

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:

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

$$\text{production}$$

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

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

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

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

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

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

- (ii) Educational approaches will emphasize partnerships with health and advocacy organizations, and include dissemination of printed materials, posting materials on the Internet, broadcast of television spots, press releases, and other measures

deemed effective such as the USDA Physician Notification Program.

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

- (b) Administration of a survey to determine the current *Vibrio vulnificus* disease reporting and education in each state;
- (c) Creation of a shellfish-borne *Vibrio vulnificus* disease investigation team that will be available to assist in collection of epidemiological information associated with confirmed shellfish-borne *Vibrio vulnificus* septicemia illness. This team will assist in gathering customary epidemiological information as well as the level of awareness of risk in those who have suffered etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses. A small ISSC team with recognized epidemiological officers will assist in rapid investigation of any case. This team will work cooperatively with existing local, state and federal disease investigation programs.
- (d) Industry-implemented post-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock which may include: time-temperature, post harvest treatment (i.e. hydrostatic pressure, cool pasteurization, IQF, and irradiation--pending approval), rapid chilling and other emerging technologies.
- (e) To encourage implementation of post harvest controls the Conference will pursue options such as SBA low interest loans; revolving loans; cost sharing; demonstration projects; state-industry partnerships; FDA label incentives; PHT specific growing area classifications; targeted time/temperature assessment by FDA during annual shellfish program evaluations; assistance, as necessary, for the further study and possible implementation of dockside icing to investigate its effects on shelf life and variations in the effectiveness of the method as a result of seasonal and regional differences and incentives to add refrigeration capacity to harvest vessels. The goal will be to provide incentives necessary to post-harvest treat 20 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a source state by the end of the third year (December 31, 2003). The assessment will include the capacity of all operational plants and the capacity of plants under construction. Should the 20 percent goal not be accomplished, the VMC will pursue additional incentives to achieve the goals.
- (f) A VMC compilation and review of the data on rates of illness will be made available to the ISSC at the ISSC Biennial meeting following the year in which the data was gathered. In the event that the data is not available at the time of the meeting, the VMC shall meet and review the data when it becomes available and issue a compilation report, which will be made available to the entire ISSC

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

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

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

COST INFORMATION: Unknown.

In addition the Committee recommended:

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

**Action by 2000
Task Force II**

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

TEXT OF PROPOSAL:

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

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

- (A) For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement a *Vibrio vulnificus* risk management plan.
- (B) The plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction program. **The Plan shall include, at a minimum, the ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses.** The goal of the *Vibrio* Risk Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses, reported in core states, ~~which may include (Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama) to be determined by the VMC after a thorough review of statistical and epidemiological information~~ from the consumption of commercially harvested raw or undercooked oysters by 40 percent, collectively, by the end of 2005 and by 60 percent, collectively, by the end of 2007. **The core states include Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama. The list of core states may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate.** The rate of illness shall be calculated as the number of illnesses adjusted for population and rate of reporting divided by the production of oysters from the states bordering the Gulf of Mexico, based on National Marine Fisheries Service landing data verified by Silver Spring, Maryland, headquarters. The goal may be reevaluated prior to the year 2005 and adjusted in the event that new science, data or information becomes available.
- (C) The plan shall also include identification and preparation for implementation of one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent ~~illness~~ **rate of illness** reduction goal not be achieved by 2007. This portion of the plan shall be completed no later than December 2006. The temperature and month-of-the-year parameters identified in the following controls may be adjusted as needed to achieve the established illness reduction goal.
- (1) Labeling all oysters, “For shucking by a certified dealer,” when the Average Monthly Maximum Water Temperature exceeds 75°F;
 - (2) Subjecting all oysters **intended for the raw, half-shell market** to an Authority-approved post-harvest treatment that reduces the *Vibrio vulnificus* levels to 3MPN/g or less,” when the Average Monthly Maximum Water Temperature exceeds 75°F;
 - (3) Closing shellfish growing areas **for the purpose of harvest of oysters intended for the raw, half-shell market** when the Average Monthly Maximum Water Temperature exceeds 75°F;
 - (4) Labeling all oysters, “For shucking by a certified dealer,” during the months of May through September, inclusive;
 - (5) Subjecting all oysters **intended for the raw, half-shell market** to a post-harvest treatment that is both approved by the Authority and reduces the *Vibrio vulnificus* levels to 3MPN/g or less during the months of May through September, inclusive;

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

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

***Vibrio vulnificus* Management Guidance Document**

***Vibrio vulnificus* Management**

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

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

$$\text{production}$$

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 2006 (average) and by 60 percent for years 2007 and collectively, by the end of 2008 (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 2006 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 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.
- (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 2005~~6~~ and by 60 percent by the end of 2007~~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 2004~~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, 2000~~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~~ 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, 2003~~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, 20056). 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 20067 - 20078 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 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;**
 - (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 .04e(C), the V.v. Subcommittee will be requested to provide guidance.

The *Vibrio vulnificus* Subcommittee further recommended the following:

- 1) **Request the Executive Board request FDA to meet with the Irradiation petition submitter to establish a timetable under which FDA will review the petition.**
- 2) **Request the Executive Board request FDA and the state of California seek additional funding to increase the education of at-risk consumers in California, particularly in southern California.**
- 3) **Recommended that the Chairman appoint a committee to develop further guidance language for implementation of .04 (C) (1)-(5).**
- 4) **Recommended adoption of an effective date of October 1, 2001, and further recommended an expedited review by FDA.**

**Action by 2001
Vibrio
Management
Committee**

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

**Action by 2001
Task Force II**

Recommended adoption of 2001 *Vibrio* Management Committee Report recommendations.

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

**Action by 2001
General Assembly**

Adopted recommendation of 2001 Task Force II.

Action by USFDA

Concurred with Conference action.

This issue was referred back to the ISSC *Vibrio vulnificus* Subcommittee following its marginal defeat at the 2000 ISSC. While FDA was disappointed that the 2000 Conference voted to refer Issue 00-201 back to committee, we believe the dedicated efforts of the *Vibrio vulnificus* Subcommittee over the ensuing year resulted in ISSC adoption of a stronger and more workable plan to reduce *Vibrio vulnificus* illnesses associated with raw shellfish consumption. Issue 00-201 was designed to reduce *Vibrio vulnificus* septicemia illnesses through post harvest treatment (PHT) processing, consumer education, and, if necessary, mandatory harvesting and/or processing controls. FDA looks forward to working with states as they develop and implement *Vibrio vulnificus* management plans. We also look forward to our continued participation on the ISSC *Vibrio* Management Committee (VMC), *Vibrio vulnificus* Subcommittee, and *Vibrio vulnificus* Education Subcommittee to implement measures (including data collection, data analysis, and development of annual work plans by the VMC) set forth in the “*Vibrio vulnificus* Management Guidance Document” which was adopted as part of Issue 00-201.

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

**Action by 2003
Vibrio vulnificus
Subcommittee** Recommended that the baseline illness reduction rate of 1995 – 99 of 0.306 per million be modified in Chapter II @ 04 B to 0.303 per million to reflect the elimination of 1 case from the database.

**Action by 2003
Vibrio
Management
Committee** Recommended adoption of Vv Subcommittee recommendation on Proposal 00-201.

**Action By 2003
Task Force II** Recommended adoption of *Vibrio* Management Committee recommendation on Proposal 00-201.

**Action By 2003
General Assembly** Adopted recommendations of 2003 Task Force II.

**Action By
USFDA** Concurred with Conference Action.

**Action by 2005
Vv Subcommittee** Recommended the *Vibrio* Management Committee communicate to the Executive Board that the Conference has made significant progress toward achieving the 40% illness reduction goal as reflected in the 2004 rates compared to the baseline in the core states. Additionally, FDA has found all states required to implement Vv Management Plan are in compliance with the Model Ordinance. It should be noted that this is not an indication for a reduction in current efforts.

**Action by 2005
Vibrio
Management
Committee** Recommended adoption of the Vv Subcommittee recommendation on Proposal 00-201. Additionally, the VMC adopted the following motion:

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

**Action by 2005
Task Force II** Recommended adoption of the *Vibrio* Management Committee recommendations on Proposal 00-201.

**Action by 2005
General Assembly** Adopted recommendation of 2005 Task Force II.

**Action by
USFDA** With reservation, FDA concurs with action taken on Proposal 00-201. Although FDA recognizes that a 47% reduction in *Vibrio vulnificus* (Vv) illnesses has been achieved in the Core reporting states, the Agency believes that this reduction is primarily the result of California’s ban on non-post harvest processed Gulf oysters. At the 2005 Conference FDA proposed that California be removed from the list of Core states and that one or more additional states with consistent Vv illness reporting records be substituted. The Vv

Subcommittee did not concur with FDA’s recommendation and retained California as a Core state for measuring the success of the Vv Action Plan. FDA maintains the position that California should be removed as a Core reporting state and that illness reduction rates that include California provide a false indication of success relative to the Vv Action Plan illness reduction goals. FDA requests that the ISSC Executive Board direct the *Vibrio* Management Committee (VMC), during its March meeting, to reconsider the decision of the Vv Subcommittee to retain California as a Core reporting state.

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

Action by 2007 Task Force II Recommended adoption of the *Vibrio* Management Committee recommendation on Proposal 00-201.

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

Action by USFDA December 20, 2007

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

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

- 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 Proposal 00-201.

**Action by 2009
Task Force II
(continued)**

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.

**Action by 2011
Task Force II**

Recommended no action on Proposal 00-201.

Rationale: This proposal is addressed in Proposal 11-201-A.

**Action by 2011
General Assembly**

Adopted recommendation of 2011 Task Force II on Proposal 00-201.

**Action by FDA
February 26, 2012**

Concurred with Conference action on Proposal 00-201.