Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	*Vibrio vulnificus* Risk Management of Oysters
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Article IV. Section II Model Ordinance, Chapter II Risk Assessment and Risk Management @.01 Outbreaks of Shellfish Related Illnesses @.04 *Vibrio vulnificus* Risk Management for Oysters Section IV. Guidance Documents, Chapter IV. Naturally Occurring Pathogens
Text of Proposal/ Requested Action	**Article IV. Executive Board, Officers, Committees** **Section 10**. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairman. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference: Education, Foreign Relations, Proposal Review, Patrol, Research Guidance, Resolutions, ~~and~~ Shellfish Restoration, and *Vibrio* Management Committee. The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Biennial Meeting. **Section 14.** The Executive Board Chairperson shall appoint a sixteen (16) member *Vibrio* Management Committee. The Committee will be comprised of a Chairperson with at least two (2) industry members from the East, Gulf and West coasts and at least one (1) state regulatory from each of the ISSC regions. The Committee will also include one voting member from NOAA, one voting member from FDA, one voting member from EPA and one voting member from CDC. The Federal entities will appoint these members. Non-voting advisors will be appointed as appropriate. The Committee will assess if additional changes are needed in the NSSP Guide for the Control of Molluscan Shellfish Model Ordinance to reduce the risk of *Vibrio* illnesses. The Committee will annually review trends in *Vibrio* illnesses. **Chapter II Risk Assessment and Risk Management** @.01 Outbreaks of Shellfish Related Illnesses ~~J. The Authority shall assess annually Vibrio parahaemolyticus illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all V. parahaemolyticus shellfish-associated illnesses reported within the state and from receiving states, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses.~~

@.02 Annual Assessment of *Vibrio vulnificus* and *Vibrio parahaemolyticus* Illnesses.

The Authority shall assess annually *Vibrio vulnificus* and Vibrio parahaemolyticus illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all *Vibrio vulnificus* and Vibrio 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.

@. 032 Presence of Human Pathogens in Shellfish Meats.

@.043 Presence of Toxic Substances in Shellfish Meats.

~~.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 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, and 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 0.303/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. State's compliance with the Plan will require States to maintain a minimum of 60% reduction in years subsequent to 2008. Determination and compliance after 2008 will be based on two-year averages beginning in 2009.~~

~~C. The Source State's 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 processing 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 processing 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 processing 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 processing 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 processing, 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 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 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; 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.

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)~~(1) 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 vulnificus Control Plan

A. Risk Evaluation

Each shellfish producing State that is not currently implementing a *Vibrio vulnificus* control plan shall conduct a *Vibrio vulnificus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining the risk of *Vibrio vulnific*us infection from the consumption of shellfish harvested from the State's growing waters.

(1) In conducting the risk evaluation the State Authority will at a minimum consider the following:

(a) The number of *Vibrio vulnificus* cases etiologically confirmed and epidemiologically linked to the consumption of commercially harvested shellfish from the State; and

(b) Levels of *Vibrio vulnificus* in the growing waters and in shellfish, to the extent that such data exists; and

(c) The quantity of harvest from the area and its uses i.e. shucking, half shell, PHP.

B. States which have previously met the illness threshold requiring a *Vibrio vulnificus* Control Plan will continue to maintain and implement a *Vibrio vulnificus* Control Plan.

C. All States not currently implementing a *Vibrio vulnificus* Control Plan shall develop and implement a *Vibrio vulnificus* Control Plan should the risk evaluation indicate two (2) or more etiologically confirmed, and epidemiologically linked *Vibrio vulnificus* septicemia illnesses from the consumption of commercially harvested raw or undercooked oysters that originated from the growing waters of that state within the previous ten (10) years

D. The State shall develop a *Vibrio vulnificus* Contingency Plan should the risk evaluation indicate:

(1) Any etiologically confirmed shellfish-borne *Vibrio vulnificus* illness from the growing waters of that State but the number of cases does not reach the threshold established in @.04 C; and
(2) Information on Levels of *Vibrio vulnificus*, if available in the growing waters or in shellfish that is reasonably likely to cause an illness;

E. Control Plan

(1) The *Vibrio vulnificus* Control Plan shall include the following:
(a) Identification of triggers which address factors that affect risks. The triggers will be used to indicate when control measures are needed. One or more of the following triggers will be used:
(i) The water temperatures in the area; and
(ii The air temperatures in the area; and
(iii) Salinity in the area; and
(iv) Harvesting techniques in the area; and
(v) Other factors which affect risk which can be used as a basis for reducing risk.
(b) Implementation of one or more of the following control measures to reduce the risk of *Vibrio vulnificus* illness:
(i) Labeling oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water Temperature exceeds 70~~5~~°F.
(ii) Subjecting all oysters intended for the raw, half-shell market to Authority approved post harvest processing when the Average Monthly Maximum Water Temperature exceeds 70~~5~~°F.
(iii) ~~Labeling oysters, "For shucking by a certified dealer", during the months of April through November, inclusive.~~
~~(iv) Subjecting oysters intended for the raw, half-shell market to Authority approved post harvest processing during the months of April through November, inclusive.~~
(iiiv) Reducing time of exposure to ambient air temperature prior to delivery to the initial certified dealer based on modeling or sampling, as determined by the Authority in consultation with FDA. For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. When this control measure is selected, State *Vv* plans will include controls when water temperature promotes *Vv* levels and risk of illness increases. The controls will minimize risk to less than three (3) illnesses per 100,000 servings when water temperature exceeds 80°F. Authority approved Best Management Practices (BMPs) will be applied to minimize *Vv* growth to the extent possible when water temperature exceeds 70°F but is less than 80°F. BMPs will ensure that when the water temperature exceeds 70°F but is less than 75°F risk is minimized to less than 1.75 illnesses per 100,000 servings and when water temperatures exceed 75°F but are less than 80°F the risk will not exceed 2.5 illnesses per 100,000 servings. These risks per serving will be determined using the FDA developed *Vibrio vulnificus* calculator.
(ivvi) The State Authority may implement other comparable to that will reduce the risk per servings alternative controls that will reduce the risk to a level comparable to the risk per serving identified above in @.05 E. (1) (b) (iii) when water temperatures exceed 70°F.

(2) Control Plan Evaluation
(a) In consultation with FDA the Authority will evaluate the implementation and effectiveness of their Control Plan.

(i) Changes in the annual number of *Vibrio vulnificus* cases associated with the State's growing waters.
(ii) Environmental changes which could affect total *Vibrio vulnificus* in shellfish pre and post-harvest.
(iii) Industry compliance with existing controls.
(iv) The Authorities enforcement of industries implementation of the controls.
(b) The Control Plan shall be modified when the evaluation shows the Plan is ineffective, or when new information or more effective technology is available as determined by the Authority.

F. Contingency Plan
(1) The Contingency Plan shall include a detailed plan outlining the regulatory steps that will be implemented should the number of illnesses reach the threshold established for development and implementation of a *Vv* Control Plan.
(2) Contingency Plan Evaluation
In consultation with FDA the Authority will evaluate the adequacy of their Contingency Plan.

@.06~~5~~ *Vibrio parahaemolyticus* Control Plan

Guidance Documents, Chapter IV. Naturally Occurring Pathogens

~~.01 *Vibrio* Risk Management for Oysters Background~~
~~Current information concerning *Vibrio vulnificus*, which is responsible for several shellfish associated illnesses and deaths each year can be found in Watkins and McCarthy (1994).~~
~~A small number of shellfish borne illnesses have also been associated with bacteria of the genus *Vibrio* (Bonner, 1983; Blake *et al.*,1979; Morris, 1985; Joseph *et al.*,1982; Roderick, 1982). The *Vibrios* are free-living aquatic microorganisms, generally inhabiting marine and estuarine waters (Joseph *et al*, 1982: Spira, 1984; Colwell 1984; Bachman, 1983). Among the marine *Vibrios* classified as pathogenic are strains of non-01 *Vibrio cholerae*, *V. parahaemolyticus*, and *V. vulnificus* (Bachman, 1983; Desmarchelier, 1984; Blake, 1980). All three species have been recovered from coastal waters in the United States and other parts of the world (Joseph, 1982; Colwell, 1984; Blake, 1980; DePoala, 1981; Madden, 1982; Davey, 1982; Oliver, 1983; Tamplin, 1982; NIH, 1984). These and other *Vibrios* have been detected in some environmental samples recovered from areas free of overt sewage contamination and coliform (Bonner, 1983; Joseph, 1982; Spira, 1984).~~

~~In general, shellfish borne vibrio infections have tended to occur in coastal areas in the summer and fall when the water was warmer and vibrio counts were higher (Bonner, 1983; Morris, 1985; Joseph, 1982). *V. parahaemolyticus* and non-01 *V. cholerae* are commonly reported as causing diarrhea illness associated with the consumption of seafood including shellfish (Bonner, 1983; Blake, 1979; Morris, 1985; Joseph, 1982; Baross and Liston, 1970; Morris, 1981). In contrast, *V. vulnificus* has been related to two distinct syndromes: wound infections, often with tissue necrosis and bacteria, and primary septicemia characterized by fulminant illness in individuals with severe chronic illnesses such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy (Bonner *et al.*, 1983; Tacket, 1984). Increasing evidence shows that individuals with such chronic diseases are susceptible to septicemia and death from raw seafood, especially raw oysters (Bonner *et al.*, 1983; Blake, 1979; Morris, 1985; Rodrick, 1982; Bachman, 1983; Blake, 1980; Oliver, 1983; NIH, 1984; Tacket, 1984; Oliver 1982; FDA, 1985). Shellfish borne vibrio infections can be prevented by cooking seafood thoroughly, keeping them from cross contamination~~

~~after cooking, and eating them promptly or storing them at hot (60°C or higher) or cold (4°C or lower) temperatures. If oysters and other seafood are to be eaten raw, consumers are probably at lower risk to vibrio infection during months when seawater is cold than when it is warm (Blake, 1983 and 1984).~~

~~.02 *Vibrio vulnificus* Management Plan~~

~~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 reviewed 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, 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 *Vv* 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 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 to 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) The Voting Delegates at the 2007 Biennial Meeting in Albuquerque, New Mexico approved appointment of a committee that will consist of three (3) epidemiologists and advisors as appropriate. The Committee will use this form to screen cases for the purposes of determining if a case is attributable to a single source state as well as whether the case is includable in the Vv Illness Reduction Goals. In addition, to ensure uniformity, the form shall be used for screening 2007-2008 cases and that cases from the baseline will be screened using the same form.

Criteria FOR INCLUDING *Vv* CASES IN ILLNESS REDUCTION CALCULATIONS and determining source states

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

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

Vibrio vulnificus Criteria Table

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

Instructions for completing Criteria Table:

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

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

(e) 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.

(f) 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 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 25 percent goal not be accomplished, the VMC will investigate and report their findings as to why the goal was not reached.~~

~~(g) 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.~~

~~(h) Provision for 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.~~

~~(i) 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.~~

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

~~(k) In 2006 the Executive Board directed the elimination of the Vv & Vp subcommittees. The VMC assumed all responsibilities of the subcommittees as outlined in the Vibrio vulnificus Management Guidance Document. Representation on the VMC Committee will be consistent with all guidance (VMC and Vv subcommittee) outlined in the Vibrio vulnificus Management Guidance Document.~~

~~(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.~~

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Public Health Significance	The level of *V.v.* in oysters at the time of harvest can cause illness in immuno compromised individuals with increased susceptibility. This risk ranges from approximately .06 to 3.33 illnesses per 100,000 servings depending upon water temperature. The controls presently required by State *Vibrio vulnificus* Control Plans, if properly implemented, can reduce growth and reduce *Vibrio vulnificus* levels after harvest. Changes will provide additional options for managing the risks associated with *Vv.* These options will not require Post-Harvest Processing (PHP) controls which are presently not economically feasible. The RTI Economic Study suggested that it would take 2 to 3 years to implement PHP and, even with that time for implementation, would create a significant economic burden. 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	
Action by 2011 Task Force II	Recommended adoption of *Vibrio* Management Committee Substitute Proposal 11-201-A as amended. Additionally, Task Force II recommended: That a committee be established to consider options for water temperature determinations which can be used in the implementation of Proposal 11-201-A. That a Committee be established to develop criteria for verifying reduction in harvest for raw consumption and the percentage of post-harvest processed product on a monthly basis for those States required to have a *Vibrio vulnificus* Control Plan. An implementation date of January 1, 2012 for Proposal 11-201-A.

	Recommended referral of Proposal 11-201-B to an appropriate committee with representation from all regions to develop Model Ordinance language changes to support the time temperature requirements of the State's *Vibrio* Management Plans. This committee will be appointed and approved by the Executive Board at its closing Board meeting. The committee will be expected to meet within two (2) weeks of the close of the Conference. After its initial meeting, the committee shall meet by teleconference biweekly prior to an Executive Board meeting until the proposal is completed and at least once subsequent to the dissemination of the proposal and prior to an Executive Board meeting. The draft proposal that is to be considered by the Executive Board shall be disseminated to the ISSC membership a minimum of three (3) weeks prior to the next Executive Board meeting and posted on the ISSC web site. The Committee is directed to make recommendations to the Executive Board for interim approval with an effective date prior to the 2012 *Vibrio* season. The State's Authorities are requested to begin advising and educating their industries of these changes. Additionally, the committee will develop guidance for implementation of these controls.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force II on Proposal 11-201 Part A. Adopted recommendation of 2011 Task Force II on Proposal 11-201 Part B.
Action by USFDA February 26, 2012	FDA concurred with Conference action on Proposal 11-201 Part B but did not concur with Conference action on Proposal 11-201 Part A. FDA comments and recommendations in response to Proposal 11-201 Part A: In October of 2009, the Food and Drug Administration (FDA) informed the Interstate Shellfish Sanitation Conference (ISSC) of its intention to reformulate the Agency's policy regarding implementation of the Seafood HACCP Regulation with the intent that post-harvest processing (PHP) or equivalent measures be implemented for the control of *Vibrio vulnificus (V.v.).* The new policy would require that oysters harvested from the Gulf of Mexico and intended for the raw half shell market be post-harvest processed during those months when illness from *V.v.* is reasonably likely to occur. Given that PHP can largely eliminate *V.v.* while preserving the sensory qualities of raw untreated product FDA remains committed to this approach as the most prudent means of reducing the risk of illness from *Vv.* The efficacy of PHP is evidenced by the fact that since 2003, when the State of California banned the sale of untreated Gulf oysters harvested between April and October, there has been only one *V.v.* illness in the State. Prior to 2003 California reported on average six *V.v.* related illnesses per year. In November 2009, having heard from elected State and Federal representatives, the oyster industry and State regulatory officials regarding the feasibility of implementing PHP or other equivalent controls, FDA acknowledged the need to further examine the process and timing of industry adoption of PHP technology and placed in abeyance the Agency's intent to change its policy for controlling *V.v.* while taking steps to complete an independent study to assess how PHP controls can be implemented. In the interim, FDA has expressed its intention to continue working cooperatively with the ISSC to implement alternate controls which would reduce illnesses and meet the goals adopted by the ISSC in Proposal 00-201. Since adoption of Proposal 00-201 FDA has repeatedly expressed concerns relative to its implementation by the ISSC, including failure to consider national illness numbers and the lack of success in achieving the 60% illness rate reduction goal. FDA reiterated its concerns during ISSC deliberation of Proposal 11-201 at the October 2011 biennial meeting and those concerns were not adequately addressed by Conference action on Proposal 11-201. It

	is the position of FDA that Proposa111-201 deviates from current FDA policy in that it weakens the control measures adopted by the ISSC in Proposal 00-201. Therefore, FDA cannot concur with Proposal11-201 without further Conference action. FDA requests that the ISSC address the following issues and concerns. ISSC adoption of Proposal 00-201 in 2001 established a 60% illness rate reduction goal. Although FDA no longer considers this the most appropriate goal given the efficacy of PHP, FDA has continued to recognize and support ISSC efforts to achieve this level of illness reduction. However, the level of reduction reported by the ISSC *Vibrio* Management Committee (VMC) indicates only marginal success in moving toward that goal. Proposal 00-201 included specific control measures to be taken by the *V.v.* Source States if the 60% goal was not met. Those measures, intended for all oysters harvested during periods of risk included; closing shellfish growing areas to harvest, labeling oysters for shucking by a certified dealer, and subjecting oysters to PHP. Although the 60% illness rate reduction goal has not been achieved, none of these control measures have been implemented. Disagreement by States and the ISSC to pursue these more effective control measures has been a significant concern to FDA. That concern is further exacerbated by the fact that Source States, with ISSC support, have now adopted a policy that focuses control efforts toward more stringent time to temperature controls, for which compliance by industry is proving difficult. Section @.05 E. (1) (b) (iii) ofProposal11-201 establishes risk per serving standards for States using time/temperature controls and Section @.05 E. (1) (b) (iv) allows for alternative controls that achieve those same risk per servings standards. The risk per serving standards in Proposal11-201 are based on controls that were derived from the FDA developed *V.v.* calculator. These controls have not yet been demonstrated to achieve a 60% illness rate reduction. The FDA maintains that until these risk per serving standards are demonstrated to achieve the intended 60% illness rate reduction, evaluation of their effectiveness is imperative. Guidance needs to be developed for how to evaluate State programs to determine if risk per serving standards are being achieved. Section @.05 E. (2) (a) ofProposal11-201 States that the State Authority in conjunction with FDA will evaluate the implementation and effectiveness of these controls. As written, FDA would consider a State to be in non-compliance when there is ineffective implementation due to industry noncompliance or when the controls are determined ineffective in achieving the risk per serving standards. FDA would expect a State to discontinue the use of the time/temperature control measures and implement other control options outlined in @.05 E. (1) (b) should the State evaluation indicate that the State is not meeting the risk per serving standards. Proposal 11-201, based on temperature modeling using the *V.v.* calculator, establishes risk per serving standards that are intended to achieve a 60% illness rate reduction. Determining the ability of the ISSC control strategy, based on implementing risk per serving standards, will focus on the number of nationally reported illnesses associated with oysters from the Source States. FDA expects that if the risk per serving standards established in Proposal 11-201 prove to be effective, the number of nationally reported *V.v.* illnesses associated with Gulf oysters will be reduced by 60%. The Source States have generically incorporated as part of their risk reduction measurement a 10% reduction in harvest attributed to stricter time/ temperature controls and a 15% reduction attributed to product diversion to PHP. Actual percentages are certain to vary from State to State and year to year, making it necessary that each State provide data supporting the use of these assumptions.

	FDA is concerned that efforts to assess the effectiveness of time/temperature controls in achieving risk per serving standards will be difficult. Given the small number of illnesses associated with oysters from an individual State, annual fluctuation of those numbers, and fluctuations in oyster production from year to year, calculating achievement of risk per serving numbers using national illness data and oyster production data from each *V.v.* Source State will be challenging. Beginning with the April2012 *V.v.* season, FDA will be evaluating State *V.v.* Control Plans, industry compliance, and State enforcement. While FDA is developing guidance regarding what Shellfish Specialists should consider when conducting *V.v.* evaluations, presently neither FDA nor the ISSC has developed specific criteria for determining compliance with State *V.v.* plan goals. FDA requests that an ISSC committee be appointed to work with FDA to develop State evaluation criteria. FDA requests development of: Evaluation criteria for determining proper and effective use of the *V.v.* calculator; Evaluation criteria for determining State *V.v.* control plan compliance with NSSP requirements; Evaluation criteria for determining the effectiveness of State regulatory efforts to ensure industry compliance with State *V.v.* Control Plan requirements; A formula for calculating State compliance with risk per serving standards; and Actions and sanctions should a State be found out of compliance. In this regard FDA envisions that the established ISSC noncompliance process would be followed, which could result in advising receiving States of issues of noncompliance and recommending that shipments of oysters intended for raw consumption from non-compliant States not be accepted. FDA remains committed to addressing *V.v.* illnesses associated with consumption of raw Gulf oysters. As stated, FDA considers these illnesses to be preventable utilizing PHP technology. FDA will continue to support ISSC efforts to better control the risk of *V.v.* until the obstacles associated with full implementation of PHP are addressed. In the interim, however, FDA cannot support Conference action to change existing *V.v.* control requirements in such a way that they are less likely to achieve the existing 60% illness rate reduction goal. As adopted, FDA considers Proposal 11-201 a less effective approach to preventing *V.v.* illnesses.
Action by USFDA October 10, 2012	Food and Drug Administration concurred with adoption of the Conference's Proposal 11-201Part A to initiate a new plan to reduce illnesses and deaths resulting from *Vibrio vulnificus* in raw oysters and looks forward to cooperating with ISSC members to put the plan in effect.
Action by 2013 Vibrio Management Committee	Recommended adoption of the following Vibrio Management Committee (VMC) recommendations: 1. Develop a database to input the *V.v.* Illness Review Committee information. 2. Develop criteria for verifying reduction in harvest for raw consumption and the percentage of post-harvest processed product. Executive Office has had very little success in identifying approaches for obtaining this kind of information and the VMC had no suggestions on how to achieve this either.
Action by 2013 Task Force II	Recommended adoption of VMC recommendation No. 1 to develop a database to input the *V.v.* Illness Review Committee information. Recommended no action on recommendation No. 2 to develop criteria for verifying

	reduction in harvest for raw consumption and the percentage and refer to ISSC Executive Office. Rationale: The Executive Office has had very little success in identifying approaches for obtaining this kind of information and the VMC had no suggestions on how to achieve this.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 11-201 Part A.
Action by USFDA May 5, 2014	Concurred with Conference action on Proposal 11-201 Part A.