Interstate Shellfish Sanitation Conference

Task Force II

(Harvesting/Handling/Distribution)

2011 Biennial Meeting

Proposals for Consideration

October 1 – 7, 2011

Proposal for Task Force Consideration at the 2011 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	Vibrio Management Committee
Affiliation:	Interstate Shellfish Sanitation Conference
Address:	209-2 Dawson Road Columbia, SC 29223
Phone: **Fax:** **Email:**	803-788-7559 803-788-7576 issc@issc.org
Proposal Subject:	*Vibrio vulnificus* Risk Management Plan
Specific NSSP Guide Reference:	1999 NSSP Guide Model Ordinance Chapter II. Risk Assessment and Risk Management
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:

(number of cases) x (CDC adjustment factor)
population

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 **<u>for Oysters</u>**.

(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. **<u>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</u>**. 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. **<u>The core states include Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama.</u>** T**<u>he list of core states may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate.</u>** 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~~ **<u>rate of illness</u>** 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 **<u>intended for the raw, half-shell market</u>** 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 **<u>for the purpose of harvest of oysters intended for the raw, half-shell market</u>** 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 **<u>intended for the raw, half-shell market</u>** 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:

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

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

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 compared ~~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~~c~~**(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) <u>Recommended that the Chairman appoint a committee to develop further guidance language for implementation of .04 (C) (1)-(5).</u>** **4) <u>Recommended adoption of an effective date of October 1, 2001, and further recommended an expedited review by FDA.</u>**
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	Recommended adoption of Vv Subcommittee recommendation on Proposal 00-201.

Management Committee	
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 Mgmt Committee	Recommended that the Vibrio Management Committee continue to monitor the activities of Proposal 00-201.
Action by 2007	Recommended adoption of the Vibrio Management Committee recommendation on

Task Force II	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.
Action by VMC October 2009	1. a. Recommended that FDA submit a proposal for deliberation by a Special ISSC conference to be held in 2010. b. In the interim, it is requested that FDA, in coordination with ISSC fund a robust economic impact and consumer acceptance analysis to inform the ISSC deliberations on the proposal. An impacts analysis guidance committee will be appointed to guide and make recommendations on the components of the impacts analysis study. 2. Recommended that a workgroup be established to develop criteria for an economic analysis. The workgroup will use the criteria for an economic impact analysis for rulemaking as a guide. The study should include a taste acceptance component. The workgroup should include, but not be limited to, at least one industry member and one regulatory member from the east, west and gulf coasts. 3. Recommended that May 1, 2011, be set as date for implementation of Model Ordinance Chapter II @ .04, *Vibrio* Management Plan for Oysters. 4. Recommended that the *Vibrio* Management Committee meet at the Spring 2010 meeting of the Executive Board. 5. Recommended that the findings of the *Vibrio* vulnificus Illness Review Subcommittee be accepted. The Subcommittee found that 17 cases in 2007 met the criteria and 13 cases in 2008 met the criteria. After adjusting for population changes, the illness rate reduction was calculated to be 35.2% from the baseline period.
Action by 2009 Task Force II	Recommended adoption of *Vibrio* Management Committee Recommendation No. 1.a. and b. on Proposal 00-201. Recommended adoption of *Vibrio* Management Committee Recommendation No. 2. on Proposal 00-201 with instruction to add a consumer representative to the work group. Recommended adoption of *Vibrio* Management Committee Recommendation No. 3 on

Action by 2009 Task Force II (continued)	Proposal 00-201. Recommended adoption of *Vibrio* Management Committee Recommendation No. 4 on Proposal 00-201. Recommended adoption of *Vibrio* Management Committee Recommendation No. 5 on Proposal 00-201.
Action by 2009 General Assembly	Voted no action on Proposal 00-201 Recommendation 1.a. Adopted recommendation of 2009 Task Force II on Proposal 00-201 Recommendation 1.b. Adopted recommendation of 2009 Task Force II on Proposal 00-201 Recommendation 2. Voted no action on Proposal 00-201 Recommendation 3. The previous implementation date of May 1, 2010 remains in effect. Adopted recommendation of 2009 Task Force II on Proposal 00-201 Recommendation 4. Adopted recommendation of 2009 Task Force II on Proposal 00-201 Recommendation 5. Adopted a motion that the Vibrio Management Committee, at its fall 2010 meeting, evaluate the effects of the Vibrio Management Plans implemented May 1, 2010, and make recommendations to the Executive Board. Adopted a motion that the Executive Board write a letter to FDA stating that the unilateral actions taken to regulate *Vv* under the Seafood HACCP Regulations are not consistent with the MOU between the ISSC and FDA.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 00-201 with the following comments and recommendations for ISSC consideration. FDA concurs with recommendations of the Conference as outlined in Proposal 00-201. Recognizing the difficult and sensitive nature of efforts to effectively control illnesses and deaths associated with *Vv*, FDA, in its January 26, 2010 letter to the ISSC, stated its desire to maintain an open dialog with the ISSC and its commitment to a process to ensure that the essential elements will be in place for the Executive Board to take action during its fall 2010 meeting to protect consumers from Vv illnesses and deaths. Toward that end, FDA is contracting with Research Triangle Institute to conduct an assessment of Post Harvest Processing implementation by the Gulf industry. As you know, efforts to conduct a consumer acceptance component of that study will be conducted through a contract let by the ISSC. In that regard, FDA stands ready to offer assistance and guidance as appropriate.

Proposal for Task Force Consideration at the 2011 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	PAC RIM Shellfish Conference (Jennifer Tebaldi)
Affiliation:	PAC RIM Shellfish Conference
Address:	Washington State Department of Health PO Box 47824 Olympia, WA 98504-7824
Phone: **Fax:** **Email:**	360-236-3330 360-236-2257 Jennifer.tebaldi@doh.wa.gov
Proposal Subject:	Identification of Wet Stored Shellstock
Specific NSSP Guide Reference:	NSSP Guide Section II 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 03-204 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.
2011 NOTE:	The only pending action associated with this proposal will be a report from FDA. The report will be shared with the membership when available.

Proposal for Task Force Consideration at the 2011 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter	ISSC Executive Board
Affiliation	Interstate Shellfish Sanitation Conference (ISSC)
Address	209-2 Dawson Road Columbia, SC 29223
Phone **Fax** **Email**	803-788-7559 803-788-7576 issc@issc.org
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 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.
2009 Action	No activity

Proposal for Task Force Consideration at the 2011 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	Alfred R. Sunseri
Affiliation:	P & J Oyster Company, Inc.
Address:	1039 Toulouse Street New Orleans, LA 70112
Phone: **Fax:** **Email:**	504-523-2651 504-529-7966 asunseri@bellsouth.net
Proposal Subject:	Post Harvest Handling Definition
Specific NSSP Guide Reference:	NSSP Guide Section II. Model Ordinance B. Definitions of Terms
Text of Proposal/ Requested Action	Add a new definition for Post Harvest Handling as follows and renumber Definitions Section appropriately. Post Harvest Handling means any handling technique which has been established by a certified dealer and/or licensed harvester using the Hazard Analysis Critical Control Point guidelines that have been proven to result in a low historical risk of incidence of illnesses to consumers from naturally occurring bacteria as determined by the SSCA.
Public Health Significance:	The use of Post-Harvest Handling techniques by certified dealers and licensed harvesters are proven to provide consumers of raw molluscan shellfish with a low incidence of illnesses caused by naturally occurring bacteria using HACCP controls
Cost Information (if available):	Less than the cost of closing oyster harvest areas, requiring oysters be shucked when shucking oysters is not profitable or requiring post-harvest processing of oysters.
Action by 2009 Task Force II	Recommended referral of Proposal 09-201 to an appropriate committee as determined by the Conference Chairman.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force II on Proposal 09-201.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 09-201.

Proposal for Task Force Consideration at the 2011 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	Alfred R. Sunseri
Affiliation:	P & J Oyster Company, Inc.
Address:	1039 Toulouse Street New Orleans, LA 70112
Phone: **Fax:** **Email:**	504-523-2651 504-529-7966 asunseri@bellsouth.net
Proposal Subject:	Continuing Education Requirement for Certified Shellfish Dealers
Specific NSSP Guide Reference:	NSSP Guide Section II. Model Ordinance Chapter I. Shellfish Sanitation Program @.02 Dealer Certification A. General
Text of Proposal/ Requested Action	(2) Certification shall be given only to persons who meet the established requirements established for certification. **a. All persons prior to applying for plant certification shall complete 3 hours annually of continuing education hours to maintain certification by the Authority and listing the ICSSL. Continuing Education hours could include attendance at ISSC meetings attendance at regional shellfish sanitation conferences, attendance at regional shellfish association meetings, or any other conference or meeting approved by the Authority.**
Public Health Significance:	This requirement will better inform certified dealers of new guidelines set forth in the NSSP.
Cost Information (if available):	The cost would include registration fee and certification certificate for dealer to attend continuing education course.
Action by 2009 Task Force II:	Recommended referral of Proposal 09-203 to an appropriate committee as determined by the Conference Chairman.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force II on Proposal 09-203.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 09-203.

Proposal for Task Force Consideration at the 2011 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	Alfred R. Sunseri
Affiliation:	P & J Oyster Company, Inc.
Address:	1039 Toulouse Street New Orleans, LA 70112
Phone: **Fax:** **Email:**	504-523-2651 504-529-7966 asunseri@bellsouth.net
Proposal Subject:	Continuing Education Requirement for Licensed Shellfish Harvesters
Specific NSSP Guide Reference:	NSSP Guide Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting @.01 Control of Shellstock Growing Areas
Text of Proposal/ Requested Action	C. Licensing of Harvesting (1) The Authority shall assure that a license is required to commercially harvest shellstock, including shellstock harvested from aquaculture. (2) Each license shall: (a) Not be valid for more than one year; (b) Require the harvester to complete 3 hours annually of continuing education hours to attain a harvester license from the Authority Continuing Education hours could include attendance at ISSC meetings, attendance at regional shellfish sanitation conferences, attendance at regional shellfish association meetings, or any other conference or meeting approved by the Authority. ~~(b)~~ (c) Require the harvester to sell only to dealers listed on the Interstate Certified Shellfish Shippers List; and ~~(c)~~ (d) Allow the harvester, at his discretion, to place shellstock in containers for transport of shellstock from a growing area to land or to a dealer.
Public Health Significance:	This requirement will better inform licensed shellfish harvesters of new guidelines set forth in the NSSP.
Cost Information (if available):	The cost would include registration fee and certification certificate for the licensed harvester to attend a continuing education course.
Action by 2009 Task Force II	Recommended referral of Proposal 09-211 to an appropriate committee as determined by the Conference Chairman.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force II on Proposal 09-211.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 09-211.

Proposal for Task Force Consideration at the 2011 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	Dealer/Harvester Education Workgroup
Affiliation:	Interstate Shellfish Sanitation Conference (ISSC)
Address:	209-2 Dawson Road Columbia, SC 29223
Phone: **Fax:** **Email:**	803-788-7559 803-788-7576 issc@issc.org
Proposal Subject:	New Food Safety Training Requirements for Harvesters and Dealers
Specific NSSP Guide Reference:	NSSP Guide Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting
Text of Proposal/ Requested Action	.02 Shellstock Harvesting and Handling. A. Harvesters. Any harvester who engages in-shellfish packing as defined in this Ordinance shall: (1) Be a dealer; or (2) Pack shellstock for a dealer. B. Harvester/Dealer Education Requirement for States that have determined, through a *Vibrio* risk assessment, that *Vibrio* illnesses are reasonably likely to occur. (1) If a harvester or dealer elects to harvest oysters intended for raw consumption during months that are typically associated with *Vibrio* illnesses, the harvester or dealer shall obtain a minimum of two hours of training in harvest and post-harvest practices, held bi-annually; or an equivalent level of training, as determined by the State authority (2) The training shall cover all phases of harvest and post harvest handling likely to result in temperature abuse or growth of *Vibrio* bacteria. The training shall include harvest and post harvest practices, transportation and handling and processing methods designed to minimize the growth of Vibrio and to reduce the risk of illness from *Vibrios*. (3) Based upon harvest practices and environmental conditions, the State Authority may determine the exact requirements of the training program, including the length and frequency of the training session. (4) Harvesters and dealers must receive a certificate for training that has been approved by the Authority prior to issuance of a new license, or before a license shall be renewed. (5) At least one representative from each company with a harvester or dealer license shall obtain the training. (6) The Authority may provide the required training course, or approve other training classes or courses provided by other government agencies,

	educational institutes, academic meetings, private institutions, non profit organizations or trade associations. ~~B~~C. Non-Vessel Harvesting ~~C~~D. Vessels ~~D~~E. Disposal of Human Sewage from Vessels ~~E~~F. Shellstock Washing ~~F~~G. Shellstock Identification
Public Health Significance:	The risk of *Vibrio* illness can be greatly reduced through appropriate harvesting, post harvesting, transportation, handling, and processing of oysters intended for raw consumption. Because harvesters are not required to obtain HACCP training, it has been recognized that critical information about temperature abuse and the growth of *Vibrio* bacteria is not being conveyed to a large number of growers that only have a harvester's license. Further, it is recognized that dealers will benefit from learning more about the advantages of utilizing certain harvest, post harvest, transportation, handling and processing techniques designed to prevent the growth of *Vibrio* bacteria.
Cost Information (if available):	Undetermined cost implications. Recommend ISSC assistance in providing training materials or support.
Action by 2009 Task Force II:	Recommended referral of Proposal 09-212 to an appropriate committee as determined by the Conference Chairman.
Action by 2009 General Assembly:	Adopted recommendation of 2009 Task Force II on Proposal 09-212.
Action by USFDA 02/16/2010:	Concurred with Conference action on Proposal 09-212.

Proposal for Task Force Consideration at the 2011 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	Pacific Rim Shellfish Sanitation Conference
Affiliation:	Pacific Rim Shellfish Sanitation Conference
Address:	12501 Yelm Hwy Se Olympia, WA 98513
Phone: **Fax:** **Email:**	360-438-8687 360-438-8742 kphelps@nwifc.org
Proposal Subject:	Research Need for Suitable Time-Temperature Monitoring Devices for Shipping Times Greater than Four Hours
Specific NSSP Guide Reference:	Section II. Model Ordinance Chapter IX. Transportation .05 Shipping Times
Text of Proposal/ Requested Action	The Pacific Rim Shellfish Sanitation Conference requests that the ISSC create an educational committee with the purpose of establishing criteria, plus research and review of suitable time-temperature monitoring devices to adequately monitor the temperature of shellstock during shipping. The educational committee will also post and maintain a clearinghouse showing potential time-temperature monitoring devices on the ISSC organization website so as to support dealers who ship shellfish. B. Shipping Time is Greater Than Four Hours. (1) When the shipping … (a) Mechanically refrigerated conveyances … (b) Containers with an … (2) Unless the dealer has an approved HACCP plan with an alternate means of monitoring time-temperature, the initial dealer shall assure that a suitable time temperature recording device accompanies each shipment of shellfish. (3) The initial dealer shall note the date and time on the temperature-indicating device, if appropriate. (4) Each receiving dealer shall write the date and time on the temperature-indicating device, if appropriate, when the shipment is received and the doors of the conveyance or the containers are opened. (5) The final receiving dealer shall keep the time-temperature recording chart or other record of time and temperature in his files and shall make it available to the Authority upon request. (6) An inoperative temperature-indicating device shall be considered as no recording device.
Public Health Significance:	Shellfish dealers are required by the NSSP to ensure that shellfish is shipped under proper temperature control to prevent possible pathogen growth. Natural marine pathogens such as *Vibrio vulnificus* and *Vibrio parahaemolyticus* show substantial growth when temperature increases. Pathogen growth has a logarithmic relationship to temperature; therefore, maintaining proper temperature control during shipping can lessen or restrict the growth of these pathogens.

	Dealers have requested guidance on what time-temperature devices and technologies are available and suitable for industry use. With ever-changing technologies, a central educational clearinghouse would best serve the conference and its members.
Cost Information (if available):	None – research request

Proposed Specific Research Need/Problem to be Addressed:

Research into appropriate time-temperature monitoring devices in order to monitor the temperature of shellstock during shipping. The current problem to be addressed focuses on whether or not shellstock is being kept at proper and controlled temperatures during shipping in order to suppress or restrict the growth of pathogens such as *Vibrio vulnificus* and *Vibrio parahaemolyticus*. These time-temperature devices could serve to inform the receiver if the product before them is safe for human consumption and the grower on whether or not their product is being shipped as agreed.

How will addressing this research support/improve the mission/role of the ISSC/NSSP/Industry? Support need with literature citations as appropriate.

This research support will improve the mission of the ISSC/NSSP/Industry by increasing the monitoring of shellstock once it leaves the growing area. Time to Temperature controls have been instituted and measured in the growing areas and people are still getting sick. The industry and regulators in the Pacific Rim are asking the questions: how can we measure whether or not the shellstock temperatures are being maintained during shipping? How can we collect this data to help narrow down where the pathogen growth may be occurring? By narrowing in on possible avenues for growth and collecting sound data to support the possibility, public health will be better served.

Relative Priority Rank in Terms of Resolving Research Need:

Immediate	☐	**Important**	☒
Required	☐	**Other**	☐
Valuable	☐		

Estimated Cost:

Proposed Sources of Funding/Support:

Time Frame Anticipated:

Action by 2009 Task Force II	Recommended adoption of Proposal 09-214 as submitted.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force II on Proposal 09-214.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 09-214.

Proposal for Task Force Consideration at the 2011 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	*Vibrio* Management Committee (VMC)
Affiliation:	Interstate Shellfish Sanitation Conference (ISSC)
Address:	209-2 Dawson Road Columbia, SC 29223
Phone: **Fax:** **Email:**	803-788-7559 803-788-7576 issc@issc.org
Proposal Subject:	Post Harvest Handling
Specific NSSP Guide Reference:	NSSP Guide Section II Model Ordinance Definitions and New Chapter XVII.
Text of Proposal/ Requested Action	Action #1 Add a new definition to B. Definition of Terms for Post Harvest Handling and renumber Definitions Section accordingly. <u>Post Harvest Handling means a control(s) employed by a dealer to further reduce, beyond controls currently in place under the NSSP, the post harvest growth of naturally occurring pathogens for the purposes of handling product outside of existing NSSP management plans.</u> Action #2: Add a new chapter to the NSSP Guide Section II. Model Ordinance as follows: <u>Chapter XVII. Post Harvest Handling</u> <u>A. If a dealer elects to use a post harvest handling control(s) to reduce the levels of a naturally occurring pathogen(s) of public health concern in shellfish, the dealer shall:</u> <u>(1) Have a HACCP plan (approved by the Authority) for the control(s) that reduces post harvest growth of the target pathogen(s).</u> <u>(a) The dealer must validate that the post harvest handling control(s) reduces the post harvest growth of naturally occurring pathogen(s). The validation study must be approved by the State Shellfish Control Authority with FDA concurrence.</u> <u>(b) The ability of the post harvest handling control(s) to reliably achieve the appropriate reduction in post harvest growth of the target pathogen(s) shall be routinely verified at a frequency determined by the State Shellfish Control Authority.</u> <u>(2) Package and label all shellfish in accordance with the requirements of this Ordinance.</u> <u>(3) Keep records in accordance with Chapter X. 07.</u>
Public Health Significance:	The changes recommended by this proposal provide added opportunities for shellfish dealers to meet the required State Control Plans for naturally occurring pathogens.

Cost Information (if available):	
Action by 2009 Task Force II:	Recommended referral of Proposal 09-231 to an appropriate committee as determined by the Conference Chairman.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force II on Proposal 09-231.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 09-231.

Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting	☐ ☒ ☐	**Growing Area Harvesting/Handling/Distribution Administrative**

Name of Submitter:	Alfred J. Sunseri
Affiliation:	P & J Oyster Company, Inc.
Address:	1039 Toulouse Street New Orleans, LA 70112
Phone: **Fax:** **Email:**	504-523-2651 504-529-7966 asunseri@bellsouth.net
Proposal Subject:	Post Harvest Handling
Specific NSSP Guide Reference:	Section II. Model Ordinance Chapter XVII. Post Harvest Handling
Key Words:	Post Harvest Handling
Text of Proposal/ Requested Action:	Post Harvest Handling A. If a dealer elects to use a post harvest handling process to reduce post harvest growth of some target pathogens of public health concern in shellfish, the dealer shall: (1) Have a HACCP plan approved by the Authority for the process that reduces post harvest growth of the target pathogen(s). (a) The dealer must demonstrate that the post harvest handling process reduces the post harvest growth of Vibrio vulnificus in the product to be determined by the State Shellfish Authority or other method approved for NSSP use. (b) The dealer must demonstrate that post harvest handling process reduces the post harvest growth of Vibrio parahaemolyticus in the product to be determined by the State Shellfish Authority or other method approved for NSSP use. (c) For handling procedure that target other pathogens the dealer must demonstrate that the level of those pathogens in the post harvest handled product has reduced post harvest growth to an adequate action level determined by the ISSC or SSCA. (d) The ability of the post harvest handling to reliably achieve the appropriate reduction of growth in the target pathogen(s) shall require the certified dealer to conduct an annual validation study approved by the SSCA with the concurrence of FDA. (e) The HACCP plan shall include: (i) Post harvest handling 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. 3. Keep records in accordance with Model Ordinance Chapter X.07.
Public Health Significance:	It is well documented that a HACCP based approach to handling oysters during and following harvest will reduce the growth of bacteria that may cause illnesses.
Cost Information (if available):	The cost associated with this proposal is far less than those that currently exist to meet guidelines set in the *Vibrio vulnificus* and *parahaemolyticus* Management Plans for oysters.
Action by 2009 Task Force II:	Recommended referral of Proposal 09-232 to an appropriate committee as determined by the Conference Chairman.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force II on Proposal 09-232.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 09-232.

Proposal for Task Force Consideration at the 2011 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	Victor Garrido
Affiliation:	University of Florida – Aquatic Food Products Lab
Address:	105 AFPL – P.O. Box 110375 Gainesville, FL 32611
Phone: **Fax:** **Email:**	352-392-1991 Ext. 305 352-392-8594 vmga@ufl.edu
Proposal Subject:	Approval of the Use of End-Product Testing as an Alternative to Validation of Post Harvest Processes
Specific NSSP Guide Reference:	Section IV. Guidance Documents Chapter IV. Naturally Occurring Pathogens
Text of Proposal/ Requested Action	.04 Post Harvest Processing (PHP) Validation/Verification Guidance for *Vibrio vulnificus* and *Vibrio parahaemolyticus* C. End Product Testing Used as an alternative to validation of new shellfish processes to ensure that the end-product contains less than 30 MPN/g of Vv and/or Vp. Prior to adding labeling claims to the product, the processor must analyze each lot of the finished product in accordance with the NSSP guidance document. Only lots having less than 30 MPN/g will be allowed to be labeled as PHP. Processor must incorporate the sampling and testing into their HACCP plan and maintain records of HACCP controls as well as laboratory analytical results for all lots tested. ~~C~~D. 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~~E. Verification
Public Health Significance:	None

Cost Information (if available):	None
Action by 2009 Task Force II:	Recommended referral of Proposal 09-235 to an appropriate committee as determined by the Conference Chairman.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force II on Proposal 09-235.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 09-235.

Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	Executive Office
Affiliation:	Interstate Shellfish Sanitation Conference
Address:	209-2 Dawson Road Columbia, SC 29223-1740
Phone: **Fax:** **Email:**	803-788-7559 803-788-7576 issc@issc.org
Proposal Subject:	Restricted Use Shellstock Definition
Specific NSSP Guide Reference:	Section II Model Ordinance Definitions; Chapter X. General Requirements for Dealers; Chapter XI. Shucking and Packing; Chapter XIII. Shellstock Shipping; and Chapter XIV. Depuration Section IV. Guidance Documents Chapter IV. Naturally Occurring Pathogens .02 *Vibrio vulnificus* Management Plan .03 *Vibrio parahaemolyticus* Control Plan Guidance Section V. NSSP Approved Forms
Key Words:	Shellstock; Shipping; Restricted Use
Text of Proposal/ Requested Action:	Approve interim controls adopted by the ISSC Executive Board effective November 15, 2010. Definitions: Add new definition and renumber as appropriate: <u>Restricted Use Shellstock means shellstock that is harvested from growing areas classified as approved under conditions that do not allow the sale of the shellstock for direct marketing for raw consumption. Restricted use shellstock is identified with a tag indicating that the shellstock is intended for further processing prior to distribution to retail or food service.</u> Model Ordinance Chapter X. General Requirements for Dealers .01 General HACCP Requirements C. Contents of the HACCP Plan (2) List the critical control points… <u>(c) Critical control points shall be designed to ensure that shellstock received with restricted use tags is processed consistent with the stated purpose. For Shellstock tagged for restricted use, critical</u>

control points shall be included in the Certified Dealer's HACCP plan to ensure that the shellstock is shipped to another Certified Dealer with the restricted use tag or processed consistent with the stated purpose

.05 Shellstock Identification

B. Tags

(4) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in §.05 B. If the shellstock is received bearing a restricted use tag all specific use language shall be transferred to the new shipping tag.

E. All restricted use shellstock shall include a tag containing all information required in § .05 of Model Ordinance Chapter X. In addition the tag will include specific language detailing the intended use of the shellstock.

FE. Transaction Record. If shellstock are sold in bulk, the dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in §.05 B. with the addition of the name of the consignee.

Chapter XI. Shucking and Packing

.01 Critical Control Points

E. Shellstock Shipping Critical Control Point

(1) The dealer shall ensure that Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

Chapter XIII. Shellstock Shipping

.01 Critical Control Points

E. Shellstock Shipping Critical Control Point

(1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

Chapter XIV. Reshipping

.01 Critical Control Points

E. Shellstock Shipping Critical Control Point

(1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock.

	Section IV. Guidance Documents Chapter IV. Naturally Occurring Pathogens .02 *Vibrio vulnificus* Management Plan (l) Shellstock Harvested in Source States Harvesters must include on the tag of all product harvested for restricted use the statement “for shucking by a certified dealer” and/or "For PHP Only." Harvesting controls must be provided by the Authority to ensure that restricted use shellstock is not diverted to retail or food service. Dealers must establish a restricted use shellstock Critical Limit as part of their HACCP Plan for receiving. A shipping Critical Control Point must include a restricted use shellstock disposition step. Restricted use shellstock is not intended for retail or food service. .03 *Vibrio parahaemolyticus* Control Plan Guidance B. *Vibrio parahaemolyticus* Control Plan (3) Plan Effectiveness as Demonstrated by: (d) The authority must notify harvesters and dealers of those areas restricted to harvest for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing or "For PHP Only." Harvesters must include on the tag of all product harvested in these areas the statement for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing or "For PHP Only." Harvesting controls must be provided by the Authority to ensure that restricted use shellstock is not diverted to retail or food service. Dealers must establish a for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing. or "For PHP Only" labeling Critical Limit as part of their HACCP plan for receiving. A shipping Critical Control Point must include for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing. or "For PHP Only" labeling requirement. Restricted Use Shellstock is not intended for retail or food service. Section V. NSSP Approved Forms Approve forms for: 1. Restricted Use Shellstock (Shucking or PHP) Shellfish Harvest/Purchase Record 2. Restricted Use Shellstock (Shucking or PHP) Sales/Disposition Record
Public Health Significance:	
Cost Information (if available):	

Restricted Use Shellstock (Shucking or PHP) Certified Dealer # ___________

SHELLFISH HARVEST/PURCHASE RECORD

Lot #	Quantity	Species	Harvest Area	Harvest Date	Purchase Date	Received from (Harvester or Certified Dealer ID)

Restricted Use Shellstock (Shucking or PHP)   Certified Dealer # ____________

SALES/DISPOSITION RECORD

Lot #	Date Sold or Processed	Sold To Dealer Cert # (N/A if Processed)	Quantity Sold Unprocessed	Quantity Processed

Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting	☐ ☒ ☐	**Growing Area Harvesting/Handling/Distribution Administrative**

Name of Submitter:	*Vibrio* Management Committee
Affiliation:	Interstate Shellfish Sanitation Conference (ISSC)
Address:	209-2 Dawson Road Columbia, SC 29223-1740
Phone: **Fax:** **Email:**	803-788-7559 803-788-7576 issc@issc.org
Proposal Subject:	*Vibrio vulnificus* Controls
Specific NSSP Guide Reference:	Section II Model Ordinance Chapter II Risk Assessment and Risk Management @.04 *Vibrio vulnificus* Risk Management for Oysters Section IV Guidance Documents Chapter IV Naturally Occurring Pathogens .04 Naturally Occurring Pathogens
Key Words:	*Vibrio vulnificus* Controls
Text of Proposal/ Requested Action:	During the January 2011 VMC meeting the Committee conducted an assessment of the effects of the 2010 *Vv* controls implemented by the *Vv* source states. The Committee also reviewed the *Vv* illness rate reductions for 2009 and 2010. The Committee concluded that the 60% goal had not been achieved for 2009, 2010 or 2009 and 2010 average. After a lengthy discussion which is described below, The VMC recommended, with Executive Board approval, the appointment of a workgroup to develop other *Vv* control options which would be included in a VMC proposal to the ISSC. The workgroup has been appointed and is working to develop new concepts. The workgroup will include Proposal 09-207, which was adopted in 2009, as a part of their discussions. The purpose of the proposal is to provide notice to the ISSC membership of this activity. The ISSC membership will be provided the full details of final recommendations when available. Points of Discussion by the VMC during the January 2011 Meeting: Chapter II @.04 includes requirements for States that have had two (2) or more etiologically confirmed shellfish borne *Vv* illnesses since 1995. Section IV Guidance Documents Chapter IV Naturally Occurring Pathogens includes guidance for implementation of the Chapter II Model Ordinance requirements. The ISSC adopted these requirements after years of encouragement by the USFDA. The very controversial *Vv* debate began in 1994 and after much resistance the ISSC adopted Proposal 00-201 in 2001. The controls of Proposal 00-201 were premised around illness rate reduction to be achieved by 2008. Proposal 00-201 included the following three (3) major components: (1) Consumer education: Each State *Vv* Management Plan was required to include a consumer education program. (2) The development of PHP capacity to treat 50% of Gulf oysters intended for raw half-shall consumption. The capacity was to be available should the 60% goals not be achieved.

	(3) Control strategies that could be implemented if the 40% and 60% goals were not met. The implementation of Proposal 00-201 has been very controversial and problematic since 2001. The problems include: (1) Our efforts to count cases for determining goal compliance has proven that illness reporting as it presently exists does not provide an adequate tool for determining the effectiveness of controls to lower risk for *Vv*. (2) The use of four (4) states, especially California, has been publicly controversial. The FDA has stated that national illnesses should be used. (3) In October 2009 FDA publicly announced that the agency no longer supported ISSC efforts to address *Vv*. The FDA stated its intent to reformulate policy and use the Fish and Fishery Product Hazards and Control Guidance 4th Edition to regulate *Vv* in raw oysters. (4) States have had difficulty enforcing industry compliance. (5) Restricted use shellstock has been diverted to restaurants and sold raw. Two (2) deaths have been attributed. (6) FDA and ISSC have had disagreements regarding the responsibility for evaluating State compliance with *Vv* controls. (7) The goal is a collective five (5) State goal. Determining compliance by individual States is problematic. The *Vibrio* Management Committee (VMC) concluded at the January 2011 meeting that the 60% goal has not been achieved. (8) Results of Consumer Acceptance Study suggest consumers prefer traditional raw oysters at seven (7) days and PHP oysters at fourteen (14) days. Report indicates that most consumers would be unwilling to pay higher price for PHP oysters. RTI report suggests FDA should slow its efforts to mandate PHP. (9) Congress passed the Food Safety Modernization Act which specifically addresses PHP in Section 114. The Senate authors of Section 114 of the Food Safety Modernization Act (FSMA) correspond with ISSC providing clarification of the intent of Congress and the Administration. (10) The present goal approach for measuring success is not consistent with the other elements of the National Shellfish Sanitation Program (NSSP). The Committee recommended additional time/temperature controls for April and November and recognized serious noncompliance issues in one Gulf State.
Public Health Significance:	*Vibrio vulnificus* is a naturally occurring bacterium found in seawater along the Gulf, Atlantic, and Pacific coasts, although it is most prevalent in the warm waters of the Gulf of Mexico. *Vibrio vulnificus* can be transmitted to humans through the consumption of raw shellfish harvested from waters containing the organism. Oysters from the Gulf of Mexico have been recognized as the primary species of molluscan shellfish associated with *Vibrio vulnificus* illnesses in consumers. *Vibrio vulnificus* does not normally affect healthy individuals, but persons who are immunocompromised, especially those with chronic liver disease, are at greater risk for contracting *Vibrio vulnificus* from oyster consumption. In immunocompromised individuals, there is a risk for the organism to invade the bloodstream, resulting in potentially fatal septicemia. Although the annual number in the US of reported *Vibrio vulnificus* illnesses associated

	with oyster consumption is low, generally in the range of 30 to 35, the incidence of death among those individuals who contract the disease is high. Between 2001 and 2010 (10 years) there were 335 cases of illnesses with 157 deaths reported to CDC. Prior to 2001 the NSSP controls did not offer a strategy for controlling *Vibrio vulnificus*. In an effort to better control *Vibrio vulnificus* in oysters, in 2001 the Interstate Shellfish Sanitation Conference (ISSC) developed a *Vibrio vulnificus* Control Plan for inclusion in the NSSP. The Plan adopted by the ISSC included a 60% illness rate reduction goal that was to be achieved by the end of 2008. To present the goal has not been achieved. The Plan also included several mandatory controls which could be implemented if necessary to achieve the 60% goal. Recognizing the potential economic damage of these controls to the industry the ISSC has continued to investigate other controls that could potentially assist the Gulf States in achieving the 60% goal. Very stringent time to temperature controls were implemented in 2010. However, the implementation of these controls did not result in goal attainment. The identified mandatory requirements included Post Harvest Processing (PHP) and closures. To evaluate the impact of requiring PHP, FDA contracted with RTI to conduct an economic assessment. The report entitled "Analysis of How Post-Harvest Processing Technologies for Controlling *Vibrio vulnificus* Can Be Implemented" suggest that it would take a minimum of 3 years and significant financial investment both by private and public sectors to prepare the industry for a PHP requirement. The other listed mandatory control which would likely result in 60% illness rate reduction was closure. Those supported the inclusion of closures thought that PHP would be a viable option by 2008. Concerns for the economic impact of *Vibrio vulnificus* control prompted Congress and the Administration to include inclusion of Section 114 in the Food Safety Modernization Act. Although Section 114 is directed to FDA, the authors of the Section have communicated that they expect ISSC to consider economic effects in addressing *Vibrio vulnificus*. These directives make it very difficult to impose mandatory PHP or closures should the present expanded time to temperature approach prove ineffective in meeting the intended goals of 00-201. The VMC Proposal Workgroup will use the guidance of Procedure XIV and the ISSC Policy Statement on Consumption of Raw Molluscan Shellfish in characterizing the *Vibrio vulnificus* problem. From this characterization the workgroup will develop *Vibrio vulnificus* recommendations for VMC consideration.
Cost Information (if available):	

Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting	☐ ☒ ☐	**Growing Area Harvesting/Handling/Distribution Administrative**

Name of Submitter:	State Shellfish Control Authorities for Delaware, Georgia, Maryland, New Jersey, New York, North Carolina, and South Carolina
Affiliation:	Delaware Department of Natural Resources and Environmental Control; Maryland Department of Environment; Maryland Department of Health and Mental Hygiene; Maryland Department of Natural Resources; Georgia Department of Agriculture; Georgia Department of Natural Resources; New Jersey Department of Health and Senior Services; New Jersey Department of Environmental Protection; New York Department of Environmental Conservation; North Carolina Department of Environment and Natural Resources South Carolina Department of Health and Environmental Control
Address:	See SSCA list on ISSC Web Site
Phone: **Fax:** **Email:**	See SSCA list on ISSC Web Site
Proposal Subject:	*Vibro vulnificus* and *Vibrio parahaemoylyticus* Risk Management of Oysters
Specific NSSP Guide Reference:	Section II Model Ordinance, Chapter II Risk Assessment and Risk Management @.01 Outbreaks of Shellfish Related Illnesses @.04 *Vibrio vulnificus* Risk Management for Oysters
Key Words:	*Vibro vulnificus*; *Vibrio parahaemolyticus*; Risk Management
Text of Proposal/ Requested Action:	Chapter II Risk Assessment and Risk Management @.01 Outbreaks of Shellfish Related Illnesses **J. The Authority shall assess annually *Vibrio vulnificus* and *Vibrio parahaemolyticus* illnesses associated wit**h the consumption of molluscan shellfish. The assessment will include a record of all *V. vulnificus* and/or *V. parahaemolyticus* shellfish-associated illnesses reported within the state and from receiving states, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses. Effective January 1, 2012: @.04 *Vibrio vulnificus* and *Vibrio parahaemolyticus* Risk Management for Oysters A. For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* or *Vibrio parahaemolyticus* illnesses ~~since 1995~~ within ~~g~~the prior five (5) years traced to the consumption of commercially harvested raw or undercooked oysters that originated from ~~the waters~~ a growing area of that state (Source State), the Authority shall develop and implement *a Vibrio vulnificus* and/or *Vibrio parahaemolyticus* ~~Risk Management~~ Control Plan.

~~B. The Source State's *Vibrio vulnificus* Risk 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 risk reduction program. The goal of the *Vibrio vulnificus* Risk Management Plan will be to reduce the risk per serving to a 60% illness rate reduction for etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, and Texas, from the consumption of commercially harvested raw or undercooked oysters to a level equivalent to a 60% illness rate reduction from 1995 – 1999 baseline average illness rate of 0.278 per million.~~

~~C.~~B. The goal of the Control Plan is to reduce the probability of occurrence of *Vibrio* 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. The Source State's *Vibrio ~~vulnificus~~* Risk Management ~~-~~ Control 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; and

~~(2)A process to collect 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)~~(2) A standardized process for tracking products implicated in ~~*Vibrio vulnificus* -~~illnesses.~~; and~~

~~(4)Identification and implementation of the controls, or equivalent controls, which produced an illness per serving equivalent to a 60% illness rate reduction in the core states.~~

~~@.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.~~C. Risk Evaluation.

Every State from which oysters are harvested shall conduct a *Vibrio vulnificus* and 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 vulnificus* and *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.~~ D. Control Plan

(1) If a State's *Vibrio vulnificus* and/or *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
(2) For *Vibrio parahaemolyticus,* ~~I~~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:
(a) Waters bordering the Pacific Ocean - 60°F.
(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south) - 81°F.
(c) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in §~~A~~**C**., that determines that it is not reasonably likely that a -*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~~**C**. for the area during periods when the temperatures exceed those listed in this section;
(ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in §~~A~~C**.** 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)~~ (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) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in §~~B~~D. (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 for *Vibrio vulnificus* may include:
(i) Labeling all oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water

Temperature exceeds 75°F;

(ii) Subjecting all oysters intended for the raw, half-shell market to an Authority- approved post harvest processing that reduces the *Vibrio vulnificus* levels to <30 MPN/gram when the Average Monthly Maximum Water Temperature exceeds 75°F;

(iii) 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;

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

(v) Subjecting all oysters intended for the raw, half-shell market to a post harvest processing that is both approved by the Authority and reduces the *Vibrio vulnificus* levels to <30 MPN/gram during the months of May through September,inclusive;

(vi) 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; and

(vii) Limiting time from harvest to refrigeration based on modeling or sampling, as determined by the Authority in consultation with FDA;

~~2.~~ The control measures for *Vibrio parahaemolyticus* may include:

(i) Post harvest processing using a process that has been validated to achieve a 2 log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and a 3 log reduction for the Pacific Coast oysters;

(ii) Closing the area to oyster harvest;

(iii) Restricting oyster harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;

(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) Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within 10 hours or less as determined by

	the Authority after placement into refrigeration during periods when the risk of *Vibrio ~~parahaemolyticus~~* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters has reached 50°F (10°C) or below within 10 hours or less as determined by the Authority of being placed into refrigeration. Oysters without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled *"for shucking only"*, or other means to allow the hazard to be addressed by further processing. (d) Evaluate the effectiveness of the Plan. (e) 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. (f) Optional cost benefit analysis of the ~~*Vibrio parahaemolyticus*~~ Control Plan. ~~C~~ E. The Time When Harvest Begins For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. F. Evaluating Effectiveness of Plans In consultation with FDA the Authority will evaluate the implementation of their control plan based on effective management and enforcement of control measures to reduce the risk of illnesses.
Public Health Significance:	Changes will provide options and improve the ability for State Shellfish Control Authorities and the shellfish industry to achieve realistic risk management related to naturally occurring *Vibrio* bacteria. It was clearly stated at the VMC meeting held in January 2011 that because of the low incidence of *Vv* illness the 60% reduction of *Vv* illnesses from the Gulf States is not attainable without post harvest processing (PHP)(1). The cost of having all product from the Gulf of Mexico post harvest processed is economically prohibitive to the industry (2) and PHP product is not desired by the oyster consuming public (3). References: (1)VMC Committee Reports (Al Rainosek's updated illness rate Calculations); (2) RTI International Report Project Number 0211460.008 (3)"Analysis of How Post-harvest processing Technologies for Controlling Vibrio vulnificus Can Be Implemented"; Dr. Steve Otwell, Laura Garrido,Victor Garrido and Dr.Charlie Sims report "Sensory Assessment Study for Post -Harvest Processed (PHP) Oysters
Cost Information (if available):	Neutral

Al Rainosek

From: "Al Rainosek" <rainosek@jaguar1.usouthal.edu>
To: "alr" <Al.Rainosek@noaa.gov>
Sent: Monday, January 10, 2011 9:45 AM
Attach: Numbers!.eml
Subject: Fw: Updated Revised Illness Rate Calculations

This will be discussed with GAO
Illness Rate Reduction

Based on updated population estimates provided by the Bureau of Census, and reviewed/confirmed Vv cases for 2007 throught 2010 from ISSC, the revised Illness Rate Calculations for the Core States (CA, FL, LA, TX) appear below.

Notes: (1) Population numbers from the Bureau of Census Annual Estimates of the Resident Population for the United States, Regions, States and Puerto Rico.
(2) Number of countable Vv cases provided by Marc Glatzer, FDA.

A. BASELINE (Core States): 1995 - 1999
Total Countable Cases = 98
Av Cases per year = 98 / 5 = 19.6
Av Population per year = 70,637,188
Av Baseline Illness Rate = 19.6 / 70,637,188 = 0.278 per million

B. Illness Rate Reductions from Baseline:

1. 2007: 17 countable (reviewed) cases
Est Population = 82,717,833
Est Illness Rate = 17 / 82,717,833 = 0.206 per million
Estimated Illness Rate Reduction from Baseline:
(0.278 - 0.206) / 0.278 = 25.9%

2. 2008: 13 countable (reviewed) cases
Est Population = 83,760,052
Est Illness Rate = 13 / 83,760,052 = 0.155 per million
Estimated Illness Rate Reduction from Baseline:
(0.278 - 0.155) / 0.278 = 44.2%

3. 2007/2008 Average Illness Rate Reduction from Baseline:
Average Cases = 15
Est Average Population = 83,238,942
Est Av Illness Rate = 15 / 83,238,942 = 0.180 per million
Est Average Illness Rate Reduction from Baseline:
(0.278 - 0.180) / 0.278 = 35.0%

---

4. 2009: 15 cases (reviewed)
Est. Pop'n = 84,774,011
Est. Illness Rate = 15 / 84,774,011 = 0.177 per million
Est Illness Rate Reduction from Baseline:
(0.278 - 0.177) / 0.278 = 36.3%

5. 2010: 14 cases (reviewed)
Est. Pop'n = 86,065,142
Est. Illness Rate = 14 / 86,065,142 = 0.163 per million
Est Illness Rate Reduction from Baseline:
(0.278 - 0.163) / 0.278 = 41.4%

6. 2009/2010 Est. Av IRR = 38.8%

---

7. 2007 - 2010 Est Av IRR = 37.0%

Cases from Illness review Sub-committee

Core State Vv Cases - Baseline & Measurable Years

Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
1995	0	0	0	2	4	1	0	2	3	3	1	0	16
1996	0	0	0	1	2	4	3	6	4	1	1	0	22
1997	0	0	0	0	4	1	1	2	4	1	1	0	14
1998	0	0	0	1	3	3	2	4	1	5	1	0	20
1999	0	0	1	4	3	2	4	2	7	2	0	1	26
2007	0	0	1	5	3	0	2	3	1	1	1	0	17
2008	0	0	0	2	2	1	3	0	3	1	1	0	13
2009	0	0	0	1	0	2	0	3	2	2	5	0	15
2010	0	0	0	3	1	1	2	3	1	0	3	0	14
Total	0	0	2	19	22	15	17	25	26	16	14	1	157

NOTE: 1995-1999 cases represent the Baseline Cases; 2007-2010 cases represent the cases used to measure the Illness Rate Reduction. The Baseline Cases and 2007-2008 Cases have been reviewed by the ISSC Vv Illness Case Review Subcommittee and accepted by the ISSC Vibrio Management Committee (VMC) as countable cases. The 2009-2010 cases have been reviewed by the ISSC Vv Illness Case Review Subcommittee and will be submitted to the VMC for acceptance at the VMC meeting in January, 2011. In addition, CDC has not closed out the 2010 Vv case submission period, and there may be additional cases reported that will require review and acceptance by the ISSC. Assignment of a case to a month is made using the date of consumption. If the date of consumption is not known, date of onset will be used.

Sensory Assessment Study

for

Post-Harvest Processed (PHP) Oysters

Dr. Steve Otwell, Laura Garrido, Victor Garrido

and Dr. Charlie Sims

Aquatic Food Products Lab

Food Science and Human Nutrition Department

University of Florida

November 22, 2010

SENSORY ASSESSMENT STUDY
for
POST- HARVEST PROCESSED (PHP) OYSTERS

ACKNOWLEDGEMENTS

This project would not have been possible without collaborative assistance by numerous individuals with special talents and shared concerns for the oyster industry and consumer health. Participants included:

Charlene Burke, University of Florida, Apalachicola, FL. Served as technical advisor and assisted in coordination and logistics of product.

David Heil, FL Department of Agriculture and Consumer Service, Tallahassee, FL. Served as a regulatory advisor to the project.

Rick Hunter, Food Technology Service, Inc. Provided plant time and personnel for Gamma Irradiation (GI) oyster process.

Jim Jones, Food Technology Service, Inc. Provided plant time and personnel for Gamma Irradiation (GI) oyster process.

Grady Leavins, Leavins Seafood, Inc., Apalachicola, FL. Served as an industry advisor to the project.

William T. Mahan, Sea Grant College Program, Apalachicola, FL. Served as technical advisor and local liaison for the project.

Michael Voisin, Motivatit Seafood, Inc. Houma, LA. Provided plant time and personnel for high pressure (HP) oyster processing.

Tommy Ward, Buddy Ward and Sons Seafood, Inc. Apalachicola, FL. Provided access to the company's oyster lease and harvest vessel necessary for the product procurement.

T.J. Ward and Jordan Todd, Apalachicola, FL. Served as expert shuckers for the project.

Robert Webb, Webb's Seafood, Inc. Youngstown, FL. Provided plant time and personnel for Heat Intervention (HI) and Low Temperature Freezing (LTF) oyster processing.

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INTRODUCTION

Persistent concerns for illnesses associated with certain consumers eating raw oysters harvested during the warmer months about the Gulf of Mexico are calling for more use of post-harvesting processing (PHP) methods that reduce or eliminate the microbial culprits, *Vibrio vulnificus and Vibrio parahaemolyticus*. The PHP methods in question include validated operations involving the application of mild temperatures, gamma irradiation, high pressure, or low temperature freezing. These methods are in various stages of commercial use and they have been validated in accordance with required analytical protocols to verify the reduction and/or elimination of the naturally occurring yet potentially pathogenic *Vibrio* bacteria. The traditional processing methods for untreated oysters do not incorporate a similar bacteria kill step.

While the PHP methods can provide reduction of the bacterial concerns they can also introduce changes in the sensory attributes of the raw oysters that could influence consumer acceptance. The successful implementation of PHP methods will depend on consumer preferences and acceptance. This situation calls for a non-biased, science-based study to determine consumer preferences and acceptance for PHP versus traditional processed oysters destine for raw consumption.

RESEARCH OBJECTIVES

The objectives of this project were to measure consumer preference and acceptance for raw oysters from untreated, traditional (T) processing compared with each of the four PHP methods (MH- mild heat intervention, HP-high pressure, GI-gamma irradiation, and LTF-low temperature freezing) using live oysters from the same harvest based on paired comparison tests and acceptability ratings. The intent was to assess preferences and acceptance for traditional verses PHP oysters rather than comparisons amongst PHP products. Procedures incorporated shelf-life considerations during the consumer sensory testing to account for any changes in PHP product attributes versus the traditional raw oysters through two separate periods of storage common in summer commerce. In addition, the same traditional and respective PHP oyster products were formally evaluated for sensory characteristics (i.e., taste, aroma, color, and texture) based on the established oyster sensory profiling system developed for ISSC (http://fshn.ifas.ufl.edu/seafood). Sensory profiling can provide some explanation for any differences measured for consumer preference and acceptance.

METHODOLOGY

All project work depended on industry cooperation in procurement and processing of the raw oysters. The work was conducted in a manner to exemplify typical oyster processing and marketing practices through existing commercial operations. All oyster products and processing were subject to a chain of custody arrangement that included continuous participation and monitoring of all products by the project investigators from the moment of harvest through processing, distribution, storage and preparation for consumer testing and sensory profiling.

All oysters (*Crassosteria virginica*) were harvested from approved waters with existing commercial procedures (small vessel dredging) from one selected site in Apalachicola Bay, Florida. The site was a private lease maintained by owner, Tommy Ward, in Apalachicola, Florida and denoted by the official Florida state designation, FL-1632 L-525. Site selection involved pre-monitoring of weather conditions and on-site prescreening by the experienced project investigators to assure the live oysters had a consistent salt flavor not subject to freshwater exposure that tends to dilute flavors. The site selection was critical in terms of uniform product condition and quality. All oysters used in this study were from the same harvest site and could not be distinguished or culled by any quality differences at the moment of harvest.

The oysters were harvested in two installments, one on September 6, 2010 and one on September 7th, 2010 (Table 1). Each harvest consisted of 15 bushels (900 lbs) that were collected in the morning and delivered to an approved processing plant (Tommy Ward's; 13 Miles) for an initial wash to remove external mud and debris. The washing procedure was a simple, short time rinse through a typical stainless-steel tumbling unit that applied a water spray on the surface of the oysters. Product post-harvest handling achieved an internal product temperature below 50^{o}F within 2 hours of delivery in accordance with harvest regulations stipulated by the Florida Department of Agriculture and Consumer Services regulations (FL DOACS, 2009).

The quantity of harvest from the selected site and time was determined by the required amount of product for testing and to assure a simultaneous period of processing through the traditional and all PHP procedures within 48 hours post-harvest. The anticipate product volume and flow of work allowed two periods for sensory assessments for shelf-life consequences after 7 and 14 days post-harvest.
The work plan is illustrated in Table 1.

Table 1. Illustration of the work schedule from harvest through respective processing methods and eventual consumer and expert assessments. Oysters for traditional (T) processing were collected simultaneously during each harvest September 6 and 7 (Harvest site – Apalachicola Bay, Florida site designation FL-1632 L-525)

<table>
<tr><th rowspan="2">Days in storage</th><th colspan="4">Post-Harvest Processing (PHP) Methods</th></tr>
<tr><th>HP</th><th>LTF</th><th>GI</th><th>MH</th></tr>
<tr><td>0</td><td colspan="2">Harvest and refrigeration</td><td>Harvest & transported to Panama City, FL - Iced and processed (stored at 0°F)</td><td>Harvest & transported to Panama City, FL - Iced</td></tr>
<tr><td>1</td><td>Transport to Houma, LA - Iced</td><td>Transported to Mulberry, FL - Iced</td><td>Transported to Gainesville, FL – Dry ice</td><td>Processed and transported to Gainesville, FL - Iced</td></tr>
<tr><td rowspan="2">2</td><td>Processed and transported to Gainesville, FL - Iced</td><td>Processed and transported to Gainesville, FL - Iced</td><td rowspan="2">Frozen storage (0°F)</td><td rowspan="2">Refrigerated storage (35°F)</td></tr>
<tr><td colspan="2">Refrigerated Storage (35°F)</td></tr>
<tr><td>7</td><td colspan="2">Day 7 Sensory Evaluations & Expert Evaluations</td><td colspan="2">Day 7 Sensory Evaluations & Expert Evaluations</td></tr>
<tr><td>14</td><td colspan="2">Day 14 Sensory Evaluations & Expert Evaluations</td><td colspan="2">Day 14 Sensory Evaluations & Expert Evaluations</td></tr>
</table>

Oyster Processing Methods

The traditional (T) processing involved simple refrigerated storage in customary burlap oyster bags stored in refrigeration (35°F). Each PHP method was conducted in accordance with prior validated and published procedures currently available for commercial use. The protocol for PHP validation is specified and maintained by the National Shellfish Sanitation Conference (NSSP 2007a and 2007b). Each State Shellfish Certification Authority is responsible for the evaluation and approval of the PHP methods with concurrence from Food and Drug Administration (FDA).

High Pressure (HP): Refrigerated oysters were initially banded with plastic strips to maintain closure before placing in a cylindrical metal container that was filled with potable water and pressurized to approximately 36,000 PSI for 3 minutes. The treated oysters were then unloaded on a table for visual sorting and final packaging in an igloo cooler with ice, then transported to the University of Florida in Gainesville for storage

refrigerated (35°F) and sensory evaluations. These procedures were conducted at the validated and approved HP processing facilities of Motivatit Seafood in Houma, Louisiana.

Gamma Irradiation (GI): Oysters were banded with rubber bands to maintain closure while being held in 30 lbs waxed carton boxes that were placed on metal racks that carried the product into the irradiation chamber. The oysters were exposed to gamma radiation for a period of time necessary to achieve a minimum absorbed dose of 0.82 kGy as indicated by dosimeters placed on the waxed cartons. Treated product was then placed into an igloo cooler with ice, then transported to the University of Florida in Gainesville for refrigerated storage (35°F) and sensory evaluations. The irradiation procedures were conducted at processing facilitates maintained by Food Technology Services, Inc based in Mulberry, Florida. This is the same operation where the gamma irradiation procedures were validated for raw oyster PHP in December 2008.

Low Temperature Freezing (LTF): Oysters were manually shucked by removing the top shell, leaving the meat attached to the bottom shell. The half-shell product was placed on a conveyor belt that traveled through a nitrogen freezing tunnel set at an ambient temperature of – 170^{o}F with a belt speed of 3 ft/minute. Product exiting the nitrogen tunnel was solidly frozen. A potable, cold-water glaze was applied on the top of each frozen oyster to provide protection against freezer burn and dehydration. All frozen oysters were placed in an igloo cooler with dry ice, then transported to the University of Florida in Gainesville for frozen storage (0°F) and sensory evaluations. The validated low temperature freezing operations were conducted at Webb's Seafood, Inc in Youngstown, Florida.

Mild Heat Treatment (MH): Oysters were banded with rubber bands to assure closure during submersion in a tank of water maintained at 150^{o}F +/- 2^{o}F. Product was kept in the warm water for approximately 5 minutes to achieve an internal temperature of 122^{o}F for 1 - 2 minutes, then immediately placed in an ice slush for 2 minutes. The treated product was drained and placed in igloo coolers with ice, then transported to the University of Florida in Gainesville for refrigerated storage (35°F) and sensory evaluations. The mild heat interventions were conducted at Webb's Seafood, Inc in Youngstown, Florida. The mild heat interventions were based on prior work by Hesselman et al 1999.

Sample Preparation

The preparation of all oysters for sensory assessments was conducted in the Aquatic Food Products Lab at the University of Florida under supervision of the project investigators. All samples were presented in half-shell product form. Shucking was performed by professional oyster shuckers hired to assure the task was done correctly so as not to damage the oyster tissues and to present a whole edible oyster product with some accompanying 'liquor' or product fluids that are commonly associated with the consumption of half-shell oysters. Shucking involved carefully severing of the adductor muscles to remove the top shell followed by careful severing of the adductor muscles from the bottom shell that provided a container for the product. In order to maintain a uniform, cold product temperature and to prevent dehydration, the oysters were shucked 20 minutes prior to each sensory session and the half-shell products were placed on ice until served. The frozen, LTF half-shell oysters were thawed in containers held at room temperature for less than one hour then placed on ice until served. After thawing, the adductor muscle was severed from the bottom shell which served as a product container. All oysters used for the consumer and the expert panels were served at an average temperature of 45^{o}F or less which is the temperature customarily used for serving raw oysters in restaurants.

Note, during the shucking and thawing process any defective products were discarded. Defects included dead oysters for traditional products, excessive mud or debris, or damaged for PHP products. At 7 days post-harvest, the traditional oysters were the sample with the highest amount of rejects (49) followed by LTF (11), MH (11) and GI (4). After 14 days post-harvest, again the traditional oysters resulted in the highest rate of rejects (68), followed by HP (16), MH (10), GI (3) and LTF (3). The higher rate of rejects for the traditional product was due to mortality which is not an issue with PHP and banded oysters.

Consumer Sensory Assessments

Consumer preferences and acceptance were determined based on paired comparison tests and acceptability ratings. The tests were conducted with a group of consumers prescreened to assure familiarity with oyster consumption and a balance for various demographics (Table 3). Although the participants were recruited from one location, Gainesville, Florida, this college location included individuals from across the United States. Total participants ranged from 84 to 90 consumers per session. In each session the consumers were presented with a set of two different, unidentified oyster products served in the same manner at the same time with instructions to direct their responses. There were four possible

sets for each consumer; T vs. HP; T vs. MH; T vs. GI; or T vs. LTF. All sets compared traditional (T) oysters to one of the PHP methods. Two sets were presented per session and there were two sessions per each period of storage, 7 and 14 days post-harvest. This approach allowed comparison tests for all possible sets at both 7 and 14 days post-harvest.

The sets were presented in a random order per consumer so as not to introduce any unintended bias by order of presentation. During each session the consumers were asked to examine and consume at least two oysters from each oyster product presented. Thus the consumers ate at least 4 oysters for each set presented. To avoid sensory exhaustion only two sets are presented during one session and consumers were only allowed to participate in one session per day (two sets and 8 oysters per session). The same consumers were used in two sessions through two consecutive days to assure the same consumers responded to all possible sets of oyster products. The sample procurement and processing schedule (Table 1) were arranged to provide sessions for all the oyster products after 7 and 14 days post-harvest. There were no intermittent questions, discussions or interviews with the consumers between sessions or the separate periods of shelf-life that would have influenced their ratings or identity of the products.

All oyster products were presented utilizing blind codes so that the consumers were not aware of traditional or PHP products. The panelists were first asked to examine then taste both products per set and select the product they preferred. Then, they were asked to rate the acceptability of each product in the set. Acceptability ratings included measures for overall likeability, appearance, flavor and texture. A 9-point hedonic scale (1=dislike extremely, 5=neither like nor dislike, 9=like extremely) was used for all acceptability ratings (Attachment #1).

All consumer paired comparison tests were conducted in the Food Science and Human Nutrition Department's sensory laboratory equipped with sensory booths and computer data entry for real-time results. Coaching was limited to only assure consumer understood of procedures. Water and un-salted crackers were provided to panelists to cleanse the palate between samples. Their responses were recorded via computer entry using the program *Compusense*. The number of responses required to distinguish a significant preference was based on reference to the established paired comparison table number 17-12 in Meilgarrd et al. 2007. The acceptability ratings were subjected to analysis of variance and mean separations (Tukey's HSD, 0.05).

It is important to note that the preferences and acceptable ratings are strictly based on sets of comparisons between traditional and each individual PHP oyster product. There were no measures or ratings based on comparisons amongst any PHP products.

Table 3. Demographics for consumers prescreened for participation in the preference and acceptance tests.

Age Range		Sex		Raw Oyster Consumption	
20-40 yrs.	66%	Female	49%	> Once /month	43%
40-60 yrs.	34%	Male	51%	< Once/month but >twice /year	41%
				Twice /year or less	16%

Expert Sensory Assessments

The trained expert panel evaluated the oyster products using standard sensory profiling concurrently (same day) with the consumer sensory assessments for both periods of shelf-life, days 7 and 14 post-harvest. Expert profiling involved an established Oyster Sensory Panel that was trained and developed for ISSC. The expert panel has been maintained with continuous raw oyster assessments since 2008 (http://fshn.ifas.ufl.edu/seafood). The expert panel involved 10 screened and trained adults using standard protocol for sensory profiling stipulated in Meilgarrd et al. 2007. This panel has developed a full slate of lexicons and respective standards for a multitude of oyster product characteristics involving appearance, flavor, aroma, texture, mouthfeel and other sensory attributes. They rated or scored the various raw oyster products relative to the established standards and score sheets (http://fshn.ifas.ufl.edu/seafood; (Attachment #2 and Attachment #3). The expert panel scores were subjected to analysis of variance and mean separations (Tukey's HSD, 0.05).

RESULTS

Consumer Sensory Assessments

Consumer preference was influenced by oyster processing methods and duration of storage after processing (Table 2). The majority of consumers preferred traditional (T) oysters at the initial 7 days post-harvest. This initial preference for traditional oysters was significant at the 95% confidence level in comparisons with MH, HP and GI oysters. The difference in preference for traditional oysters was less distinct in comparisons with LTF oysters. These initial

preferences shifted as the product was held in refrigeration. After 14 days post-harvest there were no significant differences in consumer preferences at 95% confidence levels. Although the totaled preferences per comparisons on day 14 appeared to favor traditional and GI oysters, the differences in preference ratings were not significant. The loss in distinct preference can be partially explained by changes in the sensory attributes as the products aged in refrigeration (see Expert Panel results). Likewise, the preference comparisons involving LTF oysters were less subject to sensory changes during the short period of frozen storage.

Table 2. Results of the paired comparison preference tests through 7 and 14 days post-harvest storage. The number of consumers per session and the respective preferences per oyster process are tallied under each column.

PHP Oysters	7 days post-harvest			14 days post-harvest		
	No. Consumers	**PHP**	**Traditional**	**No. Consumers**	**PHP**	**Traditional**
Mild Heat (MH)	**89**	**34**	**55****	84	34	50
Gamma Irradiation (GI)	**89**	**26**	**63****	84	49	35
High Pressure (HP)	**90**	**28**	**62****	86	38	48
Low Temp Freezing (LTF)	90	36	54	86	43	43

**** indicates these values are significantly different at the p= 0.05 or 95% confidence level**

Consumer acceptability ratings indicated general acceptance for all oyster products regardless of processing method (Figures 1-4). Average consumer ratings remained above scores of 5.0 which represents the median transition from unacceptable to acceptable products relative to overall likeability, appearance, texture and flavor. Ratings for overall likeability followed the pattern of consumer preference that was influenced by post-harvest refrigeration of the products (Figure 1). Likeability was scored significantly higher at the 95% confidence level for traditional oysters in comparisons with all PHP products after 7 days post-harvest, but there was no difference in likeability for any of the various processed oysters after 14 days post-harvest. Appearance after 7 days post-harvest was not a significant factor in acceptability except in comparisons with the LTF oysters (Figure 2), but the significantly higher ratings for acceptable texture and flavor explain the acceptability differences and preferences scored for

traditional products after 7 days post-harvest (Figures 3 and 4). Most acceptability ratings were not significantly different in comparison for all oyster products after 14 days post-harvest which explains the lack of difference in preference. In general, the acceptability ratings slightly decreased as the products aged in refrigeration and the appearance and texture of the LFT oysters still rated significantly lower than the traditional oysters after 14 days post-harvest.

Figure 1. Acceptance ratings for Overall Likeability of each PHP oyster in comparison with the traditional oysters. Significant differences (p=0.05 or 95% confidence levels) in ratings per comparisons are denoted by different letters 'a and b'.

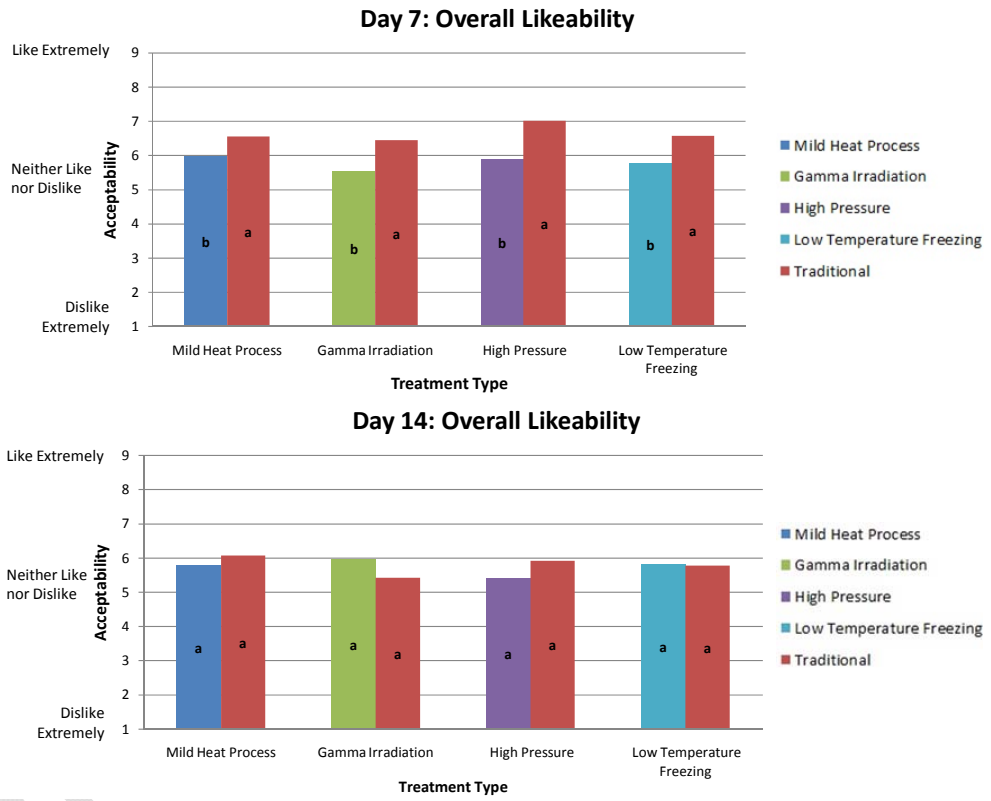


Figure 2. Acceptance ratings for Appearance of each PHP oyster in comparison with the traditional oysters. Significant differences (p=0.05 or 95% confidence levels) in ratings per comparisons are denoted by different letters 'a and b'.

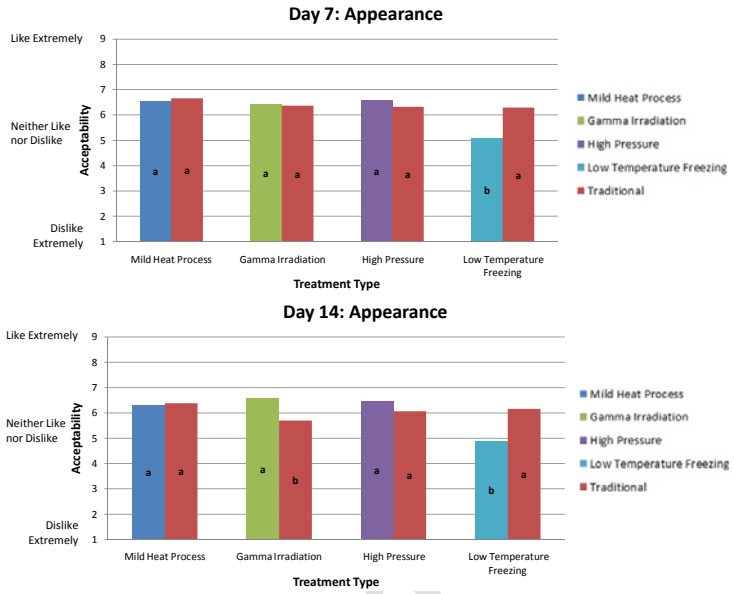


Figure 3. Acceptance ratings for Texture of each PHP oyster in comparison with the traditional oysters. Significant differences (p=0.05 or 95% confidence levels) in ratings per comparisons are denoted by different letters 'a and b'.

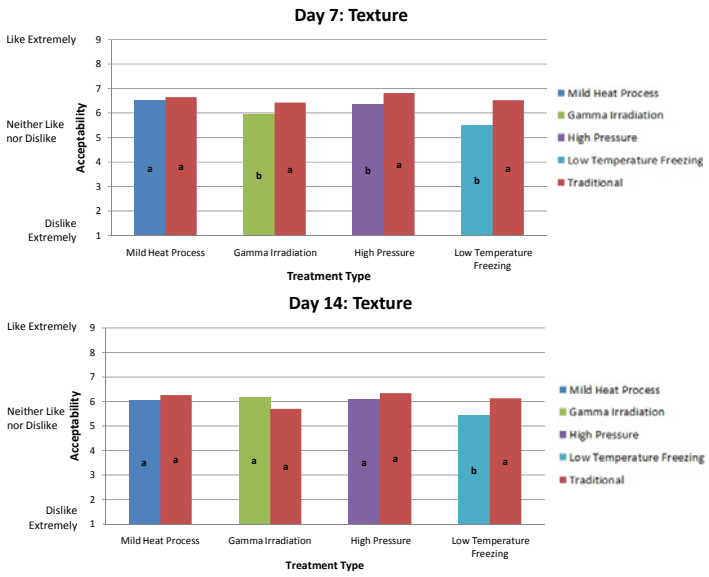
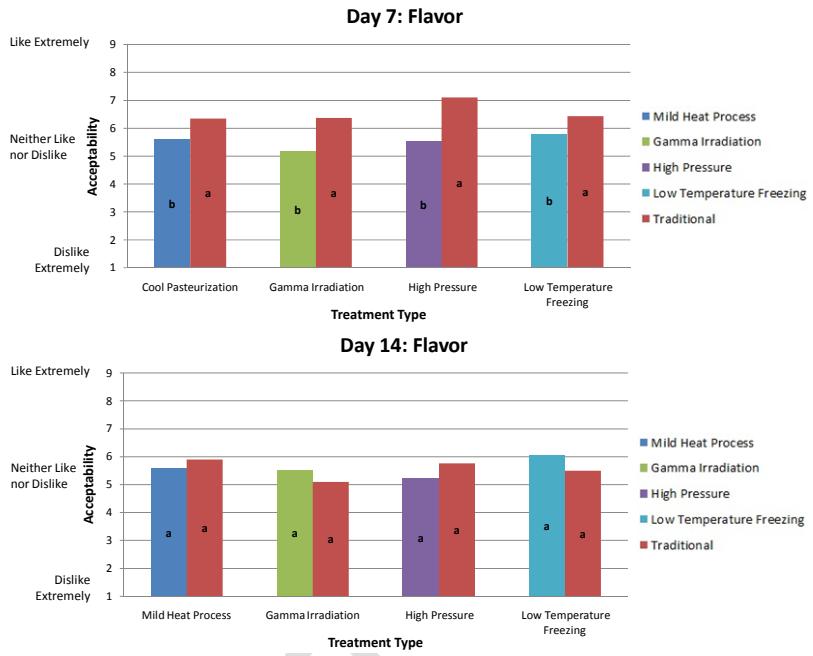


Figure 4. Acceptance ratings for Texture of each PHP oyster in comparison with the traditional oysters. Significant differences (p=0.05 or 95% confidence levels) in ratings per comparisons are denoted by different letters 'a and b'.



Expert Sensory Assessments

The sensory profiles developed by the expert panel provide some explanation for the consumer preferences and acceptability ratings (Figures 5-10). For example, the higher ratings for the traditional oysters after 7 days post-harvest can be partially explained by the higher perceived salty taste (Figure 8) and less earthy tones in flavor (Figure 9). Despite the low ratings, earthy tones are objectionable. The earthy tones noted in the flavor of the MH oysters reduced the preference for MH oysters in comparison with traditional oysters which had a similar salty taste rating. All PHP oysters had slightly higher earthy tones in aroma and flavor which persisted through 14 days shelf-life (Figure 9). Likewise, the PHP product aromas were initially scored as more briny and seaweed-like than the traditional oysters after 7 days post-harvest (Figure 7). These sensory attributes were not rated during the consumer comparison tests but they may play a role in influencing preference and acceptance. Additionally, the appearance and texture of all oyster products were similar across both periods of shelf-life,

with the exception of a drier and less plumb LTF product and the firmer more prominent textured HP product. The firmer texture attributes were persistent and more obvious for HP oysters through 14 days storage. Plump appearance and firm mouth feel or bites can influence consumer preferences.

Interestingly, the LTF oysters had the lowest score for salty taste (Figure 8) due to the use of the fresh water glaze to protect the product during frozen storage. This sensory attribute could be influenced by use of salt water glazes.

The shift in preferences and acceptance after 14 day post-harvest is distinctly obvious due to the perceived decreases in oyster liquor color (Figure 5), product aromas (Figure 7), and salty taste which was accompanied by a slight decrease in sweet and umami tastes (Figure 8). Overall, the sensory attributes became more similar as the oyster products aged in refrigerated storage. Likewise, an adverse aftertaste began to increase (Figure 10) and actual bitter flavors were noted as side observations with the standard sensory profiling. These negative attributes decrease preference and acceptance.

The various expert color ratings for shell and meats were more variable within individual oyster products than in comparisons between the various oyster products. This is not unexpected since the oysters were harvested from the same location and were similar in size and season of harvest. Likewise, the variation in color ratings did not change during storage such that color was not a useful attribute to distinguish differences between traditional and PHP products.

Figure 5. Expert sensory profiles for the volume, viscosity and color of the liquor that accompanies the oyster products are represented by bars for the average ratings based on 10 expert scores. Any bars marked by the same letter are not significantly different at the p = 0.05 or 95% confidence level.

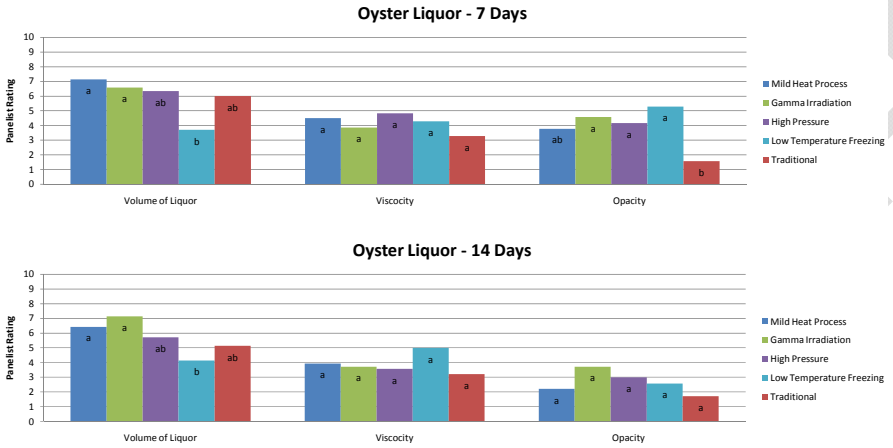


Figure 6. Expert sensory profiles for the volume, plumpness and various texture measures for the edible oyster meats are represented by bars for the average ratings based on 10 expert scores. Any bars marked by the same letter are not significantly different at the p = 0.05 or 95% confidence level.

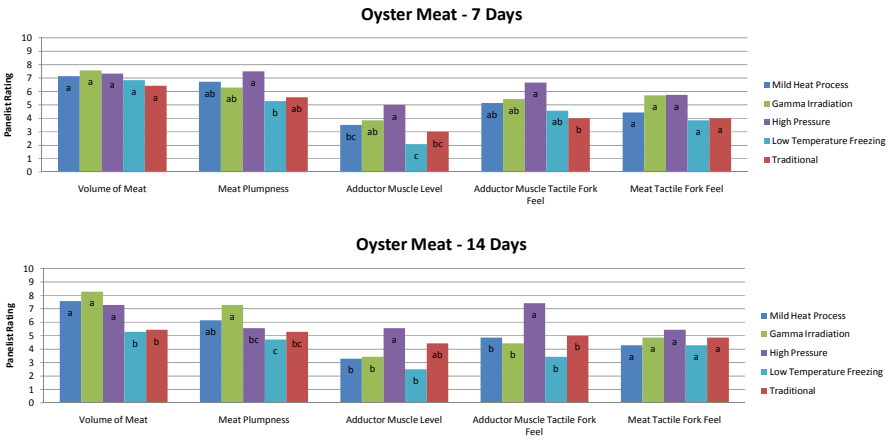


Figure 7. Expert sensory profiles for the briny, seaweed, earthy and metallic aromas associated with the oyster products are represented by bars for the average ratings based on 10 expert scores. Any bars marked by the same letter are not significantly different at the p = 0.05 or 95% confidence level.

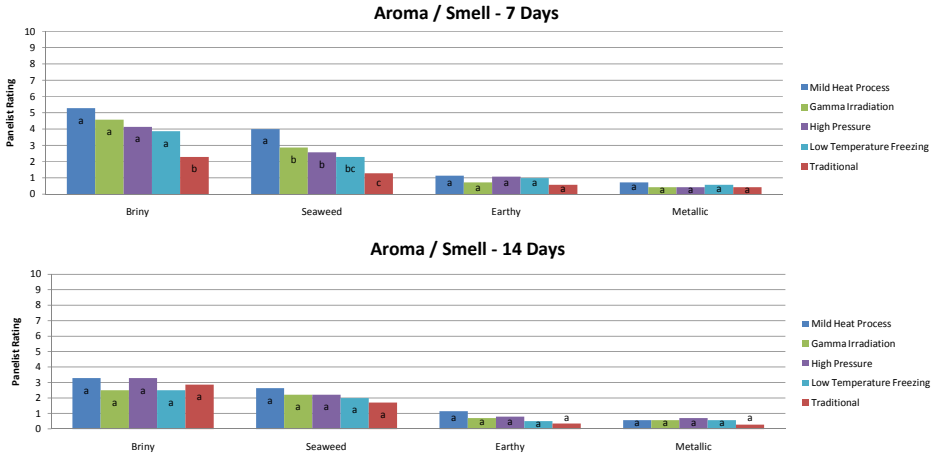


Figure 8. Expert sensory profiles for the salty, sweet and umami tastes associated with the oyster products are represented by bars for the average ratings based on 10 expert scores. Any bars marked by the same letter are not significantly different at the p = 0.05 or 95% confidence level.

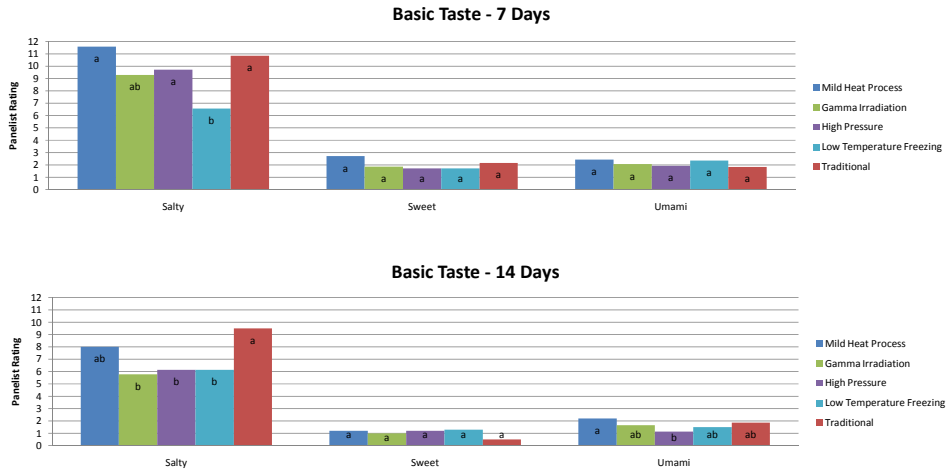


Figure 9. Expert sensory profiles for the seaweed, chick-liver-like, earthy and green-leafy flavors associated with the oyster products are represented by bars for the average ratings based on 10 expert scores. The term CLL represents chick-like-liver flavor. Any bars marked by the same letter are not significantly different at the p = 0.05 or 95% confidence level.

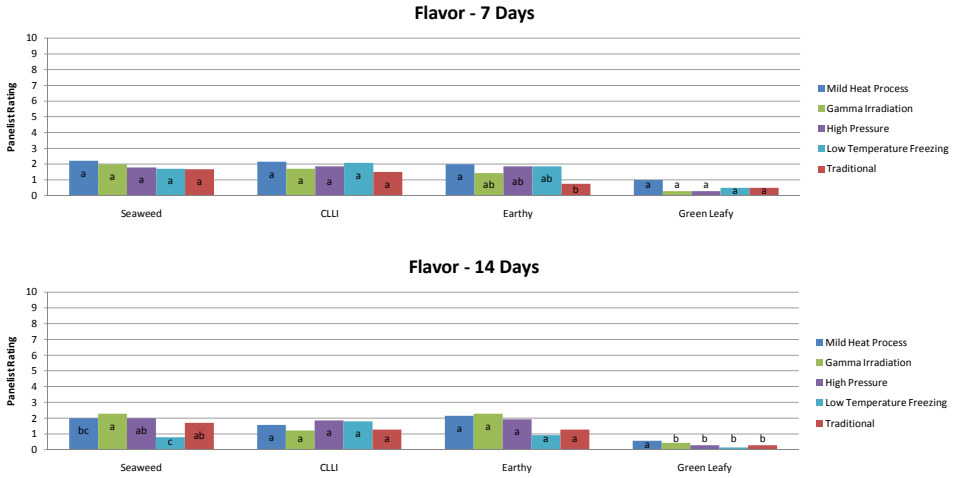


Figure 10. Expert sensory profiles for metallic and astringent aftertastes associated with the oyster products are represented by bars for the average ratings based on 10 expert scores. Any bars marked by the same letter are not significantly different at the p = 0.05 or 95% confidence level.

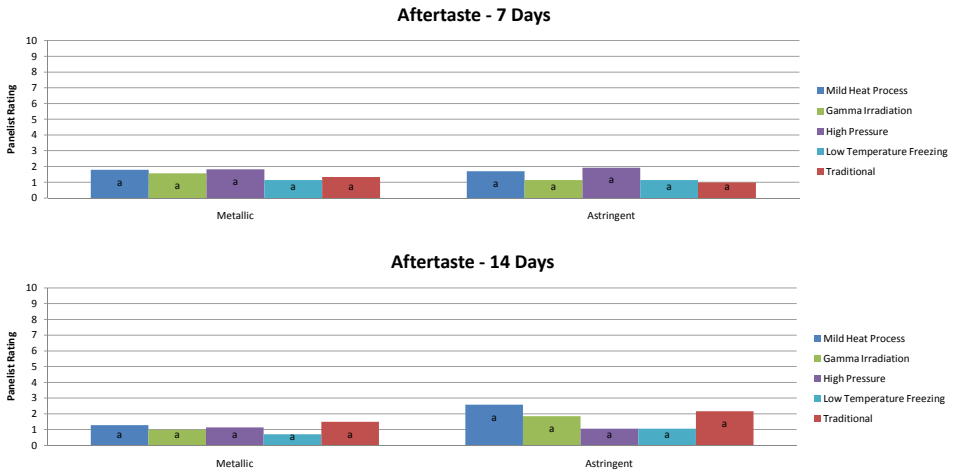
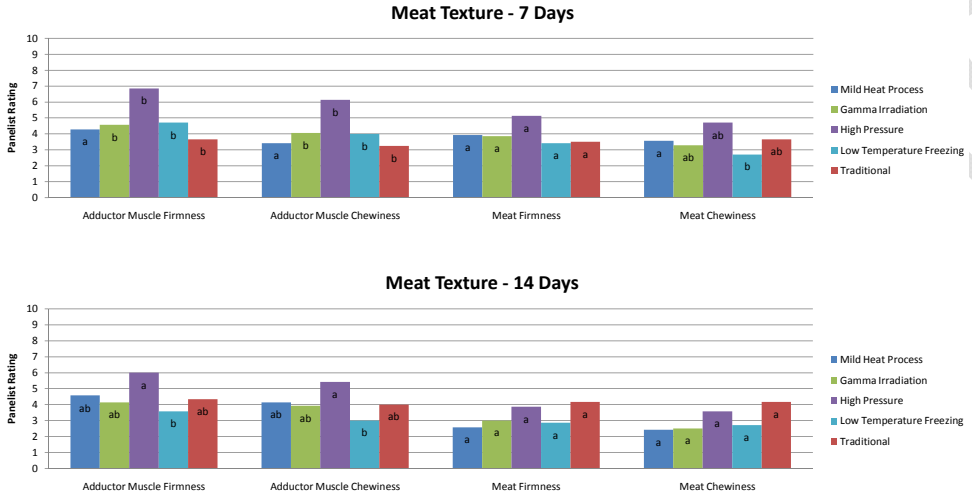


Figure 11. Expert sensory profiles for meat texture in the adductor muscle and general body or oyster meat for the oyster products are represented by bars for the average ratings based on 10 expert scores. Any bars marked by the same letter are not significantly different at the p = 0.05 or 95% confidence level.



CONCLUSIONS

Typical raw oyster consumers preferred the traditional raw oysters in comparisons with PHP oysters prepared from the same harvest during September from a typical Gulf of Mexico source (Apalachicola Bay, FL), yet this preference is diminished during prolonged refrigerated storage. The primary sensory attributes affecting preference were flavor and texture. These attributes are less distinguishable in comparisons between traditional and PHP oysters as the products aged in refrigeration. As a perishable product, the refrigerated oysters progressively change during storage. Apparently the changes caused a shift in product preference. In contrast, the preference for traditional oysters in comparisons with frozen PHP oysters (LFT) remained similar during storage as the frozen state preserves the oysters.

Despite the consumer preference expressed for traditional raw oysters during initial storage, the consumers rated all oyster products, both traditional and PHP, as acceptable. The acceptability ratings initially favored traditional raw oysters, as noted by the preference, but acceptability ratings became similar for all oyster products during more prolonged storage. Based on expert sensory profiling of the respective oyster products, the dominant sensory attributes affecting favorable acceptance were salty taste and less earthy tones in flavor and aroma.

These conclusions are based on a warm month harvest from the Gulf of Mexico. Harvest during other months with differing water temperatures that are known to influence the composition and sensory character of oysters could alter the results.

RECOMMENDATIONS

Interest for implementation of PHP methods for raw oysters harvested during warm months about the Gulf of Mexico should recognize a distinct and demonstrated consumer preference for traditional, fresh (non-frozen) products, yet a clear acceptance for both traditional and PHP oysters. This situation provides opportunities to market oysters in both traditional and PHP forms to suit particular markets relative to consumer demand, cost, convenience, and regulatory guidance.

REFERENCES

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NSSP. 2007a. National Shellfish Sanitation Program. Guide for the Control of Molluscan Shellfish. 2007a. Model Ordinance Section II Chapter XVI. Post Harvest Processing. www.issc.org

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ATTACHMENT #1

Excerpt of the questionnaire presented to the consumers for each raw oyster product evaluated during the consumer acceptability ratings

Please indicate how much you like or dislike the following attributes in **sample A**

Sample A

Overall Likeability

dislike extremely	dislike very much	dislike moderately	dislike slightly	neither like nor dislike	like slightly	like moderately	like very much	like extremely
1	2	3	4	5	6	7	8	9

Appearance

dislike extremely	dislike very much	dislike moderately	dislike slightly	neither like nor dislike	like slightly	like moderately	like very much	like extremely
1	2	3	4	5	6	7	8	9

Texture

dislike extremely	dislike very much	dislike moderately	dislike slightly	neither like nor dislike	like slightly	like moderately	like very much	like extremely
1	2	3	4	5	6	7	8	9

Flavor

dislike extremely	dislike very much	dislike moderately	dislike slightly	neither like nor dislike	like slightly	like moderately	like very much	like extremely
1	2	3	4	5	6	7	8	9

Please indicate how much you like or dislike the following attributes in **sample B.**

ATTACHMENT #2

Sensory Standards for the Evaluation of Raw Oyster Products

Contains standards for the various sensory attributes use in the profiling of raw oysters by expert panel. This document aligns with the score sheets (Attachment 3).

Source:

http://fshn.ifas.ufl.edu/seafood/oysters/sensory%20school/services.shtml#tools

Contact: Laura Garrido
University of Florida
shrimp@ufl.edu

Sensory Standards for the Evaluation of Raw Oyster Products

The following attributes are rated using a scale 0-10; 0 typically represents absence , 1 represents very low, 5 represents either moderate or intermediate while10 represents either very high or extreme. For each of the attributes one or more standards were developed to help guide the panelists. The rating of the standards for each attribute can be identified by the number (i.e. Std 4,Std 5, etc) and the triangle(s) placed on each respective rating scale (attachment 3). For example a standard 4 represents the 4 in the scale 1-10.

Lexicon	Description	Scale
APPEARANCE		
Color	**Color (s) of the oyster parts captured by human eye**	**Figures 1 & 2**
APPEARANCE OF OYSTER LIQUOR		
Milkiness	**Presence of a milky-like substance more noticeable in the oyster liquor. This is related to reproduction not to processing.**	**Figure 3- Presence or absence**
Air Bubbles	**Presence of small air bubbles trapped in the oyster's liquor, most likely around the meat.**	**Figure 4 - Presence or absence**
Volume of Liquor	**Quantity of oyster liquor in the shell.**	**Figure 5**
Viscosity	**How freely the liquor flows on the shell (watery vs. gluey).**	**Actual samples**
Opacity	**How clear/translucent or how cloudy/opaque the oyster liquor is.**	**Figure 6**
APPEARANCE OF OYSTER MEAT		
Shattered Meat	**If the meat appears and/or is broken into pieces.**	**Actual samples - Presence or absence**
Volume of the Meat	**Refers to how much of the oyster shell is covered by the meat.**	**Figure 7**
Plumpness	**How well-rounded and full in form the oyster meat.**	**Figure 8**
Adductor muscle	**How raised the adductor muscle is when compared to the meat.**	**Figure 9**
Adductor muscle tactile-fork feel	**How the adductor muscle feels when touch by a plastic fork.**	**Std 2 - Soft Gelatine (Knox)*** Std 5 - Canned Peaches-Diced-4oz pull top cup (Del Monte) Std 8 – Hard Gelatine Knox****
Meat tactile-fork feel	**How the meat feels when touch by a plastic fork.**	

AROMA		
Briny	Related to or resembling saltiness or the sea	Std 5* &10**- Ito-Wakame dried seaweed imported by Rhee Bros, Inc - Columbia, MD
Seaweed	Related to the aroma of seaweed.	
Earthy	Refers to the characteristics of damp soil, and wet plants.	Std 10 - Whole White Mushrooms with soil - cut in half and smell.
Metallic	Relating to, or having the characteristic of a metal.	Std 10 - 2 capsules of Sundown Iron 28 mg capsules in 440 ml of water. Rub on skin and smell; or shake bottle, open and smell.
UNDESIRABLE/OBJECTIONABLE AROMAS		
Agar	Related to the odor of agar.	Std 10 - Difco Bacto Agar (Fisher Scientific Catalog)
Ammonia	Related to ammonia.	Std 10 - Ammonia for household cleaning.
Boiled potato	Refers to earthy/dirty aroma in the internal portion of a boiled potato.	Std 10 - Canned Potato (Del Monte fresh cut whole new potatoes)
Fecal	Aroma associated with feces.	Std 10 - Past experiences
Fishy	Refers to the aroma associated with strong fish odors.	Std 10 - Can of Sardines in water(King Oscar) Std 10 - Clam Juice (Doxsee/Snows Clam juice)
Garlic	Refers to the aroma of garlic.	Std 5 - Garlic Butter Papa John's Std 10 - Kalsec Garlic Oil
Sour	The aroma stimulated by acids, such as citric, malic, phosphoric, etc. (Meilgaard, Civille et al.)	Std 10 - shucked oyster placed in the refrigerator for about 21-28 days will produce a maximum sour odor.
Wet dog	Refers to smell of a wet dog.	Std 8 - Canned of shrimp (Chicken of the sea or bumble bee)
Wet burlap sack	Refers to the smell of a wet burlap sack used in the oysters business to transport oysters	Std 10 - wet burlap sacks (cream, brown, or beige) from Wal-Mart.

BASIC TASTES		
Salty	Taste stimulated by sodium salts, such as sodium chloride and sodium glutamate and in part by other salts such as potassium chloride. (Meilgaard, Civille et al.)	Std 5 - 0.3% salt Std 10 - 0.55% salt Std 15 - 0.7 % salt (Meilgaard, Civille et al.)
Sweet	Taste stimulated by sucrose and other sugars, such as fructose, glucose, etc. and by other sweet substances.(Meilgaard, Civille et al.)	Std 4 - Ritz crackers (Meilgaar Civille et al.)
Umami	Taste produced by substances such as Monosodium Glutamate (MSG). A meaty, savory, or mouth filling sensation (Codex).	Std 5 - 1/4 tsp Accent in 500 ml of water Std 10 - ½ tsp Accent in 500 ml of water
UNDESIRABLE/OBJECTIONABLE BASIC TASTES		
Sour	The taste stimulated by acids, such as citric, malic, phosphoric, etc. (Meilgaard, Civille et al.)	Std 5 - 0.1% citric acid; Presence or absence (Meilgaard, Civille et al.)
Bitter	The taste stimulated by substances such as caffeine, and hop bitters (Meilgaard, Civille et al.).	Std 5 - 0.08% caffeine solution Presence or absence (Meilgaard, Civille et al.)
FLAVOR		
Seaweed	Relating to or having the characteristic to a flavor like seaweed.	Std 10- Ito-Wakame dried seaweed imported by Rhee Bros, Inc Columbia,MD
Chicken liver like / iron-	Relating to the iron flavor of cooked liver (organ) meat.	Std 4 - Chicken liver (Tyson's) Add to boiling water and keep boiling for 10 minutes
Earthy	Refers to the characteristics of damp soil, and wet plants.	Std 10 – mushrooms, white and whole with soil - cut and taste.
Green Leafy (spinach)-	Relating to or having the characteristic flavor of spinach.	Std 5- Fresh spinach (ready pac)
UNDESIRABLE/OBJECTIONABLE FLAVORS		
Boiled Potato	Refers to earthy/dirty flavor in the internal portion of a boiled potato.	Std 6 - Potato (Del Monte fresh cut whole new potatoes)
Fishy	Refers to a fishy flavor.	Std 10 - Can of sardines in water (any brand)
Garlic	Relating to or having the characteristic flavor of garlic.	Std 4- Garlic butter Papa John's Std 10 - Kalsec garlic oil
Raw Cabbage	Relating to or having the characteristic to the flavor of raw cabbage.	Std 7 - Red cabbage Std 8 - Green cabbage

Wet Burlap Sac	**Relating to or having the characteristic of the flavor imparted by a wet.**	**Std 10- wet burlap sacks (cream, brown, and beige) from Wal-Mart.**
Aftertastes		
Metallic	**Relating to or having the characteristic of a metal.**	**Std 5 - 1 capsules of Sundown Iron 28 mg capsules in 440 ml of water. Std 6 - Canned oysters - Chicken of the Sea whole oysters juice only (strain juice though fine wire strainer).**
Astringency	**The chemical feeling factor combining three different aspects: drying of the mouth, roughing of oral tissues and drawing (shrinking) sensation felt in the cheeks and the muscles of the face.**	**Std 5- 1/8 teaspoon (0.5g) of alum (McCormick) in 500 ml of water. Std 5- Fresh Spinach (Ready Pac).**
Chalkiness	**In reference to texture, a product which is composed of small particles which imparts a drying sensation in the mouth (Codex).**	**Std10- 14 ml of milk of magnesia in 400 ml of water or Std 10 - 3/4 teaspoon of Tricalcium phosphate food grade –Budenheim, Germany in 400 ml of water.**

Texture & Mouth feels		
Firmness Chewiness	**Refers to consistency of how soft versus how firm in resistance the oysters flesh holds. Amount of maceration required to comfortably swallow the oyster.**	**Std 1- Soft gelatin (Knox) *** Std 3 -Tofu – Nasoya soft Std 5 -Canned peaches-diced- 4oz pull top cups (Del Monte) Std 6 – Hard gelatine (Knox)**** Std 8 – Cooked chicken breast-salad topping (Plain-Purdue) Std 10 - Dried apricots (Sunmaid – Mediterranean)**
Grittiness	**Presence of sand**	**Actual samples**

***Briny Std 5**

Use approximately 1 to 1 1/2 cups of water for 2 to 3 strands of seaweed. Bring water to boil or close to boil. Break dried seaweed into 2 to 3 inch pieces and put in hot water. Allow to soak overnight and cool. Use seaweed for areas needed and liquid for briny standard. For a strong briny solution use more seaweed (about 6 - 8 strands) per cur of hot water.

****Briny Std 10**

For a strong briny (standard 10), leave the seaweed for48 hours or more at refrigerated temperature after warm liquid on the soaked seaweed cools down.

*****Soft Gelatin**

4 cups of water
2 envelopes KNOX Gelatine unflavored

Measure 4 cups of water.
Put 1 to 2 cups of the measured water in a container, (big enough for about 5 cups)
Doesn't have to be exact. Sprinkle 2 KNOX envelopes on top of the water, let it stand for 2 minutes or until the gelatin is hydrated. (DO NOT mix it or stir it it will be a mess!)
Meanwhile heat the rest of the water for 2 minutes in the microwave.
When hot pour the water into the hydrated gelatin and stir until it is completely dissolved. Pour the liquid gelatin in the little containers and let it stand in the refrigerator for about 5 hours.

******Hard Gelatin**

3 cups of water
6 envelopes KNOX Gelatine unflavored

Measure 3 cups of water.
Put 1 to 1 1/2 cups of the measured water in a container, (big enough for about 5 cups)
Doesn't have to be exact. Sprinkle 6 KNOX envelopes on top of the water, let it stand for 2 minutes or until the gelatin is hydrated. (DO NOT mix it or stir it it will be a mess!)
Meanwhile heat the rest of the water for 2 minutes in the microwave.
When hot pour the water into the hydrated gelatin and stir until it is completely dissolved. Pour the liquid gelatin in the little containers and let it stand in the refrigerator for about 5 hours.

Figure 1. Diagram of an oyster for color assessment

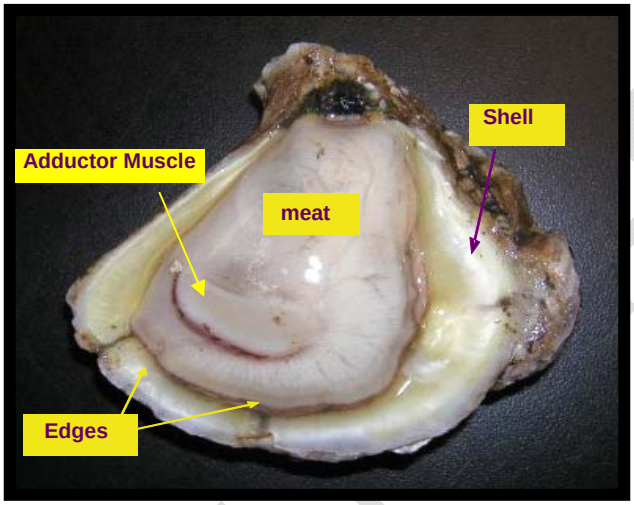


Figure 2. Color Scales

White

	1	***2***	***3***	***4***	***5***
Colors					
Munsell					
RGB					
Glidden Name	**Nature's Whisper**	**Natural White**	**Fencepost**	**White High**	**White Swan**
Glidden Code	**43YY 78/053**	**50YY 83/029**	**81YY 87/031**	**98YY 82/022**	**60YY 83/062**

Pink

	1 Lightest	2	3	4	6 Darkest
Colors					
Munsell					
RGB	241/232/233	211/200/172	229/202/215	229/167/190	206/109/137
Glidden Name	Whimsical	Carnation Pink	Saltmarsh Pink	Checkerberry	Fiesta Pink
Glidden Code	30RR 83/040	41RR 79/079	29RR 66/154	32RR 50/260	53RR 27/417

Gray to Black

	1 Lightest	2	3	4	5	6 Darkest
Colors						
Munsell						
RGB	217/219/217	204/205/204	188/188/187	160/160/159	94/94/94	62/62/61
Glidden Name	Snowfield	Universal Grey	Veil	Granite Grey	Obsidian Glass	Dark Secret
Glidden Code	00NN 72/000	00NN 62/000	00NN 53/000	00NN 37/000	00NN 13/000	00NN 05/000

Gray / Brown

	1 Lightest	2	3	4	5	6 Darkest
Colors						
Munsell						
RGB	231/228/219	221/215/205	203/196/185	182/171/157	125/115/104	91/80/69
Glidden Name	Kitten White	Carolina Strand	Fossil Grey	Scroll Beige	Fauna	Pebble Mosaic
Glidden Code	30YY 78/035	30YY 69/048	30YY 56/060	20YY 43/083	10YY 18/074	10YY 08/093

Gray/Green

	1 Lightest	2	3	4	5	6 Darkest
Colors						
Munsell	5Y/8.5/2	5Y/8/2	7.5Y/7/2	2.5Y/6/4	5Y/4/4	5Y/3/4
RGB	222/214/183	208/201/171	179/174/146	166/145/100	110/96/52	85/72/35
Glidden Name	Wishes	Autumn Haze	Chatham Green	Surrey Beige	Calm Water	Oak Alley
Glidden Code	45YY 75/110	45YY 67/120	40YY53/119	30YY 36/185	30YY 20/193	30YY/09/175

Green scale

	1 Lightest	2	3	4	5	6 Darkest
Colors						
Munsell	10Y/9/2	10Y/8.5/2	10Y/8/4	2.5GY/7/4	10Y/5/4	10Y/4/2
RGB	231/230/194	217/216/182	206/203/144	139/184/151	126/124/73	99/98/75
Glidden Name	Brocade Cream	Hint of Gold	Mount Olive	Pennyroyal	Retro Green	Laurentian
Glidden Code	60YY 70/189	60YY 64/211	60YY 54/255	60YY 40/243	60YY23/227	70YY15/160

Emerald Green

	1 Lightest	2	3	4	5	6 Darkest
Colors						
Munsell						
RGB	228/236/223	212/228/205	199/222/190	154/185/141	108/140/96	86/117/74
Glidden Name	Boudoir	Nature Mist	Sea Scent	Summer Picnic	Frog Pad	Splendor
Glidden Code	50GY 83/060	50GY 75/122	50GY 69/165	50GY 44/248	50GY 23/280	50GY 15/289

Blue/Green (Teal)

	1 Lightest	2	3	4	5	6 Darkest
Colors						
Munsell						
RGB	221/237/230	206/228/221	189/220/211	160/199/189	91/149/136	13/113/99
Glidden Name	Bubbling Brook	Aquabell	Warm Meadow	Country Cottage	Kelly's Island	Forest Hush
Glidden Code	50GG 83/057	50GG 74/077	50GY 69/165	50GG 53/144	50GG 26/228	50GG 13/314

Maroon

	1 Lightest	2	3	4	5	6 Darkest
Colors						
Munsell						
RGB	217/207/210	196/180/185	165/142/151	135/107/117	108/83/93	88/71/77
Glidden Name	Whisper	Soft Wine	Sonata	Mystic	Alakazam	Black Currant
Glidden Code	30RR 64/043	30RR 49/067	30RR 30/103	30RR 17/140	30RR 10/131	30RR 07/094

Purple

	1 Lightest	***2***	***3***	***4***	***5***	***6 Darkest***
Colors						
Munsell						
RGB	**224/222/228**	**215/211/226**	**165/142/151**	**159/154/184**	**126/119/153**	**92/86/121**
Glidden Name	**Mystic Purple**	**Touch of Violet**	**Giggles**	**Elevator**	**Coat of Arms**	**Purple Polka**
Glidden Code	**10RB 74/038**	**10RB 68/081**	**30RR 30/103**	**10RB 35/167**	**30RR 10/131**	**10RB 10/219**

Tan

	1 Lightest	***2***	***3***	***4***	***5***	***6 Darkest***
Colors						
Munsell	**2.5Y/9/2**	**2.5Y/8/4**	**10YR/8/6**	**10YR/7/8**	**10YR/6/10**	**10YR/6/8**
RGB	**240/227/198**	**220/198/148**	**236/194/129**	**216/165/81**	**194/137/24**	**188/139/57**
Glidden Name	**Lis Crème**	**Stucco**	**Light Topaz**	**Honeysweet**	**Golden Gate**	**Ovation**
Glidden Code	**30YY 77/169**	**20YY69/238**	**10YY58/295**	**10YY49/378**	**10YY 38/501**	**10YY 30/478**

Brown/Yellow

	1 Lightest	***2***	***3***	***4***	***5***	***6 Darkest***
Colors						
Munsell	**2.5Y/8.5/2**	**2.5Y/8/2**	**2.5Y/7/4**	**10YR/6/6**	**2.5Y/5/4**	**2.5Y/4/6**
RGB	**225/213/185**	**211/200/172**	**194/171/123**	**181/141/81**	**140/119/76**	**120/93/32**
Glidden Name	**Oyster White**	**Ivory Sampler**	**Cookie Crumb**	**First Anniversary**	**New Suede**	**American Bronze**
Glidden Code	**30YY 64/149**	**30YY 58/178**	**20YY 46/236**	**10YY34268**	**10YY 26/239**	**10YY 15/280**

Brown

	1 Lightest	***2***	***3***	***4***	***5***	***6 Darkest***
Colors						
Munsell	**10YR/9/2**	**10YR/8/2**	**10YR/7/4**	**10YR/6/4**	**10YR/4/4**	**10YR/3/6**
RGB	**242/22600**	**214/198/175**	**198/169/127**	**171/143/104**	**119/92/57**	**99/67/16**
Glidden Name	**Desert Floor**	**Dapper Tan**	**Family Legacy**	**Golden Pond**	**Side saddle**	**Timbre Trail**
Glidden Code	**20YY 69/120**	**10YY 55/163**	**00YY43/196**	**00YY 33/246**	**90YR 17/245**	**90YR 10/244**

Figure # 3

Standard for presence of milkiness (Std 10)

Figure 4. Standards for presence of bubbles

Presence

Figure 5. Standards for volume of liquor

Low (2)

High (10)

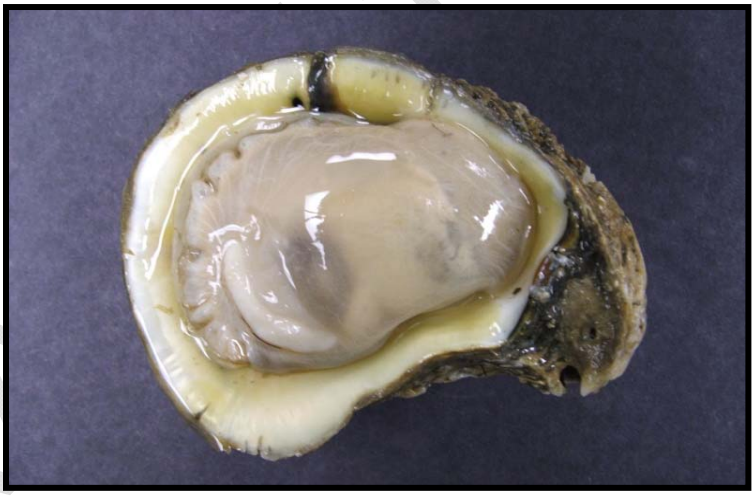


Figure 6. Standards for liquor opacity

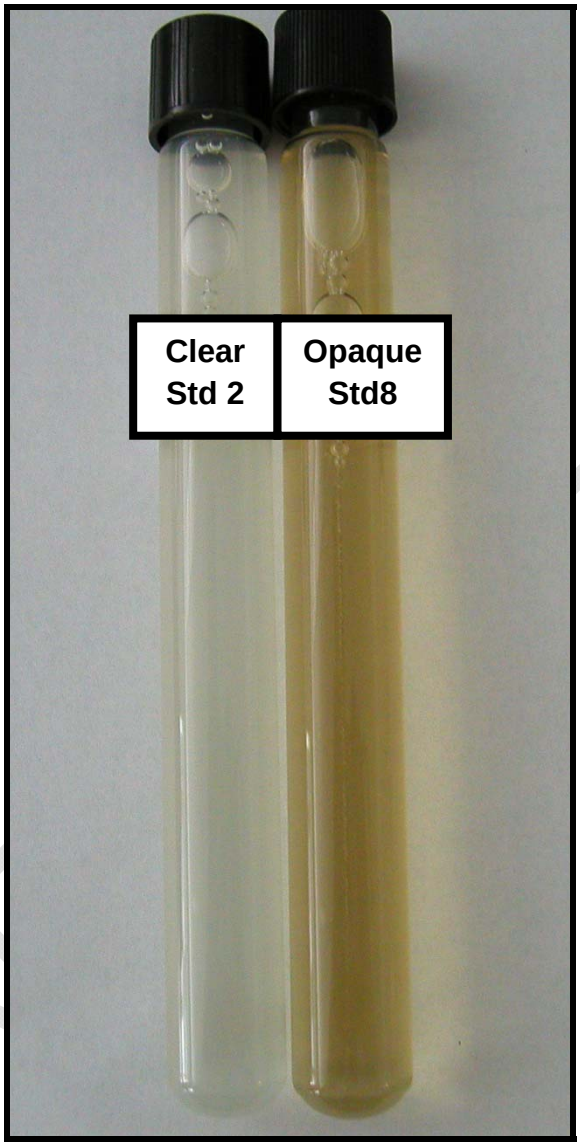


Figure 7. Standards for volume of meat

Hardly Covered (Std 2)

Fully Covered (Std 10)

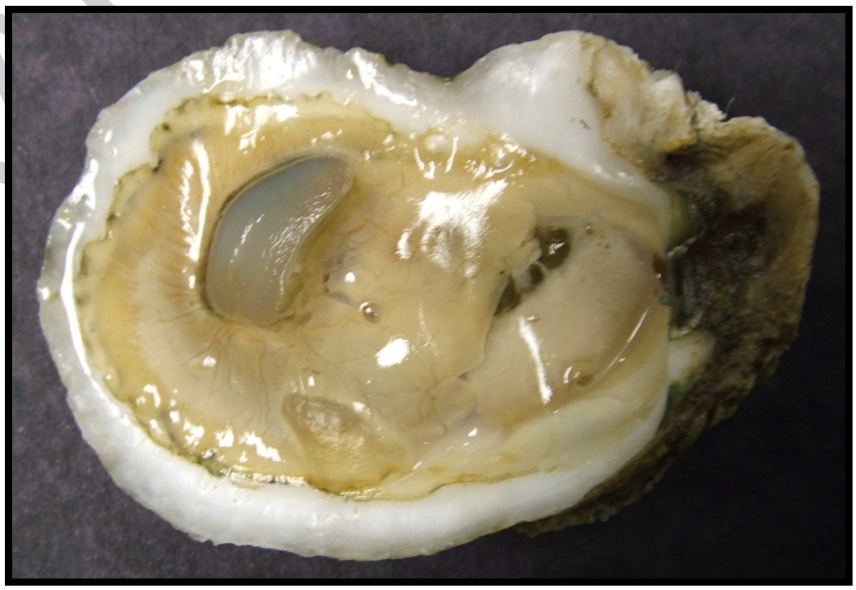


Figure 8. Standards for plumpness

Flaccid (Std 2)

Plump (Std 8)

Figure 9. Standards for adductor muscle

Level (Std 1)

Raised (Std 5)

Very Raised (Std 8)

39

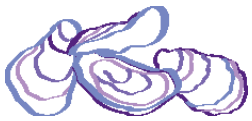
ATTACHMENT #3

Score Sheet for Raw Oyster Products

Contains the score sheet use to profile the sensory attributes raw oysters by expert panel. This document aligns with the list of standards (Attachment 2).

Source:
http://fshn.ifas.ufl.edu/seafood/oysters/sensory%20school/services.shtml#tools

Contact: **Laura Garrido**
University of Florida
shrimp@ufl.edu



Oyster Product Characterization Form

Sample Code: _____
Date: _____
Panelist: _____

Appearance

Color Break-down - Circle all that apply

Oyster Meat:

1. White		1	2	3	4	5	
2. Pink		1	2	3	4	5	
		Light					*Dark*
3. Gray to Black		1	2	3	4	5	6
4. Gray/Brown		1	2	3	4	5	6
5. Grey/Green	1	2	3	4	5	6	
6. Green		1	2	3	4	5	6
7. Emerald Green		1	2	3	4	5	6
8. Blue/Green (Teal)		1	2	3	4	5	6
9. Maroon		1	2	3	4	5	6
10. Purple		1	2	3	4	5	6
11. Tan		1	2	3	4	5	6
12. Brow/Yellow		1	2	3	4	5	6
14. Brown		1	2	3	4	5	6

Edges:

1. White		1	2	3	4	5	
2. Pink		1	2	3	4	5	
		Light					*Dark*
3. Gray to Black		1	2	3	4	5	6
4. Gray/Brown		1	2	3	4	5	6
5. Grey/Green	1	2	3	4	5	6	
6. Green		1	2	3	4	5	6
7. Emerald Green		1	2	3	4	5	6
8. Blue/Green (Teal)		1	2	3	4	5	6
9. Maroon		1	2	3	4	5	6
10. Purple		1	2	3	4	5	6
11. Tan		1	2	3	4	5	6
12. Brow/Yellow		1	2	3	4	5	6

14. Brown		1	2	3	4	5	6

Inner Rim of Shell:

1. White		1	2	3	4	5	
2. Pink		1	2	3	4	5	
		Light					*Dark*
3. Gray to Black		1	2	3	4	5	6
4. Gray/Brown		1	2	3	4	5	6
5. Grey/Green	1	2	3	4	5	6	
6. Green		1	2	3	4	5	6
7. Emerald Green		1	2	3	4	5	6
8. Blue/Green (Teal)		1	2	3	4	5	6
9. Maroon		1	2	3	4	5	6
10. Purple		1	2	3	4	5	6
11. Tan		1	2	3	4	5	6
12. Brow/Yellow		1	2	3	4	5	6
14. Brown		1	2	3	4	5	6

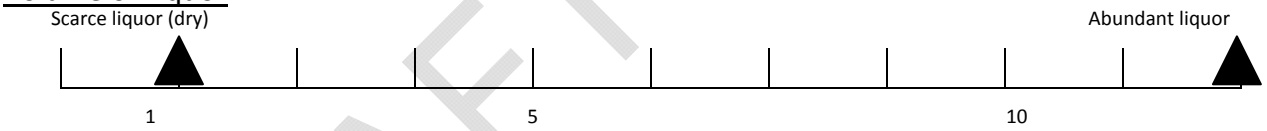
Oyster Liquor

Please circle appropriate descriptor(s):

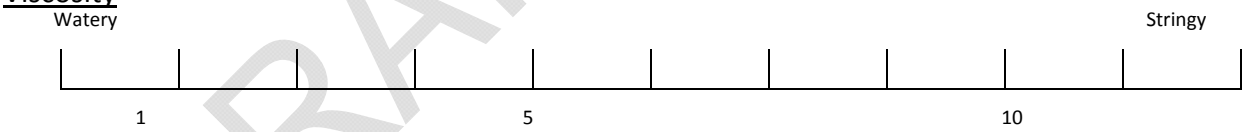
Milkiness: Not Milky Milky

Air Bubbles: Absent Present

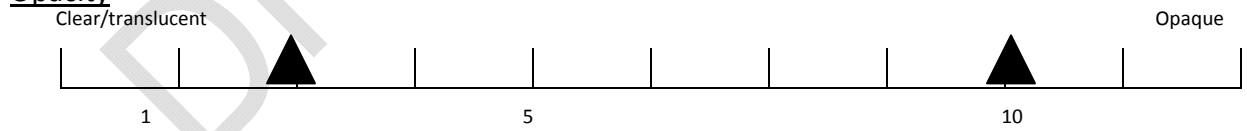
Volume of Liquor



Viscosity



Opacity

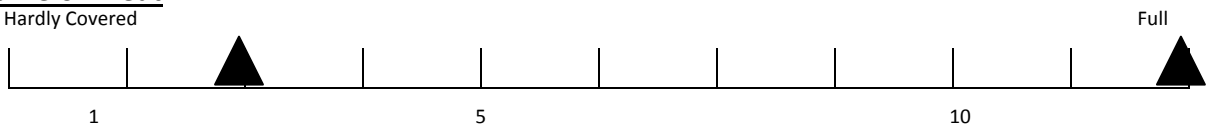


Oyster Meat

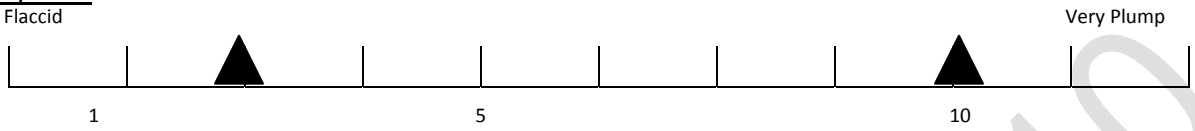
Please circle appropriate descriptor(s):

Shattered Meat: Yes No

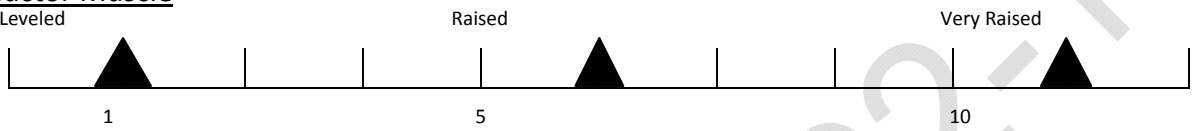
Volume of Meat



Plumpness



Adductor Muscle

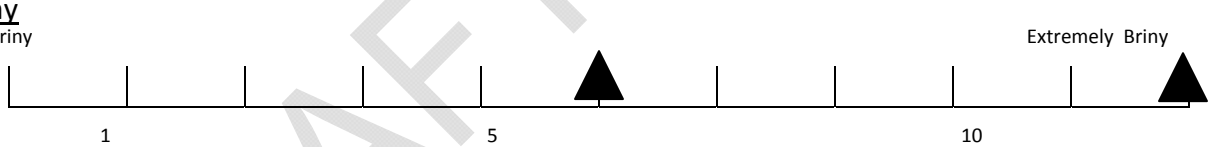


Adductor Muscle Tactile-Fork Feel

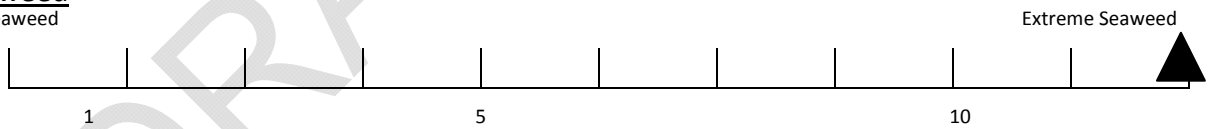
Meat Tactile-Fork Feel

Aroma/Smell

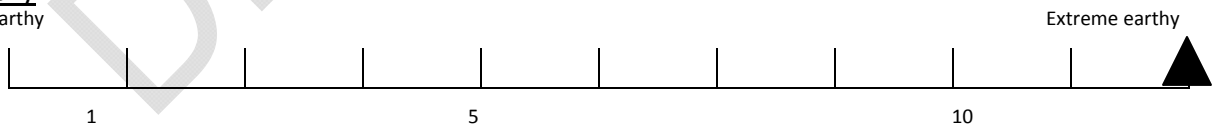
Briny



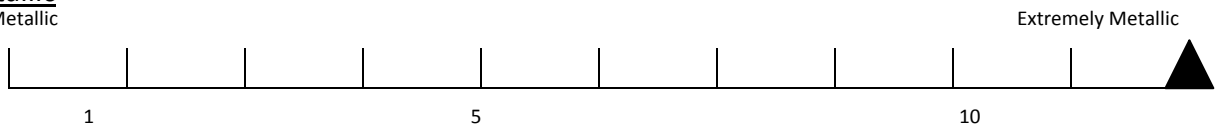
Seaweed



Earthy



Metallic

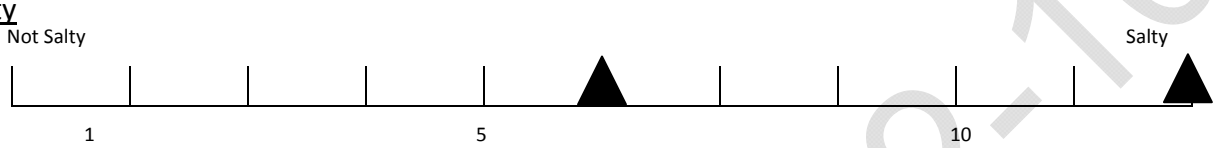


If any objectionable odors are detected, please circle the appropriate descriptor(s):

Agar	Ammonia	Boiled Potato	Fecal	Fishy
Garlic	Sour	Wet Burlap Sac	Wet Dog	Other:_____

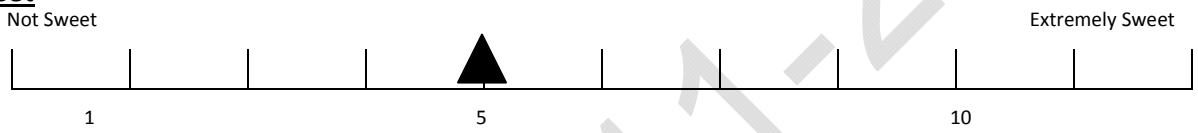
Basic Tastes

Salty



If saltiness is higher than 10, please specify:_____

Sweet



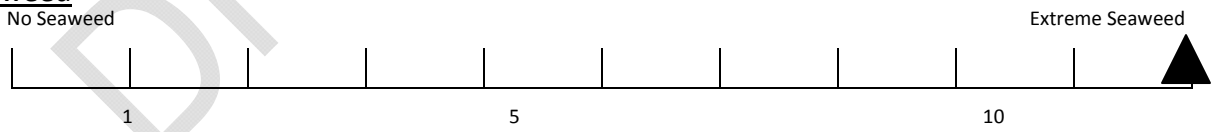
Umami

If any objectionable basic tastes are detected, please circle the appropriate descriptor(s):

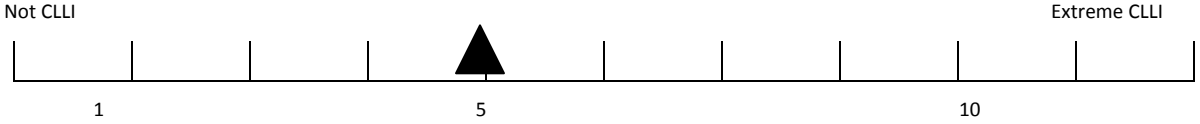
Sour Bitter

Flavor

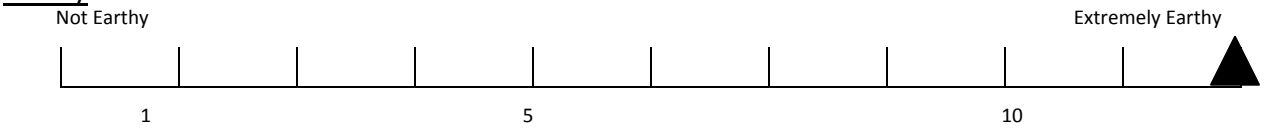
Seaweed



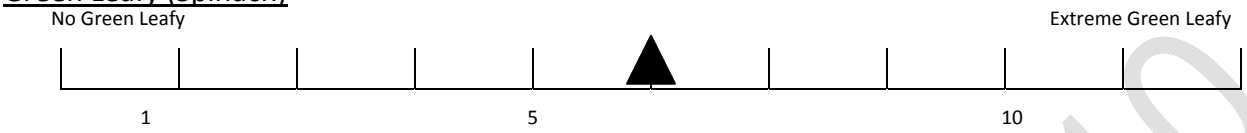
Chicken-Liver-Like/Iron(CLLI)



Earthy



Green Leafy (Spinach)



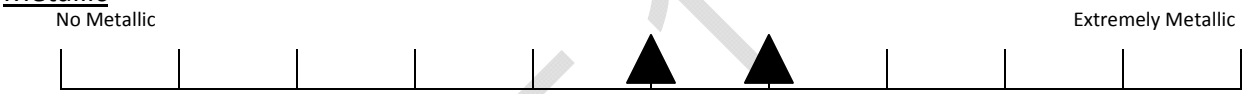
If any objectionable flavors are detected, please circle the appropriate descriptor(s):

Boiled Potato-Like Fishy Garlic (Oil) Raw Cabbage

Wet Burlap Sac Other:_____

Aftertastes

Metallic



Astringent

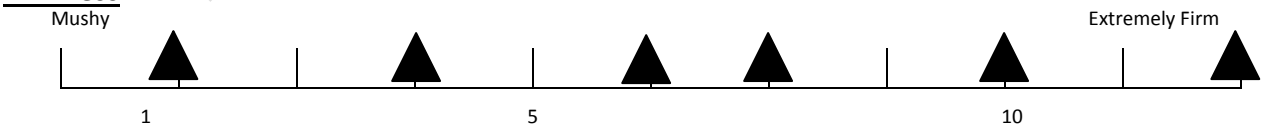
If any objectionable aftertastes are detected, please circle the appropriate descriptor(s):

Chalky Other:_____

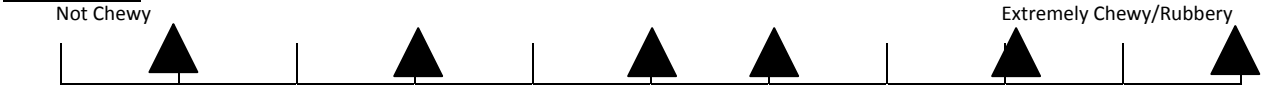
Texture & Mouth feels

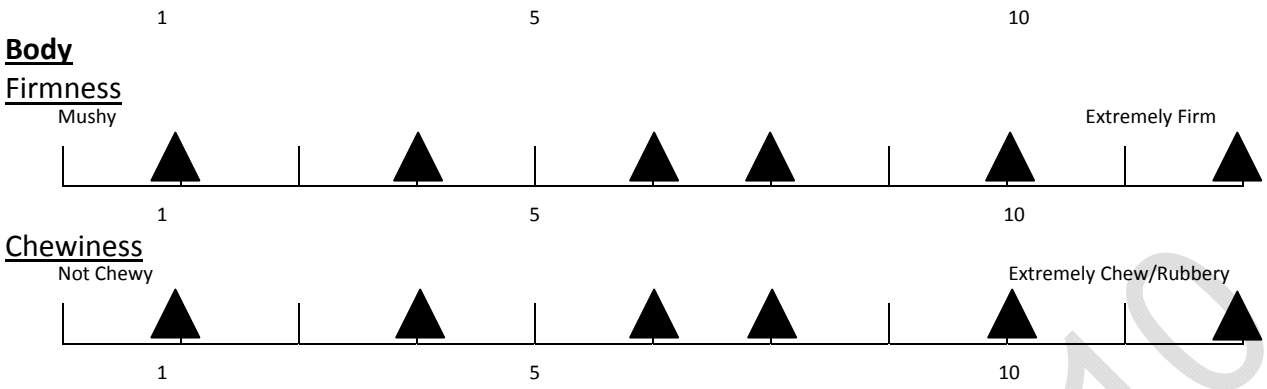
Adductor Muscle

Firmness



Chewiness





If any objectionable mouth feels are detected, please circle the appropriate descriptor(s):

Grittiness from sand Grittiness from shell

Other:_____

Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting	☐ ☒ ☐	**Growing Area Harvesting/Handling/Distribution Administrative**

Name of Submitter:	John Tesvich
Affiliation:	AmeriPure Processing Company, Inc.
Address:	803 Willow Street Franklin, LA 70538
Phone: **Fax:** **Email:**	504-912-2750 337-413-8003 jtesvich@ameripure.com
Proposal Subject:	*Vibrio vulnificus* Management
Specific NSSP Guide Reference:	Section II Model Ordinance Chapter II Risk Assessment and Risk Management @04 *Vibrio vulnificus* Risk Management for Oysters
Key Words:	*Vibrio vulnificus* Risk Management Plan; Post Harvest Process
Text of Proposal/ Requested Action:	Effective January 1, 2012: @.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* Risk 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 risk reduction program. The goal of the *Vibrio vulnificus* Risk Management Plan will be to reduce the risk per serving to a 60% illness rate reduction for etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, and Texas, from the consumption of commercially harvested raw or undercooked oysters to a level equivalent to a 60% illness rate reduction from 1995 – 1999 baseline average illness rate of 0.278 per million. C. The Source State's *Vibrio vulnificus* Risk 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 collect 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; and (4) Identification and implementation of the controls, or equivalent

	controls, which produced an illness per serving equivalent to a 60% illness rate reduction in the core states. These controls include: (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 processing that reduces the *Vibrio vulnificus* levels to <30 MPN/gram 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 an Authority-approved post harvest processing that reduces the *Vibrio vulnificus* levels to <1000 MPN/gram when the Average Monthly Maximum Water Temperature exceeds 75°F; and (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.
Public Health Significance:	A control standard that is easier to achieve will encourage industry acceptance by allowing for more PHP options (ie. high-salinity relay, and depuration). This would still very likely have a significant impact on reducing illnesses (considering the quagmire that the conference is in when dealing with V.v management). For the scientists: The <1000 MPN/gram level of V.v. may not be proven to reduce all risk of V.v. illness, but it is not disproven, either, that such a control level would help to significantly reduce the number of illnesses.
Cost Information (if available):	None

Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting	☐ ☒ ☐	**Growing Area Harvesting/Handling/Distribution Administrative**

Name of Submitter:	Robert Rheault
Affiliation:	East Coast Shellfish Growers' Association (ECSGA)
Address:	1121 Mooresfield Road Wakefield, RI 02879
Phone: **Fax:** **Email:**	401-783-3360 None bob@ECSGA.org
Proposal Subject:	*Vibrio vulnificus* Management Plan
Specific NSSP Guide Reference:	Section IV. Guidance Documents Chapter IV. Naturally Occurring Pathogens .02 *Vibrio vulnificus* Management Plan
Key Words:	*Vibrio vulnificus; Vibrio vulnificus* Management Plan; Source States
Text of Proposal/ Requested Action:	*Vibrio vulnificus* source states are those states reporting two (2) or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses in the previous five (5) years ~~since 1995~~ traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state.
Public Health Significance:	Currently there is no path for a state to be removed from the list of Illness Source States. The proposed change would alter the definition of *Vibrio vulnificus* Source State to remove states that have not had an illness for five (5) years.
Cost Information (if available):	None available.

Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting	☐ ☒ ☐	**Growing Area Harvesting/Handling/Distribution Administrative**

Name of Submitter:	Executive Office
Affiliation:	Interstate Shellfish Sanitation Conference (ISSC)
Address:	209-2 Dawson Road
Phone: **Fax:** **Email:**	803-788-7559 803-788-7576 issc@issc.org
Proposal Subject:	*Vibro* Management Committee Membership
Specific NSSP Guide Reference:	Section IV. Guidance Documents Chapter IV. Naturally Occurring Pathogens .02 *Vibrio vulnificus* Management Plan
Key Words:	*Vibro* Management Committee
Text of Proposal/ Requested Action:	The ~~V.v. subcommittee~~ *Vibrio* Management Committee 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 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.
Public Health Significance:	
Cost Information (if available):	

Proposal for Task Force Consideration at the 2011 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	Interstate Shellfish Sanitation Conference (ISSC)
Affiliation:	Interstate Shellfish Sanitation Conference (ISSC)
Address:	209-2 Dawson Road Columbia, SC 29223
Phone: **Fax:** **Email:**	803-788-7559 803-788-7576 issc@issc.org
Proposal Subject:	Review of CDC *Vp* Illness Information
Specific NSSP Guide Reference:	Section II Model Ordinance Chapter II @.05
Text of Proposal/ Requested Action	
Public Health Significance:	The number of cases of *Vp* associated with consumption of shellfish reported to the CDC by states in 2009 shows a significant increase from previous years. There were not any large outbreaks that occurred during the year, but the total number of reported cases was the second highest since 1998, which included cases from outbreaks associated with product from all three coasts. The large number of 2009 cases, in the absence of a large outbreak, suggests that the ISSC needs to review current CDC *Vp* illness information and determine the adequacy of current control strategies in the NSSP. The VMC and the ISSC Executive Board briefly discussed the 2009 reported illnesses and agreed that a *Vp* subcommittee should discuss the CDC reported information and make appropriate recommendations for VMC review. The purpose of this proposal is to notify the interested parties that change to the controls of Chapter II @.05 may be discussed at the ISSC 2011 Biennial Meeting.
Cost Information (if available):	

Proposal for Task Force Consideration at the 2011 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	ISSC Executive Office Leslie Palmer, Director, Division of Aquaculture
Affiliation:	Interstate Shellfish Sanitation Conference (ISSC) Florida Department of Agriculture & Consumer Services
Address:	209-2 Dawson Road Columbia, SC 29223 1203 Governors Square Blvd, Suite 501 Tallahassee, FL 32301
Phone: **Fax:** **Email:**	803-788-7559 803-788-7576 issc@issc.org 850-488-5471 850-410-0893 Leslie.Palmer@FreshFromFlorida.com
Proposal Subject:	*Vibrio cholera*
Specific NSSP Guide Reference:	Section II Model Ordinance Chapter II Risk Assessment and Risk Management
Text of Proposal/ Requested Action	
Public Health Significance:	In April of 2011, the State of Florida reported a shellfish related illness outbreak associated with a toxigenic strain of *Vibrio cholera* O75. Current knowledge of *Vibrio cholera* O75 suggests that this toxigenic strain can be pollution oriented or naturally occurring. The National Shellfish Sanitation Program (NSSP) requirements for addressing outbreaks are different for pollution related hazards and naturally occurring hazards. The determination of whether an outbreak of *Vibrio cholera* O75 is pollution related or naturally occurring is difficult and creates management problems for public health officials and shellfish control authorities. Procedure XIV of the ISSC Constitution, Bylaws, and Procedures outlines steps for addressing pathogens and deleterious substances newly recognized in shellfish. The purpose of this proposal is to provide notice to the membership that FDA and the ISSC will be discussing appropriate steps to address the *Vibrio cholera* situation. If recommendations for NSSP controls are developed for consideration at the 2011 Biennial Meeting, the ISSC membership will be notified.
Cost Information (if available):	

Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting	☐ ☒ ☐	**Growing Area Harvesting/Handling/Distribution Administrative**

Name of Submitter:	Robert Rheault
Affiliation:	East Coast Shellfish Growers' Association (ECSGA)
Address:	1121 Mooresfield Road Wakefield, RI 02879
Phone: **Fax:** **Email:**	401-783-3360 None bob@ECSGA.org
Proposal Subject:	Aquaculture Facility Inspection Frequency
Specific NSSP Guide Reference:	Section II Model Ordinance Chapter VI. Shellfish Aquaculture @.01 General C.
Key Words:	Aquaculture; Inspection; Frequency
Text of Proposal/ Requested Action:	The Authority shall inspect commercial aquaculture systems at least ~~every six months~~ annually.
Public Health Significance:	Moving to a lesser number of inspections per year will not impact public health.
Cost Information (if available):	States are facing serious budget restrictions. Some find the current requirement for semi annual inspections to be excessive and not in furtherance of public health. States may maintain a higher frequency of inspection if they choose while allowing other states to decrease the frequency. States should, within limits, be able to determine priorities and allocate resources accordingly.

Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting	☐ ☒ ☐	**Growing Area Harvesting/Handling/Distribution Administrative**

Name of Submitter:	U.S. Food and Drug Administration (USFDA) Interstate Shellfish Sanitation Conference Executive Office(ISSC)	
Affiliation:	U.S. Food and Drug Administration (USFDA) Interstate Shellfish Sanitation Conference Executive Office(ISSC)	
Address:	5100 Paint Branch Parkway College Park, Maryland 20740-3835	209-2 Dawson Road Columbia, SC 29223
Phone: **Fax:** **Email:**	240-402-1562 floyd.burditt@fda.hhs.gov	803-788-7559 803-788-7576 issc@issc.org
Proposal Subject:	Certification Requirements for Retail Distribution Centers	
Specific NSSP Guide Reference:	Section II. Model Ordinance Chapter X. General Requirements for Dealers	
Key Words:	Retail; Chain; Warehouse; Distribution	

Text of Proposal/ Requested Action:

.04 Certification Requirements.

A. General.

(1) Except as specified in (4) below, ~~N~~no person shall act as a dealer prior to obtaining certification.

(2) Any person who wants to be a dealer shall:

(a) Make application to the Authority for certification;

(b) Have and implement a HACCP Plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the *Federal Register* of December 18, 1995, except for the requirement for harvester identification on a dealer's tag.

(3) Each dealer shall have a business address at which inspections of facilities, activities, or equipment can be conducted.

(4) *A Retailer that operates a Distribution Center that receives and distributes molluscan shellfish is not required to obtain certification as a shellfish dealer if:*

(a) the Distribution Center ships shellfish only to retail outlets that are owned and operated by the same company that owns and operates the Distribution Center;

(b) the Distribution Center receives the shellfish from a source listed on the ICSSL and distributes the product to the retail stores in the original containers in which it was received; and

(c) from the time the shellfish is received at the distribution center to the time of sale or service to the consumer, the shellfish is maintained under the ownership and control of the company that owns and operates the Distribution Center and the retail stores.

Public Health Significance:	FDA considers retail food stores that receive molluscan shellfish from company-owned Distribution Centers that operate in the manner described above to be in compliance with 3-201.15 of the FDA Food Code, even if those Distribution Centers are not listed in the ICSSL. State and local regulatory authorities that license food stores may wish to take additional steps to be assured that the Distribution Centers can be considered an acceptable source, such as verifying that the Distribution Center maintains the shellfish as 45 deg F or below during storage and transit to the retail store. This exception to II.X.04 applies regardless of whether one or more of the retail stores to which the product is shipped is located in a different State from where the distribution center is located and regardless of whether the distribution center and/or the stores are located in a State that has a program for certifying shellfish dealers. If all three conditions listed in the proposed X.04.A. (4) are not met, then a Distribution Center that receives and ships shellfish in interstate commerce should seek certification and listing on the ICSSL. Food safety concerns related to this policy should be minimal since no breakdown or repacking of shellfish is taking place and safe distribution and receiving is the responsibility of a single retail company and their own stores. Also the ability to effective conduct a product traceback should not be compromised by this because ownership of the product isn't being transferred if the stores and Distribution Center are part of same company.
Cost Information (if available):	

Proposal for Consideration at the Interstate Shellfish Sanitation Conference 2011 Biennial Meeting	☐ ☒ ☐	**Growing Area Harvesting/Handling/Distribution Administrative**

Name of Submitter:	Julie Henderson
Affiliation:	Virginia Department of Health – Division of Shellfish Sanitation
Address:	109 Governor Street, 6th Floor Richmond, VA 23219
Phone: **Fax:** **Email:**	804-382-3223 804-864-7481 julie.henderson@vdh.virginia.gov
Proposal Subject:	In-Shell Product Labeling and the Use of Shellstock Tags
Specific NSSP Guide Reference:	Section II. Model Ordinance Chapter X. General Requirements for Dealers .07 In-Shell Product or Post Harvest Processed In-Shell Labeling
Key Words:	In-Shell Product Labeling
Text of Proposal/ Requested Action:	A. The dealer shall label all in-shell product~~ with tags meeting the requirements of Chapter X .05. B. (1).~~ B. In-Shell Product ~~Tags~~ Labels. C. (1) The dealer ~~tag~~ label on in-shell product 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 in-shell product 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 in-shell product; 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 in-shell product intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-603.11 of the Current Food Code, or an equivalent statement, shall be included on all shellstock: "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.~~ (l) At a minimum the dealer shall label each individual container 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. ~~oIf the in-shell product is removed from the original container, the tag on the new container shall meet the requirements in §.07B.~~ ~~(3)~~(2) Country of origin information (USDA 2004) may be included on the ~~shucker-packer or reshipper tag~~ label. ~~(4)~~(3) When in-shell product intended for retail sale are packed in containers of 5 pounds or less and shipped in a master container which includes a tag in compliance with Chapter X .05 B. (1), the individual containers of 5 pounds or less shall not require tags as specified in Chapter X .05 B. (1) but may be labeled in some other manner with indelible, legible, information which at a minimum is adequate to trace the in-shell shellfish back to the lot of in-shell product it is part of. Consumer advisory information identified in Chapter X .07 B. (1) (j) shall be included on each retail package. NOTE: A transition period of up to twelve (12) months should be allowed to allow dealer to utilize their current inventory of shellfish and supplies before the new labeling requirements must be met. ~~NOTE: The Consumer Advisory shall be required for both A and B.~~
Public Health Significance:	Shellfish dealers are required by the NSSP to tag or label shellfish to ensure that shellfish are from an approved source and in the event of a shellfish related illness, tags, labels and records provide for trace ability. In-shell product is defined as "non-living, processed shellfish with one or both shells present." In 2007 the ISSC amended the Model Ordinance to require dealers to label in-shell product with shellstock tags. In-shell product is packaged differently than live shellstock and is often individually quick frozen (IQF), and packed in sealed containers. Since the inception of this requirement in 2007, the Virginia Division of Shellfish Sanitation has routinely found

	in-shell oysters from Texas and Mississippi and in-shell mussels from New Zealand at Reshipper and Shellstock Shipper facilities without tags. The labels provided on these containers have had varying degrees of the required information. The Texas and Mississippi Authorities were notified as well as the ISSC Executive Office and the FDA. As a result of notifying the FDA, the Virginia Division of Shellfish Sanitation received a response via email from Paul DiStefano stating, "FDA does not consider it necessary to oppose the fact that the labeling is on the box and not a tag. As long as all the labeling information is there FDA would consider that acceptable." In light of this correspondence and interpretation by the FDA, Virginia Division of Shellfish Sanitation proposes to allow for labels to be used on in-shell product.
Cost Information (if available):	

Proposal for Task Force Consideration at the 2011 Biennial Meeting Interstate Shellfish Sanitation Conference	☐ **Growing Area** ☒ **Harvesting/Handling/Distribution** ☐ **Administrative**
Name of Submitter:	ISSC Executive Office and USFDA
Affiliation:	ISSC and USFDA
Address:	209-2 Dawson Road Columbia, SC 29223
Phone: **Fax:** **Email:**	803-788-7559 803-788-7576 issc@issc.org
Proposal Subject:	Guidance Document for 2 and 3 Log Reduction Method
Specific NSSP Guide Reference:	Section IV. Guidance Documents Chapter IV. Naturally Occurring Pathogens .06 Guidance for 2 or 3 Log Reduction of *Vibrio parahaemolyticus* PHP Validation as an Alternative for Rapid Cooling
Text of Proposal/ Requested Action	.06 Method for Validation and Verification of a Two or Three Log Reduction of *Vibrio parahaemolyticus* (*V.p.*) in Oysters. A. VALIDATION 1. Introduction: Rapid refrigeration can slow the growth of *Vibrio parahaemolyticus* (*V.p.*) in recently harvested oysters. An alternative to rapid refrigeration requirements under NSSP is a post harvest process (PHP) which requires at least a two log reduction in *V.p.* levels for the Gulf and a three log reduction for the Pacific. This document provides guidance for the validation of a PHP to achieve either the two or three log reduction of *V.p.* density as appropriate. 2. Overview: Validation of the PHP to achieve a two or three log reduction in *V.p.* levels is conducted on three harvest lots, with one initial measurement prior to PHP, or "pre-process", and ten measurements after the PHP or "post-process". This process is divided into three basic parts: 1) the pre-process *V.p* density determination of the lot, 2) determination of tube number and concentration of oyster homogenate aliquoted (inoculum) to obtain post-process *V.p.* density 3) validation and/or verification of the two or three log reduction as prescribed. Samples must be taken from three independent harvest lots to test the efficacy of the PHP process with confidence. Although the pre-process sampling protocol requires three dilutions from one sample, post-process sampling protocol requires only a single dilution as indicated for each of the ten samples. These ten samples for each of three lots make a total of thirty samples. The number of positive tubes in each post-processed sample determines whether the sample passes or fails. The PHP is validated if no more than five of the thirty samples collected after processing fail. The PHP must be verified in each month it is performed. The method of analysis will be the same MPN method as is utilized in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, used for

the regulatory analyses for *V.p.* in shellfish as approved under the NSSP and cited in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2009 Section IV. Guidance Document Chapter II. Growing Areas.10 Approved National Shellfish Sanitation Program Laboratory Tests. *Although a* Most Probable Number (MPN) *series will be performed, an MPN/g value will not be attained or used throughout the validation process. Instead, the information used to validate and verify, and the data generated, is based on the statistical analysis of probability.*

3. Initial *V.p.* Density Determination:

For each pre-process lot, a ten-tube decimal dilution MPN is performed. The tube code obtained establishes initial *V.p.* density on the pre-processed lot to determine how to perform the post-process lot measurements. For confidence in the initial measurement at least three dilutions are necessary. (The amount of the original sample in each dilution is one tenth as much as in the previous dilution. For example, if the lowest dilution has x grams, the next dilution has x/10, then x/100, etc.)

For a lot to be included in the validation the dilutions selected for the analysis must not result in all positive or all negative tubes. *It should be noted that in the unlikely event that the pre-processed sample tube code is not listed in the attached table, a problem in the determination of the initial V.p. level likely occurred and that the initial V.p density of the lot will have to be retested before continuing the validation study.* If unsure of the initial *V.p.* density it may be necessary to use more than three dilutions in the initial analysis. When more than three dilutions are used, the results from only three contiguous dilutions are significant in determination of the outcome. To select the three dilutions to be used, the following guidance is provided. In each example the selected dilutions are underlined in bold.

(a) When more than one of the dilutions used has all ten tubes positive, select the highest dilution (most dilute sample portion) having all ten tubes positive and the two following dilutions (i.e. 10,10,6,0).
(b) When only one of the dilutions used has all ten tubes positive, select that dilution and the two following dilutions (i.e. 10,8,4,0)
(c) When a positive tube or tubes occur in dilutions higher than the three dilutions chosen, add the number of positive tubes in the higher dilutions to the third dilution chosen (i.e. 10,9,3,1 becomes 10,9,4).
(d) When the sum of the tubes in the third dilution would exceed ten, select the three highest consecutive dilutions having at least one positive tube among them (i.e. 10,9,9,2).

4. Post PHP Process *V.p.* density determination (see attached table):

The three dilutions so determined form a tube code for the initial density of *V.p.* in the pre-processed samples. This tube code, listed in column one of the attached table in Appendix A. (see *Appendix A: Tube Code Table for Validation and Verification*), determines both the number of tubes used and the amount of inoculum in each of the post-processed samples. Once the tube code from the initial pre-process *V.p.* density measurement is obtained from the first column of the attached table, the number of tubes to be used in each of the ten post-processed samples can be obtained from the same row in the third column. Directly adjacent to column three in this same row, column

four, indicates the maximum number of tubes allowed to be positive for that sample to pass.

Column two of the table shows three possible dilutions of the original sample that could have been used in the initial *V.p.* density determination. If these dilutions were used to generate the tube codes in column one of the attached table, then the volume of sample to be inoculated into each of the post-process single dilution MPN tubes for the sample lot is given directly adjacent. Hence the amount to inoculate for *V.p.* density determination of post-process samples is in column five for the Gulf (2 log) and column six for the Pacific (3 log).

Since the initial density of *V.p.* may vary considerably, dilutions other than the dilutions given in column two of the table may be used. When this occurs an adjustment must be made in the volume of post-process sample inoculated into each of the single dilution MPN tubes used.

For example, the dilutions prescribed in column 2 for tube code 10, 1, 0 are 0.001, 0.0001, 0.00001. If the dilutions used were actually 0.01, 0.001, 0.0001, the amount in column five or six would be multiplied by ten. Thus, the nine tube post-process single dilution MPN would have an adjusted sample inoculum of 0.1 gram/mL (0.01 x 10) and must be used for each sample from the lot rather than the 0.01 gram/mL sample inoculum specified in column five of the table to validate the two log reduction. In the same example, to validate the three log reduction, the adjusted sample inoculum of 1.0 gram/mL (0.1 x 10) must be used for each post-process sample from the lot instead of the 0.1 gram/mL specified in column six of the table.

5. Determining validation of two or three log reduction post PHP process:
Individual post-process samples pass or fail based on the number of positive tubes which result from the single dilution MPN, as found in column four of the table. In the example above for a pre-process sample tube code of 10,1,0 using a nine tube, single dilution MPN for the analysis, column four directly across from the tube code indicates that no more than four of the nine tubes per sample may be positive for the sample to pass. For the three lots to pass and the PHP to be validated for a two or three long reduction in *V.p.* density, no more than five of the thirty individual samples from the three lots tested post-process can fail.

B. VERIFICATION

1. Initial V.p. density determination:
In each month that oysters are post harvest processed, the first lot for processing is selected for testing. The method of testing the lot is similar to the testing for validation. An initial measurement uses ten tubes at three dilution levels. This initial measurement determines the number of tubes, mass of homogenate, and number of allowed turbid growth (positive) tubes used to test the oysters after PHP processing. The table used for validation is also used for the verification process.

If the initial measurement has all negative (non turbid)tubes and the mass of inoculum in the least dilute tube contains at least 1 gram of the oyster

homogenate, then the process is considered verified for that month. If the least dilute tube contains less than 1 gram of homogenate the process should be repeated with 1 gram of sample. If an all negative result is again obtained the process is considered verified for that month. If growth is observed post-process verification testing must be performed.

2. Post PHP Process *V.p.* density verification:
Post processed verification testing uses the first lot of the month. Three outcomes are possible;

(a) the process is verified for the month, or
(b) the process fails verification and the process must be revalidated, or
(c) additional testing using a subsequent lot is needed.

Four parameters determine the verification test and they are outlined in the following table. The first parameter is the number of samples taken from a lot. When the process is validated ten samples are selected from each lot; however, for verification seven samples are to be taken from the lot. The second parameter is the maximum number of growth tubes for the process to be verified with the first lot. The maximum number of samples allowed to be positive for the process to verify is 1. The third parameter is the minimum number of positive tubes that causes the process to require revalidation, which is three.

Table 1. Positive Sample Maximum and Minimum

Number of Samples	First Lot Maximum Positive for Pass	First Lot Minimum Positive for Fail	Second Lot Maximum Positive for Pass	Probability of Passing for Non-degenerate Process
7	1	3	1	96%

If the number of positive tubes in the testing of the first lot is 2, then a second lot is selected. The fourth parameter is the maximum number of positive tubes allowed for verification when the second lot is used. The following table outlines this scenario.

Table 2. Pass/Fail Schematic

Monthly Verification	
First Lot	Second Lot
7	7
6	6
5	5
Fail 4	4
3	Fail 3
Second Lot Needed 2	2
1	1
Pass 0	Pass 0

The process has a 96% probability of passing verification as long as it is

	working optimally; should the process degenerate in efficacy, the probability of passing significantly decreases.
Public Health Significance:	In 2009, the ISSC adopted Proposal 09-208 which allows for processors to utilized shellstock that is harvested outside the *Vp* controls established as part of the States' *Vp* Plans. The proposal established a 2 log reduction requirement for the Gulf of Mexico and the Mid-Atlantic States and a 3 log reduction requirement for the Pacific Coast States. This proposal provides guidance for the validation and verification for processors choosing to use this processing option
Cost Information (if available):	

Appendix A: Tube Code Table for Validation and Verification

Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(0,0,1)	0.0001, 0.00001, 0.000001	10	2	0.01	0.1
(0,0,2)	0.0001, 0.00001, 0.000001	9	3	0.01	0.1
(0,1,0)	0.0001, 0.00001, 0.000001	10	2	0.01	0.1
(0,1,1)	0.0001, 0.00001, 0.000001	9	3	0.01	0.1
(0,2,0)	0.0001, 0.00001, 0.000001	9	3	0.01	0.1
(0,2,1)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(0,3,0)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(1,0,0)	0.0001, 0.00001, 0.000001	6	5	0.1	1
(1,0,1)	0.0001, 0.00001, 0.000001	9	3	0.01	0.1
(1,0,2)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(1,1,0)	0.0001, 0.00001, 0.000001	9	3	0.01	0.1
(1,1,1)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(1,1,2)	0.0001, 0.00001, 0.000001	10	1	0.001	0.01
(1,2,0)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(1,2,1)	0.0001, 0.00001, 0.000001	10	1	0.001	0.01
(1,3,0)	0.0001, 0.00001, 0.000001	10	1	0.001	0.01
(1,3,1)	0.0001, 0.00001, 0.000001	8	1	0.001	0.01
(1,4,0)	0.0001, 0.00001, 0.000001	8	1	0.001	0.01
(2,0,0)	0.0001, 0.00001, 0.000001	5	2	0.01	0.1
(2,0,1)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(2,0,2)	0.0001, 0.00001, 0.000001	10	1	0.001	0.01
(2,1,0)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(2,1,1)	0.0001, 0.00001, 0.000001	10	1	0.001	0.01
(2,1,2)	0.0001, 0.00001, 0.000001	10	6	0.01	0.1
(2,2,0)	0.0001, 0.00001, 0.000001	7	4	0.01	0.1
(2,2,1)	0.0001, 0.00001, 0.000001	10	6	0.01	0.1
(2,2,2)	0.0001, 0.00001, 0.000001	8	0	0.0001	0.001
(2,3,0)	0.0001, 0.00001, 0.000001	8	5	0.01	0.1
(2,3,1)	0.0001, 0.00001, 0.000001	8	0	0.0001	0.001
(2,4,0)	0.0001, 0.00001, 0.000001	8	0	0.0001	0.001
(2,4,1)	0.0001, 0.00001, 0.000001	7	0	0.0001	0.001
(2,5,0)	0.0001, 0.00001, 0.000001	7	0	0.0001	0.001
(3,0,0)	0.0001, 0.00001, 0.000001	6	3	0.01	0.1
(3,0,1)	0.0001, 0.00001, 0.000001	9	5	0.01	0.1
(3,0,2)	0.0001, 0.00001, 0.000001	10	0	0.0001	0.001
(3,1,0)	0.0001, 0.00001, 0.000001	9	5	0.01	0.1
(3,1,1)	0.0001, 0.00001, 0.000001	10	0	0.0001	0.001
(3,1,2)	0.0001, 0.00001, 0.000001	8	0	0.0001	0.001
(3,2,0)	0.0001, 0.00001, 0.000001	10	0	0.0001	0.001
(3,2,1)	0.0001, 0.00001, 0.000001	8	0	0.0001	0.001
(3,2,2)	0.0001, 0.00001, 0.000001	8	6	0.01	0.1
(3,3,0)	0.0001, 0.00001, 0.000001	8	0	0.0001	0.001
(3,3,1)	0.0001, 0.00001, 0.000001	8	6	0.01	0.1
(3,3,2)	0.0001, 0.00001, 0.000001	6	0	0.0001	0.001
(3,4,0)	0.0001, 0.00001, 0.000001	8	6	0.01	0.1
(3,4,1)	0.0001, 0.00001, 0.000001	6	0	0.0001	0.001

Appendix A: Tube Code Table for Validation and Verification

Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(3,5,0)	0.0001, 0.00001, 0.000001	6	0	0.0001	0.001
(4,0,0)	0.0001, 0.00001, 0.000001	8	1	0.001	0.01
(4,0,1)	0.0001, 0.00001, 0.000001	9	0	0.0001	0.001
(4,0,2)	0.0001, 0.00001, 0.000001	10	7	0.01	0.1
(4,1,0)	0.0001, 0.00001, 0.000001	9	0	0.0001	0.001
(4,1,1)	0.0001, 0.00001, 0.000001	10	7	0.01	0.1
(4,1,2)	0.0001, 0.00001, 0.000001	5	4	0.01	0.1
(4,2,0)	0.0001, 0.00001, 0.000001	10	7	0.01	0.1
(4,2,2)	0.001, 0.0001, 0.00001	10	2	0.01	0.1
(4,3,0)	0.0001, 0.00001, 0.000001	5	4	0.01	0.1
(4,3,1)	0.001, 0.0001, 0.00001	10	8	0.1	1
(4,3,2)	0.001, 0.0001, 0.00001	7	6	0.1	1
(4,4,0)	0.001, 0.0001, 0.00001	10	8	0.1	1
(4,4,1)	0.001, 0.0001, 0.00001	7	6	0.1	1
(4,5,0)	0.001, 0.0001, 0.00001	7	6	0.1	1
(4,5,1)	0.001, 0.0001, 0.00001	8	2	0.01	0.1
(4,6,0)	0.001, 0.0001, 0.00001	8	2	0.01	0.1
(5,0,0)	0.0001, 0.00001, 0.000001	9	6	0.01	0.1
(5,0,1)	0.0001, 0.00001, 0.000001	7	0	0.0001	0.001
(5,0,2)	0.0001, 0.00001, 0.000001	6	0	0.0001	0.001
(5,0,3)	0.001, 0.0001, 0.00001	5	0	0.001	0.01
(5,1,0)	0.0001, 0.00001, 0.000001	7	0	0.0001	0.001
(5,1,1)	0.0001, 0.00001, 0.000001	6	0	0.0001	0.001
(5,1,2)	0.001, 0.0001, 0.00001	5	0	0.001	0.01
(5,1,3)	0.001, 0.0001, 0.00001	8	7	0.1	1
(5,2,0)	0.0001, 0.00001, 0.000001	6	0	0.0001	0.001
(5,2,1)	0.001, 0.0001, 0.00001	5	0	0.001	0.01
(5,2,2)	0.001, 0.0001, 0.00001	8	7	0.1	1
(5,3,0)	0.001, 0.0001, 0.00001	5	0	0.001	0.01
(5,3,1)	0.001, 0.0001, 0.00001	8	7	0.1	1
(5,3,2)	0.001, 0.0001, 0.00001	9	8	0.1	1
(5,4,0)	0.001, 0.0001, 0.00001	8	7	0.1	1
(5,4,1)	0.001, 0.0001, 0.00001	9	8	0.1	1
(5,4,2)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(5,5,0)	0.001, 0.0001, 0.00001	9	8	0.1	1
(5,5,1)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(5,6,0)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(6,0,0)	0.0001, 0.00001, 0.000001	5	4	0.01	0.1
(6,0,1)	0.001, 0.0001, 0.00001	10	2	0.01	0.1
(6,0,2)	0.001, 0.0001, 0.00001	7	6	0.1	1
(6,0,3)	0.001, 0.0001, 0.00001	8	2	0.01	0.1
(6,1,0)	0.001, 0.0001, 0.00001	10	2	0.01	0.1
(6,1,1)	0.001, 0.0001, 0.00001	7	6	0.1	1
(6,1,2)	0.001, 0.0001, 0.00001	8	2	0.01	0.1
(6,1,3)	0.001, 0.0001, 0.00001	10	9	0.1	1
(6,2,0)	0.001, 0.0001, 0.00001	7	6	0.1	1

Appendix A: Tube Code Table for Validation and Verification					
Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(6,2,1)	0.001, 0.0001, 0.00001	8	2	0.01	0.1
(6,2,2)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(6,2,3)	0.001, 0.0001, 0.00001	10	3	0.01	0.1
(6,3,0)	0.001, 0.0001, 0.00001	8	2	0.01	0.1
(6,3,1)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(6,3,2)	0.001, 0.0001, 0.00001	10	3	0.01	0.1
(6,4,0)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(6,4,1)	0.001, 0.0001, 0.00001	10	3	0.01	0.1
(6,4,2)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(6,5,0)	0.001, 0.0001, 0.00001	10	3	0.01	0.1
(6,5,1)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(6,5,2)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(6,6,0)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(6,6,1)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(6,7,0)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(7,0,0)	0.001, 0.0001, 0.00001	5	0	0.001	0.01
(7,0,1)	0.001, 0.0001, 0.00001	8	7	0.1	1
(7,0,2)	0.001, 0.0001, 0.00001	10	9	0.1	1
(7,0,3)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(7,1,0)	0.001, 0.0001, 0.00001	8	7	0.1	1
(7,1,1)	0.001, 0.0001, 0.00001	10	9	0.1	1
(7,1,2)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(7,1,3)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(7,2,0)	0.001, 0.0001, 0.00001	10	9	0.1	1
(7,2,1)	0.001, 0.0001, 0.00001	10	3	0.01	0.1
(7,2,2)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(7,2,3)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(7,3,0)	0.001, 0.0001, 0.00001	10	3	0.01	0.1
(7,3,1)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(7,3,2)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(7,3,3)	0.001, 0.0001, 0.00001	5	2	0.01	0.1
(7,4,0)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(7,4,1)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(7,4,2)	0.001, 0.0001, 0.00001	5	2	0.01	0.1
(7,4,3)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(7,5,0)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(7,5,1)	0.001, 0.0001, 0.00001	5	2	0.01	0.1
(7,5,2)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(7,6,0)	0.001, 0.0001, 0.00001	5	2	0.01	0.1
(7,6,1)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(7,6,2)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(7,7,0)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(7,7,1)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(8,0,0)	0.001, 0.0001, 0.00001	9	8	0.1	1
(8,0,1)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(8,0,2)	0.001, 0.0001, 0.00001	6	2	0.01	0.1

Appendix A: Tube Code Table for Validation and Verification

Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(8,0,3)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(8,1,0)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(8,1,1)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(8,1,2)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(8,1,3)	0.001, 0.0001, 0.00001	5	2	0.01	0.1
(8,2,0)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(8,2,1)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(8,2,2)	0.001, 0.0001, 0.00001	5	2	0.01	0.1
(8,2,3)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(8,3,0)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(8,3,1)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(8,3,2)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(8,3,3)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(8,4,0)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(8,4,1)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(8,4,2)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(8,4,3)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(8,5,0)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(8,5,1)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(8,5,2)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(8,5,3)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(8,6,0)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(8,6,1)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(8,6,2)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(8,7,0)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(8,7,1)	0.001, 0.0001, 0.00001	8	4	0.01	0.1
(8,7,2)	0.001, 0.0001, 0.00001	10	5	0.01	0.1
(8,8,0)	0.001, 0.0001, 0.00001	8	4	0.01	0.1
(8,8,1)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(9,0,0)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(9,0,1)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(9,0,2)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(9,0,3)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(9,1,0)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(9,1,1)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(9,1,2)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(9,1,3)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(9,1,4)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(9,2,0)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(9,2,1)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(9,2,2)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(9,2,3)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(9,2,4)	0.001, 0.0001, 0.00001	10	5	0.01	0.1
(9,3,0)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(9,3,1)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(9,3,2)	0.001, 0.0001, 0.00001	6	3	0.01	0.1

Appendix A: Tube Code Table for Validation and Verification

Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(9,3,3)	0.001, 0.0001, 0.00001	10	5	0.01	0.1
(9,3,4)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(9,4,0)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(9,4,1)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(9,4,2)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(9,4,3)	0.001, 0.0001, 0.00001	7	4	0.01	0.1
(9,4,4)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(9,5,0)	0.001, 0.0001, 0.00001	8	4	0.01	0.1
(9,5,1)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(9,5,2)	0.001, 0.0001, 0.00001	7	4	0.01	0.1
(9,5,3)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(9,5,4)	0.001, 0.0001, 0.00001	10	0	0.0001	0.001
(9,6,0)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(9,6,1)	0.001, 0.0001, 0.00001	9	5	0.01	0.1
(9,6,2)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(9,6,3)	0.001, 0.0001, 0.00001	10	0	0.0001	0.001
(9,7,0)	0.001, 0.0001, 0.00001	9	5	0.01	0.1
(9,7,1)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(9,7,2)	0.001, 0.0001, 0.00001	6	4	0.01	0.1
(9,7,3)	0.001, 0.0001, 0.00001	9	6	0.01	0.1
(9,8,0)	0.001, 0.0001, 0.00001	10	6	0.01	0.1
(9,8,1)	0.001, 0.0001, 0.00001	7	1	0.001	0.01
(9,8,2)	0.001, 0.0001, 0.00001	8	0	0.0001	0.001
(9,8,3)	0.001, 0.0001, 0.00001	10	7	0.01	0.1
(9,9,0)	0.001, 0.0001, 0.00001	9	0	0.0001	0.001
(9,9,1)	0.001, 0.0001, 0.00001	8	0	0.0001	0.001
(9,9,2)	0.001, 0.0001, 0.00001	7	0	0.0001	0.001
(10,0,0)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(10,0,1)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(10,0,2)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(10,0,3)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(10,1,0)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(10,1,1)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(10,1,2)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(10,1,3)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(10,1,4)	0.001, 0.0001, 0.00001	10	0	0.0001	0.001
(10,2,0)	0.001, 0.0001, 0.00001	8	4	0.01	0.1
(10,2,1)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(10,2,2)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(10,2,3)	0.001, 0.0001, 0.00001	6	4	0.01	0.1
(10,2,4)	0.001, 0.0001, 0.00001	8	0	0.0001	0.001
(10,3,0)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(10,3,1)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(10,3,2)	0.001, 0.0001, 0.00001	9	0	0.0001	0.001
(10,3,3)	0.001, 0.0001, 0.00001	7	5	0.01	0.1
(10,3,4)	0.001, 0.0001, 0.00001	5	4	0.01	0.1

Appendix A: Tube Code Table for Validation and Verification					
Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(10,3,5)	0.001, 0.0001, 0.00001	6	0	0.0001	0.001
(10,4,0)	0.001, 0.0001, 0.00001	10	6	0.01	0.1
(10,4,1)	0.001, 0.0001, 0.00001	9	0	0.0001	0.001
(10,4,2)	0.001, 0.0001, 0.00001	7	0	0.0001	0.001
(10,4,3)	0.001, 0.0001, 0.00001	5	4	0.01	0.1
(10,4,4)	0.001, 0.0001, 0.00001	6	5	0.01	0.1
(10,4,5)	0.01, 0.001, 0.0001	7	6	0.1	1
(10,5,0)	0.001, 0.0001, 0.00001	8	0	0.0001	0.001
(10,5,1)	0.001, 0.0001, 0.00001	7	0	0.0001	0.001
(10,5,2)	0.001, 0.0001, 0.00001	6	0	0.0001	0.001
(10,5,3)	0.01, 0.001, 0.0001	5	0	0.001	0.01
(10,5,4)	0.01, 0.001, 0.0001	8	7	0.1	1
(10,5,5)	0.01, 0.001, 0.0001	9	8	0.1	1
(10,5,6)	0.01, 0.001, 0.0001	7	2	0.01	0.1
(10,6,0)	0.001, 0.0001, 0.00001	5	4	0.01	0.1
(10,6,1)	0.01, 0.001, 0.0001	6	5	0.1	1
(10,6,2)	0.01, 0.001, 0.0001	7	6	0.1	1
(10,6,3)	0.01, 0.001, 0.0001	9	8	0.1	1
(10,6,4)	0.01, 0.001, 0.0001	7	2	0.01	0.1
(10,6,5)	0.01, 0.001, 0.0001	10	3	0.01	0.1
(10,6,6)	0.01, 0.001, 0.0001	6	2	0.01	0.1
(10,7,0)	0.01, 0.001, 0.0001	5	0	0.001	0.01
(10,7,1)	0.01, 0.001, 0.0001	8	2	0.01	0.1
(10,7,2)	0.01, 0.001, 0.0001	10	9	0.1	1
(10,7,3)	0.01, 0.001, 0.0001	10	3	0.01	0.1
(10,7,4)	0.01, 0.001, 0.0001	6	2	0.01	0.1
(10,7,5)	0.01, 0.001, 0.0001	9	3	0.01	0.1
(10,7,6)	0.01, 0.001, 0.0001	8	3	0.01	0.1
(10,7,7)	0.01, 0.001, 0.0001	10	4	0.01	0.1
(10,8,0)	0.01, 0.001, 0.0001	9	8	0.1	1
(10,8,1)	0.01, 0.001, 0.0001	10	3	0.01	0.1
(10,8,2)	0.01, 0.001, 0.0001	6	2	0.01	0.1
(10,8,3)	0.01, 0.001, 0.0001	5	2	0.01	0.1
(10,8,4)	0.01, 0.001, 0.0001	8	3	0.01	0.1
(10,8,5)	0.01, 0.001, 0.0001	10	4	0.01	0.1
(10,8,6)	0.01, 0.001, 0.0001	9	4	0.01	0.1
(10,8,7)	0.01, 0.001, 0.0001	6	3	0.01	0.1
(10,8,8)	0.01, 0.001, 0.0001	8	4	0.01	0.1
(10,9,0)	0.01, 0.001, 0.0001	6	2	0.01	0.1
(10,9,1)	0.01, 0.001, 0.0001	5	2	0.01	0.1
(10,9,2)	0.01, 0.001, 0.0001	8	3	0.01	0.1
(10,9,3)	0.01, 0.001, 0.0001	7	3	0.01	0.1
(10,9,4)	0.01, 0.001, 0.0001	6	3	0.01	0.1
(10,9,5)	0.01, 0.001, 0.0001	8	4	0.01	0.1
(10,9,6)	0.01, 0.001, 0.0001	10	1	0.001	0.01
(10,9,7)	0.01, 0.001, 0.0001	8	1	0.001	0.01

Appendix A: Tube Code Table for Validation and Verification					
Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(10,9,8)	0.01, 0.001, 0.0001	10	0	0.0001	0.001
(10,9,9)	0.01, 0.001, 0.0001	8	0	0.0001	0.001
(10,10,0)	0.01, 0.001, 0.0001	10	4	0.01	0.1
(10,10,1)	0.01, 0.001, 0.0001	9	4	0.01	0.1
(10,10,2)	0.01, 0.001, 0.0001	8	4	0.01	0.1
(10,10,3)	0.01, 0.001, 0.0001	9	5	0.01	0.1
(10,10,4)	0.01, 0.001, 0.0001	6	4	0.01	0.1
(10,10,5)	0.01, 0.001, 0.0001	7	0	0.0001	0.001
(10,10,6)	0.10, 0.01, 0.001	10	2	0.01	0.1
(10,10,7)	0.10, 0.01, 0.001	8	2	0.01	0.1
(10,10,8)	0.10, 0.01, 0.001	10	3	0.01	0.1
(10,10,9)	0.10, 0.01, 0.001	8	3	0.01	0.1

Appendix A: Tube Code Table for Validation and Verification					
Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(0,0,1)	0.0001, 0.00001, 0.000001	10	2	0.01	0.1
(0,0,2)	0.0001, 0.00001, 0.000001	9	3	0.01	0.1
(0,1,0)	0.0001, 0.00001, 0.000001	10	2	0.01	0.1
(0,1,1)	0.0001, 0.00001, 0.000001	9	3	0.01	0.1
(0,2,0)	0.0001, 0.00001, 0.000001	9	3	0.01	0.1
(0,2,1)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(0,3,0)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(1,0,0)	0.0001, 0.00001, 0.000001	6	5	0.1	1
(1,0,1)	0.0001, 0.00001, 0.000001	9	3	0.01	0.1
(1,0,2)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(1,1,0)	0.0001, 0.00001, 0.000001	9	3	0.01	0.1
(1,1,1)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(1,1,2)	0.0001, 0.00001, 0.000001	10	1	0.001	0.01
(1,2,0)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(1,2,1)	0.0001, 0.00001, 0.000001	10	1	0.001	0.01
(1,3,0)	0.0001, 0.00001, 0.000001	10	1	0.001	0.01
(1,3,1)	0.0001, 0.00001, 0.000001	8	1	0.001	0.01
(1,4,0)	0.0001, 0.00001, 0.000001	8	1	0.001	0.01
(2,0,0)	0.0001, 0.00001, 0.000001	5	2	0.01	0.1
(2,0,1)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(2,0,2)	0.0001, 0.00001, 0.000001	10	1	0.001	0.01
(2,1,0)	0.0001, 0.00001, 0.000001	9	4	0.01	0.1
(2,1,1)	0.0001, 0.00001, 0.000001	10	1	0.001	0.01
(2,1,2)	0.0001, 0.00001, 0.000001	10	6	0.01	0.1
(2,2,0)	0.0001, 0.00001, 0.000001	7	4	0.01	0.1
(2,2,1)	0.0001, 0.00001, 0.000001	10	6	0.01	0.1
(2,2,2)	0.0001, 0.00001, 0.000001	8	0	0.0001	0.001
(2,3,0)	0.0001, 0.00001, 0.000001	8	5	0.01	0.1
(2,3,1)	0.0001, 0.00001, 0.000001	8	0	0.0001	0.001
(2,4,0)	0.0001, 0.00001, 0.000001	8	0	0.0001	0.001
(2,4,1)	0.0001, 0.00001, 0.000001	7	0	0.0001	0.001
(2,5,0)	0.0001, 0.00001, 0.000001	7	0	0.0001	0.001
(3,0,0)	0.0001, 0.00001, 0.000001	6	3	0.01	0.1
(3,0,1)	0.0001, 0.00001, 0.000001	9	5	0.01	0.1
(3,0,2)	0.0001, 0.00001, 0.000001	10	0	0.0001	0.001
(3,1,0)	0.0001, 0.00001, 0.000001	9	5	0.01	0.1
(3,1,1)	0.0001, 0.00001, 0.000001	10	0	0.0001	0.001
(3,1,2)	0.0001, 0.00001, 0.000001	8	0	0.0001	0.001
(3,2,0)	0.0001, 0.00001, 0.000001	10	0	0.0001	0.001
(3,2,1)	0.0001, 0.00001, 0.000001	8	0	0.0001	0.001
(3,2,2)	0.0001, 0.00001, 0.000001	8	6	0.01	0.1
(3,3,0)	0.0001, 0.00001, 0.000001	8	0	0.0001	0.001
(3,3,1)	0.0001, 0.00001, 0.000001	8	6	0.01	0.1
(3,3,2)	0.0001, 0.00001, 0.000001	6	0	0.0001	0.001
(3,4,0)	0.0001, 0.00001, 0.000001	8	6	0.01	0.1
(3,4,1)	0.0001, 0.00001, 0.000001	6	0	0.0001	0.001

Appendix A: Tube Code Table for Validation and Verification

Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(3,5,0)	0.0001, 0.00001, 0.000001	6	0	0.0001	0.001
(4,0,0)	0.0001, 0.00001, 0.000001	8	1	0.001	0.01
(4,0,1)	0.0001, 0.00001, 0.000001	9	0	0.0001	0.001
(4,0,2)	0.0001, 0.00001, 0.000001	10	7	0.01	0.1
(4,1,0)	0.0001, 0.00001, 0.000001	9	0	0.0001	0.001
(4,1,1)	0.0001, 0.00001, 0.000001	10	7	0.01	0.1
(4,1,2)	0.0001, 0.00001, 0.000001	5	4	0.01	0.1
(4,2,0)	0.0001, 0.00001, 0.000001	10	7	0.01	0.1
(4,2,2)	0.001, 0.0001, 0.00001	10	2	0.01	0.1
(4,3,0)	0.0001, 0.00001, 0.000001	5	4	0.01	0.1
(4,3,1)	0.001, 0.0001, 0.00001	10	8	0.1	1
(4,3,2)	0.001, 0.0001, 0.00001	7	6	0.1	1
(4,4,0)	0.001, 0.0001, 0.00001	10	8	0.1	1
(4,4,1)	0.001, 0.0001, 0.00001	7	6	0.1	1
(4,5,0)	0.001, 0.0001, 0.00001	7	6	0.1	1
(4,5,1)	0.001, 0.0001, 0.00001	8	2	0.01	0.1
(4,6,0)	0.001, 0.0001, 0.00001	8	2	0.01	0.1
(5,0,0)	0.0001, 0.00001, 0.000001	9	6	0.01	0.1
(5,0,1)	0.0001, 0.00001, 0.000001	7	0	0.0001	0.001
(5,0,2)	0.0001, 0.00001, 0.000001	6	0	0.0001	0.001
(5,0,3)	0.001, 0.0001, 0.00001	5	0	0.001	0.01
(5,1,0)	0.0001, 0.00001, 0.000001	7	0	0.0001	0.001
(5,1,1)	0.0001, 0.00001, 0.000001	6	0	0.0001	0.001
(5,1,2)	0.001, 0.0001, 0.00001	5	0	0.001	0.01
(5,1,3)	0.001, 0.0001, 0.00001	8	7	0.1	1
(5,2,0)	0.0001, 0.00001, 0.000001	6	0	0.0001	0.001
(5,2,1)	0.001, 0.0001, 0.00001	5	0	0.001	0.01
(5,2,2)	0.001, 0.0001, 0.00001	8	7	0.1	1
(5,3,0)	0.001, 0.0001, 0.00001	5	0	0.001	0.01
(5,3,1)	0.001, 0.0001, 0.00001	8	7	0.1	1
(5,3,2)	0.001, 0.0001, 0.00001	9	8	0.1	1
(5,4,0)	0.001, 0.0001, 0.00001	8	7	0.1	1
(5,4,1)	0.001, 0.0001, 0.00001	9	8	0.1	1
(5,4,2)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(5,5,0)	0.001, 0.0001, 0.00001	9	8	0.1	1
(5,5,1)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(5,6,0)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(6,0,0)	0.0001, 0.00001, 0.000001	5	4	0.01	0.1
(6,0,1)	0.001, 0.0001, 0.00001	10	2	0.01	0.1
(6,0,2)	0.001, 0.0001, 0.00001	7	6	0.1	1
(6,0,3)	0.001, 0.0001, 0.00001	8	2	0.01	0.1
(6,1,0)	0.001, 0.0001, 0.00001	10	2	0.01	0.1
(6,1,1)	0.001, 0.0001, 0.00001	7	6	0.1	1
(6,1,2)	0.001, 0.0001, 0.00001	8	2	0.01	0.1
(6,1,3)	0.001, 0.0001, 0.00001	10	9	0.1	1
(6,2,0)	0.001, 0.0001, 0.00001	7	6	0.1	1

Appendix A: Tube Code Table for Validation and Verification					
Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(6,2,1)	0.001, 0.0001, 0.00001	8	2	0.01	0.1
(6,2,2)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(6,2,3)	0.001, 0.0001, 0.00001	10	3	0.01	0.1
(6,3,0)	0.001, 0.0001, 0.00001	8	2	0.01	0.1
(6,3,1)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(6,3,2)	0.001, 0.0001, 0.00001	10	3	0.01	0.1
(6,4,0)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(6,4,1)	0.001, 0.0001, 0.00001	10	3	0.01	0.1
(6,4,2)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(6,5,0)	0.001, 0.0001, 0.00001	10	3	0.01	0.1
(6,5,1)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(6,5,2)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(6,6,0)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(6,6,1)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(6,7,0)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(7,0,0)	0.001, 0.0001, 0.00001	5	0	0.001	0.01
(7,0,1)	0.001, 0.0001, 0.00001	8	7	0.1	1
(7,0,2)	0.001, 0.0001, 0.00001	10	9	0.1	1
(7,0,3)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(7,1,0)	0.001, 0.0001, 0.00001	8	7	0.1	1
(7,1,1)	0.001, 0.0001, 0.00001	10	9	0.1	1
(7,1,2)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(7,1,3)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(7,2,0)	0.001, 0.0001, 0.00001	10	9	0.1	1
(7,2,1)	0.001, 0.0001, 0.00001	10	3	0.01	0.1
(7,2,2)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(7,2,3)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(7,3,0)	0.001, 0.0001, 0.00001	10	3	0.01	0.1
(7,3,1)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(7,3,2)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(7,3,3)	0.001, 0.0001, 0.00001	5	2	0.01	0.1
(7,4,0)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(7,4,1)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(7,4,2)	0.001, 0.0001, 0.00001	5	2	0.01	0.1
(7,4,3)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(7,5,0)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(7,5,1)	0.001, 0.0001, 0.00001	5	2	0.01	0.1
(7,5,2)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(7,6,0)	0.001, 0.0001, 0.00001	5	2	0.01	0.1
(7,6,1)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(7,6,2)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(7,7,0)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(7,7,1)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(8,0,0)	0.001, 0.0001, 0.00001	9	8	0.1	1
(8,0,1)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(8,0,2)	0.001, 0.0001, 0.00001	6	2	0.01	0.1

Appendix A: Tube Code Table for Validation and Verification					
Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(8,0,3)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(8,1,0)	0.001, 0.0001, 0.00001	7	2	0.01	0.1
(8,1,1)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(8,1,2)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(8,1,3)	0.001, 0.0001, 0.00001	5	2	0.01	0.1
(8,2,0)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(8,2,1)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(8,2,2)	0.001, 0.0001, 0.00001	5	2	0.01	0.1
(8,2,3)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(8,3,0)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(8,3,1)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(8,3,2)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(8,3,3)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(8,4,0)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(8,4,1)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(8,4,2)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(8,4,3)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(8,5,0)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(8,5,1)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(8,5,2)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(8,5,3)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(8,6,0)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(8,6,1)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(8,6,2)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(8,7,0)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(8,7,1)	0.001, 0.0001, 0.00001	8	4	0.01	0.1
(8,7,2)	0.001, 0.0001, 0.00001	10	5	0.01	0.1
(8,8,0)	0.001, 0.0001, 0.00001	8	4	0.01	0.1
(8,8,1)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(9,0,0)	0.001, 0.0001, 0.00001	6	2	0.01	0.1
(9,0,1)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(9,0,2)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(9,0,3)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(9,1,0)	0.001, 0.0001, 0.00001	9	3	0.01	0.1
(9,1,1)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(9,1,2)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(9,1,3)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(9,1,4)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(9,2,0)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(9,2,1)	0.001, 0.0001, 0.00001	10	4	0.01	0.1
(9,2,2)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(9,2,3)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(9,2,4)	0.001, 0.0001, 0.00001	10	5	0.01	0.1
(9,3,0)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(9,3,1)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(9,3,2)	0.001, 0.0001, 0.00001	6	3	0.01	0.1

Appendix A: Tube Code Table for Validation and Verification

Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(9,3,3)	0.001, 0.0001, 0.00001	10	5	0.01	0.1
(9,3,4)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(9,4,0)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(9,4,1)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(9,4,2)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(9,4,3)	0.001, 0.0001, 0.00001	7	4	0.01	0.1
(9,4,4)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(9,5,0)	0.001, 0.0001, 0.00001	8	4	0.01	0.1
(9,5,1)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(9,5,2)	0.001, 0.0001, 0.00001	7	4	0.01	0.1
(9,5,3)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(9,5,4)	0.001, 0.0001, 0.00001	10	0	0.0001	0.001
(9,6,0)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(9,6,1)	0.001, 0.0001, 0.00001	9	5	0.01	0.1
(9,6,2)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(9,6,3)	0.001, 0.0001, 0.00001	10	0	0.0001	0.001
(9,7,0)	0.001, 0.0001, 0.00001	9	5	0.01	0.1
(9,7,1)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(9,7,2)	0.001, 0.0001, 0.00001	6	4	0.01	0.1
(9,7,3)	0.001, 0.0001, 0.00001	9	6	0.01	0.1
(9,8,0)	0.001, 0.0001, 0.00001	10	6	0.01	0.1
(9,8,1)	0.001, 0.0001, 0.00001	7	1	0.001	0.01
(9,8,2)	0.001, 0.0001, 0.00001	8	0	0.0001	0.001
(9,8,3)	0.001, 0.0001, 0.00001	10	7	0.01	0.1
(9,9,0)	0.001, 0.0001, 0.00001	9	0	0.0001	0.001
(9,9,1)	0.001, 0.0001, 0.00001	8	0	0.0001	0.001
(9,9,2)	0.001, 0.0001, 0.00001	7	0	0.0001	0.001
(10,0,0)	0.001, 0.0001, 0.00001	8	3	0.01	0.1
(10,0,1)	0.001, 0.0001, 0.00001	7	3	0.01	0.1
(10,0,2)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(10,0,3)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(10,1,0)	0.001, 0.0001, 0.00001	9	4	0.01	0.1
(10,1,1)	0.001, 0.0001, 0.00001	6	3	0.01	0.1
(10,1,2)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(10,1,3)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(10,1,4)	0.001, 0.0001, 0.00001	10	0	0.0001	0.001
(10,2,0)	0.001, 0.0001, 0.00001	8	4	0.01	0.1
(10,2,1)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(10,2,2)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(10,2,3)	0.001, 0.0001, 0.00001	6	4	0.01	0.1
(10,2,4)	0.001, 0.0001, 0.00001	8	0	0.0001	0.001
(10,3,0)	0.001, 0.0001, 0.00001	10	1	0.001	0.01
(10,3,1)	0.001, 0.0001, 0.00001	8	1	0.001	0.01
(10,3,2)	0.001, 0.0001, 0.00001	9	0	0.0001	0.001
(10,3,3)	0.001, 0.0001, 0.00001	7	5	0.01	0.1
(10,3,4)	0.001, 0.0001, 0.00001	5	4	0.01	0.1

Appendix A: Tube Code Table for Validation and Verification					
Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(10,3,5)	0.001, 0.0001, 0.00001	6	0	0.0001	0.001
(10,4,0)	0.001, 0.0001, 0.00001	10	6	0.01	0.1
(10,4,1)	0.001, 0.0001, 0.00001	9	0	0.0001	0.001
(10,4,2)	0.001, 0.0001, 0.00001	7	0	0.0001	0.001
(10,4,3)	0.001, 0.0001, 0.00001	5	4	0.01	0.1
(10,4,4)	0.001, 0.0001, 0.00001	6	5	0.01	0.1
(10,4,5)	0.01, 0.001, 0.0001	7	6	0.1	1
(10,5,0)	0.001, 0.0001, 0.00001	8	0	0.0001	0.001
(10,5,1)	0.001, 0.0001, 0.00001	7	0	0.0001	0.001
(10,5,2)	0.001, 0.0001, 0.00001	6	0	0.0001	0.001
(10,5,3)	0.01, 0.001, 0.0001	5	0	0.001	0.01
(10,5,4)	0.01, 0.001, 0.0001	8	7	0.1	1
(10,5,5)	0.01, 0.001, 0.0001	9	8	0.1	1
(10,5,6)	0.01, 0.001, 0.0001	7	2	0.01	0.1
(10,6,0)	0.001, 0.0001, 0.00001	5	4	0.01	0.1
(10,6,1)	0.01, 0.001, 0.0001	6	5	0.1	1
(10,6,2)	0.01, 0.001, 0.0001	7	6	0.1	1
(10,6,3)	0.01, 0.001, 0.0001	9	8	0.1	1
(10,6,4)	0.01, 0.001, 0.0001	7	2	0.01	0.1
(10,6,5)	0.01, 0.001, 0.0001	10	3	0.01	0.1
(10,6,6)	0.01, 0.001, 0.0001	6	2	0.01	0.1
(10,7,0)	0.01, 0.001, 0.0001	5	0	0.001	0.01
(10,7,1)	0.01, 0.001, 0.0001	8	2	0.01	0.1
(10,7,2)	0.01, 0.001, 0.0001	10	9	0.1	1
(10,7,3)	0.01, 0.001, 0.0001	10	3	0.01	0.1
(10,7,4)	0.01, 0.001, 0.0001	6	2	0.01	0.1
(10,7,5)	0.01, 0.001, 0.0001	9	3	0.01	0.1
(10,7,6)	0.01, 0.001, 0.0001	8	3	0.01	0.1
(10,7,7)	0.01, 0.001, 0.0001	10	4	0.01	0.1
(10,8,0)	0.01, 0.001, 0.0001	9	8	0.1	1
(10,8,1)	0.01, 0.001, 0.0001	10	3	0.01	0.1
(10,8,2)	0.01, 0.001, 0.0001	6	2	0.01	0.1
(10,8,3)	0.01, 0.001, 0.0001	5	2	0.01	0.1
(10,8,4)	0.01, 0.001, 0.0001	8	3	0.01	0.1
(10,8,5)	0.01, 0.001, 0.0001	10	4	0.01	0.1
(10,8,6)	0.01, 0.001, 0.0001	9	4	0.01	0.1
(10,8,7)	0.01, 0.001, 0.0001	6	3	0.01	0.1
(10,8,8)	0.01, 0.001, 0.0001	8	4	0.01	0.1
(10,9,0)	0.01, 0.001, 0.0001	6	2	0.01	0.1
(10,9,1)	0.01, 0.001, 0.0001	5	2	0.01	0.1
(10,9,2)	0.01, 0.001, 0.0001	8	3	0.01	0.1
(10,9,3)	0.01, 0.001, 0.0001	7	3	0.01	0.1
(10,9,4)	0.01, 0.001, 0.0001	6	3	0.01	0.1
(10,9,5)	0.01, 0.001, 0.0001	8	4	0.01	0.1
(10,9,6)	0.01, 0.001, 0.0001	10	1	0.001	0.01
(10,9,7)	0.01, 0.001, 0.0001	8	1	0.001	0.01

Appendix A: Tube Code Table for Validation and Verification

Initial Pre-Process *V.p. Density* Measurement		Post-Process *V.p.* Density Measurement			
Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Before: 10 tubes, 3 dilutions		After: 1 dilution; Total tubes	Allowed Positive (turbid) Tubes	2 log reduction	3 log reduction
Tube Codes	Homogenate Mass			Homogenate Mass	Homogenate Mass
(10,9,8)	0.01, 0.001, 0.0001	10	0	0.0001	0.001
(10,9,9)	0.01, 0.001, 0.0001	8	0	0.0001	0.001
(10,10,0)	0.01, 0.001, 0.0001	10	4	0.01	0.1
(10,10,1)	0.01, 0.001, 0.0001	9	4	0.01	0.1
(10,10,2)	0.01, 0.001, 0.0001	8	4	0.01	0.1
(10,10,3)	0.01, 0.001, 0.0001	9	5	0.01	0.1
(10,10,4)	0.01, 0.001, 0.0001	6	4	0.01	0.1
(10,10,5)	0.01, 0.001, 0.0001	7	0	0.0001	0.001
(10,10,6)	0.10, 0.01, 0.001	10	2	0.01	0.1
(10,10,7)	0.10, 0.01, 0.001	8	2	0.01	0.1
(10,10,8)	0.10, 0.01, 0.001	10	3	0.01	0.1
(10,10,9)	0.10, 0.01, 0.001	8	3	0.01	0.1