3 _____ SI_{avg} _____ Significant difference from 1 _____
Interfering organism #n _____ SI_{avg} _____ Significant difference from 1 _____

VALIDATION CRITERIA

6. Linear Range is the range within the working range where the results are proportional to the concentration of the analyte or measurand present in the sample.

7. Limit of Detection is the minimum concentration at which the analyte or measurand can be identified.

8. Limit of Quantitation/Sensitivity is the minimum concentration of the analyte or measurand that can be quantified with an acceptable level of precision and accuracy under the conditions of the test.

Procedure: For each shellfish type of interest use a minimum of 10-12 animals per sample. For each sample take ten (10) aliquots of homogenate appropriately sized for your work and spike the first aliquot with 10^8 *Vibrio vulnificus* or *Vibrio parahaemolyticus* organisms as appropriate. Spike the second, third, fourth, fifth, sixth, seventh, eighth and ninth aliquots with 10^7, 10^6, 10^5, 10^4, 10^3, 10^2, 10^1 and 10^0 *Vibrio vulnificus* or *Vibrio parahaemolyticus* organisms as appropriate. Do not spike the tenth aliquot of each sample. This is the sample blank. Determine the concentration of *Vibrio vulnificus* or *Vibrio parahaemolyticus* used to spike each aliquot of each sample by plating on appropriate agar. Process each aliquot including the sample blank for QPCR. Do two (2) replicates for each aliquot including the sample blank. Do five (5) samples for each shellfish tissue type of interest. Use samples from a variety of growing areas, the same growing area harvested on different days or from different process lots.

Data:
Plot the standard curve for the Critical Threshold (Ct) Value for the QPCR of the samples analyzed (on the y-axis) versus the plate count in logs for either *Vibrio vulnificus* or *Vibrio parahaemolyticus* as appropriate (on the x-axis). Provide the equation of the line produced. Tabulate the data in the following manner.

Spike level	0**	10^0	10^1	10^2	10^3	10^4	10^5	10^6	10^7	10^8
Sample 1										
Plate count (cfu)*										
Ct value, replicate 1										
Ct value, replicate 2										
Sample 2										
Plate count (cfu)*										
Ct value, replicate 1										
Ct value, replicate 2										
Sample 3										
Plate count (cfu)*										
Ct value, replicate 1										
Ct value, replicate 2										

Spike level	0**	10^0	10^1	10^2	10^3	10^4	10^5	10^6	10^7	10^8
Sample 4										
Plate count (cfu)*										
Ct value, replicate 1										
Ct value, replicate 2										
Sample 5										
Plate count (cfu)*										
Ct value, replicate 1										
Ct value, replicate 2										

***Plate count converted to logs**
****Unspiked sample blank**

Linear Range – Data handling
In an MPN the more target bacteria present the greater the number of tubes and dilutions expected to show positives. The more positive tubes in each dilution, the higher the MPN count will be. Thus, a linear relationship must exist between the number of target organisms and the method of detecting their presence. In this case a linear relationship must exist between the number of *Vibrios* and the means of detecting their presence, the number of PCR cycles required for the fluorescent signal to cross the threshold referred to as the critical threshold or Ct value.

Procedure: To determine if a linear relationship exists between the number of *Vibrios* and the critical threshold or Ct value generated by the method as implemented by the laboratory, the data is tabulated for ease in calculation as follows:

X	Y		∑Y	$(\sum Y)^2$	$\sum Y^2$	n_i	n_iX	n_iX^2	∑XY	$(\sum Y)^2/n_i$
	R_1	R_2								
			T_1	T_2	n	T_3	T_4	T_5	T_6	

Legend

X is the number of *Vibrios* from the plate count in logs.
Y is the corresponding Critical Threshold or Ct value for each spike.
R_1 and **R_2** are replicate Ct values for each spike.
T_1, T_2, n, T_3, T_4, T_5 and T_6 are column totals.
n_i is the number of replicate Ct values for each spike. In this case **n_i** is 2.
k = n/2

1. Let α = .05, the level of significance of the test and 1 - α = .95%, the confidence level of the test.
2. Calculate $Y_{avg} = T_1/n$ and $X_{avg} = T_3/n$
3. Calculate $S_1 = T_6 - (T_1)^2/n$.
4. Calculate $b = T_5 - (T_3T_1/n)/T_4 - (T_3)^2/n$.
5. Calculate $S_2 = b[T_5 - (T_3T_1/n)]$.
6. Calculate $S_3 = T_2 - (T_1)^2/n$.
7. Look up $F_{1-\alpha}$ for (k-2, n-k) degrees of freedom in the Table of the *F* distribution.
8. Calculate $F = (S_1-S_2/S_3-S_1)\ (n - k/k - 2)$.
9. If $F>F_{1-\alpha}$ decide that the relationship between the number of *Vibrios* and the Ct value is not linear and that the method as implemented may not be appropriate for its intended use.

Limit of Detection - Data handling
In an MPN test, one organism should be capable of producing a positive test. Consequently, one *Vibrio* cell should be the limit of detection of this MPN based real time PCR procedure.

Procedure: Assuming that the relationship between the number of *Vibrios* present and the Ct value is linear, the equation of the line describing this relationship can be used to determine the limit of detection of the method as it is implemented.

y = mx + b

where: y is the number of cycles of amplification of the analysis.
m is the slope of the line describing the relationship between the number of *Vibrios* present and the Ct value.
x is the number of *Vibrios* in logs.
b is the y-intercept of the line.

In order to determine the limit of detection of the method as implemented, set y in the above equation equal to the total number of PCR amplification cycles used and solve the equation for x. Take the antilog of x and this value is the limit of detection of the method as implemented. If the limit of detection as implemented is a value other than one (1), it must be determined whether this value is significantly different than one (1). To do this, the 95% confidence interval estimate for the y-intercept, the Critical Threshold (Ct) value must be determined at a density of one (1) *Vibrio* cell. If this confidence interval estimate encompasses the y-intercept derived from the data of the line, then it can be concluded that the limit of detection of the method as implemented is one cell consistent with the MPN requirement that a single cell should be able to produce a positive test. The data is manipulated as indicated in the worksheet below. Use the log values for bacterial counts.

Worksheet

X is the bacterial counts in logs _____ Y is the Critical Threshold (Ct) Value _____
∑X _____ ∑Y _____
X_{avg} _____ Y_{avg} _____

Number of determinations, n = _____
Step 1. ∑XY _____
Step 2. (∑X)(∑Y)/n _____
Step 3. S_{xy} (Step 1 - Step 2) _____
Step 4. $\sum X^2$ _____

Step 5. $(\sum X)^2/n$ _____
Step 6. S_{xx} (Step 4 – Step 5) _____
Step 7. $\sum Y^2$ _____
Step 8. $(\sum Y)^2/n$ _____
Step 9. S_{yy} (Step 7 – Step 8) _____
Step 10 $(S_{xy})^2/S_{xx}$
Step 11 $(n-2)s^2y$ (Step 9 – Step 10) _____
Step 12. s^2y (Step 11 /n-2) _____
Step 13 s_y (Step $12^{0.5}$) _____

14. Let $_{1-\alpha}$ = the 95% confidence interval. Look up $t_{1-\alpha}$ for n -2 degrees of freedom
15. S_y from Worksheet above _____
16. Set X^1 to 0, the y-intercept
17. Calculate $W_2 = t_{1-\alpha}s_y[1/n + (X^1 - X_{avg})^2/s_{xx}]^{0.5}$ _____
18. Calculate $Y_c = Y_{avg} + m(X^1 - X_{avg})$
19. The 95% confidence interval estimate for the Critical Threshold (Ct) Value at a bacterial concentration of one (1) cell is given by $Y_c \pm W_2$. If this confidence interval estimate encompasses the y-intercept (Ct value) derived from the data of the line, it can be concluded that the method as implemented is capable of determining one (1) cell and is consistent with the requirement that one (1) cell should produce a positive test in the MPN procedure.

Limit of Quantitation/Sensitivity – Data handling
If the method as implemented by the laboratory is capable of detecting one (1) cell, then the limit of quantitation/sensitivity is easily calculated. Because the QPCR procedure is MPN based, the bacterial concentration that can be quantified with an acceptable level of precision and accuracy depends on the number of tubes used for each dilution and the dilution ratio employed. For *Vibrio vulnificus* and *Vibrio parahaemolyticus* assuming the method as implemented is capable of a limit of detection of a single cell, use of a 3-tube MPN and a dilution ratio of 0.01, 0.001 and 0.0001 will result in a limit of quantitation/sensitivity of 30 cfu/gram or 3 cfu/0.1gram which is consistent with the action levels for both organisms in post harvest processing operations and to meet the requirements of the Interim Control Plan for *Vibrio parahaemolyticus*.

VALIDATION CRTITERIA

9. Ruggedness is the ability of a particular method to withstand relatively minor changes in analytical technique, reagents or environmental factors likely to arise in different test environments.

Procedure: For each shellfish type of interest use a minimum of 10 – 12 animals. For each sample take two (2) aliquots of homogenate appropriately sized for your work. Spike both aliquots with a suitable concentration of either *Vibrio vulnificus* or *Vibrio parahaemolyticus* as appropriate. Process both aliquots of the sample as usual to determine the QPCR MPN. For the second aliquot of each sample, however, use a different batch or lot of PCR buffer, dNTPs, enhancer solution, the fluorescent dye, primers and DNA polymerase to process this aliquot. Do ten (10) samples for each shellfish tissue type of interest using the same two sets of solutions to process each sample such that "set 1" is used to process "aliquot 1" of each sample and "set 2" is used to process "aliquot 2" of each sample. Use a range of concentrations (from low but detectable by QPCR MPN through 10^8) to spike sample homogenates. Use samples from a variety of growing areas, the same growing area harvested on different days or from different process lots. Process samples over a period of several days if possible.

Data:

Sample	QPCR MPN "Set 1 Reagents"	QPCR MPN "Set 2 Reagents"
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

DATA HANDLING

9. Ruggedness – Data handling
In the day to day operations of the laboratory there will be changes in the batches/lots of reagents used to process samples by these PCR methods. Environmental factors are also likely to change over time. None of these factors,

however, should adversely impact test results if the method as implemented is to be used routinely as a tool for monitoring post harvest processing operations or the Interim Control Plan for *Vibrio parahaemolyticus*.

Procedure: To determine whether the method as implemented is sufficiently rugged to withstand the types of changes anticipated to occur in routine use, a two-sided t-test at a significance level (α) of .05 will be used to ascertain if the results obtained using different reagent lots/batches under slightly varying environmental conditions are significantly affected by such minor changes.

1. Convert the QPCR MPNs to logs.
2. Let $\alpha = .05$, the significance level of the test.
3. Look up $t_{1-\alpha/2}$ for $(n_A + n_B - 2)$ degrees of freedom in the Table of the *t* distribution.
4. Calculate the average QPCR MPN count (X_{Aavg}) in logs of the samples treated with "Set 1 Reagents."
5. Calculate the standard deviation (s_A) in logs of the samples treated with "Set 1 Reagents." Square it (s^2_A).
6. Calculate the average QPCR MPN count (X_{Bavg}) in logs of the samples treated with "Set 2 Reagents."
7. Calculate the standard deviation (s_B) in logs of the samples treated with "Set 2 Reagents." Square it (s^2_B).
8. Calculate $s_p = [(n_A - 1)s^2_A + (n_B - 1)s^2_B/n_A + n_B - 2]^{0.5}$
9. Calculate $u = t_{1-\alpha/2}s_p[n_A + n_B/n_An_B]^{0.5}$
10. If $| X_{Aavg} - X_{Bavg}| > u$, decide that the method as implemented is not sufficiently rugged to withstand minor changes.
11. If $| X_{Aavg} - X_{Bavg}|$ is not $> u$, conclude that the method as implemented is sufficiently rugged to withstand the minor changes anticipated to occur in routine use.

Proposal Subject	Laboratory Methods
Specific NSSP Guide Reference	NSSP Guide Model Ordinance Chapter XVI. Post-Harvest Processing A. (1) (a)
Text of Proposal/ Requested Action	For processes that target *Vibrio vulnificus*, the level of *Vibrio vulnificus* in the product that has been subjected to the process shall be non-detectable (<30 MPN/gram), to be determined by the use of ~~the *Vibrio vulnificus* FDA approved EIA procedure of Tamplin, et al., as described in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th Edition, 1992, or other~~ method**s** approved **by the Laboratory Methods Review Committee** for NSSP use. It has been reported by laboratories that the reagents for the Tamplin EIA test are not readily available. Other testing procedures are needed to do perform the analysis of *Vibrio vulnificus*. However, since not all methods listed in the *Bacteriological Analytical Manual* (BAM) are collaboratively tested and approved, methods that appear in the BAM cannot be accepted into the program based solely on the method's inclusion in the BAM. The Laboratory Methods Review Committee must review laboratory methods that are to be accepted into the ISSC program.
Public Health Significance	Laboratory methods detecting the direct or indirect presence of human pathogens must be proven to consistently work at various laboratories throughout the country and in participating MOU countries. Detailed review of scientific data (preferably from collaborative studies) by the Laboratory Methods Review Committee must be done.
Cost Information (if available)	None
Action by 2005 Task Force III	Recommended referral of Proposal 05-305 to the Executive Board to investigate ISSC approaches to adopting laboratory methods for use in the NSSP.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force III.
Action by ISSC Executive Board August 19, 2005	Recommended appointment of a workgroup to determine what the role of the ISSC should be in adoption of laboratory methods. The workgroup is also directed to look at similar conferences' procedures regarding laboratory methods approval. The workgroup will report their findings to the Executive Board at the March 2006 meeting.
Action by USFDA	Concurred with Conference action.
Action by 2007 Laboratory Methods Review Committee	Recommended referral of Proposal 05-305 to an appropriate committee as determined by the Conference Chairman.
Action by 2007 Task Force III	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 05-305.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject	Laboratory Methods
Specific NSSP Guide Reference	Public Health Reasons and Explanation, Chapter III Laboratory @ .02 Methods
Text of Proposal/ Requested Action	American Public Health Association (APHA) Recommended Procedures for the Examination of Seawater and Shellfish shall be followed for the collection, transportation, and examination of samples of shellfish and shellfish waters. The official references of the NSSP for the examination of shellfish for Vibrio cholerae, V. vulnificus, and V. parahaemolyticus ~~is the FDA Bacteriological Analytical Manual (BAM)~~ **are the methods approved by the Laboratory Methods Review Committee and listed in Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory tests: Microbiological and Biotoxin Analytical Methods.** Since not all methods listed in the Bacteriological Analytical Manual (BAM) are collaboratively tested and approved, methods that appear in the BAM cannot be accepted into the program based solely on the method's inclusion in the BAM. The Laboratory Methods Review Committee must review laboratory methods that are to be accepted into the ISSC program.
Public Health Significance	Laboratory methods detecting the direct or indirect presence of human pathogens must be proven to consistently work at various laboratories throughout the country and in participating MOU countries. Detailed review of scientific data (preferably from collaborative studies) by the Laboratory Methods Review Committee must be done.
Cost Information (if available)	None
Action by 2005 Task Force III	Recommended referral of Proposal 05-306 to the Executive Board to investigate ISSC approaches to adopting laboratory methods for use in the NSSP.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force III.
Action by ISSC Executive Board August 19, 2005	Recommended appointment of a workgroup to determine what the role of the ISSC should be in adoption of laboratory methods. The workgroup is also directed to look at similar conferences' procedures regarding laboratory methods approval. The workgroup will report their findings to the Executive Board at the March 2006 meeting.
Action by USFDA	Concurred with Conference action.
Action by 2007 Laboratory Methods Review Committee	Recommended referral of Proposal 05-306 to an appropriate committee as determined by the Conference Chairman.
Action by 2007 Task Force III	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 05-306.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject	Modification of Plant Inspection Checklist
Specific NSSP Guide Reference	Guidance Documents, Chapter III. Harvesting, Handling, Processing, Distribution, Section 02. Shellfish Plant Inspection Standardization Procedures, NSSP Standardized Shellfish Processing Plant Inspection Form, Page 400.
Text of Proposal/ Requested Action	Modify the NSSP Standardized Shellfish Processing Plant Inspection Form by removing the Overall Code boxes in the HACCP Plan Elements and HACCP Plan Implementation sections of the Standardized Shellfish Processing Plant Inspection Form (attached).
Public Health Significance	Action by the 2000 ISSC approving certification requirements Chapter I.@.02.B. eliminates the need for using the Overall Code Boxes. FDA is submitting this issue to remove these Overall Code boxes.
Cost Information (if available)	N/A
Action by 2005 Task Force III	Recommended referral of Proposal 05-307, and documents submitted by SSSOG (attached) to an appropriate committee as determined by the Conference Chairperson.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force III.
Action by USFDA	Concurred with Conference action.
Action by 2007 Plant Standardization Advisory Committee	Recommended adoption of Proposal 05-307 with the following amendments: 1. Eliminate the overall code box to the right 2. Revise the boxes on the form as shown below with the exception of the top item "Corrective Actions recorded" in the upper right hand box. 3. Revise the Corrective Actions recorded item to no longer be a critical violation but rather a key (K). Include the (K) next to the item on the inspection form.
Action by 2007 Task Force III	Recommended adoption of the Plant Standardization Advisory Committee recommendation on Proposal 05-307.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.

NSSP Standardized Shellfish Processing Plant Inspection Form

Agency Name:			Date
Type of Inspection	☐ Certification ☐ Pre-operational ☐ Routine ☐ Follow-up ☐ Standardization		
Dealer Name:		Certification Number	
Dealer Address:			

Hazard Analysis Critical Control Point (HACCP)

1. **HACCP Plan** Yes No ☐ Required for Certification

2. **Plan Elements** Identified and Adequate	✔/✘ **NA**	Code		✔/✘ **NA**	Code
(a) Hazards		O	(e) Critical Control Points		K
(b) Records		O	(f) Monitoring		K
(c) Critical Limits		K	(g)Verification Procedures		O
(d) Name, Address, Signed and Dated		O	(h) Corrective Action if identified		K

3. HACCP Training o Yes o No **Code** O

4. Plan Implementation

		Corrective Actions (C)		**Verification Procedures (K)**		**Monitoring Procedures (K)**		**Records Accurate/ Maintained (K) Records Format Signed/Dated Firm's Name (O)**	
		✔/✘	Code	✔/✘	Code	✔/✘	Code	✔/✘	Code
(a)	Receiving								
(b)	Shellstock Storage								
(c)	Processing								
(d)	Shucked Meat Storage								
(e)	Other Critical Limits								

5.	Approved Source Control Failure			C
6.	Time/Temperature Control Failure			C
7.	Other Critical Control Failure			C
	Sanitation Items	Citation	✔/✘	Code
8.	Safety of water for processing and ice production	.02A		
9.	Condition and cleanliness of food contact surfaces	.02B		
10.	Prevention of cross-contamination	.02C		
11.	Maintenance of hand-washing, hand sanitizing, and toilet facilities	.02D		
12.	Protection from adulterants	.02E		
13.	Proper labeling, storage, and use of toxic compounds	.02F		
14.	Control of employees with adverse health conditions	.02G		
15.	Exclusion of pests	.02H		
16.	Sanitation Monitoring and Records			K
	Additional Model Ordinance Requirements	Citation	✔/✘	Code
17.	Plants and Grounds	.03A		
18.	Plumbing and related facilities	.03B		
19.	Utilities	.03C		
20.	Insects and vermin control	.03D		
21.	Disposal of other waste	.03E		
22.	Equipment construction (non-food contact surfaces)	.03F		
23.	Cleaning non-food contact surfaces	.03G		
24.	Shellfish storage and handling	.03H		
25.	Heat shock	.03I		
26.	Personnel	.03J		
27.	Supervision	.03K		
28.	Transportation (To include only the person shipping)	IX.05		K
29.	Labeling and Tagging (Other than receiving)	X.05, .06		S (K/O)
30.	Shipping Documents and Records	X.07		K

Dealer's Signature	Inspector's Signature

SSSOG Attachment

Simplify Item #4 on the NSSP Standardized Shellfish Processing Plant Inspection Form to read as follows:

4.	**Plan Implementation**		**Corrective Actions recorded Verification Procedures Monitoring Procedures Records Accurate/Maintained Records Format Signed/Dated Firm Name on Plan S (K, O)**	
			✔/✘	**Code**
	(a)	Receiving		
	(b)	Shellstock Storage		
	(c)	Processing		
	(d)	Shucked Meat Storage		
	(e)	Other Critical Limits		

The specific deficiencies listed on Item #4 of the existing NSSP inspection form are already detailed by the inspector on the NSSP narrative inspection form when reviewing the firm's HACCP records. Trying to determine where to debit deficiencies under #4 is often confusing, takes additional time and serves little purpose. The proposed change would group all categories on the existing form into one and would designate a Swing (Key or Other) for deficiencies noted.

This proposed change would also remove the "Critical" deficiency listed for records of Corrective Actions. Under the NSSP Model Ordinance, Chapter I., §.02 H (2) (Actions Triggered by Inspections), critical deficiencies must be corrected during that inspection or the dealer must cease production affected by the deficiency. Corrective Action *record keeping* deficiencies in #4 however may be weeks or months old when discovered by an inspector and

Proposal Subject	ISSC Policy Statement on the "Consumption of Raw Oysters"
Specific NSSP Guide Reference	NSSP Policy Setting Documents Chapter VI., ISSC Policy Statement, Paragraph 3
Text of Proposal/ Requested Action	"Certain medically compromised individuals are at increased risk from common marine bacteria that are unrelated to pollution. Therefore, it may not be possible to address this risk through environmental controls. Although the reported number of illnesses and fatalities from these bacteria in the United States each year is small in comparison with other food borne illnesses, **shellfish that have been processed to reduce the levels of all pathogens of public health concern to safe levels can be eaten by the at-risk population or the at-risk population should eat molluscan shellfish fully cooked or,** total abstinence from raw molluscan shellfish is the best advice for medically compromised."
Public Health Significance	This new ISSC policy setting language for the consumption of raw oysters will confirm the use of the labeling allowed for PHP shellfish listed in Chapter XVI. This new policy statement language will show the ISSC supports PHPs and that medically compromised individuals can choose safer post harvest processed shellfish rather than consume other raw shellfish that has not undergone a PHP and/or eat shellfish fully cooked.
Cost Information (if available)	None
Action by 2005 Task Force III	Recommended referral of Proposal 05-308 to an appropriate committee as determined by the Conference Chairperson to investigate the possibility of a change to the ISSC Policy Statement on the Consumption of Raw Molluscan Shellfish.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force III.
Action by USFDA	Concurred with Conference action.
Action by 2007 Executive Board	Executive Board directed the Executive Director to discuss the ISSC Consumption Policy with the FDA. These discussions were not productive in identifying meaningful language for incorporating changes to the Policy Statement.
Action by 2007 Task Force III	Recommended no action on the proposed changes to the ISSC Policy Statement on the Consumption of Raw Molluscan Shellfish but, recommends the Executive Board continue to pursue ways to acknowledge Post Harvest Processing in the National Shellfish Sanitation Program.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject Shellfish Sanitation Plant Element Evaluation Criteria

Specific NSSP Guide Reference ISSC Constitution, Bylaws, and Procedures
Procedure XV. Procedure for Evaluation of Shellfish Sanitation Elements
Section 6. Subdivision b. Subdivision iv. (NEW)

Text of Proposal/ Requested Action Add new Subdivision iv. as follows:

iv. Shellfish sanitation program element compliance will be based on the following criteria:

(a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.

(b) 95% of the certified dealers evaluated must have been inspected by the state at the frequency required by the current Guide for the Control of Molluscan Shellfish.

(c) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.

(d) States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance schedules were not met, that proper administrative action was taken by the state.

(e) All critical deficiencies have been addressed by the state inspector in accordance with the Guide for the Control of Molluscan Shellfish.

Public Health Significance These criteria will be helpful to both the USFDA and States in the state evaluation process.

Cost Information (if available) No costs associated with this program addition.

Action by 2005 NSSP Evaluation Criteria Committee Recommended adoption of Proposal 05-310 as amended by the NSSP Evaluation Criteria Committee, the submitter.

iv. **Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This** ~~shellfish sanitation~~ program element compliance will be based on the following criteria:

(a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.

(b) 95% of the certified dealers evaluated must have been inspected by the state at the frequency required by the current Guide for the Control of Molluscan Shellfish.

(c) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.

(d) States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance schedules were not met, that proper administrative action was taken by the state.

(e) All critical deficiencies have been addressed by the state inspector in accordance with the Guide for the Control of Molluscan Shellfish.

Action by 2005 Task Force III Recommended adoption of the recommendations in the NSSP Evaluation Criteria Committee report with an effective date of October 1, 2004.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force III.

Action by USFDA

FDA concurs with adoption of the five evaluation criteria for identifying state programs whose plant processing element is seriously out of compliance with the NSSP. FDA recommends that the ISSC continue with efforts to develop additional criteria that may be used to define when a state program element is sufficiently out of compliance as to pose a public health risk. In particular, criteria are needed that focus on the in-field component of the FDA evaluation process, i.e. criteria to be used during the plant visit component of FDA's evaluation process. The criteria adopted by the 2005 Conference are more specific to the administrative aspects of a state's plant sanitation element. These criteria are examined as part of the central file review of a state program evaluation. Criteria that focus on the in-field component of the evaluation are also needed. New criteria should consider the distinction between sporadic plant deficiencies and those of an egregious and chronic nature that are indicative of systemic plant sanitation and safety problem.

Action by 2007 NSSP Evaluation Criteria Committee

The NSSP Evaluation Criteria Committee recommended that the following criteria be used by the USFDA in evaluating the state Plant Sanitation Element. FDA should provide a report to the ISSC regarding the effectiveness of the criteria.

ISSC Plant Evaluation Guidance

I. Plant Evaluation Criteria

1. Legal Authority – Chapter VIII. @.01 A. (2) (c)
   The plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the Dealer Certification requirements listed in Chapter I @.01 and @ 02. [Critical]
2. Initial Certification-Chapter I @ 02 B
   The Plant Sanitation Element will be deemed in compliance with this requirement when all plants are certified in accordance with criteria listed below:
   a. HACCP requirements:
      (i) A HACCP plan accepted by the Authority;
      (ii) No critical deficiencies;
      (iii) Not more than 2 key deficiencies;
      (iv) Not more than 2 other deficiencies
   b. Sanitation and additional Model Ordinance Requirements
      (i) No critical deficiencies;
      (ii) Not more than 2 key deficiencies;
      (iii) Not more than 3 other deficiencies.

3. Inspection frequency - Chapter I @ 02 F and G
   The Plant Sanitation Element will be deemed in compliance with this requirement when no more than one plant inspected doesn't meet the required inspection frequency.

4. Compliance schedules
   The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated are found to be without schedules.

5. Follow-up
   The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that they have performed proper follow-up for compliance schedules for 90% of dealers evaluated and if the compliance schedules were not met that administrative action was taken.

6. Deficiency Follow-up
   The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that all critical deficiencies have been addressed.

7. In-Field Plant Criteria
   The in-field Plant Sanitation Element will be deemed in compliance with this requirement when the plant meets the following criteria:

   a. Shucker/packers and repackers
      (i) HACCP requirements:
         (a) A HACCP plan accepted by the Authority; and
         (b) No critical deficiencies; and
         (c) Not more than 4 key deficiencies; or
         (d) Not more than 4 other deficiencies.
      (ii) Sanitation and additional Model Ordinance Requirements
         (a) No critical deficiencies; and
         (b) Not more than 4 key deficiencies; or
         (c) Not more than 6 other deficiencies.
   b. Shellstock shippers and reshippers
      (i) HACCP requirements:
         (a) A HACCP plan accepted by the Authority; and
         (b) No critical deficiencies; and
         (c) Not more than 3 key deficiencies; or
         (d) Not more than 3 other deficiencies.
      (ii) Sanitation and additional Model Ordinance Requirements
         (a) No critical deficiencies; and
         (b) Not more than 3 key deficiencies; or
         (c) Not more than 5 other deficiencies.

II. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria.

1. The overall Plant Sanitation Program element will be assigned one of the following designations:
   a. Conformance: The program is in compliance with all of the criteria listed above.
   b. Conformance with Deficiencies: The program is in compliance with I.1., I.2., I.3., I.4., I.5., I.6 and has less than 25% of plants with deficiencies associated with key or other compliance items in I.7.
   c. Non-Conformance: The program is in compliance with I.1., but, does not meet the criteria in I.2., or I.3 or I.4 or I.5 or I.6 has greater than 25% (but less than 51%) of plants with deficiencies associated with key or other compliance items in I.7.
   d. Major Non-Conformance: The program has multiple deficiencies. It is noncompliant with I.1, or 2 or more of I.2 or I.3 or I.4 or I.5 or I.6 or 51% or greater of plants with deficiencies associated with I.7.
2. FDA will follow the current compliance program for communication with the state agencies.

Action by 2007 Task Force III

Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 05-310. The guidance documents will be incorporated into the NSSP Guide and will be referenced in the ISSC Constitution, By Laws and Procedures. The Task Force recommended these criteria become effective October 1, 2007.

Action by 2007 General Assembly

Approved referral of Proposal 05-310 to the NSSP Evaluation Criteria Committee with the following recommendations:

1. That FDA use the criteria in this proposal as a two-year pilot program beginning October 2007; and
2. That FDA provide in-plant compliance rates for the states evaluated for the past two years and report those compliance rates to the first 2008 ISSC Executive Board meeting.

Action by USFDA

December 20, 2007

Concurred with Conference action with the following comments and recommendations for ISSC consideration.

On December 3, 2007, FDA forwarded correspondence to the ISSC Executive Office regarding the plant sanitation evaluation criteria adopted in Proposal 05-310. That correspondence, which asked for clarification regarding the use of the plant evaluation criteria during FDA's 2008 state program evaluation process, is provided below.

At the 2007 ISSC meeting Task Force II recommended adoption of Proposal 05-310 which set forth criteria developed by the NSSP Evaluation Criteria Committee for evaluating a state's Plant Sanitation Element with an effective date for use by FDA of October 1, 2007. However, the Voting Delegates, at the final General Assembly meeting, voted to refer Proposal 05-310 back to the NSSP Evaluation Criteria Committee with the following recommendations.

1. That FDA use the criteria as a two year pilot program beginning October 1, 2007; and
2. That FDA provide in-plant compliance rates for the states evaluated for the past two years and report those compliance rates to the first 2008 ISSC Executive Board meeting.

There is some confusion regarding the intent o the above ISSC action and how FDA should use the evaluation criteria during the recommended pilot. It was FDA's understanding that during the two year pilot the criteria would be used for purposes of determining the level of compliance of a state's Plant Sanitation Element and for recommending appropriate corrective/regulatory action. However, the State of Florida has indicated that this was not the intent of action taken by the 2007 ISSC. Florida suggests that the intent was for FDA to **not** use the evaluation criteria during the pilot for purposes of determining a state's level of compliance, but rather, for FDA to use the criteria to examine the appropriateness of the criteria by measuring the level of compliance. If this was the intended purpose then FDA does note see the need to conduct both a two year pilot and provide in-plant compliance rates for the states evaluated for the past two years and report those compliance rates to the first 2008 ISSC Executive Board meeting. By implementing #1 only, the ISSC can obtain the data necessary to examine the ability of the criteria and the associated levels of compliance (Conformance, Conformance with Deficiencies, etc.) to accurately reflect how well a state's program conforms with NSSP requirements without expending limited FDA and state resources to conduct a two year retrospective review.

The FDA further suggests that the previous plant evaluation criteria be used until the Conference (Voting Delegates or Executive Board) can give approval to use Proposal 05-310 criteria for compliance purposes.

Proposal Subject State Laws and Regulations

Specific NSSP Guide Reference Model Ordinance Chapter I @.01 Shellfish Sanitation Program

Text of Proposal/ Requested Action

Chapter I @.01 Administration.

A. Scope. The Authority shall establish a statewide shellfish safety and sanitation program to regulate:
(1) The classification of shellfish growing areas;
(2) The harvesting of shellfish;
(3) Shellfish processing procedures and facilities;
(4) Product labeling;
(5) Storage, handling and packing;
(6) Shellfish shipment in interstate commerce;
(7) Shellfish dealers; and
(8) Bivalve aquaculture

B. State Laws and Regulations. The Authority shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of all program elements including but not limited to the elements outlined in @.01.A.

~~B.~~ **C.** Records. The Authority shall maintain records to demonstrate the effective administration of a statewide shellfish safety and sanitation program. These records shall be maintained in a central file and made available to any interested person upon request, consistent with appropriate state and federal law.

~~C.~~ **D.** Shared Responsibilities. If more than one agency is involved in the administration of the statewide shellfish safety and sanitation program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities.

~~D.~~ **E.** Administrative Procedures. The Authority shall have administrative procedures sufficient to:
(1) Regulate shellfish harvesting, sale, or shipment; and
(2) Ensure that all shellfish shipped in interstate commerce originate from a dealer located within the state from which the shellstock are harvested or landed, unless the Authority has a memorandum of understanding with the Authority in another State to allow dealers from its state to purchase the shellstock.
(3) Detain, condemn, seize, and embargo shellfish.
(4) Assure compliance with Shellfish Plant Inspection Standardization.

~~E.~~ **F.** Epidemiologically Implicated Outbreaks of Shellfish-Related Illness. The Authority shall have procedures for investigating incidents of shellfish borne disease.

~~F.~~ **G.** Commingling.
(1) Except for any shellstock included in the Authority's commingling plan, the Authority shall not permit the commingling of shellstock.
(2) If the Authority permits shellstock commingling, the Authority shall develop a commingling management plan. The plan shall:
(a) Minimize the commingling dates of harvest and growing areas;
(b) Define a primary dealer;
(c) Limit the practice of commingling to primary dealers;
(d) Limit commingling to shellstock harvested from specific growing areas within the State as identified by the Authority and purchased directly from harvesters; and

(e) Define how the commingled shellstock will be identified.

Public Health Significance	The requirement for SSCA's to have laws and regulations which provide an adequate legal basis was included in Parts I & II of the Manual of Operation. When the ISSC converted the requirements of the Manual of Operations to the Model Ordinance this requirement was omitted. The requirement is fundamental to the effectiveness of State shellfish programs.
Cost Information (if available)	None
Action by 2007 Task Force III	Recommended adoption of Proposal 07-300 as submitted
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject ISSC Membership, Registration, and Fees

Specific NSSP Guide Reference ISSC Constitution

Text of Proposal/ Requested Action

ARTICLE III. REGISTRATION AND FEES

Section 4. There shall **be two (2)** categories of membership:

Subdivision a. State

Subdivision i. Shellfish producing states

Subdivision ii. Non-producing states

Subdivision b. ~~Participating~~ **Individual** member

~~Subdivision c. Affiliate~~

The fee for each category of membership and the membership period shall be set by the Executive Board. **The membership fees may be paid annually or biennially.** The state authority membership dues shall include membership for one voting delegate. ~~The Participating Member category of membership provides for members who register and attend the Biennial Meeting to receive all pertinent mailings from the ISSC.~~ **Persons other than Voting Delegates shall be considered members by payment of the membership fee.** ~~The Affiliate category of membership provides for those who do not attend the Biennial Meeting but want to receive all pertinent mailings from the ISSC.~~ The membership periods shall coincide with the fiscal year. Applications for membership shall be mailed at least thirty (30) days prior to the beginning of the membership period to the two (2) previous years' membership rolls.

ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES

Section 10. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. **Committee appointments will be made from the Conference membership.** The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive

Board or Chairperson of the Conference: Education, Foreign Relations, Proposal Review, Patrol, Research Guidance, Resolutions, and Shellfish Restoration. The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Biennial meeting.

Public Health Significance None

Cost Information (if available) N/A

Action by 2007 Task Force III Recommended adoption of Proposal 07-301 as amended and also recommended the Executive Board consider ways to incorporate membership fees into registration fees with an implementation date of 2009.

ARTICLE III. REGISTRATION AND FEES

Section 4. There shall be two (2) categories of membership:

Subdivision a. State
Subdivision i. Shellfish producing states
Subdivision ii. Non-producing states
Subdivision b. Individual member

The fee for each category of membership and the membership period shall be set by the Executive Board. The membership fees may be paid annually or biennially. The state authority membership dues shall include membership for one voting delegate. Persons other than Voting Delegates shall be considered members by payment of the membership fee. The membership periods shall coincide with the fiscal year. Applications for membership shall be mailed at least thirty (30) days prior to the beginning of the membership period to the two (2) previous years' membership rolls.

ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES

Section 10. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership **by the Executive Board Chairman.** The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive

Board or Chairperson of the Conference: Education, Foreign Relations, Proposal Review, Patrol, Research Guidance, Resolutions, and Shellfish Restoration. The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Biennial meeting.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force III.

Action by USFDA December 20, 2007
Concurred with Conference action.

Proposal Subject	State of Pennsylvania
Specific NSSP Guide Reference	ISSC Constitution Article XI. Rules of the Biennial Conference Meetings, Section 3. Business Rules of Conference Meetings; Subdivision b.
Text of Proposal/ Requested Action	Pennsylvania Vote When the Conference was formed, the State of Pennsylvania declared that it was a shellfish producing state. In 2005, Pennsylvania declared that it was a non-producing state and requested to be viewed as a non-producing state by the ISSC. Pennsylvania is a member of Region 3. The Executive Board recommends changing Pennsylvania to a non-producing state.
Public Health Significance	None
Cost Information (if available)	N/A
Action by 2007 Task Force III	Recommended adoption of Proposal 07-302 as submitted.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject	Guidance on Equivalence Criteria for Food
Specific NSSP Guide Reference	N/A
Text of Proposal/ Requested Action	Under Article 4 of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) (the SPS Agreement), each member nation of the WTO, including the United States, is obligated to accept as equivalent a food regulatory system of another country if it provides the same level of health protection as is provided to consumers by its own system. Equivalent regulatory systems need not be identical. Under the concept of equivalence, the "sanitary or phytosanitary measures" used by an exporting country may differ from the measures applied domestically by an importing country as long as these measures "achieve the importing Member's appropriate level of sanitary or phytosanitary protection". Under the SPS Agreement, the burden of demonstrating that equivalence exist rest with the exporting country. The exporting country has the right to decide for itself whether the regulatory system of the exporting country is equivalent to its own or is inadequate to achieve "the importing Member's appropriate level of sanitary or phytosanitary protection," or that inadequate evidence has been provided to demonstrate equivalence. One of the roles of the USFDA in the National Sanitation Shellfish Program (NSSP) is the evaluation of foreign programs and the establishment of MOU's with countries that meet the requirements of the NSSP. This responsibility of FDA is outlined in IV. A. 4. of the ISSC/FDA Memorandum of Understanding, March 14, 1984. Article 4 of the WTO Agreement obligates the FDA to accept equivalency in foreign programs. The Agreement requires that the USFDA consider acceptance of foreign shellfish safety programs that, while having a system of sanitary measures that differ from those applied domestically, are recognized as providing an equivalent level of public health protection. The FDA is seeking input from the ISSC for purposes of incorporating the concept of equivalency into the NSSP. Recognizing that FDA has a clear obligation under the WTO Agreement to take responsibility for equivalency determination, it is important to the Agency that this responsibility be recognized within the NSSP.
Public Health Significance	N/A
Cost Information (if available)	N/A
Action by 2007 Task Force III	Recommended referral of Proposal 07-303 to Executive Board for developing short term and long term approaches to incorporating equivalency into the NSSP and the ISSC.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Proposal Subject Revisions to Procedure XVI of the Constitution, Bylaws & Procedures of the ISSC

Specific NSSP Guide Reference ISSC Constitution, Bylaws & Procedures, Procedure XVI. Procedure for Acceptance for Acceptancce and Approval of Analytical Methods for the NSSP

Text of Proposal/ Requested Action At the request of the Executive Board of the ISSC, in November of 2005 the Method Validation Protocol Workgroup was formed to address the issue of method approval within the NSSP and to develop criteria for method validation. The workgroup developed a complete method validation protocol that included a comprehensive checklist for method developers, definitions of validation criteria, a detailed protocol for submission of a method for review and SOP's to specifically address Vibrio PCR methods. In April of 2006 the Executive Board granted interim approval of these documents for use in the ISSC (submitted as a separate proposal for conference approval). The ISSC has a procedure for acceptance of analytical methods for use in the NSSP as detailed in Procedure XVI of the Constitution, Bylaws & Procedures of the ISSC. The Laboratory Methods Review Committee (LMR) recognized that the interim approved Single Lab Validation Protocol package and SOP's for Vibrio PCR methods required changes to Procedure XVI to conform with the new protocol for method approval.

The LMR Committee has proposed changes to Procedure XVI to satisfy the requirements of the SLV Protocol and has also developed the remaining SOP's to address approval of methods other than the Vibrio PCR methods to complete and improve the method approval process within the ISSC. (See attached)

To aid the conference delegates a flow chart has been developed to clearly see the approach to method validation the committee has taken and is attached to this proposal.

Procedure XVI. PROCEDURE FOR ~~ACCEPTANCE AND~~ **THE** APPROVAL OF ANALYTICAL METHODS FOR USE IN THE NSSP

Section 1. Systematic evaluation of the analytical method using the validation criteriadeveloped by the ISSC as detailed in the Single Laboratory Validation Protocol ;

Section ~~1~~2. Proposal to **the** ISSC **requesting** ~~for acceptance and/or~~ approval of ~~an~~ **the** analytical method for use in the NSSP

Subdivision a. Submission of ~~a~~ **the** Proposal;

Subdivision b. Proposal **presented t**o Executive Director for Committee review and **consideration for** acceptance.

Section ~~2~~3. Review by Laboratory Methods Review Committee;

Subdivision a. Committee review~~, assessment,~~ and **evaluation of the data submitted describing the performance characteristics of the method;** ~~conclusions concerning all information available on a method, including:~~

Subdivision i. **These** ~~P~~performance characteristics~~:~~ **include**:

Subdivision (a). Accuracy ~~(recovery);~~ **(Trueness)**;

Subdivision (b). **Measurement uncertainty;** ~~Specificity (rates of false positive and false negative results);~~

Subdivision (c). Precision ~~(confidence limits, repeatability, reproducibility, and other measures of variability)~~;

Subdivision (d). **Recovery** ~~Sensitivity (limit of detection)~~;

Subdivision (e). **Specificity** ~~Selectivity (target versus non-target analyses)~~;

Subdivision (f). **Linear range** ~~Assay interval (time required for results)~~;

Subdivision (g). **Limit of detection** ~~Assay costs (expendable supplies and analyst time)~~;
Subdivision (h). **Limit of quantitation (sensitivity)** ~~Comparability (other characteristics of comparison).~~;
Subdivision (i). Ruggedness;
Subdivision (j). Comparability if applicable (comparison of the performance of the new/modified method to the accepted method).

Subdivision ii. ~~Results from reports on~~ **Method documentation** including:
Subdivision (a). **Method title, scope and references** ~~Laboratory Studies~~;
Subdivision (b). **Equipment and reagents required** ~~Environmental Studies~~;
Subdivision (c). **Sample collection, preservation and storage requirements** ~~Performance comparability (if applicable).~~;
Subdivision (d). Safety requirements;
Subdivision (e). Step by step procedure;
Subdivision (f). Specific quality control measures associated with the method;
Subdivision (g). Cost of the method;
Subdivision (h). Sample turnaround time.

Subdivision iii. ~~Specified~~ **Specific** application(s);

Subdivision b. Review of need **for the method;**
Subdivision i. **Method** ~~M~~**m**eets **an** immediate or continuing need;
Subdivision ii. Improves analytical capability under the NSSP as an alternative to ~~other approved or~~ **an** accepted method(s);
Subdivision iii. Replaces other ~~approved or~~ accepted method(s).

Section ~~3~~4. Possible Actions by **the** Laboratory Methods Review Committee;
Subdivision a. Non-acceptance pending further ~~scientific~~ information as defined by the ~~c~~**C**ommittee;
Subdivision b. Accept as **a** Type IV Method;
Subdivision c. Accept as a Type III Method;
Subdivision d. Accept as **a** Type III Method, and recommend adoption as a Type II or Type I Method~~.~~;
Subdivision e. Rescind acceptance for cause (the need no longer exists, poor performance, equipment or reagents no longer available, etc.)

Section ~~4~~5. Task Force recommendation (non-recommendation) for adoption by ISSC;

Section ~~5~~6. Adoption (or non-adoption) by ISSC General Assembly;

Section ~~6~~7. Review and Acceptance by FDA's Office of Food Safety ~~Seafood~~ in the Summary of Actions;

Section ~~7~~8. Addition **to/Removal from the** ~~of Approved Type I and II Methods to~~ NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods.

Section ~~8~~9. Types of **NSSP** analytical ~~NSSP~~ methods.
Subdivision a. Type I Methods. Type I methods are ~~approved~~ methods **accepted for use in the NSSP** ~~which include those adopted by the ISSC~~ and cited in the NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests:

Microbiological and Biotoxin Analytical Methods that have been:

Subdivision i. Described in a scientific or other peer-reviewed professional publication;

Subdivision ii. Used successfully to detect or quantify;

Subdivision iii. Evaluated, ~~at least in part,~~ and the performance characteristics ~~(at least~~ for specific applications~~)~~ have been ~~reported~~ determined and found fit for purpose;

Subdivision iv. Collaboratively studied and/or collaboratively tested; and/or

Subdivision v. Long used as an ~~acceptable~~ accepted method **in the NSSP**. Examples: APHA MPNs for total and fecal coliforms ~~(MPN)~~, Modified A-1 ~~Modified~~ MPN (MA-1 ~~A1M~~), ~~Standard Plate Count~~ **and** the mouse bioassay for saxitoxins (PSP).

Subdivision b. Type II Methods. Type II methods are ~~approved~~ methods **accepted for use in the NSSP** ~~which include those adopted by the ISSC~~ and cited in the NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods that have been:

Subdivision i. Described in a scientific or other peer-reviewed professional publication;

Subdivision ii. Used successfully to detect or quantify;

Subdivision iii. Evaluated, ~~at least in part,~~ and the performance characteristics ~~(at least~~ for specific applications~~)~~ have been ~~reported~~ **determined and found fit for purpose;**

Subdivision iv. Long used and accepted **for use in the NSSP.** Examples: Elevated Temperature Coliform Plate Method (ETCP)~~;~~ **and the** mouse bioassay for brevetoxins (NSP).

Subdivision c. Type III Methods. Type III methods include those **methods** accepted by unanimous vote of the Laboratory Methods Review Committee for use on an interim basis **and cited in the NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents, Chapter II, Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods** that have been:

Subdivision i. Described in a scientific or other peer-reviewed professional publication;

Subdivision ii. Used successfully to detect or quantify;

Subdivision iii. Evaluated~~, at least in part,~~ and the performance characteristics ~~(at least~~ for specific applications~~)~~ have been ~~reported~~ **determined and found fit for purpose;**

Subdivision iv. Selected to fulfill a continuing need;

Subdivision v. Designated for review and assessment by the Laboratory Methods Review Committee for continued use, re-designation~~,~~ ~~adoption by the ISSC,~~ or deletion. ~~Examples: HPLC for domoic acid (ASP), bioassay for DSP, various FDA BAM methods~~.

Subdivision d. Type IV Methods. Type IV methods include those **methods** accepted by majority vote of the Laboratory Methods Review Committee for use on an interim basis **and cited in the NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods** that have been:

Subdivision i. Described in a scientific or other peer-reviewed professional publication;

Subdivision ii. Used successfully to detect or quantify;

Subivision iii. Evaluated~~, at least in part,~~ and the performance characteristics ~~(at least~~ for specific applications~~)~~ have been ~~reported~~ **determined and found fit for purpose**;

Subdivision iv. Selected to fulfill an immediate need;

Subdivision v. Designated for review and assessment by the Laboratory Methods Review Committee for continued use, re-designation~~,~~ ~~adoption by the ISSC,~~ or deletion. ~~Example: Direct plating + DNA probes method for total and virulent~~

Public Health Significance

There has been a need of the ISSC to develop a systematic approach for method approval for use in the NSSP and to determine the methods "fit for purpose" within the NSSP. The current procedure for integrating new analytical methods into the NSSP under Procedure XVI of the Constitution, Bylaws & Procedures of the ISSC requires method developers to provide data on specific performance characteristics of the method but does not inform method developers on how to proceed in acquiring the data or how to analyze the results so that an objective assessment of the data can be made by the Laboratory Methods Review Committee of the ISSC. The LMR Committee through the Method Validation Protocol Workgroup has developed the tools necessary in the form of a Single Lab Validation Protocol (SLV) to objectively evaluate the suitability of methods for their intended use within the NSSP. Method developers can use the SLV Protocol package to submit methods for approval that will give the LMR Committee the necessary data in an appropriate format for review.

The recommended changes to Procedure XVI are required to incorporate the SLV Protocol into the ISSC for acceptance of a method for use in the NSSP. The approach of the LMR Committee to method approval by use of a single laboratory method validation is internationally recognized and used by the AOAC and others.

Cost Information (if available)

Variable and dependent on the type of method requested for approval.

Action by 2007 Task Force III

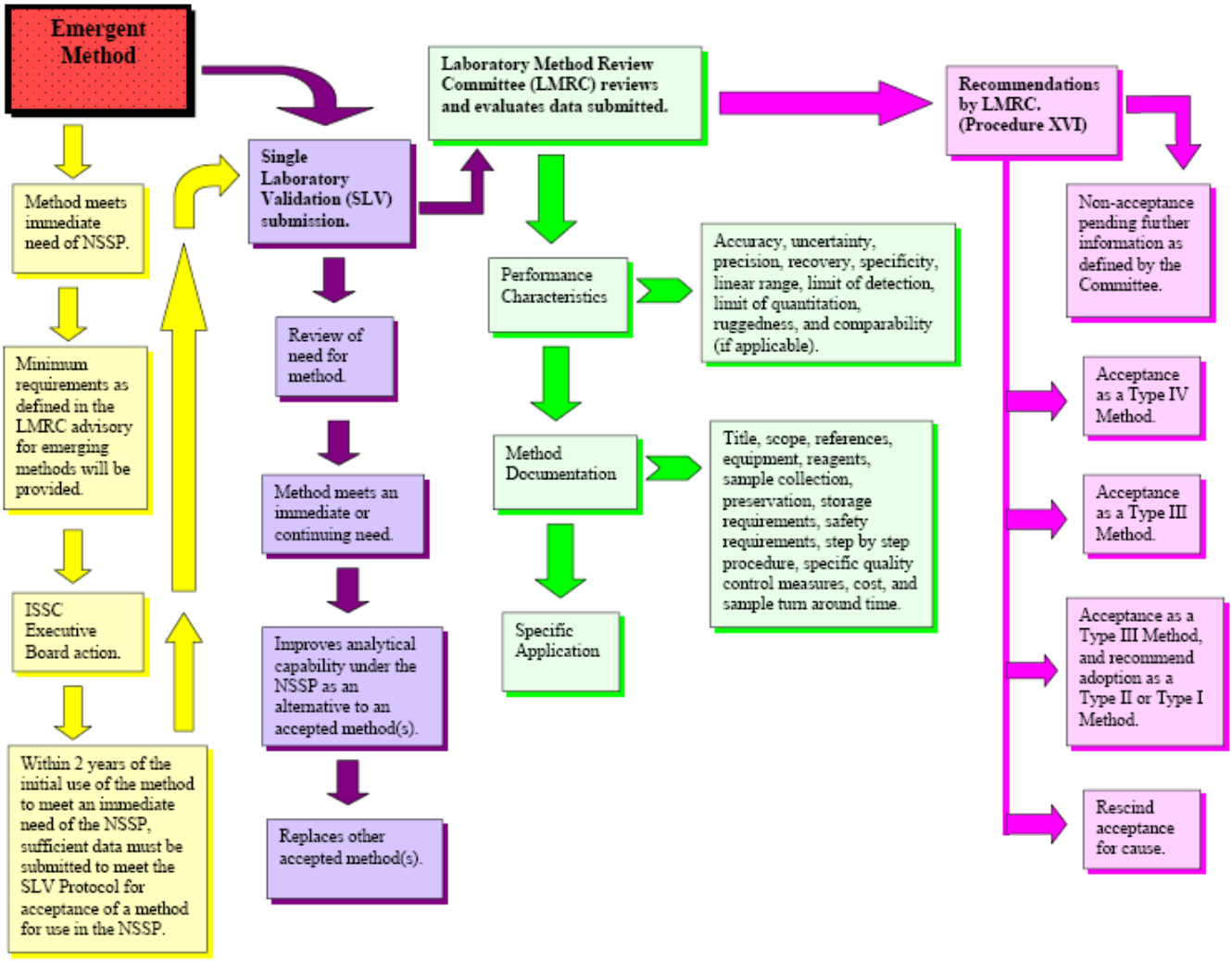
Recommended adoption of Proposal 07-304 as submitted.

Action by 2007 General Assembly

Adopted recommendation of 2007 Task Force III.

Action by USFDA

December 20, 2007
Concurred with Conference action.


Emergent Method
Method meets immediate need of NSSP.
Minimum requirements as defined in the LMRC advisory for emerging methods will be provided.
ISSC Executive Board action.
Within 2 years of the initial use of the method to meet an immediate need of the NSSP, sufficient data must be submitted to meet the SLV Protocol for acceptance of a method for use in the NSSP.
Single Laboratory Validation (SLV) submission.
Review of need for method.
Method meets an immediate or continuing need.
Improves analytical capability under the NSSP as an alternative to an accepted method(s).
Replaces other accepted method(s).
Laboratory Method Review Committee (LMRC) reviews and evaluates data submitted.
Performance Characteristics
Accuracy, uncertainty, precision, recovery, specificity, linear range, limit of detection, limit of quantitation, ruggedness, and comparability (if applicable).
Method Documentation
Title, scope, references, equipment, reagents, sample collection, preservation, storage requirements, safety requirements, step by step procedure, specific quality control measures, cost, and sample turn around time.
Specific Application
Recommendations by LMRC. (Procedure XVI)
Non-acceptance pending further information as defined by the Committee.
Acceptance as a Type IV Method.
Acceptance as a Type III Method.
Acceptance as a Type III Method, and recommend adoption as a Type II or Type I Method.
Rescind acceptance for cause.

I. SLV Documents for MPN Based Microbiological Methods (5 documents):

I. #1. MPN based SOP – Accuracy/Trueness & Measurement Uncertainty
I. #2. MPN based SOP - Ruggedness
I. #3. MPN based SOP - Precision & Recovery
I. #4. MPN based SOP - Specificity
I. #5. MPN based SOP - Linear Range, Limit of Detection, Limit of Quantitation/Sensitivity

II. SLV Documents for Marine Biotoxin and Non-MPN Based Microbiological Methods (5 documents):

II. #1. Marine Biotoxin & Non MPN based SOP – Accuracy/Trueness & Measurement Uncertainty
II. #2. Marine Biotoxin & Non MPN based SOP – Ruggedness
II. #3. Marine Biotoxin & Non MPN based SOP – Precision & Recovery
II. #4. Marine Biotoxin & Non MPN based SOP – Specificity
II. #5. Marine Biotoxin & Non MPN based SOP - Linear Range, Limit of Detection, Limit of Quantitation/Sensitivity

III. SLV Documents for Qualitative Analytical Methods

III. #1. SOP for the Single Laboratory Validation of Qualitative Analytical Methods - Specificity
III. #2. SOP for the Single Laboratory Validation of Qualitative Analytical Methods - Ruggedness

IV. SLV Documents for New or Modified Methods as Alternatives to NSSP Methods

IV. #1. SOP for the Single Laboratory Validation of New or Modified Analytical Methods Intended as Alternatives to Officially Recognized NSSP Methods – Comparing Methods
IV. #2. SOP for the Single Laboratory Validation of New or Modified Analytical Methods Intended as Alternatives to Officially Recognized NSSP Methods – Ruggedness
IV. #3. SOP for the Single Laboratory Validation of New or Modified Analytical Methods Intended as Alternatives to Officially Recognized NSSP Methods - Specificity

I. SOP for the Single Laboratory Validation of MPN based Microbiological Methods

#1

Validation Criteria

Accuracy/Trueness is the closeness of agreement between test results and the accepted reference value. To determine method accuracy/trueness, the concentration of the target organism of interest as measured by the MPN based method under study is compared to a reference concentration.

Measurement uncertainty is a single parameter (usually a standard deviation or confidence interval) expressing the possible range of values around the measured result within which the true value is expected to be with a stated degree of probability. It takes into account all recognized effects operating on the result including: overall precision of the complete method, the method and laboratory bias and matrix effects.

Procedure: This procedure is applicable for use with either growing waters or shellfish tissues. Make every effort to use samples free of the targeted organism of interest. For each shellfish type of interest use a minimum of 10-12 animals per sample. For each sample take two (2) aliquots of either the homogenate or growing water sample appropriately sized for your work and spike one(1) of the two (2) aliquots with a suitable concentration of the target organism of interest. Do not spike the second aliquot. This is the sample blank. Determine the concentration of the target organism of interest used to spike each sample by plating on appropriate agar. Process both aliquots of sample as usual to determine the method MPN. For growing waters do twenty (20) samples collected from a variety of growing areas. For shellfish do twenty (20) samples for each shellfish tissue type of interest collected from a variety of growing areas, the same growing area harvested on different days or from different process lots. **Use a variety of concentrations spanning the range of counts (the working range) of importance in the application of the method to spike sample homogenates or growing water samples**. Both the low and high level spike concentrations must be determinable by the MPN based method under study.

Data:
Working Range _____
Sample Type _____
Agar used to determine spike concentration _____
Organism used for spiking _____

Sample	Plate count (CFU)	Sample blank, MPN	Spiked sample, MPN
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			

Sample	Plate count (CFU)	Sample blank, MPN	Spiked sample MPN
14			
15			
16			
17			
18			
19			
20			

For shellfish samples, repeat for each tissue type of interest.

Data Handling

Accuracy/Trueness
The accuracy/trueness of a method consists of two distinct components, the portion due to the method itself regardless of the laboratory performing it and the portion contributed by the laboratory's performance. In a single laboratory method validation, it is impossible to distinguish the contribution of each to the overall accuracy/trueness of the method. Consequently, what is being estimated is the accuracy/trueness of the method as implemented by the laboratory performing the analysis. Good accuracy/trueness suggests the appropriateness of the method and the laboratory's performance of it for the intended work. Poor accuracy/trueness on the other hand indicates the potential unsuitability of the method and/or the laboratory's performance of it for the intended work.
Accuracy /trueness will be determined by calculating the closeness of agreement between the test results and a reference value obtained by plate count.

To determine the accuracy/trueness of the method as implemented by the laboratory over the range in concentrations important to the intended application of the method, the data is worked-up in the following manner.

1. Convert plate counts and MPNs to logs.
2. If necessary use the sample blank to correct the MPNs of the spiked samples for matrix effects.
3. Calculate the average plate count of the data in logs.
4. Calculate the average MPN of the data in logs.
5. Divide the average MPN in logs by the average plate count in logs.
6. Multiply the quotient by 100. This provides an estimate in percent of the accuracy/trueness of the method as implemented by the laboratory over the range in concentrations of importance to the intended application of the method.

Measurement uncertainty
Measurement uncertainty can be determined by subtracting the MPN results for each sample from the reference values for the samples as determined from the accompanying plate counts in logs and calculating the 95% confidence interval of these differences. The confidence interval of these differences represents the range in values within which the true measurement uncertainty lies. A narrow range in values indicates that the method as implemented by the laboratory produces reliable results.

Use the log transformed data for both the plate count and the MPN results. If necessary use the sample blank to correct the MPNs of the spiked sample for matrix effects and calculate the two-sided, 95% confidence interval for the difference in log counts between the reference (plate count) and the MPN method under study. This range in counts represents the measurement uncertainty of the method as implemented by the laboratory.

Data Summary:
Calculated % accuracy/trueness _____
Calculated measurement uncertainty _____

I. SOP for the Single Laboratory Validation of MPN Based Microbiological Methods

#2

Validation Criteria

Ruggedness is the ability of a particular method to withstand relatively minor changes in analytical technique, reagents or environmental factors likely to arise in different test environments.

Procedure: This procedure is applicable for use with either growing waters or shellfish tissue. Make every effort to use samples free of the target organism of interest. For each shellfish type of interest use a minimum of 10 – 12 animals. For each sample take two (2) aliquots of either the growing water sample or shellfish homogenate appropriately sized for your work. Spike both aliquots with a suitable concentration of the target organism of interest. Process both aliquots of the sample as usual to determine the method MPN. For the second aliquot of each sample, however, use a different batch or lot of culture media or test reagents as appropriate to process this aliquot. For growing waters, do ten (10) samples collected from a variety of growing waters. For shellfish do ten (10) samples for each shellfish tissue type of interest collected from a variety of growing areas, the same growing area harvested on different days or from different process lots. Use the same two batches or lots of culture media or test reagents as appropriate to process each sample such that "batch or lot 1" is used to process the first aliquot of each sample and "batch or lot 2" is used to process the second aliquot of each sample. Use a range of concentrations which spans the range of the method's intended application to spike the sample aliquots. However both aliquots of the same sample must be spiked with the same concentration of the target organism. Process samples over a period of several days.

Data:

Sample type _____

Sample	MPN "Batch or Lot 1" Media or Reagents	MPN "Batch or Lot 2" Media or Reagents
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

For shellfish samples, repeat for each tissue type of interest.

Data Handling

Ruggedness

In the day to day operations of the laboratory there will be changes in the batches/lots of culture media and/or test reagents used to process samples. Environmental factors are also likely to change over time. None of these factors, however, should adversely impact test results if the method as implemented is sufficiently rugged to be used routinely for regulatory monitoring.

Procedure: To determine whether the method as implemented is sufficiently rugged to withstand the types of changes anticipated to occur in routine use, a two-sided t-test at a significance level (α) of .05 will be used on the log transformed data to ascertain if results obtained using different culture media or test reagent batches/lots under slightly varying environmental conditions are significantly affected by such minor changes.

Data Summary:

Is there a significant difference between batch/lot 1 samples and batch/lot 2 samples ____Y/N_____

I. SOP for the Single Laboratory Validation of MPN Based Microbiological Methods

#3

Validation Criteria

Precision is the closeness of agreement between independent test results obtained under stipulated conditions.

Recovery is the fraction or percentage of an analyte or measurand recovered following sample analysis.

Procedure: This procedure is applicable for use with either growing waters or shellfish tissue. Make every effort to use samples free of the target organism of interest. For each shellfish type of interest use a minimum of 10-12 animals per sample. For each sample take four (4) aliquots of either the shellfish homogenate or growing water sample appropriately sized for the work. Spike one of the four aliquots with a low (but determinable by the MPN based method under study) concentration of the target organism of interest. Spike the second aliquot of the growing water sample or shellfish homogenate with a medium concentration of the target organism of interest. Spike the third aliquot of the growing water sample or shellfish homogenate with a high (but determinable by the MPN based method under study) concentration of the target organism of interest. Do not spike the fourth aliquot of the growing water sample or shellfish homogenate. This is the sample blank. Spiking levels must cover the range in counts important to the application of the method (working range). Determine the concentration of the target organism of interest used to spike each aliquot by plating on appropriate agar. Process each aliquot including the sample blank as usual to determine the method MPN. Do two (2) replicates for each of the three (3) spiked aliquots. Replicate analysis is unnecessary for the sample blank. Do only one sample blank per sample. For growing waters, do ten (10) samples collected from a variety of growing areas. For shellfish, do ten (10) samples for each shellfish tissue type of interest collected from a variety of growing areas, the same growing area harvested on different days or from different process lots. Use the same spiking levels for each of the ten (10) samples analyzed in this exercise (i.e. 10^1, 10^3 and 10^5).

Data:
Working Range _____
Sample Type _____
Agar used to determine spike concentration _____
Organism used for spiking _____

Sample	Plate count (CFU)/MPN of Blank	Spiked Sample MPN
1L		$1L_a$
		$1L_b$
1M		$1M_a$
		$1M_b$
1H		$1H_a$
		$1H_b$
1B		
2L		$2L_a$
		$2\ L_b$
2M		$2M_a$
		$2M_b$
2H		$2H_a$
		$2H_b$
2B		
"		"
"		"
"		"
"		"
10L		$10L_a$
		$10L_b$
10M		$10M_a$
		$10M_b$
10H		$10H_a$
		$10H_b$
10B		

L, M and H refer to low, medium and high concentrations respectively. L_a, L_b, M_a, M_b, H_a and H_b refer to the replicate determinations of the sample aliquots spiked with low (L), medium (M) and high (H) concentrations of the target organism of interest. B refers to the sample blank.

For shellfish samples, repeat for each tissue type of interest.

Data Handling

Precision

The MPN provides the means by which these methods become quantitative in application. As an MPN, they are limited in their maximum level of precision to that achievable through the combination of tubes and dilution ratios employed. In practice, MPN methods are limited to the maximum precision described by the equation $\mathbf{0.5487/n^{0.5}(D)}$ where n is the number of tubes in each dilution and D is the log of the dilution ratio used. In order for these MPN based methods to be effective, they should not be significantly more variable than the MPN test at their basis over the entire range of concentrations important for the intended application (working range).

To determine the precision of the method as implemented by the laboratory over the range in concentrations important to the intended application of the method, the data is manipulated in the following manner:

1. Calculate the precision of the MPN based test under study from the equation $0.5487/n^{0.5}(D)$; where n = the number of tubes in each dilution and D is the log of the dilution ratio used.
2. Convert plate counts and MPNs for the spiked samples to logs.
3. If necessary, use the sample blank to correct the MPNs of the spiked samples for matrix effects.
4. Perform a nested or hierarchical analysis of variance (ANOVA) on the corrected spiked sample data using the following variance components.

Source of variation	Degrees of freedom	Sum of Squares	Mean Square
Samples	9		
Concentrations in samples	20		
Determinations within concentrations	30		
Total	59		

5. Calculate the variance ratio (F) at the 95% confidence interval for the variance components, concentrations in samples/determinations within concentrations. If the variance ratio is significant this indicates that the precision of the method as implemented by the laboratory is not consistent over the range in concentrations important to the intended application.

If the variance ratio is not significant, compare the standard deviation (Mean Square$^{0.5}$) of the ANOVA variance component, Total to the standard deviation for the MPN test being used [$0.5487/n^{0.5}(D)$] by performing a one-sided t-test at the .05 significance level to determine if the variability of the MPN method under study exceeds the variability permissible based on the combination of tubes and dilutions used.

Recovery

The recovery of the target organisms of interest must be consistently good over the range of concentrations of importance to the application of the MPN based method under study to be of benefit in the intended work. To determine whether recovery by the method as implemented by the laboratory recovers consistently over the range in concentrations important to the application of the MPN based method under study, the data is manipulated in the following manner:

1. Convert plate count and MPN data for the spiked samples to logs.
2. If necessary, use the sample blank to correct the MPNs of the spiked samples for matrix effects.
3. For each sample determine the average in logs of the replicate MPN counts at each concentration such that there is only one log value, the average of the two replicate counts at each concentration.
4. For each sample subtract the average MPN count in logs from its associated log plate count value at each concentration.
5. Perform a one way analysis of variance (ANOVA) on the data formatted by sample concentration with the following variance components:

Source of variation	Degrees of freedom	Sum of Squares	Mean Square
Concentration	2		
Error	27		
Total	29		

6. Calculate the variance ratio (F) at the 95% confidence interval for the mean square

for concentration divided by the mean square for error. If the variance ratio or F test is significant at the 95% confidence interval, perform Tukey's Honestly Significant Difference (HSD) to compare recovery by concentration. A significant F test suggests that recovery of the method as implemented by the laboratory is not consistent over the range in concentrations important to the application of the MPN based method under study and may not be suitable for the work intended.

If the variance ratio or F test is not significant at the 95% confidence interval, conclude that the recovery is consistent over the range in concentrations important to the application of the MPN based method under study and calculate the overall percent recovery of the method as implemented by the laboratory.

To determine the percent recovery of the method as implemented by the laboratory, the data is manipulated in the following manner:

1. Convert plate count and MPN data for the spiked samples into logs.
2. If necessary use the sample blank to correct the MPNs of the spiked samples for matrix effects.
3. Calculate the average plate count in logs by summing over concentrations and dividing by 30.
4. Calculate the average MPN in logs by summing over concentrations and replicates and dividing by 60.
5. Divide the average MPN in logs by the average plate count in logs and then multiply by 100. This is the percent recovery of the method as implemented by the laboratory.

Data Summary:

- Is the variance ratio at the 95% confidence interval for the variance components, concentrations in samples/determinations within concentrations significant? **Y/N**
- Does the variability of the MPN method under study exceed the variability permissible for the MPN method based on the combination of tubes and dilutions being used? **NA/Y/N**
- Is the one way analysis of variance to determine the consistency of recovery of the MPN based method under study significant? **Y/N**
- At what concentrations is the one way analysis of variance significant? **NA/**_____
- What is the overall percent recovery of the MPN based method under study? **NA/_____%**

I. SOP for the Single Laboratory Validation of MPN Based Microbiological Methods

#4

Validation Criteria

Specificity is the ability of the method to measure only what it is intended to measure. To determine method specificity samples containing suspected interferences (i.e. interfering organisms) are analyzed in the presence of the analyte/measurand (target organism) of interest.

Procedure: This procedure is applicable for use with either growing waters or shellfish tissue. Make every effort to use samples free of the target organism. For each shellfish tissue type of interest use a minimum of 10-12 animals per sample. For each sample take three (3) aliquots of either the shellfish homogenate or growing water sample appropriately sized for the work and spike two (2) of the three (3) with a low but determinable level (by the MPN based method under study) of the target organism of interest. Take one of these two (2) aliquots and also spike it with a moderate to high level of a suspected interfering organism. Do not spike the third aliquot. This is the sample blank. Process each aliquot, the blank, the aliquot spiked with the target organism and the aliquot spiked with the target organism plus the suspected interfering organism as usual to determine the method MPN. Do five (5) replicates for each aliquot excluding the sample blank. Do one sample blank per analysis. Repeat this process for all suspected interfering organisms.

Data:

Name of suspected interfering organism #1 _____

Sample type _____
Sample blank MPN _____

	MPN of aliquot spiked with target organism	MPN of aliquot spiked with target organism and suspected interfering organism
Replicate 1		
2		
3		
4		
5		

Repeat for each suspected interfering organism tested.

Data Handling

The **Specificity index** will be used to test the specificity of the method in the presence of suspected interfering organisms. The **Specificity index (SI)** is calculated as indicated below:

Specificity index (SI) = Sample spiked with target organism only
Sample spiked with both target and suspected interfering organism

All MPN count data is converted to logs. Samples spiked with the target organism and the target organism in the presence of a suspected interfering organism may have to be corrected for matrix effects before determining the Specificity index (SI). The sample blank accompanying the analysis is used for this purpose. Any corrections that may be necessary for matrix effects are done using the log transformed data.

The Specificity index should equal one (1) in the absence of interferences. To test the significance of a specificity index other than one (1) for any suspected interfering organism, a two-sided t-test is used. For each suspected interfering organism calculate the average **Specificity Index (SI)** for each of the 5 replicates analyzed for each sample by obtaining the average log MPN for both target organisms only and target organisms in the presence of suspected interfering organisms and using the formula below.

SI_{avg} = Avg log MPN of sample spiked with target organism only
Avg log MPN of sample spiked with both target and suspected interfering organism

Perform a two-sided t-test at the .05 significance level to determine if the average Specificity index (SI) obtained from the 5 replicates of each analysis differs from one (1).
Repeat for all interfering organisms tested.

Data Summary:
Interfering organism #1 _____ SI_{avg}_____ Significant difference from 1 ____
Interfering organism #2 _____ SI_{avg}_____ Significant difference from 1 ____
Interfering organism #3 _____ SI_{avg} _____Significant difference from 1 ____
Interfering organism #n _____ SI_{avg} _____Significant difference from 1 ____

I. SOP for the Single Laboratory Validation of MPN Based Microbiological Methods

#5

Validation Criteria

Linear Range is the range within the working range where the results are proportional to the concentration of the analyte or measurand present in the sample.

Limit of Detection is the minimum concentration at which the analyte or measurand can be identified.

Limit of Quantitation/Sensitivity is the minimum concentration of the analyte or measurand that can be quantified with an acceptable level of precision and accuracy under the conditions of the test.

Procedure: This procedure is applicable for use with either growing waters or shellfish tissue. Make every effort to use samples free of the target organism of interest. For each shellfish type of interest use a minimum of 10-12 animals per sample. For each sample take at least six (6) aliquots of either the growing water sample or shellfish homogenate appropriately sized for your work and spike five (5) of the six (6) aliquots with five (5) different concentrations (i.e. 10^a, 10^b…10^n) of the target organism of interest spanning the working range/range of interest of the method under study. Do not spike the sixth or last aliquot of each sample. This is the sample blank. Determine the concentration of the target organism of interest used to spike each aliquot of each sample by plating on appropriate agar. Process each aliquot including the sample blank by the method MPN. Do two (2) replicates for each aliquot excluding the sample blank. Do only one blank per sample. For growing waters do ten (10) samples collected from a variety of growing areas. For shellfish do ten (10) samples for each shellfish tissue type of interest collected from a variety of growing areas, the same growing area harvested on different days or from different process lots. Use the same spiking levels for each of the ten (10) samples analyzed (10^a, 10^b…10^n).

Data:
Sample type _____
Working range/Range of interest _____
Spiking levels _____
Agar used to determine spike concentration _____
Organism used for spiking _____

Spike level	**0****	**10^a**	**10^b**	**10^c**	**10^d …..**	**10^n**
Sample 1						
Plate count (cfu)*						
Log MPN, replicate 1						
Log MPN, replicate 2						
Sample 2						
Plate count (cfu)*						
Log MPN, replicate 1						
Log MPN, replicate 2						
Spike level	**0****	**10^a**	**10^b**	**10^c**	**10^d …..**	**10^n**
Sample 3						
Plate count (cfu)*						
Log MPN, replicate 1						
Log MPN, replicate 2						
Sample 4						
Plate count (cfu)*						
Log MPN, replicate 1						
Log MPN, replicate 2						
Sample 5						
Plate count (cfu)*						
Log MPN, replicate 1						
Log MPN, replicate 2						
Sample 6						
Plate count (cfu)*						
Log MPN, replicate 1						

Log MPN, replicate 2

Sample 7
Plate count (cfu)*
Log MPN, replicate 1
Log MPN, replicate 2

Sample 8
Plate count (cfu)*
Log MPN, replicate 1
Log MPN, replicate 2

Sample 9
Plate count (cfu)*
Log MPN, replicate 1
Log MPN, replicate 2

Sample 10
Plate count (cfu)*
Log MPN, replicate 1
Log MPN, replicate 2

***Plate count converted to logs**
****** Unspiked sample blank**
10^a, 10^b, 10^c, 10^d, and 10^n represent the spiking levels

For shellfish samples repeat for each tissue type of interest.

Data Handling

Linear Range
In an MPN the more target organisms present the greater the number of tubes and dilutions expected to be positive. The more positive tubes in each dilution, the higher the MPN count will be. Thus a linear relationship must exist between the number of target organisms and the method of detecting positives. In this case a linear relationship must exist between the number of target organisms present introduced through spiking and the MPN based method used to detect and quantify them.

Procedure:
If necessary use the sample blank to correct the replicate MPNs of the spiked samples for matrix effects. To determine if a linear relationship exists between the number of target organisms present in the samples and the MPN generated by the method as implemented by the laboratory, calculate the correlation coefficient (Pearson's r) and test for significance by performing a two-sided t-test at the .05 significance level. If Pearson's r is significant a linear relationship is supported between the number of target organisms present and the MPN based method used to detect and quantify them.

If Pearson's r is significant plot the data for the log MPN of the samples on the y-axis versus the plate count in logs on the x-axis and calculate the equation of the line which results.

Limit of Detection
In an MPN based test, one organism should be capable of producing a positive test. Consequently one target organism cell should be the limit of detection of any MPN based method.
Procedure:
Assuming that the relationship between the number of target organisms present and the MPN based method used to detect and quantify them is linear, the equation of the line describing this relationship can be used to determine the limit of detection of the method as implemented.

The equation of the line is given by the formula, **y = mx +b** where: **y** is the log MPN of the samples; **m** is the slope of the line describing the relationship between the number of target organisms present and the MPN of the method as implemented; **x** is the number of target organisms spiked into the sample and **b** is the y-intercept of the line. In order to determine the limit of detection of the method as implemented, set **x** in the above equation equal to one (1), the theoretical limit of detection of the MPN based method and solve the equation for **y**. Convert **x** = 1 to its log value which is zero (0). The terms **mx** in the equation then cancel out and **y** is equal to **b**, the y-intercept of the line. Take the antilog of **b**, the y-intercept. This value is the limit of detection of the method as implemented. If the limit of detection as implemented is a value other than one (1), it must be determined whether this value is significantly different from one. To do this, the 95% confidence interval estimate for the y-intercept is determined. If this confidence interval estimate encompasses the y-intercept derived from the data of the line, then it can be concluded that the limit of detection of the method as implemented is one cell consistent with the MPN requirement that a single cell should be able to produce a positive test.

Limit of Quantitation/Sensitivity
If the method as implemented by the laboratory is capable of detecting one (1) cell then the limit of quantitation/sensitivity is easily calculated. Because the method under study is MPN based, the bacterial concentration that can be quantified with an acceptable level of precision and accuracy depends on the number of tubes used for each dilution and the dilution ratio employed. As an example, use of a 3-tube MPN and a dilution ratio of 0.01, 0.001 and 0.0001 will result in a limit of quantitation/sensitivity of 3.6 MPN/gram or 36 MPN per ml.

Data Summary:
Correlation coefficient (Pearson's r) calculated is _____
The equation for the line obtained is _____.
Is Pearson's r significant Y/N
Antilog of the y-intercept (limit of detection) _____
95% confidence interval estimate for the y-intercept (limit of detection) if applicable_____
Limit of quantitation/ sensitivity of the method as implemented _____

II. SOP for the Single Laboratory Validation of Marine Biotoxin & Non-MPN Based Microbiological Methods

#1

Validation Criteria
Accuracy/Trueness is the closeness of agreement between test results and the accepted reference value. To determine method accuracy/trueness, the concentration of the targeted analyte/measurand/organism of interest as measured by the analytical method under study is compared to a reference concentration.

Measurement uncertainty is a single parameter (usually a standard deviation or confidence interval) expressing the possible range of values around the measured result within which the true value is expected to be with a stated degree of probability. It takes into account all recognized effects operating on the result including: overall precision of the complete method, the method and laboratory bias and matrix effects.

Procedure: This procedure is applicable for use with either growing waters or shellfish tissues. Make every effort to use samples free of the target analyte/measurand/organism of interest. For each shellfish type of interest use a minimum of 10-12 animals per sample. For each sample take two (2) aliquots of either the homogenate or growing water sample appropriately sized for your work and spike one(1) of the two (2) aliquots with a suitable known concentration of the target analyte/measurand/organism of interest. Do not spike the second aliquot. This is the sample blank. For microbiological methods determine the concentration of the target organism of interest used to spike each sample by plating on/in appropriate agar. Process both aliquots of sample as usual to determine the method concentration for the target analyte/measurand/organism of interest. For growing waters do twenty (20) samples collected from a variety of growing areas. For shellfish do twenty (20) samples for each shellfish tissue type of interest collected from a variety of growing areas, the same growing area harvested on different days or from different process lots. **Use a variety of concentrations spanning the range of concentrations of importance in the application of the method to spike**

sample homogenates or growing water samples. Both the low and high level spike concentrations must yield determinate values when analyzed by the method under study.

Data:

Working Range _____

Sample Type _____

Agar used to determine spike concentration _____

Organism used for spiking _____

Sample	Spike conc/plate count	Sample blank conc	Spiked sample conc from analysis
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Sample	Spike conc/plate count	Sample blank conc	Spiked sample conc from analysis
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

For shellfish samples, repeat for each tissue type of interest.

Data Handling

Accuracy/Trueness

The accuracy/trueness of a method consists of two distinct components, the portion due to the method itself regardless of the laboratory performing it and the portion contributed by the laboratory's performance. In a single laboratory method validation, it is impossible to distinguish the contribution of each to the overall accuracy/trueness of the method. Consequently, what is being estimated is the accuracy/trueness of the method as implemented by the laboratory performing the analysis. Good accuracy/trueness suggests the appropriateness of the method and the laboratory's performance of it for the intended work. Poor accuracy/trueness on the other hand indicates the potential unsuitability of the method and/or the laboratory's performance of it for the intended work.

Accuracy /trueness will be determined by calculating the closeness of agreement between the test results and either a known reference value or a reference value obtained by plate count for microbiological methods.

To determine the accuracy/trueness of the method as implemented by the laboratory over the range in concentrations important to the intended application of the method, the data is worked-up in the following manner.

~~1.~~7. Convert plate counts to logs.

~~2.~~8. If necessary use the sample blank (converted to logs for microbiological methods) to correct the results from the spiked samples for matrix effects.

~~3.~~9. Calculate the average reference concentration of the analyte/measurand used to spike the samples; or, for microbiological methods calculate the average plate count of the data in logs. The average plate count represents the average reference concentration for the microbiological method.

4.10. Calculate the average concentration of the analyte/measurand/organism of interest in the spiked samples. For microbiological methods log transformed data is used for this calculation.

5.11. Divide the average concentration calculated from the spiked samples by the average reference concentration.

6.12. Multiply the quotient by 100. This provides an estimate in percent of the accuracy/trueness of the method as implemented by the laboratory over the range in concentrations of importance to the intended application of the method.

Measurement uncertainty

Measurement uncertainty can be determined by subtracting the results for each spiked sample from the reference value for the sample and calculating the 95% confidence interval of these differences. The confidence interval of these differences represents the range in values within which the true measurement uncertainty lies. A narrow range in values indicates that the method as implemented by the laboratory produces reliable results.

Use the log transformed data for both the plate count and the microbial results obtained from the spiked samples. If necessary use the sample blank (converted to logs for microbiological methods) to correct the spiked sample for matrix effects and calculate the two-sided, 95% confidence interval for the difference in concentrations between the reference and the spiked samples. This range in counts represents the measurement uncertainty of the method as implemented by the laboratory.

Data Summary:

Calculated % accuracy/trueness _____

Calculated measurement uncertainty _____

II. SOP for the Single Laboratory Validation of Marine Biotoxin & Non-MPN Based Microbiological Methods

#2

Validation Criteria

Ruggedness is the ability of a particular method to withstand relatively minor changes in analytical technique, reagents or environmental factors likely to arise in different test environments.

Procedure: This procedure is applicable for use with either growing waters or shellfish tissue. Make every effort to use samples free of the target analyte/measurand/organism of interest. For each shellfish type of interest use a minimum of 10 – 12 animals. For each sample take two (2) aliquots of either the growing water sample or shellfish homogenate appropriately sized for your work. Spike both aliquots with a suitable concentration of the target analyte/measurand/organism of interest. Process both aliquots of the sample as usual to determine method concentration for the target analyte/measurand/organism of interest. For the second aliquot of each sample, however, use a different batch or lot of culture media and/or test reagents as appropriate to process this aliquot. For growing waters, do ten (10) samples collected from a variety of growing waters. For shellfish do ten (10) samples for each shellfish tissue type of interest collected from a variety of growing areas, the same growing area harvested on different days or from different process lots. Use the same two batches or lots of culture media and/or test reagents to process each sample such that "batch or lot 1" is used to process the first aliquot of each sample and "batch or lot 2" is used to process the second aliquot of each sample. Use a range of concentrations which spans the range of the method's intended application to spike the sample aliquots. However both aliquots of the same sample must be spiked with the same concentration of the target analyte/measurand/organism of interest. Process samples over a period of several days.

Data:

Sample type _____

Sample	Conc "Batch or Lot 1" Media and/or Reagents	Conc "Batch or Lot 2" Media and/or Reagents
1		
2		

For shellfish samples, repeat for each tissue type of interest.

Data Handling

Ruggedness

In the day to day operations of the laboratory there will be changes in the batches/lots of culture media and/or test reagents used to process samples. Environmental factors are also likely to change over time. None of these factors, however, should adversely impact test results if the method as implemented is sufficiently rugged to be used routinely for regulatory monitoring.

Procedure: To determine whether the method as implemented is sufficiently rugged to withstand the types of changes anticipated to occur in routine use, a two-sided t-test at a significance level (α) of .05 will be used on the data to ascertain if results obtained using different culture media and/or test reagent batches/lots under slightly varying environmental conditions are significantly affected by such minor changes. Either a paired t-test or Welch's t-test will be used depending upon the shape of the distribution produced by the data for each batch/lot and their respective variances. Use log transformed data for the results obtained from microbiological methods. The appropriate t-test to be used for the analysis is determined in the following manner.

1. Test the symmetry of the distribution of results from both batch/lot 1 and batch/lot 2.
2. Calculate the variance of both batch/lot 1 and batch/lot 2 data.
3. Values for the test of symmetry for either batch/lot 1 or batch/lot 2 outside the range of -2 to +2 indicate a significant degree of skewness in the distribution.
4. A ratio of the larger of the variances of either batch/lot 1 or batch/lot 2 to the smaller of the variances of either batch/lot 1 or batch/lot 2 >2 indicates a lack of homogeneity of variance.
5. Use either the paired t-test or Welch's t-test for the analysis based on the following considerations.
    - If the distributions of the data from batch/lot 1 and batch/lot 2 are symmetric (within the range of -2 to +2) and there is homogeneity of variance, use a paired t-test for the analysis.
    - If the distributions of the data from batch/lot 1 and batch/lot 2 are symmetric (within the range of -2 to +2) but there is a lack of homogeneity of variance in the data, use Welch's t-test for the analysis.
    - If the distribution of the data from batch/lot 1 and batch/lot 2 are skewed (outside the range of -2 to +2) and the skewness for both groups is either positive for both or negative for both and there is homogeneity of variance in the data, use the paired t-test for the analysis.
    - If the distributions of the data from batch/lot 1 and batch/lot 2 are skewed and the skewness for both groups is either positive for both or negative for both but the data lacks homogeneity of variance, use Welch's t-test to analyze the data.

Data Summary:

Value for the test of symmetry of the distribution of batch/lot 1 data _____

Value for the test of symmetry of the distribution of batch/lot 2 data _____

Variance of batch/lot 1 data _____

Variance of batch/lot 2 data _____

Ratio of the larger to the smaller of the variances of batch/lot 1 and batch/lot 2 _____

Is there a significant difference between batch/lot 1 samples and batch/lot 2 samples ____Y/N_____

II. SOP for the Single Laboratory Validation of Marine Biotoxin & Non-MPN Based Microbiological Methods

#3

Validation Criteria

Precision is the closeness of agreement between independent test results obtained under stipulated conditions.

Recovery is the fraction or percentage of an analyte/measurand/organism of interest recovered following sample analysis.

Procedure: This procedure is applicable for use with either growing waters or shellfish tissue. Make every effort to use samples free of the target analyte/measurand/organism of interest. For each shellfish type of interest use a minimum of 10-12 animals per sample. For each sample take four (4) aliquots of either the shellfish homogenate or growing water sample appropriately sized for the work. Spike one of the four aliquots with a low (but determinable by the method under study) concentration of the target analyte/measurand/organism of interest. Spike the second aliquot of the growing water sample or shellfish homogenate with a medium concentration of the target analyte/measurand/organism of interest. Spike the third aliquot of the growing water sample or shellfish homogenate with a high (but determinable by the method under study) concentration of the target analyte/measurand/organism of interest. Do not spike the fourth aliquot of the growing water sample or shellfish homogenate. This is the sample blank. Spiking levels must cover the range in concentrations important to the application of the method (working range). For microbiological methods determine the concentration of the target organism of interest used to spike each aliquot by plating in/on appropriate agar. Process each aliquot including the sample blank as usual to determine the method concentration for the target analyte/measurand/organism of interest. Do two (2) replicates for each of the three (3) spiked aliquots. Replicate analysis is unnecessary for the sample blank. Do only one sample blank per sample. For growing waters, do ten (10) samples collected from a variety of growing areas. For shellfish, do ten (10) samples for each shellfish tissue type of interest collected from a variety of growing areas, the same growing area harvested on different days or from different process lots. Use the same spiking levels for each of the ten (10) samples analyzed in this exercise (i.e. 10^1, 10^3 and 10^5).

Data:
Working Range _____
Sample Type _____
Agar used to determine spike concentration _____
Organism used for spiking _____

Sample	Spike conc/Plate count/Conc of blank	Conc in spiked sample from analysis
1L		$1L_a$
		$1L_b$
1M		$1M_a$
		$1M_b$
1H		$1H_a$
		$1H_b$
1B		
2L		$2L_a$
		$2\ L_b$
2M		$2M_a$
		$2M_b$
2H		$2H_a$

	$2H_b$
2B	
"	"
"	"
"	"
"	"
10L	$10L_a$
	$10L_b$
10M	$10M_a$
	$10M_b$
10H	$10H_a$
	$10H_b$
10B	

L, M and H refer to low, medium and high concentrations respectively. L_a, L_b, M_a, M_b, H_a and H_b refer to the replicate determinations of the sample aliquots spiked with low (L), medium (M) and high (H) concentrations of the target analyte/measurand/organism of interest. B refers to the sample blank.

For shellfish samples, repeat for each tissue type of interest.

Data Handling

Precision

To determine the precision of the method as implemented by the laboratory over the range in concentrations important to the intended application of the method, the data is manipulated in the following manner:

~~1.~~5. Convert the plate counts and spiked sample results for the microbiological methods to logs.

~~2.~~6. If necessary, use the sample blank (converted to logs for the microbiological methods) to correct the results from the spiked samples for matrix effects.

~~3.~~7. Perform a nested or hierarchical analysis of variance (ANOVA) on the corrected spiked sample data using the following variance components.

Source of variation	Degrees of freedom	Sum of Squares	Mean Square
Samples	9		
Concentrations in samples	20		
Determinations within concentrations	30		
Total	59		

4. Calculate the variance ratio (F) at the 95% confidence interval for the variance components, concentrations in samples/determinations within concentrations. If the variance ratio is significant this indicates that the precision of the method as implemented by the laboratory is not consistent over the range in concentrations important to the intended application.

If the variance ratio is not significant, calculate the coefficient of variation of the spiked sample data by:

1. Calculating the average concentration of the analyte/measurand/organism of interest in the spiked samples. For microbiological methods log transformed data is used for this calculation.
2. Calculate the standard deviation of the spiked sample data by taking the square root of the nested ANOVA variance component, **Total**.
3. Divide the standard deviation of the spiked sample data by the average concentration of the analyte/measurand/organism of interest calculated for the spiked samples. For microbiological methods log transformed data is used for this calculation; and,
4. Multiply the quotient above by 100. This is the coefficient of variation of the method over the range of concentrations of importance in the application of the method as implemented by the laboratory.

Recovery

The recovery of the target analyte/measurand/organisms of interest must be consistently good over the range of concentrations of importance to the application of the method under study to be of benefit in the intended work. To determine whether recovery by the method as implemented by the laboratory is consistent over the range in concentrations important to the application of the method, the data is manipulated in the following manner:

~~1.~~6. Convert plate count and spiked sample results for the microbiological methods to logs.
~~2.~~7. If necessary, use the sample blank (converted to logs for microbiological methods) to correct the results from the spiked samples for matrix effects.
~~3.~~8. For each sample determine the average of the replicates at each concentration such that there is only one value, the average of the two replicates at each concentration tested.
~~4.~~9. For each sample subtract the average for the replicates from its associated spike concentration/plate count value.
~~5.~~10. Perform a one way analysis of variance (ANOVA) on the data formatted by sample concentration with the following variance components:

Source of variation	Degrees of freedom	Sum of Squares	Mean Square
Concentration	2		
Error	27		
Total	29		

6. Calculate the variance ratio (F) at the 95% confidence interval for the mean square for concentration divided by the mean square for error. If the variance ratio or F test is significant at the 95% confidence interval, perform Tukey's Honestly Significant Difference (HSD) to compare recovery by concentration. A significant F test suggests that recovery of the method as implemented by the laboratory is not consistent over the range in concentrations important to the application of the method and may not be suitable for the work intended.

   If the variance ratio or F test is not significant at the 95% confidence interval, conclude that the recovery is consistent over the range in concentrations important to the application of the method and calculate the overall percent recovery of the method as implemented by the laboratory.

To determine the percent recovery of the method as implemented by the laboratory, the data is manipulated in the following manner:

~~1.~~6. Use log transformed data for microbiological methods.
~~2.~~7. If necessary use the sample blank (converted to logs for microbiological methods) to correct the results from the spiked samples for matrix effects.
~~3.~~8. Calculate the average spike concentration/plate count by summing over concentrations and dividing by 30.
~~4.~~9. Calculate the average concentration of analyte/measurand/organism of interest in the spiked samples from the analysis by summing over concentrations and replicates and dividing by 60.
~~5.~~10. Divide the average concentration of analyte/measurand/organism of interest from the analysis of the spiked samples by the average concentration from the spike/plate counts then multiply by 100. This is the percent recovery of the method as implemented by the laboratory.

Data Summary:

- Is the variance ratio at the 95% confidence interval for the variance components, concentrations in samples/determinations within concentrations significant? **Y/N**
- If the variability of the method as implemented by the laboratory is consistent over the range in concentrations important to its intended applications, what is the coefficient of variation? **NA/_____%**
- Is the one way analysis of variance to determine the consistency of recovery of the method under study significant? **Y/N**
- At what concentrations is the one way analysis of variance significant? **NA/_____**
- What is the overall percent recovery of the MPN based method under study? **NA/_____%**

II. SOP for the Single Laboratory Validation of Marine Biotoxin & Non-MPN Based Microbiological Methods

#4

Validation Criteria

Specificity is the ability of the method to measure only what it is intended to measure. To determine method specificity samples containing suspected interferences (interfering organisms/compounds/toxins) are analyzed in the presence of the analyte/measurand/targeted organism of interest.

Procedure: This procedure is applicable for use with either growing waters or shellfish tissue. Make every effort to use samples free of the targeted analyte/measurand/organism of interest. For each shellfish tissue type of interest use a minimum of 10-12 animals per sample. For each sample take three (3) aliquots of either the shellfish homogenate or growing water sample appropriately sized for the work and spike two (2) of the three (3) with a low but determinate level (by the method under study) of the targeted analyte/measurand/ organism of interest. Take one of these two (2) aliquots and also spike it with a moderate to high level of a suspected interfering organism/compound/toxin if not naturally incurred. Do not spike the third aliquot. This is the sample blank. Process each aliquot, the sample blank, the aliquot spiked with the targeted analyte/measurand/organism of interest and the aliquot spiked with the targeted analyte/measurand/organism of interest in the presence of the suspected interfering organism/compound/toxin as usual to determine the method concentration for the targeted analyte/measurand/organism of interest. Do five (5) replicates for each aliquot excluding the sample blank. Do one sample blank per analysis. Repeat this process for all suspected interfering organisms/compounds/toxins.

Data:
Name of suspected interfering organism/compound/toxin #1 _____

Sample type _____
Sample blank concentration for the targeted analyte/measurand/organisn of interest ____

	Concentration of aliquot spiked with targeted analyte/measurand/ organism of interest	Concentration of aliquot spiked with targeted analyte/measurand/ organism of interest and suspected interfering organism/ compound/toxin
Replicate 1		
2		
3		
4		
5		

Repeat for each suspected interfering organism tested.

Data Handling

The **Specificity index** will be used to test the specificity of the method in the presence of suspected interfering organisms/compounds/toxins. The **Specificity index (SI)** is calculated as indicated below:

$$\textbf{Specificity index (SI)} = \frac{\textbf{Sample spiked with target of interest only}}{\textbf{Sample spiked with both target and suspected interferences}}$$

All microbiological count data must be converted to logs before analysis. Samples spiked with both the targeted analyte/measurand/organism of interest and the targeted anaalyte/measurand/organism of interest in the presence of a suspected interfering organism/compound/toxin may have to be corrected for matrix effects before determining the Specificity index (SI). The sample blank accompanying the analysis is used for this purpose. Any corrections that may be necessary to microbiological data for matrix effects are done using log transformed data.

The Specificity index should equal one (1) in the absence of interferences. To test the significance of a Specificity index other than one (1) for any suspected interfering organism/compound/toxin, a two-sided t-test is used. For each suspected interfering organism/compound/toxin calculate the average **Specificity Index (SI)** for the 5 replicates analyzed for each sample by obtaining the average concentration for both the aliquot containing the targeted

analyte/measurand/organism of interest only and the aliquot containing the targeted analyte/measurand/organism of interest in the presence of suspected interfering organisms/compounds/toxins and using the formula below.

$$SI_{avg} = \frac{\text{Avg concentration of sample spiked with target of interest only}}{\text{Avg concentration of sample spiked with both target and suspected interferences}}$$

Perform a two-sided t-test at the .05 significance level to determine if the average Specificity index (SI) obtained from the 5 replicates of each analysis differs from one (1).
Repeat for all interfering organisms/compounds/toxins tested.

Data Summary:
Interfering organism/compound/toxin #1 _____ SI_{avg}_____
Significant difference from 1 _____

Interfering organism/compound/toxin #2 _____ SI_{avg}_____ Significant difference from 1 _____

Interfering organism/compound/toxin #3 _____ SI_{avg} _____
Significant difference from 1 _____

Interfering organism/compound/toxin #n _____ SI_{avg} _____ Significant difference from 1 _____

II. SOP for the Single Laboratory Validation of Marine Biotoxin & Non-MPN Based Microbiological Methods

#5

Validation Criteria
Linear Range is the range within the working range where the results are proportional to the concentration of the analyte/measurand/organism of interest present in the sample.

Limit of Detection is the minimum concentration at which the analyte/measurand/organism of interest can be identified.

Limit of Quantitation/Sensitivity is the minimum concentration of the analyte/measurand/organism of interest that can be quantified with an acceptable level of precision and accuracy under the conditions of the test.

Procedure: This procedure is applicable for use with either growing waters or shellfish tissue. Make every effort to use samples free of the target analyte/measurand/organism of interest. For each shellfish type of interest use a minimum of 10-12 animals per sample. For each sample take at least six (6) aliquots of either the growing water sample or shellfish homogenate appropriately sized for your work and spike five (5) of the six (6) aliquots with five (5) different concentrations (i.e. 10^a, 10^b…10^n) of the target analyte/measurand/organism of interest spanning 50 – 150% of the working range/range of interest for the method under study. Do not spike the sixth or last aliquot of each sample. This is the sample blank. For microbiological methods determine the concentration of the target analyte/measurand/organism of interest used to spike each aliquot of each sample by plating in/on appropriate agar. Do not use aliquots of the same master solution/culture to spike all the samples in this exercise. A separate master solution /culture should be used for each sample. Process each aliquot including the sample blank as usual to determine method concentration for the target analyte/measurand/organism of interest. Do three (3) replicates for each aliquot excluding the sample blank. Do only one blank per sample. For growing waters do ten (10) samples collected from a variety of growing areas. For shellfish do ten (10) samples for each shellfish tissue type of interest collected from a variety of growing areas, the same growing area harvested on different days or from different process lots. Use the same spiking levels for each of the ten (10) samples analyzed (10^a, 10^b…10^n).

Data:
Sample type _____

Working range/Range of interest _____
Range in spiking levels used _____
Agar used to determine spike concentration _____
Organism used for spiking _____

Aliquot	**0***	**1**	**2**	**3**	**4**	**5**
Sample 1						
Spike conc./plate count						
Response, replicate 1						
Response, replicate 2						
Response, replicate 3						

Aliquot	**0***	**1**	**2**	**3**	**4**	**5**
Sample 2						
Spike conc./plate count						
Response, replicate 1						
Response, replicate 2						
Response, replicate 3						

Sample 3
Spike conc./plate count
Response, replicate 1
Response, replicate 2
Response, replicate 3

Sample 4
Spike conc./plate count
Response, replicate 1
Response, replicate 2
Response, replicate 3

Sample 5
Spike conc./plate count
Response, replicate 1
Response, replicate 2
Response, replicate 3

Sample 6
Spike conc./plate count
Response, replicate 1
Response, replicate 2
Response, replicate 3

Sample 7
Spike conc./plate count
Response, replicate 1
Response, replicate 2
Response, replicate 3

Sample 8
Spike conc./plate count
Response, replicate 1
Response, replicate 2
Response, replicate 3

Aliquot	**0***	**1**	**2**	**3**	**4**	**5**
Sample 9						
Spike conc./plate count						
Response, replicate 1						
Response, replicate 2						
Response, replicate 3						
Sample 10						
Spike conc./plate count						
Response, replicate 1						
Response, replicate 2						
Response, replicate 3						

*** Unspiked sample blank**
Response is the signal data (absorbance, florescence, Ct value), colonies, plaques, etc resulting from the analysis. For shellfish samples repeat for each tissue type of interest.

Data Handling

Linear Range
To determine the range within the working range where the results are proportional to the concentration of the target analyte/measurand/organism of interest present, the data is manipulated in the following manner.

1. Convert the plate counts and spiked sample results for the microbiological methods to logs.
2. If necessary, use the sample blank (converted to logs for microbiological methods) to correct the results from the spiked samples for matrix effects.
3. Divide the response obtained for each replicate tested by the concentration of the spiked analyte/measurand/organism of interest which gave rise to it. Use log values for the microbiological data.
4. Plot the data obtained above on the y-axis against the log of the concentration of the spiked analyte/measurand/organism of interest which gave rise to the respective data point on the x-axis. Connect the points. This is the relative response line.
5. Calculate the mean of the values obtained (in step 3) when the response for each replicate tested is divided by the concentration of the spiked analyte/measurand/organism of interest which gave rise to it.
6. Plot this value on the y-axis of the graph obtained in step 4 at each log concentrations of the analyte/measurand/organism of interest spiked into the samples. Connect the points to form a horizontal line. This constitutes the line of constant response
7. Multiply the value obtained in step 5 by 0.95 and 1.05.
8. Plot these values on the y-axis of the graph obtained in steps 4 and 6 at each log concentration of the analyte/measurand /organism of interest spiked into the samples. Connect the points to form two horizontal lines which bracket the line of constant response.
9. The method is linear up to the point where the relative response line (obtained in step 4) intersects either of the lines obtained above.
10. The linear range of the method as implemented by the laboratory is comprised of the range in concentrations obtained by taking the antilogs of the concentrations of the spiked analyte/measurand/organism of interest bracketed within the horizontal lines of the plot obtained in step 8 above.

Limit of Detection and Limit of Quantitation/Sensitivity
To determine the minimum concentration at which the analyte/measurand/organism of interest can be identified and subsequently quantified with an acceptable level of precision and accuracy under the conditions of the test, the data is manipulated in the following manner.

1. Calculate the coefficient of variation or relative standard deviation for each concentration of analyte/measurand/organisn of interest spiked into the samples. Use the log transformed data for manipulating microbiological results.
2. Plot the coefficient of variation/relative standard deviation on the y-axis for each concentration of analyte/measurand/organism of interest spiked into the samples and plotted on the x-axis. Use log transformed concentration values for the microbiological data.

3. Fit the curve and determine from the graph the concentration of analyte/measurand/organism of interest which gave rise to a coefficient of variation/relative standard deviation of 10%. This is the limit of quantitation/sensitivity of the method as implemented by the laboratory.
4. Divide the value for the limit of quantitation/sensitivity obtained from step 3 above by 3.3 or determine the concentration of analyte/measurand/organism of interest that gave rise to a coefficient of variation/relative standard deviation of 33%. This value is the limit of detection of the method as implemented by the laboratory.

For single laboratory validation, the concepts of "blank + 3σ" and "blank + 10σ" generally suffice for determining the limit of detection and the limit of quantitation/sensitivity. Since the blank is in theory zero (0), then the limit of detection and the limit of quantotation /sensitivity become 3σ and 10σ respectively. An absolute standard deviation of 3 and 10 equates to a coefficient of variation/relative standard deviation of 33% and 10% respectively. Accordingly the limit of detection and the limit of quantitation/sensitivity become the concentration of analyte/measurand/organism of interest which give rise to these values.

Data Summary:
Linear range of the method as implemented _____
The limit of detection of the method as implemented _____
The limit of quantitation/sensitivity of the method as implemented _____

III. SOP for the Single Laboratory Validation of Qualitative Analytical Methods

#1

Validation Criteria
Specificity is the ability of a qualitative method to accurately determine the presence of the analyte/measurand/organism of interest in the sample. For qualitative methods the specificity of the method can be divided into four (4) zones, zone 1 where the response of the method is always negative; zones 2 and 3 where the response of the method consists of false positive (zone 2) and negative (zone 3) results; and zone 4 where the response of the method is always positive. To determine the specificity of the qualitative method as implemented, zones 1, 2, 3 and 4 are determined.

Procedure: This procedure is applicable for use with either growing waters or shellfish tissue. For each shellfish type of interest use a minimum of 10 – 12 animals. For each sample take ten (10) aliquots of either the growing water sample or shellfish homogenate appropriately sized for the work. Spike all ten (10) aliquots of each sample with the same concentration of the target analyte/measurand/organism of interest. Process all ten (10) aliquots for each sample as usual to determine whether the test response is positive or negative. Use a minimum of five (5) concentrations which span the range of the method's intended application to spike the samples. If spatial or geographic influences on method performance are suspected, follow the procedure above for all samples suspected of being so influenced.

Data:
Sample type _____

Concentration	Positive/Negative results	Percent positive
1		
2		
3		
4		
5		
*n		

*n is the last concentration tested

Repeat for each shellfish tissue type of interest and/or samples suspected of being affected by spatial or geographic influences.

Data Handling

Specificity
To determine the specificity of the qualitative method, plot the response curve with percent positive results versus concentration. Calculate the concentration of target analyte/measurand/organism of interest at 5, 50 and 95% positive results. Concentrations of analyte/measurand/organism of interest which give positive results less than 5% of the time constitute zone 1 where the response of the method is always negative. Concentrations of analyte/measurand/organism of interest which give positive results between 5 and 50% of the time constitute zone 2 where the method results in false positives. The concentration of target analyte/measurand/organism of interest which gives positive results between 50 and 95% of the time constitute zone 3 where the method results in false negatives. Concentrations of target analyte/measurand /organism of interest which give positive results more than 95% of the time constitute zone 4 where the method results are always positive.

Data Summary:
Concentration of target analyte/measurand/organism of interest below which the results are always negative (zone 1) ≤_____

Range in concentration of target analyte/measurand/organism of interest where false positive results occur (zone 2) _____

Range in concentrations of target analyte/measurand/organism of interest where false negative results occur (zone 3) _____

Concentration of target analyte/measurand/organism of interest above which test results are always positive (zone 4) ≥_____

III. SOP for the Single Laboratory Validation of Qualitative Analytical Methods

#2

Validation Criteria
Ruggedness is the ability of the qualitative method to withstand relatively minor changes in analytical technique, reagents or environmental factors likely to arise in different test environments.

Procedure: This procedure is applicable for use with either growing waters or shellfish tissue. For each shellfish type of interest use a minimum of 10 – 12 animals. For each sample take two (2) aliquots of either the growing water sample or shellfish homogenate appropriately sized for your work. Spike both aliquots of each sample with a suitable concentration of the target analyte/measurand/organism of interest. Process both aliquots of sample as usual to determine whether the test response is positive or negative. For the second aliquot from each sample, however, use a different batch or lot of culture media and/or test reagents as appropriate to process this aliquot. Do a minimum of 30 samples using a variety of concentrations to spike the samples which span the range of the method's intended application. Use the same two batches or lots of culture media and/or test reagents to process each sample such that "batch or lot 1" is used to process the first aliquot of each sample and batch or lot 2" is used to process the second aliquot from each sample. Both aliquots of the same sample must be spiked with the same concentration of target analyte/measurand/organism of interest. If spatial or geographic influences on method performance are suspected, follow the above procedure for all samples suspected of being so influenced. If possible, process samples over a period of several days using different analysts to process and read "batch or lot 1" and batch or lot 2" samples.

Data:
Sample type _____
Sample # Concentration Positive results Negative results

	Batch/lot 1	Batch/lot 2	Batch/lot 1	Batch/lot 2
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
″				
″				
*n				

*n is the last sample tested.

Repeat for each shellfish tissue type of interest and/or samples suspected of being affected by spatial or geographic influences.

Data Handling

Ruggedness

In the day to day operations of the laboratory there will be changes in the batches/lots of culture media and/or test reagents used to process samples. Analysts may change and environmental factors may vary over time. None of these factors, however, should adversely impact test results if the method as implemented is sufficiently rugged to be used routinely for regulatory monitoring.

To determine whether the method as implemented is sufficiently rugged to withstand the types of changes anticipated to occur in routine use, the numbers of positive and negative results produced from the use of batch or lot 1 and batch or lot 2 culture media and/or test reagents will be compared. If the numbers of positive and negative results produced by batch or lot 1 and batch or lot 2 culture media and/or test reagents are identical, the method as implemented is not affected by relatively minor changes in the day to day operations of the laboratory and is sufficiently rugged as implemented for routine use. If the numbers of positive and negative results generated by batch or lot 1 and batch or lot 2 culture media and/or test reagents are not alike then a two-sided statistical test comparing the numbers (proportions) of positive and negative results produced by each batch or lot of culture media and/or test reagents is undertaken to determine significance at the .05 level. From the number of positive and negative results produced by batch or lot 1 and batch or lot 2 culture media and/or test reagents determine the "observed contrast pair". The "observed contrast pair" is the smallest value from either the positive or the negative results of either batch or lot 1 or batch or lot 2 and the value from the same category of results (positive or negative) produced by the other batch or lot of culture media and/or test reagents. The "observed contrast pair" once determined is compared to statistical table values for the minimum contrast (a pair of values) required to demonstrate significance at the .05 level from a standard 2x2 table for equal sample numbers.

Data Summary:

Number of samples tested _____

Number of positive results from batch or lot 1 _____
Number of negative results from batch or lot 1 _____

Number of positive results from batch or lot 2 _____
Number of negative results from batch or lot 2 _____

The "observed contrast pair" if applicable _____

Is there a significant difference between batch or lot 1 and batch or lot 2 __Y/N____

IV. SOP for the Single Laboratory Validation of New or Modified Analytical Methods Intended as Alternatives to Officially Recognized NSSP Methods

#1

Validation Criteria

Comparability is the acceptability of a new or modified analytical method as a substitute for an established method in the NSSP. To be acceptable the new or modified method must not produce a significant difference in results when compared to the officially recognized method. Comparability must be demonstrated for each substrate or tissue type of interest by season and geographic area if applicable.

Comparison of Methods:

New or modified methods demonstrating comparability to officially recognized methods must not produce significantly different results when compared

Procedure to compare the new or modified method to the officially recognized method: This procedure is applicable for use with either growing waters or shellfish tissue. For each shellfish type of interest use a minimum of 10-12 animals per sample. For each sample take two (2) aliquots and analyze one by the officially recognized method and the other by the alternative method. Actual samples are preferable; but, in cases where the occurrence of the analyte/measurand/organism of interest is intermittent (such as marine biotoxins), spiked samples can be used. Samples having a variety of concentrations which span the range of the method's intended application should be used in the comparison. Analyze a minimum of thirty (30) paired samples for each season from a variety of growing areas for a total of at least 120 samples over the period of a year for naturally incurred samples. For spiked samples analyze a minimum of ten (10) samples for each season from a variety of growing areas for a total of at least 40 samples over the period of a year.

Data:

Sample type _____

Date	Sample/Station #	Conc. Recognized method	Conc. Alternative Method
	1		
	2		
	3		
	4		
	5		
	6		
	7		
	8		
	9		
	10		
	n		

n is the last sample in the comparison

For shellfish samples, repeat for each tissue type of interest

Data handling to compare the new or modified method to the officially recognized

Two methods of analysis are considered to be comparable when no significant difference can be demonstrated in their results. To determine whether comparability in methods exists, a two-sided t-test at a significance level (α) of .05 will be used to test the data. Either a paired t-test or Welch's t-test will be used depending upon the shape of the distributions produced by the data for each method and their respective variances. Use log transformed data for the results obtained from microbiological methods. The appropriate t-test to be used for the analysis is determined in the following manner.

1. Test the symmetry for the distribution of results from both the officially recognized analytical method and the proposed alternative analytical method.

2. Calculate the variance of the data for both the officially recognized analytical method and the proposed alternative analytical method.
3. Values for the test of symmetry for either method outside the range of -2 to +2 indicate a significant degree of skewness in the distribution.
4. A ratio of the larger of the variances of either method to the smaller of the variances of either method >2 indicates a lack of homogeneity of variance.
5. Use either the paired t-test or Welch's t-test for the analysis of the data based on the following considerations.
    - If the distribution of the data from the officially recognized analytical method and the proposed alternative analytical method are symmetric (within the range of -2 to +2) and there is homogeneity of variance use a paired t-test for the data analysis.
    - If the distributions of the data for both analytical methods are symmetric (within the range -2 to +2) but there is a lack of homogeneity of variance in the data, use Welch's t-test for the analysis of the data.
    - If the distributions of the data from the officially recognized and proposed alternative analytical methods are skewed (outside the range -2 to +2) and the skewness for both methods is either positive for both or negative for both and there is homogeneity of variance in the data, use the paired t-test for the analysis of the data.
    - If the distributions of the data from the officially recognized and the proposed alternative analytical methods are skewed and the skewness for both analytical methods is either positive or negative for both but the data lacks homogeneity of variance, use Welch's t-test to analyze the data.

Data summary for the comparison of the new or modified method to the officially recognized method:

Value for the test of symmetry for the distribution of the data generated by the officially recognized method _____

Value for the test of symmetry for the distribution of the data generated by the proposed alternative method _____

Variance of the data generated from the officially recognized analytical method _____

Variance of the data generated from the proposed alternative analytical method _____

Ratio of the larger to the smaller of the variances generated by the officially recognized and proposed analytical methods _____

Is there a significant difference between the analytical methods Y/N

V. SOP for the Single Laboratory Validation of New or Modified Analytical Methods Intended as Alternatives to Officially Recognized NSSP Methods

#2

Validation Criteria

Comparability is the acceptability of a new or modified analytical method as a substitute for an established method in the NSSP. To be acceptable the new or modified method must be sufficiently rugged to withstand the relatively minor day to day changes likely to occur in routine use. Comparability must be demonstrated for each substrate or tissue type of interest by season and geographic area if applicable.

Ruggedness of the new or modified method is the ability of the new or modified method to withstand relatively minor changes in analytical technique, reagents or environmental factors likely to arise in different test environments.

Procedure for testing the ruggedness of new or modified methods: This procedure is applicable for use with either growing waters or shellfish tissue. Make every effort to use samples free of the target analyte/measurand/organism of interest. For each shellfish type of interest use a minimum of 10-12 animals. For each sample take two aliquots of either the growing water sample or shellfish homogenate appropriately sized for your work. Spike both aliquots with a suitable concentration of the target analyte/measurand/organism of interest. Process both aliquots of the sample as usual to determine new method/modified method concentration for the target analyte/measurand/ organism of interest. For the second aliquot of each sample, however, use a different batch or lot of culture media and/or test reagents as appropriate to process this aliquot. For growing waters, do ten (10) samples collected from a variety of growing waters. For shellfish do ten (10) samples for each shellfish tissue type of interest collected from a variety of growing areas, the same growing area harvested on different days or from different process lots. Use the same two batches or lots of culture media and/or test reagents to process each sample such that "batch or lot 1" is used to process the first aliquot of each sample and "batch or lot 2" is used to process the second aliquot of each sample. Use a range of concentrations which spans the range of the new method or modified method's intended application to spike sample aliquots. Both aliquots of the same sample must be spiked with the same concentration of the target analyte/measurand/organism of interest. Process samples over a period of several days if possible.

Data for demonstrating the ruggedness of the new or modified method:

Sample type _____

Sample	Conc. "Batch or lot 1" Media and/or Reagents	Conc. "Batch or lot 2" Media and/or Reagents
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

For shellfish samples, repeat for each tissue type of interest.

Data handling to demonstrate the ruggedness of the new or modified method

In the day to day operations of the laboratory there will be changes in the batches/lots of culture media and/or test reagents used to process samples. Environmental factors are also likely to change over time. None of these factors, however, should adversely impact test results if the new or modified method as implemented is sufficiently rugged to be used routinely for regulatory monitoring.

To determine whether the new or modified method as implemented is sufficiently rugged to withstand the types of changes anticipated to occur in routine use, a two-sided t-test at a significance level (α) of .05 will be used on the data to ascertain if results obtained using different culture media and/or test reagent batches/lots under slightly varying environmental conditions are significantly affected by such minor changes. Either a paired t-test or Welch's t-test will be used depending upon the shape of the distributions produced by the data for each batch/lot and their respective variances. Use log transformed data for the results obtained from microbiological methods. The appropriate t-test to be used for the analysis is determined in the following manner.

1. Test the symmetry of the distribution of results from both batch/lot 1 and batch/lot 2.
2. Calculate the variance of both batch/lot 1 and batch/lot 2 data.
3. Values for the test of symmetry for either batch/lot 1 or batch/lot 2 outside the range of -2 to +2 indicate a significant degree of skewness in the distribution.
4. A ratio of the larger of the variances of either batch/lot 1 or batch/lot 2 to the smaller of the variances of either batch/lot 1 or batch/lot 2 greater than 2 indicates a lack of homogeneity of variance.

5. Use either the paired t-test or Welch's t-test for the statistical analysis based on the following considerations.
    - If the distributions of the data from batch/lot 1 and batch/lot 2 are symmetric (within the range of -2 to +2) and there is homogeneity of variance, use a paired t-test for the statistical analysis.
    - If the distributions of the data from batch/lot1 and batch/lot 2 are symmetric (within the range of -2 to +2) but there is a lack of homogeneity of variance in the data, use Welch's t-test for the statistical analysis.
    - If the distribution of the data from batch/lot 1 and batch/lot 2 are skewed (outside the range -2 to +2) and the skewness for both groups is either positive for both or negative for both and there is homogeneity of variance in the data, use the paired t-test for the statistical analysis.
    - If the distribution of the data from batch/lot 1 and batch/lot 2 are skewed and the skewness for both groups is either positive for both or negative for both; but, the data lacks homogeneity of variance, use Welch's t-test to statistically analyze the data.

Data summary for demonstrating the ruggedness of the new or modified method:

Value for the test of symmetry of the distribution of batch/lot 1 _____

Value for the test of symmetry of the distribution of batch/lot 2 _____

Variance of batch/lot 1 data _____

Variance of batch/lot 2 data _____

Ratio of the larger to the smaller of the variances of batch/lot 1 and batch/lot 2 _____

Is there a significant difference between batch/lot 1 samples and batch/lot 2 samples
_____Y/N_____

VI. SOP for the Single Laboratory Validation of New or Modified Analytical Methods Intended as Alternatives to Officially Recognized NSSP Methods

#3

Validation Criteria

Comparability is the acceptability of a new or modified analytical method as a substitute for an established method in the NSSP. To be acceptable, the new or modified method must be specific for the analyte/measurand/organism of interest. Comparability must be demonstrated for each substrate or tissue type of interest by season and geographic area if applicable.

Specificity of the new or modified method is the ability of this new or modified method to measure only what it is intended to measure. To determine the specificity of new or modified methods, samples containing suspected interferences (interfering organisms/compounds/toxins) are analyzed in the presence of the analyte/measurand/target organism of interest.

Procedure for demonstrating the specificity of the new or modified method: This procedure is applicable for use with either growing waters or shellfish tissue. Make every effort to use samples free of the target analyte/measurand/organism of interest. For each shellfish tissue type of interest use a minimum of 10-12 animals per sample. For each sample take three (3) aliquots of either the shellfish homogenate or growing water sample appropriately sized for the work and spike two (2) of the three (3) with a low but determinate level (by the method/modified method under study) of the target analyte/measurand/organism of interest. Take one of these two (2) aliquots and also spike it with a moderate to high level of a suspected interfering organism/compound/toxin if not

naturally incurred. Do not spike the third aliquot. This is the sample blank. Process each aliquot, the sample blank , the aliquot spiked with the target analyte/measurand/organism of interest and the aliquot spiked with the target analyte/measurand/organism of interest in the presence of the suspected interfering organism/compound/toxin as usual to determine the method/modified method concentration for the target analyte/measurand/organism of interest. Do five (5) replicates for each aliquot excluding the sample blank. Do one (1) sample blank per analysis. Repeat this process for all suspected interfering organisms/compounds/toxins.

Data for demonstrating the specificity of the new or modified method:

Name of suspected interfering organism/compound/toxin #1 _____

Sample type _____

Sample blank concentration for the target analyte/measurand/organism of interest _____

	Conc. of aliquot spiked with target analyte/measurand/organism of interest	Conc. of aliquot spiked with target analyte/measurand/organism of interest of interest in the presence of suspected interfering organism/compound/toxin
Replicate 1		
2		
3		
4		
5		

Repeat for each suspected interfering organism/compound/toxin tested.

Data handling for demonstrating specificity of the new or modified method
The specificity index will be used to test the specificity of the new or modified method in the presence of suspected interfering organisms/compounds/toxins. The specificity index (SI) is calculated as indicated below:

$$\text{Specificity index (SI)} = \frac{\text{Sample spiked with only target of interest}}{\text{Sample spiked with target in presence if suspected interferences}}$$

All microbiological count data must be converted to logs before statistical analysis. Samples spiked with both the target analyte/measurand/organism of interest and the target analyte/measurand/organism of interest in the presence of a suspected interfering organism/compound/toxin may have to be corrected for matrix effects before determining the Specificity index (SI). The sample blank accompanying the analysis is used for this purpose. Any correction that may be necessary to microbiological data for matrix effects are done using log transformed data.

The Specificity index (SI) should equal one (1) in the absence of interferences. To test the significance of a Specificity index (SI) other than one (1) for any suspected interfering organism/compound/toxin, a two-sided t-test at the .05 significance level is used. For each suspected interfering organism/compound/toxin calculate the average Specificity index (SI_{avg}) for the five (5) replicates analyzed for each sample by obtaining the average concentration for both the aliquot containing the target analyte/measurand/organism of interest only and the aliquot containing the target analyte/measurand/organism of interest in the presence of suspected interfering organisms/compounds/toxins and using the formula below.

$$SI_{avg} = \frac{\text{Avg. conc. of sample spiked only with target of interest}}{\text{Avg. conc. of sample spiked with target in the presence of suspected interferences}}$$

Perform the t-test to determine if the average Specificity index (SI) obtained from the five (5) replicates from each analysis differs from one (1). Repeat for all the suspected interfering organisms/compounds/toxins tested.

Data summary for testing the specificity of the new or modified method:

Interfering organism/compound/toxin #1 _____ SI_{avg} _____
SI different from 1 _____

Interfering organism/compound/toxin #2 _____ SI_{avg} _____
SI different from 1 _____

Interfering organism/compound/toxin #3 _____ SI_{avg} _____
SI different from 1 _____

Interfering organism/compound/toxin #n _____ SI_{avg}_____
SI different from 1 _____

Proposal Subject	Press Releases
Specific NSSP Guide Reference	NSSP Model Ordinance Chapter II. Risk Assessment and Risk Management
Text of Proposal/ Requested Action	The US FDA issued press releases associated with outbreaks in the Pacific Northwest in the summer of 2006 and in Texas in March of 2007. These press releases created concern regarding the appropriateness and effectiveness of press releases as a public health measure to address an illness outbreak. Use of press is to inform consumers. The ISSC Executive Board discussed the issuance of these press releases and directed the formation of a working group to further investigate and review the use of press by state and federal agencies. The workgroup is to look for ways to coordinate use of press and provide recommendations for discussion at the 2007 Biennial Meeting.
Public Health Significance	
Cost Information (if available)	
Action by 2007 Use of Press Committee	Recommended that this Committee continue its deliberations and that a meeting be held in January 2008 in conjunction with appropriate FDA officials and report back to the Executive Board in March 2008. In the interim FDA will consult with the involved state regulatory agency on the content and timing of the release of press.
Action by 2007 Task Force III	Recommended adoption of the Press Release Committee recommendation on Proposal 07-305.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Resolution Subject *Vibrio vulnificus* Management Plan for Oysters Unprecedented Regulatory Approach

Text of Resolution

Whereas, the National Shellfish Sanitation Program, (NSSP), was developed in 1925 when the U. S. Public Health Service responded to a request for assistance from local and state public health officials in controlling disease associated with the consumption of raw shellfish, and

Whereas, each shellfish shipping state has adopted adequate laws and regulations for sanitary control of the shellfish industry, completed sanitary surveys of harvest areas, delineated and patrolled restricted areas, inspected shellfish plants, and conducted such additional inspections, laboratory investigations, and control measures as were necessary to insure that the shellfish reaching the consumer had been grown, harvested and processed in a sanitary manner, and

Whereas, the shellfish industry has cooperated by obtaining shellfish from safe sources, by providing plants which met the agreed upon sanitary standards, by maintaining sanitary operating conditions, by placing the proper certificate number on each package of shellfish, and by keeping and making available to the control authorities records which showed the origin and disposition of all shellfish, and

Whereas, in 1982, a delegation of state officials met in Annapolis, Maryland and formed the Interstate Shellfish Sanitation Conference (ISSC), that is composed of state shellfish regulatory officials, industry officials, FDA, and other federal agencies, and

Whereas, the ISSC has provided a forum for state shellfish regulatory officials, industry officials, FDA, and other federal agencies, to establish uniform national guidelines and to exchange information regarding sources of safe shellfish, and

Whereas, under the guidance of the ISSC, the NSSP has lead the United States in the prevention of food-borne illnesses by requiring the States, to monitor bacteriological water quality of shellfish growing areas, to label shellfish with exact growing area information for trace-back purposes, to inspect and certify shellfish processing facilities, to require refrigeration of shellfish to reduce the growth of food-borne pathogens, and

Whereas, other than molluscan shellfish, no other State or Federal regulatory agency requires through regulation that the food they regulate be made safer for the high-risk, immune compromised consumer to eat either raw or cooked, and

Whereas**,** *Vibrio vulnificus* is not considered to be one of the most common causes of foodborne disease by the Centers for Disease Control and Prevention, and

Vibrio vulnificus Management Plan for Oysters unprecedented regulatory approach
Whereas**,** when the *Vibrio vulnificus* Management Plan was introduced at the ISSC, the members were told that the plan was based on other foodborne disease reduction goals such as those stated in the FDA Egg Safety Plan, and

Whereas, after careful examination of other foodborne disease reduction plans, including the FDA Egg Safety Plan, none require that foods that cause illnesses associated with either *Salmonella enteritidis, Campylobacter, Escherichia coli* O157, *Giardia lamblia , Listeria monocytogenes*, *Shigella*, *Cryptosporidia, or Clostridium botulinum,* must be regulated to make those foods safer for the high-risk, immune compromised consumer to eat either raw or cooked by requiring strict harvest controls or mandatory post harvest processing of those foods, and

Whereas, no other foodborne disease reduction plan mandates that illnesses associated with the bacteria or toxins listed above be reduced by 40% in 2007 and 60% in 2008, and if those

goals are not met, strict harvest controls and/or mandatory post harvest processing of those foods will be established, Therefore,

Be it Resolved that the ISSC acknowledge that *Vibrio vulnificus* is not one of the top 10 causes of foodborne illnesses in the United States and that the *Vibrio vulnificus* Management Plan for oysters is one of the most restrictive foodborne disease reduction plans implemented by any Federal Program or Agency, given that the target population is high risk consumers, and

Be it Further Resolved that the ISSC reevaluate the *Vibrio vulnificus* Management Plan for oysters since the Plan was introduced and developed solely to protect high risk individuals which makes it different from other Plans,

Be it Further Resolved that the ISSC, when evaluating progress in *Vibrio vulnificus* illness reduction, take into consideration the unprecedented nature of the goals set forth in the *Vibrio vulnificus* Management Plan for oysters with respect to reducing the numbers of illnesses exclusively within the high risk consumer population.

Supporting Documents

Supporting Documents Available Upon Request: NSSP, Egg Safety Plan, and Most Common Food Borne Illnesses according to CDC.

Action by 2005 ISSC Executive Board

Recommended referral of Resolution 05-001 to the Vibrio Management Committee for referral to the *Vibrio vulnificus* Subcommittee.

Action by USFDA

Concurred with Conference action.

Action by 2006 Vibrio Management Committee

Recommended adoption of Resolution 05-001 as amended for submission at the 2007 Biennial Meeting.

Whereas, the National Shellfish Sanitation Program (NSSP) was developed in 1925 when the U. S. Public Health Service responded to a request for assistance from local and state public health officials in controlling disease associated with the consumption of raw molluscan shellfish, and

Whereas, each shellfish shipping state adopts laws and regulations for sanitary control of the shellfish industry, completes sanitary surveys of harvest areas, delineates and patrols growing areas, inspects shellfish plants, and conducts such additional inspections, laboratory investigations, and control measures as are necessary to ensure that the shellfish reaching the consumer has been grown, harvested and processed in a sanitary manner, and

Whereas, the shellfish industry cooperates by obtaining shellfish from appropriately classified growing areas, by providing plants which are maintained and operated following strict sanitation guidelines, by properly identifying shellfish, and maintaining accurate records, and

Whereas, in 1982, a delegation of state officials met in Annapolis, Maryland and formed the Interstate Shellfish Sanitation Conference (ISSC), that is composed of state shellfish regulatory officials, industry representatives, FDA, and other federal agencies, and

Whereas, the ISSC provides a forum for state shellfish regulatory officials, industry representatives, FDA, and other federal agencies, to establish uniform national public health guidelines for the classification of growing waters and the sanitary harvest, processing and distribution of shellfish, and

Whereas, state shellfish control authorities under the guidance of the NSSP monitor bacteriological water quality of, and naturally occurring biotoxins in shellfish growing areas and inspect and certify shellfish processing facilities, and

Whereas, the ISSC is committed to providing molluscan shellfish which are safe to consume either raw or cooked, and

Whereas, naturally occurring bacteria and biotoxins intermittently present in shellfish growing areas require exceptional measures to protect public health, and

Whereas, *Vibrio vulnificus* is not one of the top ten causes of foodborne illnesses in the US, and

Whereas, the high mortality rate, specifically in immunocompromised individuals consuming oysters containing this naturally occurring marine bacteria calls for an unparalleled regulatory approach with extraordinary measures, and

Whereas, unlike with other food borne illness reduction plans, the high mortality rate associated with *Vibrio vulnificus* resulted in the ISSC cooperatively adopting the *Vibrio vulnificus* Management Plan with illness reduction goals of 40% by 2007 and 60% by 2008, and

Whereas, extraordinary at risk consumer education efforts coupled with enhanced time/temperature controls, voluntary post harvest processing, labeling incentives, on-board refrigeration and market restrictions have contributed to Vibrio vulnificus illness reductions ahead of pace with established goals, therefore,

Be it Resolved that the ISSC remains committed to semiannually reevaluating implementation and effectiveness of the *Vibrio vulnificus* Management Plan for oysters striving to further reduce illnesses of at risk individuals.

Action by 2006 Executive Board	Recommended adoption of Vibrio Management Committee recommendation on Resolution 05-001.
Action by 2007 Vibrio Management Committee	Recommended adoption of Executive Board's recommendation on Resolution 05-001.
Action by 2007 Task Force III	Recommended adoption of the Vibrio Management Committee recommendation on Resolution 05-001.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Resolution Subject	Leeland Jefferson Wiegardt Memorial Resolution
Text of Resolution	***Whereas***, Leeland Jefferson Wiegardt was born in Ogden, Utah on February 12, 1927 and died 79 years later on December 17, 2006 in Seaside, Oregon; and ***Whereas***, Lee carried on a family tradition which began with his grandfather Heinrich in Willapa Bay, Washington in 1873 culturing and processing oysters; and ***Whereas***, Lee was a partner in Wiegardt Brothers, Inc. oyster processors and was sole owner of Wiegardt & Sons, oyster growers; and ***Whereas***, Lee was a leader in the promotion of the shellfish industry and protection of the environment; and ***Whereas***, Lee participated actively at Pacific Rim Shellfish Sanitation Conference and Interstate Shellfish Sanitation Conference meetings from their inception developing public health regulations for the harvest and processing of shellfish; and ***Whereas***, Lee effectively represented the entire West Coast industry for many years on the Interstate Shellfish Sanitation Executive Board ensuring public health measures were practical by sharing his knowledge of how shellfish are cultured and processed; and ***Whereas***, Lee was well known for adding color, humor, and candor to all the meetings he attended and ***Whereas***, his presence is greatly missed due to his passing; now ***Be It Therefore Resolved*** that the Interstate Shellfish Sanitation Conference extends its gratitude for Lee's leadership and lasting contributions to the organization; and ***Be It Further Resolved***, that the Interstate Shellfish Sanitation Conference acknowledge his contributions by a letter to that effect to his family.
Action by 2007 Resolutions Committee	Recommended approval of Resolution No. 07-001.
Action by 2007 General Assembly	Adopted recommendation of 2007 Resolutions Committee.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Resolution Subject	Lewis A. Byrd Memorial Resolution
Text of Resolution	***Whereas,*** Lewis A. Byrd was born in the community of Sweetwater, Marengo County, Alabama on June 17, 1946 and died 61 years later on June 27, 2007 in Bay Minette, Alabama; and ***Whereas,*** Lewis obtained his Ph.D. in Environmental Microbiology from Auburn University in 1976 and carried a love for the University all his life; and ***Whereas,*** Lewis began work with the Alabama Department of Public Health beginning in 1967 in environmental laboratory testing; and ***Whereas,*** Lewis became affiliated with the Alabama Department of Public Health's Seafood Program beginning in 1986 as Director of Seafood Quality Assurance and as Alabama's State Shellfish Standardization Officer; and ***Whereas,*** Lewis served as Director of the Alabama Department of Public Health's Seafood Branch from 1997; and ***Whereas,*** under Lewis' direction, the program received numerous commendations and recognitions from the public, industry, organizations, and government entities; and ***Whereas,*** Lewis was fondly remembered and eulogized at his funeral by friends, members of his staff, representatives from government entities, and the seafood industry he regulated; and ***Whereas,*** Lewis served the Interstate Shellfish Sanitation Conference in numerous capacities including technical reviews and informal consultations; now ***Be It Therefore Resolved,*** that the Interstate Shellfish Sanitation Conference formally recognizes Lewis Byrd's dedication to advancing public health standards for consumers of shellfish and his contributions to the National Shellfish Sanitation Program, and be it further resolved that the executive board, executive committee, office staff and membership of the Interstate Shellfish Sanitation Conference wish to extend their deepest sympathies and condolences to his wife and daughter, Jody and Lisa Byrd.
Action by 2007 Resolutions Committee	Recommended approval of Resolution No. 07-002.
Action by 2007 General Assembly	Adopted recommendation of 2007 Resolutions Committee.
Action by USFDA	December 20, 2007 Concurred with Conference action.

Resolution Subject Support for the ISSC Vibrio Education Program and Request for Continued Funding

Text of Resolution

Whereas, the National Shellfish Sanitation Program (NSSP) is the federal/state cooperative program recognized by the U.S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption, and

***Whereas*,** the purpose of the NSSP is to promote and improve the sanitation of shellfish moving in interstate commerce through cooperation and uniformity of State shellfish programs,
and

Whereas, the FDA recognizes the ISSC as the national organization of State shellfish regulatory officials to provide guidance and counsel on matters relating to the sanitary control of shellfish,
and

Whereas, the ISSC provides a formal structure to establish guidelines and procedures for uniform application of the NSSP,
and

Whereas, a small number of shellfish-borne illnesses have been associated with bacteria of the genus Vibrio, and these Vibrios are free-living aquatic microorganisms generally inhabiting marine and estuarine waters,
and

Whereas, shellfish control agencies provide the greatest level of public health protection by managing the shellfish growing areas and processing facilities in compliance with the goals and objectives of the NSSP,
and

Whereas, shellfish-borne Vibrio infections continue to occur,
and

Whereas, the ISSC has and continues to develop appropriate illness control measures for Vibrio vulnificus and Vibrio parahaemolyticus, including the NSSP Vibrio Education Outreach Program,
and

Whereas, the goal of the Vibrio Education Outreach Program is to reduce the rate of illnesses due to the consumption of commercially harvested raw or undercooked oysters,
and

Whereas, it appears that preliminary results seem to indicate that the Vibrio Education Outreach Program is achieving its intended result in these, and

Whereas, funding for this crucial program seems to be coming to an end,
and

***Whereas*,** there is a continuing need to provide education outreach, as well as to increase that education effort in terms of the scope of activities, as relates to both Vibrio vulnificus and Vibrio parahaemolyticus,

NOW THEREFORE BE IT RESOLVED that the ISSC express its unequivocal support for the continuation of the Education Outreach Program, and

BE IT FURTHER RESOLVED that the ISSC send notification to the appropriate state's shellfish control authorities acknowledging ISSC support for the continuation of the Education Outreach Program in their respective state,
and

BE IT FURTHER RESOLVED that the ISSC also encourage, through communication with the state's shellfish control authorities, continued funding for this program that is so vital to the shellfish industry and the consuming public,
and

BE IT FURTHER RESOLVED that the ISSC send notification to the U.S. Food and Drug Administration acknowledging ISSC support for the continuation of the Vibrio Education Outreach Program,
and

BE IT FURTHER RESOLVED that the ISSC also send notification to the U.S. Food and Drug Administration to encourage FDA to provide continued funding for the Vibrio Education Outreach Program, to include both Vibrio vulnificus and Vibrio parahaemolyticus education activities that are so vital to the shellfish industry and the consuming public,
and

BE IT FURTHER RESOLVED that the ISSC communicate with Members of Congress regarding the success and merits of the Education Outreach Program, and the need for continued congressional funding, in the amount of $250,000 per year to the ISSC and $1,000,000 per year to the Gulf and South Atlantic Fisheries Foundation, specifically to continue the efforts of the Education Outreach Program.

Action by 2007 Resolutions Committee

Recommended approval of Resolution No. 07-003.

Action by 2007 General Assembly

Adopted recommendation of 2007 Resolutions Committee.

Action by USFDA

December 20, 2007
Concurred with Conference action.

Resolution Subject Resolution of Appreciation

Text of Resolution

WHEREAS, the twenty-second meeting of the Interstate Shellfish Sanitation Conference convened August 11-17, 2007, at The Hotel Albuquerque at Old Town, Albuquerque, New Mexico and

WHEREAS, several individuals and organizations were instrumental in contributing to the outstanding success of this meeting,

BE IT THEREFORE RESOLVED, that the Interstate Shellfish Sanitation Conference goes on record expressing appreciation to:

The Staff of The Hotel Albuquerque at Old Town particularly,
Kirstin Ramsay, Sales Manager
Mitchell Madrid, Assistant Director of Catering and Convention Services
Odessa Waquiu, Group Rooms Coordinator
Marty Huerrara, Audio Visual Manager

The Volunteer ISSC Staff,
Program Chairman, Robert Wittman, VA Department of Health
Office Manager, William Eisele, Retired

Volunteer Task Force Recorder,
Gregg Goblick, USFDA

AND BE IT FINALLY RESOLVED, that the Conference directs the Executive Director to write a letter of appreciation to each of the above-mentioned individuals and organizations.

Action by 2007 Resolutions Committee Recommended approval of Resolution No. 07-004.

WHEREAS, the twenty-second meeting of the Interstate Shellfish Sanitation Conference convened August 11-17, 2007, at The Hotel Albuquerque at Old Town, Albuquerque, New Mexico and

WHEREAS, several individuals and organizations were instrumental in contributing to the outstanding success of this meeting,

BE IT THEREFORE RESOLVED, that the Interstate Shellfish Sanitation Conference goes on record expressing appreciation to:

The Staff of The Hotel Albuquerque at Old Town particularly,
Kirstin Ramsay, Sales Manager
Mitchell Madrid, Assistant Director of Catering and Convention Services
Odessa Waquiu, Group Rooms Coordinator
Marty Huerrara, Audio Visual Manager

The Volunteer ISSC Staff,
Program Chairman, Robert Wittman, VA Department of Health
Office Manager, William Eisele, Retired

Volunteer Task Force Recorder,
Gregg Goblick, USFDA

AND BE IT FINALLY RESOLVED, that the Conference directs the Executive Director to write a letter of appreciation to each of the above-mentioned individuals and organizations.

Action by 2007 General Assembly	Adopted recommendation of 2007 Resolutions Committee as amended by adding: Dorothy L. Leonard; Dorothy Jean McCoubrey; and Gulf Oyster Industry Council.
Action by USFDA	December 20, 2007 Concurred with Conference action.