# FINAL REPORT

September 30, 2005

Grant Number 89-01-37400/0

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#### I. TITLE

Final Report – Facilitation of State Vv Activities

Ken B. Moore, Executive Director

**Interstate Shellfish Sanitation Conference** 

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#### II. **ABSTRACT**

Vibrio vulnificus is a marine bacterium which is found throughout the marine environment within U. S. coastal waters. It is also found in brackish water environments. The bacteria are highly motile, free-living, gram negative, curved, rod-shaped, autochthonous inhabitants of the waters from which molluscan shellfish are harvested. Vibrio vulnificus is a halophilic, non-cholera, marine vibrio which is most frequently isolated from marine environments with a temperature greater than 20°C (68°F) and a salinity of 7 ppt to 16 ppt and is only rarely found in environments cooler than 17°C (62.6°F). Oysters harvested from waters which exhibit these salinity and temperature regimes have the potential to cause Vibrio vulnificus infections. The unique characteristics of Vibrio vulnificus associated with human illnesses are: (1) Vibrio vulnificus is not a contaminant. It is a naturally occurring bacterium. (2) Vibrio vulnificus does not cause illness in the general population. It only affects persons with compromised immune systems. (3) The infectious dose of Vibrio vulnificus is unknown. (4) The incidence rate is very low even within the population which is at-risk (341 cases 1989-2002.) (5) The mortality rate is very high (179 deaths 1989 – 2002).

The ISSC began discussion of the human health effects of Vibrio vulnificus in the early 90s. Recognizing the severity of the illnesses associated with Vv, the Conference recommended several non-regulatory approaches for reducing illnesses. These efforts did not achieve the desired level of reduction and in 1997 time temperature controls were adopted as a regulatory measure to reduce illnesses. To further promote illness reduction, the ISSC in 2001 adopted a Vv Risk Management Plan that incorporated several strategies for significantly reducing Vv illnesses.

The ISSC entered into a contractual agreement with the Gulf and South Atlantic Fisheries Foundation (GSAFF) on October 1, 2004, to facilitate state efforts to achieve the illness reduction goals of the ISSC *Vv* Risk Management Plan.

#### III. EXECUTIVE SUMMARY

The ISSC and the GSAFF entered into a contractual agreement on October 1, 2004. The contractual agreement provided funding to support ISSC to assist states in achieving the goals of the *Vibrio vulnificus* Risk Management Plan. The stated goals of the Plan are as follows:

• 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.

Grant 89-01-37400/0 provided the funding for ISSC efforts to facilitate state Vv education efforts.

The ISSC facilitation efforts focused on the primary components of the ISSC Risk Management Plan adopted in 2001. These components are as follows:

- 1. *Vv* Education
- 2. Post-Harvest Processing Promotion
- 3. Additional Control Strategies.

The funded activities are outlined later in the report. Although not funded by Grant 89-01-37400/0, the efforts of the ISSC and states can be evaluated by comparison of raw oyster consumer surveys conducted in 2002 and in 2004 by ISSC funded grantees.

#### IV. PURPOSE

The purpose of Grant 89-01-37400/0 is to support ISSC in their efforts to assist states in accomplishing the goals of the *Vibrio vulnificus* Risk Management Plan. The major goal is to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses from the consumption of commercially harvested raw or undercooked oysters by 40 percent as reported by core reporting states collectively, for years 2005 and 2006 (average), and by 60 percent for years 2007 and 2008 (average), from the current rate of 0.306/million. The core reporting states include

Florida, Texas, California, and Louisiana. The illness rate shall be calculated as the number of illnesses per unit of population.

### Background

Historically, the National Shellfish Sanitation Program (NSSP) has addressed illnesses associated with pathogens from fecal contamination and marine biotoxins, both of which affect the general population. In 1987 shellfish specialists from the Food and Drug Administration's (FDA) Southeast Region identified *Vibrio vulnificus* as a public health concern. *Vibrio vulnificus* was first discussed by the Interstate Shellfish Sanitation Conference at the 1987 annual meeting. The following year FDA and the ISSC co-sponsored a workshop in Washington, DC. Recommendations from the workshop included: (1) targeting and educating the at-risk population, (2) educating the industry concerning good handling practices, (3) collecting illness data to determine the scope of the problem, (4) conducting research to answer unknowns and (5) analyzing results of data collection and research to determine reasonable controls. The ISSC notified state shellfish regulatory officials of these findings and recommendations and urged states to begin efforts to alert physicians and other medical support groups.

In 1994 FDA, ISSC and NMFS sponsored a second workshop in Washington, DC, to discuss the latest findings on *Vibrio vulnificus*. Following the workshop, the FDA submitted a proposal, outlining several options for addressing *Vibrio vulnificus* illness through time and temperature controls. FDA recommended Conference adoption of the option which contained regulatory controls requiring that oysters harvested from Gulf States from April 1 through October 31 meet rigid time and temperature controls, or be labeled for shucking and cooking only. The voting delegates of the ISSC referred the proposal to a committee for further deliberation.

Following the 1994 annual meeting, the ISSC, highlighted three main approaches for reducing illnesses and deaths associated with *Vibrio vulnificus*. These approaches include educating the "high-risk" group to avoid raw shellfish, more rapid post-harvest refrigeration of shellfish to prevent increases in numbers of the pathogen, and advocating and encouraging post-harvesting processes to reduce *Vibrio vulnificus* to non-detectable levels to provide alternative forms of raw shellfish for high-risk consumers.

In 1997 the ISSC adopted an Interim Control plan which significantly reduced the time from harvest to refrigeration during the periods of the year when *Vibrio vulnificus* levels are elevated (April-October). In 1998 the ISSC adopted requirements for a consumer information message on all shellstock shipping tags. The required message is as follows:

#### "RETAILERS, INFORM YOUR CUSTOMERS"

"Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, poultry, or shellfish reduces the risk of food borne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information."

In addition to the consumer information message, the ISSC, with Salton-Stall Kennedy funding, initiated a National Consumer Education Program to advise high-risk consumers of the risk of consuming raw molluscan shellfish. To promote post-harvest treatment, the ISSC supported the development of a petition to the Food and Drug Administration (FDA) requesting approval of irradiation for shellfish. In an effort to provide incentive, the Conference also approved labeling for shellstock processed to reduce *Vibrio vulnificus* levels to non-detectable. Despite these efforts, the ISSC was unable to demonstrate significant reductions in illness.

At the 1999 Conference the ISSC Voting Delegates established a *Vibrio* Management Committee to review of the universe of issues associated with vibrios and other naturally occurring organisms which have the potential to cause illness in some or all people. Specific activities were to include development, oversight and evaluation of strategies for reducing illnesses. A *Vibrio vulnificus* subcommittee and a *Vibrio parahaemolyticus* subcommittee were appointed to provide technical support to the committee

The *Vibrio* Management Committee met in January 2000 to discuss the status of vibrio illnesses and the effects of current NSSP efforts to minimize these illnesses. The *Vibrio vulnificus* Subcommittee met in March and April of 2000 and, using the Egg Safety Action Plan as a model, began development of a *Vibrio vulnificus* Risk Management Plan. The Plan, which included goals and control options, was incorporated into a proposal for discussion at the 2000 ISSC Annual Meeting. The plan included a disease reduction goal for decreasing the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses from the consumption of commercially harvested raw or undercooked oysters by 40% in five years and by 60% within seven years. Several

options for implementation of the controls were included. Those states having two 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, would develop and implement a state *Vv* risk management plan. The state risk management plans would include the administrative procedures and resources necessary to accomplish state involvement in a collective plan that would meet the illness reduction goals of the ISSC Plan. Should the goals not be met, the states would identify and prepare for implementation of specific harvest and/or labeling controls or other controls that would provide equivalent illness reduction.

The Risk Management Plan included a Consumer Education Program targeting individuals whose health condition(s) increase their risk for *Vibrio vulnificus* infection. As an additional reduction strategy, the Conference encourages and promotes post-harvest treatment with hydrostatic pressure, cool pasteurization, IQF, irradiation, time/temperature controls, rapid chilling and other emerging technologies. To encourage implementation of post-harvest controls the Conference would pursue options such as Small Business Loans (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 state shellfish program evaluations. Should the Conference not achieved the 40% five-year illness reduction goal, or adequately achieved performance measures set forth in prior work plans, the Committee would evaluate the need for incorporation of additional harvest controls to assure achievement of the 60% illness reduction goal by the end of the seventh year. The voting delegates referred the Risk Management Plan back to the *Vibrio* Management Committee (VMC) with specific instructions to refine the Plan.

The ISSC *Vibrio vulnificus* Subcommittee met twice in 2001 to develop acceptable language for review and adoption at the 2001 Conference. At the July 2001 meeting of the ISSC, the modified Plan was adopted as Proposal 00-201 (Appendix VIII. 6.) with confirmation by the US Food and Drug Administration. The *National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish* now includes requirements (Model Ordinance Section II@4 and Guidance Document Chapter IV .01,.02) that in each state having 2 or more etiologically confirmed shellfishborne *Vibrio vulnificus* illnesses since 1995 which can be traced to the consumption of commercially harvested raw or undercooked oysters originating from the waters of that state

(Source State), the Authority will develop and implement a *Vibrio vulnificus* Risk Management Plan. (ISSC 2002) The plans will receive oversight from the Vibrio Management Committee of the ISSC and will be evaluated by FDA.

The goal of the *Vibrio vulnificus* Risk Management Plan is to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses from the consumption of commercially harvested raw or undercooked oysters by 40 percent as reported by core reporting states collectively, for years 2005 and 2006 (average), and by 60 percent for years 2007 and 2008 (average), from the current rate of 0.306/million. The core reporting states include Florida, Texas, California, and Louisiana. The illness rate shall be calculated as the number of illnesses per unit of population.

#### **Education Program**

The adoption of Proposal 00-201 by the ISSC in July, 2001 incorporated *Vv* illness reduction into the Model Ordinance requiring that each state with two or more etiologically confirmed cases of *Vibrio vulnificus* develop and implement a *Vibrio vulnificus* Education Program which will be reviewed annually by FDA. Each program must address the following populations and evaluate their progress:

At-risk population

State Partnerships (ALF, IHF, ADA, AHEC)

Distribution of ISSC materials

Articles in state magazines and newspapers

Medical/Health Community

**State Medical Association Meetings** 

Continuing Education Courses/Credits

Physicians

Health Care Professionals

**Emergency Room Personnel** 

General Population

State Partnerships (AHEC, NRA,)

Television Media

Magazines and Newspapers

Marketing Events, i.e.: seafood festivals)

Labeling

Retail/Food Service Posting

The success of the ISSC *Vibrio vulnificus* education activities has been tracked by consumer surveys conducted the winter of 2002 and then again in 2004. In 2002, the initial findings from

calls to over 62,000 households in four states (California, Louisiana, Florida and Texas) resulted in a total of 1,975 interviews with raw oyster consumers. Results showed that 38 percent of all respondents reported eating oysters less often over the past year. The difference between states was noteworthy, with 39 percent of respondents in California and Texas reporting eating oysters less frequently, compared to 30 percent of Florida and Louisiana respondents. Health concerns and limited availability were most frequently cited for decreased oyster consumption. In individual states, however, health concerns about consumption ranged from a low of 22 percent in California to a high of 46 percent in Florida. More than any other group, individuals with liver disease reported decreasing consumption of raw oysters for health reasons (58 percent). Most respondents had taken no action to reduce their risk of illness. Some reported eating fewer oysters; some now eat only cooked oysters. Consumer responses also suggest confusion about when oysters are "in-season" and presumably safe. Two-thirds of those with liver disease or weakened immunity (66 percent) mentioned their health services provider as their primary source of information on raw oysters and risk. This compares with 26 percent of all respondents. Respondents frequently cited mass media (newspapers 49 percent; television 40 percent; and magazines 41 percent) as sources of information on raw oysters and risk. Radio was mentioned much less often (16 percent). About a third of all respondents also mentioned "posted notices" as a source of information on risk.

#### **Post-Harvest Processing (PHP)**

Oyster processors have developed post-harvest technologies to ensure alternatives to traditional raw oysters for certain at-risk consumers. While different technologies are employed, each post-harvest process is designed to allow at-risk consumers to enjoy uncooked oysters with an added margin of safety. These processes were developed and successfully marketed by private entrepreneurs in response to consumer demand. Existing post-harvest processes take variations of three forms: Individual Quick Freezing (IQF), low heat pasteurization, and Hydrostatic High Pressure (HPP) treatment. Although these technologies currently account for less than 10% of all domestic raw oyster sales in the United States, on-going marketing and educational efforts geared toward the at-risk consumer are expanding consumer acceptance and knowledge regarding these PHP oyster products. Such efforts will clearly expand the market for these products, thereby creating lower risk for the consumers of half-shell raw oysters. Specific processes include IQF, a technology that has been applied to oysters since 1989. Freezing is done either cryogenically or using conventional blast

freezing. IQF oysters are typically sold with the top shell removed. The IQF process has been shown to eliminate or reduce *Vibrio vulnificus* to non-detectable levels. The second process is Low Heat Pasteurization, in use since 1995.A private firm in Louisiana, in cooperation with Louisiana State University, developed the process which involves a simple warm and cold-water temperature treatment of in-shell oysters to reduce *Vibrio vulnificus* to non-detectable levels. In 1999 a Louisiana company began producing in-shell oysters, which are subjected to a hydrostatic pressure of up to 45,000 psi. Oysters are placed in a specially developed pressure chamber capable of generating high levels of hydrostatic pressure. During this process *Vibrio vulnificus* is reduced to non-detectable levels and oysters are separated from their shell.

Each process has unique advantages and characteristics, which create alternatives for those consumers who are at-risk of illness from *Vibrio vulnificus*. Cumulatively these processes will help the industry provide customers with the ability to choose oyster products which meet their individual preference and health concerns.

The ISSC Risk Management plan requires that each source state achieve post-harvest processing capacity for 25 percent of all landed oysters intended for the raw, half-shell market (during the months of May through September) by December 31, 2004. Total capacity will include all operational plants as well as plants under construction. If illness reduction goals are still not met by December 31, 2006, the source state is required to meet a harvest treatment capacity of 50% of all oysters intended for the raw, half-shell market during the months of May through September. ISSC recommendations include:

- Completion of a study and recommendations on dockside icing;
- The capability of providing incentives to add refrigeration to harvest vessels;
- Support of the commercialization of post-harvest technologies;
- Development of new/improved post-harvest technologies; and
- Implementation of *Vv* Education Evaluation Criteria.

#### **Additional Control Strategies**

As an alternative, the state may utilize the measures listed below or others, 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. The source state's *Vibrio vulnificus* management plan

must 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 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 *Vibrio vulnificus* 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 VMC on a state-by-state basis. 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. Measures include:

- (1) Labeling all oysters, "For shucking by a certified dealer," when the average monthly maximum water temperature exceeds 75°F or during the months of May through September, inclusive.
- (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 or during the months of May through September, inclusive.
- (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 during the months of May through September, inclusive.

The source states of Florida, Alabama, Louisiana and Texas responded by developing *Vibrio vulnificus* risk management programs with the technical and financial assistance of ISSC, the National Oceanic & Atmospheric Administration and the Gulf of Mexico Program. The enhanced education programs are progressing. In partnership with the states, ISSC Executive Office has disseminated consumer brochures and fact sheets to agencies and individuals interested in *Vibrio vulnificus* education. Over the last two years the ISSC has fulfilled requests for over of 120,000 brochures in English and 60,000 in Spanish, and over 20,000 fact sheets. Material requests have come predominantly from state agencies (57 percent); followed by federal agencies (14 percent), partner organizations (23 percent) and industry (2 percent). States' increased demand for print materials parallels their growing involvement in education and prevention activities.

The ISSC has developed distribution partnerships with organizations that have direct links to persons at-risk. The National Office of the American Liver Foundation (ALF) reached over 50,000 vulnerable individuals via direct mail. The ALF also included an article on *Vibrio vulnificus* and liver disease in their newsletter *Progress* reaching about 35,000 high-risk households. At its medical advisory committee meeting, the ALF also provided ISSC fact sheets to 3,000 participating physicians, gastroenterologists and other health care providers.

#### V. APPROACH

This grant afforded ISSC the opportunity to continue facilitation of the state efforts to reduce the risk of Vv from the consumption of raw shellfish. The approach included support and improvement of state Vv education programs by providing information, producing educational materials as needed and evaluating education efforts. The ISSC also assisted in the development and advancement of post-harvest techniques to reduce Vv risk. In addition the ISSC kept the states informed of all Vv developments (illness reports, funding sources, successful Vv risk reduction projects). The structure within the ISSC included close coordination with the Vibrio Management Committee, Education Committee,  $Vibrio\ vulnificus\ subcommittee$ , Vv Education Subcommittee and the ISSC Executive Board.

The approach used by the ISSC in facilitation of state Vv management plans was developed through consultation with the states identified in the ISSC Vv Management Plan as source states. These include Texas, Louisiana, Alabama, and Florida. Industry representatives from these states were also included in consultation efforts. The ISSC contracted with Dorothy Leonard to coordinate the activities of the project. The approach was to provide assistance to the ISSC source states in developing and implementing their state Vv risk management plans. This focus of the assistance was to identify obstacles and challenges for states and provide clarification for state implementation and compliance. Each of the three risk management plan components were addressed in the project, i.e. education, post-harvest processing, and regulatory controls. From consultation activities the ISSC continues to identify activities which are needed to assist states in developing and implementing effective Vv Risk Management Plan.

#### VI. FINDINGS

The specific tasks associated with the strategy were incorporated into the contractual agreement with the Gulf and South Atlantic Fisheries Foundation. These tasks and accomplishments are as follows:

#### SCHEDULED TASKS:

1. Meet with State *Vv* Representatives (FL, AL, MS, LA, and TX) to review and update *Vv* Management Plans.

#### Accomplishments:

State plans were reviewed and updated and are included in Section VIII Appendices.

2. Work with all six participating states (FL, AL, LA, TX, MS, and GA) to expand and improve *Vv* Education programs tailored to state needs.

#### Accomplishments:

The six participating states expanded and improved their *Vv* education programs. A report of state education programs and activities are included in Section VIII. Appendices 6. Section VIII. Appendices 13. provides an organizational chart of involved individuals and groups.

3. Support state coordinators in implementing their *Vv* education programs.

#### Accomplishments:

State coordinators were supported and made advisors to the ISSC Vv Education Subcommittee. This involvement enhanced the efforts of state coordinators. The Vv Education activities are listed in Section VIII. Appendices 3.

4. Coordinate efforts in participating states, particularly LA, TX, AL, MS and FL to formulate plans for illness reduction proposals for 2007. This should include but not be limited to, arranging for meetings with public health personnel and industry participants from Gulf states to provide a forum for sharing idea and formulating plans for the creation of a "Draft" cooperative illness reduction plan to be available for the August 2005 ISSC Board Meeting.

#### Accomplishments:

The ISSC developed a list of implementation questions and concerns from source states (Section VIII. Appendices 5.). The Executive Office presented these questions to the Vv Subcommittee, the Vibrio Management Committee, and the Executive Board in March of 2005 for clarification. These clarifications will facilitate state implementation of Vv Risk Management Plans.

5. Work with each participating state to promote and encourage industry to voluntarily adopt post-harvest processes where feasible. Provide assistance to ISSC *Vv* Subcommittee in collecting and evaluating information related to the PHP goals established by the Conference.

#### Accomplishments:

Voluntary industry adoption of post-harvest processing is continuing to expand. Results of industry PHP efforts are included in Section VIII Appendices.

6. Identify funding sources to assist in the development of educational materials and states' implementation of *Vv* Management Plans.

#### Accomplishments:

Funding sources for Vv education programs were shared with state Vv education coordinators as they became available and ISSC provided assistance to states in acquiring funds. The ISSC identified several Vv education funding sources.

7. Work closely with Federal agencies, industry groups and non-governmental organizations to expand knowledge and support for the *Vv* Disease Reduction Effort. Maintain a contact listing for use by anyone interested in learning more about *Vv*. Accomplishments:

The ISSC provided updates of Vv education activities at 4 regional shellfish conferences and maintains a contact list for all parties requesting Vv education materials. The ISSC also provides an educational display for use at food safety conferences. The contact list is attached as Section VIII. Appendices 7. Vv Education Summary a. and b.

8. Encourage, assist and support each participating state in the implementation of their *Vv* Management Plan.

#### Accomplishments:

Through individual telephone calls, conference calls, and email the ISSC provided encouragement, assistance, and support to states. These activities included state legislative education, consultation and financial assistance, design, development and distribution of educational materials. Examples of educational materials provided are included in Section VIII. Appendices 11.

#### VII. EVALUATION

Evaluation of the success of this project can be determined by reviewing the reduction in illnesses which occurred in 2004 and 2005. The ISSC Vv Subcommittee has assessed illness and computed reduction in these years and has determined that illness reduction has occurred. The 2004 rates compared to the baseline in the core states indicate a 32% reduction in the three Gulf core states and a 47% reduction in all core states (CA, FL, LA, and TX). The data used for the assessment and the computation is from the Food and Drug Administration (FDA) Southeastern Region Vv Illness Database

Although not funded through this contract, the ISSC in 2002 and 2004 conducted consumer surveys to determine the knowledge level of high risk consumers regarding the risk of consuming raw molluscan shellfish. These surveys do not specifically evaluate this contract but may offer some insight as to the effectiveness of collective *Vv* education activities (See Section VIII Appendices).

#### VIII. APPENDICES

#### 1. State Vibrio vulnificus Management Plans

The National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish now includes requirements (Model Ordinance Section II@4 and Guidance Document Chapter IV .01.02) that in each state having 2 or more etiologically confirmed shellfish-borne Vibrio vulnificus illnesses since 1995 which can be traced to the consumption of commercially harvested raw or undercooked oysters originating from the waters of that state (Source State), the Authority will develop and implement a Vibrio vulnificus risk management plan (ISSC 2002). Currently (August 2005) the Source States include Florida, Alabama, Louisiana and Texas. The plans will receive oversight from the Vibrio Management Committee of the ISSC and be evaluated by FDA.

The goal of the *Vibrio vulnificus* Risk Management Plan is to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses from the consumption of commercially harvested raw or undercooked oysters by 40 percent as reported by core reporting states collectively, for years 2005 and 2006 (average), and by 60 percent for years 2007 and 2008 (average), from the current rate of 0.306/million. The core reporting states include Florida, Texas, California, and Louisiana. The illness rate shall be calculated as the number of illnesses per unit of population.

The goal may be reevaluated before the year 2006 and adjusted should new science, data, or information suggest a change is appropriate. For example, population adjustments can be made in consultation with statisticians and epidemiologists from core reporting states and federal agencies. The baseline data for measuring illness reduction shall be the reported illnesses in the core reporting states for the period 1995 to 1999, as compiled by the Southeast Regional Office of the FDA. The data used for measuring goal attainment begins with 2002 data.

#### VIII. APPENDICES

- 1. State Vv Management Plans
- a. Florida

## Florida Vibrio vulnificus Risk Reduction Plan for Oysters

File: Florida Vibrio vulnificus Risk Reduction Plan for Oysters Revision.doc

The purpose of the National Shellfish Sanitation Program and the Florida shellfish sanitation program is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate and intrastate commerce through federal/state cooperation and uniformity of State Shellfish Programs. This includes protection of the public health by reducing the prevalence of foodborne illness from shellfish. 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, processing controls. This plan has been developed and will continue to be reviewed with the assistance of the following entities: Southeastern Fisheries Association, Apalachicola Bay Oyster Dealers Association, Franklin County Seafood Workers Association, Florida oyster industry, and Florida hard clam industry, University of Florida, Florida Sea Grant, Florida Department of Health, and Florida Department of Agriculture and Consumer Services.

Florida Vibrio vulnificus Risk Management Plan for Oysters:

This Plan implements the Interstate Shellfish Sanitation Conference requirement that states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw oysters that originated from the waters of this state. This Plan will focus on the administrative procedures, responsibilities, and goals to be achieved in the State of Florida.

- (A) The goal of the Florida *Vibrio vulnificus* Risk Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported from the consumption of commercially harvested raw oysters in 1) Florida; or 2) from oysters processed by Florida certified processors.
- (B) Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met. The Florida Department of Health illness data will be used for illnesses reported in Florida. The U. S. Food and Drug Administration illness data will be used for illnesses reported in the identified core states. The baseline rates of illness will include the years 1995 through 1999. Illnesses will also be evaluated according to each source state. The State of Florida's baseline rate of illness for *Vibrio vulnificus* is 0.600 per million (average of 8.8 illnesses reported per year during the 1995-1999 baseline period).
- (C) The Interstate Shellfish Sanitation Conference, ISSC, established rates of reduction for *Vibrio vulnificus* in each of the source states. These rates of reduction are 40 percent for years 2005 and 2006 (average) and 60 percent for years 2007 and 2008 (average). For the

State of Florida, these rates of reduction will require that the average number of illnesses from *Vibrio vulnificus* for years 2005 and 2006 (averaged) is estimated to be 5 [Note: since the illness rate is based on Florida population, the exact number can not be predetermined, but an estimate is possible based on historical population trends], and for years 2007 and 2008 (averaged) is estimated to be 3 [Note: since the illness rate is based on Florida population, the exact number can not be predetermined, but an estimate is possible based on historical population trends]. The ISSC has reserved the right to reevaluate the reduction goal prior to 2006 and adjust it in the event that new science, data, or information becomes available. If the ISSC does reevaluate the reduction goal, the State of Florida's goals will likewise be adjusted to conform to the new ISSC goal.

- (D) The State of Florida believes that consumer education is the first and foremost tool to reduce illnesses related to *Vibrio vulnificus*. As the cornerstone of this plan, the State of Florida will:
  - (1) Improve and assess the requirements that retail establishments that sell raw oysters provide educational information through notices, tent cards, placards, etc., to their patrons of the risk to certain individuals when eating raw oysters; Determine if the Florida Department of Business and Professional Regulation can adopt the consumer information statement language into rule; Evaluate the compliance of the consumer information statement language at production, retail, and food service; and Evaluate the potential of providing the shellfish tag to the retail customer.
  - (2) Continue to provide educational workshops and materials to the Florida medical community and high risk individuals on the risks to certain individuals of eating raw oysters as well as the signs and symptoms of *Vibrio vulnificus* illnesses;
  - (3) Continue to provide educational workshops and materials to the Florida nurses and registered dieticians on the risks to certain individuals of eating raw oysters;
  - (4) Continue to provide educational materials to the general public regarding the risks of consuming raw oysters via advisories, public service announcements, pamphlets and workshops on request.
  - (5) Continue to collect the following information, as practicable, using the approved CDC form or other form as required by the ISSC on each person who is diagnosed with exposure to *Vibrio vulnificus* from raw oysters:
    - a. underlying medical conditions;
    - b. knowledge of disease status;
      - 1. Was the person aware he/she had liver disease?
      - 2. Was the person seeing a physician for the liver problem?
    - c. preexisting knowledge of risk associated with eating raw or improperly cooked oysters;
      - 1. If oysters were eaten in a restaurant, and a warning was displayed, did the person see the warning and understand it?
    - d. did the physician warn the person about eating raw oysters?
    - e. existence of consumer advisories at point of purchase or consumption;
      - 1. If oysters were eaten in a restaurant, was an oyster warning displayed?
    - f. patient level of awareness and understanding of advisories;
      - 1. If oysters were eaten in a restaurant, and a warning was displayed, is there evidence that the person saw the warning and understood it?
    - g. place of purchase; and

- h. prior counseling on avoidance of high risk foods, including raw oysters
- (6) Continue to trace back each disease incident to the place of harvest and report the information to the Florida Department of Health, Department of Agriculture and Consumer Services, and the *Vibrio vulnificus* Risk Reduction work group;
- (E) In order to determine the capacity for Post-Harvest Processing in the State of Florida as required by the ISSC, the Department of Agriculture and Consumer Services will send out a survey each year in January to the shellfish processors certified under s. 597.020, FS, to determine each processor's capacity for Post-Harvest Processing of oysters intended for the raw and/or half-shell market. The Department of Agriculture and Consumer Services will collect the information from the surveys and calculate the total Post-Harvest Processing capacity for the state for that calendar year. A Post-Harvest Processing capacity of 25 percent of all oysters intended for the raw, half-shell market during the months of May through September is required by the ISSC. If the surveys show that the state has not maintained the ISSC required 25 percent Post-Harvest Processing capacity, then those resources approved by the ISSC for achieving the required goal may be used. Capacity is defined for this plan to include all operational plants as well as those under construction.
  - (1) The survey, at a minimum, will collect the following information:
    - a. processor's capacity for Post-Harvest Processing of oysters intended for the raw and/or half-shell market; and
    - b. if necessary, the total number of oysters sold for the raw or half-shell trade for the surveyed year.
- (F) The Department of Agriculture and Consumer Services' will capture the Post-Harvest Processing capacity, will obtain from the Florida Fish and Wildlife Conservation Commission the total number of oysters harvested for the surveyed year, the total number of oysters sold for the raw or half-shell trade for the surveyed year, the total number of illnesses attributed to Florida under paragraph (A) above for the surveyed year, and publish that information as well as the analysis on how this plan is working the meet the objectives of the ISSC goals.
- (G) The yearly compilation for the years 2005 and 2006 (averaged) must demonstrate that the average *Vibrio vulnificus* illness rate be at a 40 percent reduced level from the base number, which is estimated to be 5 [Note: since the illness rate is based on Florida population, the exact number can not be predetermined, but an estimate is possible based on historical population trends] illnesses for Florida.
- (H) Should the yearly compilation for the years 2005 and 2006 (averaged) demonstrate that the average illness rate for 2005 and 2006 meets the 40 percent reduction, and then the Department of Agriculture and Consumer Services will continue with the plan outlined above.
- (I) If the ISSC goal of *Vibrio vulnificus* illness reduction of 40 percent in Florida is not obtained by December 31, 2006, then the Department of Agriculture and Consumer Services will immediately notify all shellfish processors of the illness rate for that year and the ISSC requirement under the Model Ordinance of a Post-Harvest Processing capacity of 50 percent for all oysters going to the raw or half-shell market. Capacity is defined for this plan to include all operational plants as well as those under construction. If the FDA has not

approved Post-Harvest Processings, and should the next state survey demonstrate that Florida cannot obtain the 50 percent capacity requirement, each certified dealer will be required to implement one of the following or equivalent measures:

- (1) Label all oysters, "For shucking by a certified dealer," or "For cooking only" when the Average Monthly Maximum Water Temperature exceeds 75°F;
- (2) Subject all oysters intended for the raw, half-shell market to a department-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) Label all oysters, "For shucking by a certified dealer," or "For cooking only" during the months of May through September, inclusive; or
- (4) Subject all oysters intended for the raw, half-shell market to a post-harvest treatment that is both approved by the department and reduces the *Vibrio vulnificus* levels to 3MPN/g or less during the months of May through September, inclusive. The temperature, *Vibrio vulnificus* levels and months of the year parameters can be adjusted as needed to achieve the established illness reduction goal. Upon notification by the department of the above illness rate which does not meet the goal, each certified dealer will in writing notify the department which measure the certified dealer has chosen. The department will investigate legal authorities for specific controls and will work with the ISSC and the oyster industries to identify possible additional controls. The *Vibrio vulnificus* risk assessment may prove useful for quantifying specific environmental controls.
- (J) The yearly compilation for the years 2007 and 2008 (averaged) must demonstrate that the average *Vibrio vulnificus* illness rate be at a 60 percent reduced level from the base number, which is estimated to be 3 [Note: since the illness rate is based on Florida population, the exact number can not be predetermined, but an estimate is possible based on historical population trends] illnesses for Florida.
- (K) If the ISSC goal of *Vibrio vulnificus* illness reduction of 60 percent in Florida is not achieved by December 31, 2008, then the Department of Agriculture and Consumer Services will immediately notify all shellfish processors of the illness rate and the ISSC requirement under the Model Ordinance. On January 1, 2009, if the FDA has not approved Post-Harvest Processings, each certified dealer will be required to implement one of the following or equivalent measures:
  - (1) Label all oysters, "For shucking by a certified dealer," or "For cooking only" when the Average Monthly Maximum Water Temperature exceeds 75°F;
  - (2) Subject all oysters intended for the raw, half-shell market to a department-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) Label all oysters, "For shucking by a certified dealer," or "For cooking only" during the months of May through September, inclusive; or
  - (4) Subject all oysters intended for the raw, half-shell market to a post-harvest treatment that is both approved by the department and reduces the *Vibrio vulnificus* levels to 3MPN/g or less during the months of May through September, inclusive. The temperature, *Vibrio vulnificus* levels and months of the year parameters can be adjusted as needed to achieve the established illness reduction goal. Upon notification by the department of the above illness rate which does not meet the goal,

each certified dealer will in writing notify the department which measure the certified dealer has chosen.

- (L) In addition, the State of Florida will continue to work with the federal government and Congress to further develop Post-Harvest Processing technology; compile analytical data concerning *Vibrio vulnificus* levels in Florida waters and Florida oysters; consider developing a monitoring program; increase harvester education with current harvesting requirements shading, time to refrigeration and other current control measures; investigate analytical methodologies; and integrate the existing industry laboratory dedicated to post-harvest processing.
- (M) The *Vibrio vulnificus* Risk Reduction work group will meet at least annually to review the Plan and review progress. The work group will deliver a written annual progress report. The work group suggests that the following be accomplished:
  - (1) Evaluate the ISSC national surveys to determine the current *Vibrio vulnificus* disease reporting and education in Florida.
  - (2) Continuation of the ongoing *Vibrio vulnificus* investigation team system within the Florida Department of Health which has been in place since 1994. This *Vibrio vulnificus* investigation system consists of a Florida Department of Health statewide food and waterborne disease coordinator, nine regional food and waterborne disease epidemiologists and epidemiological teams from each of 67 County Health Departments. The Department of Health coordinates findings and information flow with the Department of Agriculture and Consumer Services, Division of Aquaculture (Florida Molluscan Shellfish Sanitation Program), Division of Food Safety (Florida Retail Food Safety Program) and with the Department of Business and Professional Regulation (Florida Restaurant Inspection Program).
- (N) Performance Based Incentives:

A sub workgroup was established to develop and recommend regulatory rewards for excellent performance.

#### VIII. APPENDICES

- 1. State Vv Management Plans
- b. Alabama

#### Alabama Vibrio vulnificus Risk Reduction Plan For Oysters

**Introduction** The purpose of the National Shellfish Sanitation Program and the Alabama Department of Public Health's shellfish sanitation program is to promote and improve the sanitation of shellfish (oysters) moving in interstate and intrastate commerce through federal/state cooperation and uniformity of State Shellfish Programs. This includes protection of the public health by reducing the prevalence of foodborne illness from shellfish. This plan is designed to assure as low a number as possible of *Vibrio vulnificus* septicemia illnesses through a combination of consumer education, processing incentives and, if necessary, processing controls.

This Plan implements the Interstate Shellfish Sanitation Conference requirement that 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 this state. This Plan will focus on the administrative procedures, responsibilities, and goals to be achieved in the State of Alabama.

Goal The goal of the Alabama Department of Public Health's *Vibrio vulnificus* Risk Management Plan will be to reduce to the extent possible the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported from the consumption of commercially harvested raw oysters in 1) Alabama or 2) from oysters processed by Alabama certified processors. The Alabama Department of Public health will evaluate each reported illness to determine if they were under the control of Alabama or not.

**Note** Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met. The U. S. Food and Drug Administration illness data will be used for illnesses reported in the identified core states. Illnesses will also be evaluated according to each source state. Alabama had 3 cases of foodborne *Vibrio vulnificus* reported from commercially harvested Alabama oysters during the 1995-1999 baseline period, 1 in 1995 and 2 in 1996.

#### (A)Consumer education – ADPH will:

(1). Assess the requirements that retail establishments that sell raw oysters to provide educational information through notices, tent cards, placards, etc., to their patrons of the risk to certain individuals when eating raw or improperly cooked oysters;

#### Alabama Administrative Code 420-3-22.06(10) states:

- (10) Consumer advisories
- (a) If raw or undercooked molluscan shellfish is offered for sale, the permit holder shall inform consumers of the increased risk associated with eating such food in a raw or undercooked form.
- (b) Placards, display case or menu advisories, table tents or other effective written means approved by the Health Officer shall be used.
  - (c) Only wording approved by the Health Officer shall be used for written notices.

This Administrative Rule was adopted effective date December 25, 1996, and continues in effect through 2004. This Administrative Rule applies to all retail establishments; enforcement is conducted through the county health department environmental offices.

(2). Continue to provide educational materials to the medical community and the general public sector on the risks to certain individuals of eating raw as well as the signs and symptoms of *Vibrio valuificus* illnesses:

The ISSC pamphlet is distributed to county health departments for public display as they deem appropriate. Medical staff were approached to let them know the ADPH Environmental/Seafood staff have educational materials available on Vv if wanted for handout/display at meetings. None were requested for 2004.

(3). Continue to provide educational materials to the nurses and registered dicticians on the risks to certain individuals of eating raw ovsters:

Presentation given by Ron Dawsey at Dothan, Alabama on August 14, 2004 to Association of Practictioners of Infection Control Southeast Chapter. This group consists primarily of Infection Control Nurses for hospitals in southeast Alabama, southwest Georgia, and north Florida. Approximately 80 people were in attendance.

(4). Continue to provide educational materials to the general public regarding the risks of consuming raw ovaters via advisories, public service announcements and pamphlets;

The ISSC pamphlet is distributed to county health departments for public display as they deem appropriate. The ISSC PSA video was not distributed under the auspices of ADPH as it was reviewed by ADPH medical staff and was deemed to provide medically inappropriate information to the public.

(5) Identify training and educational opportunities for Seafood Branch staff in the areas of epidemiology, risk management and consumer education.

Several courses in Epidemiology have been identified - CDC online or computer based courses including Botalism in Argentina, CDC Principles of Epidemiology, and FDA ORA-U Epidemiology. Other courses may be available in any given year as offered by the ADPH Division of Epidemiology. ADPH Scafood Branch staff (shellfish program) will take at least one of these in calendar year 2005.

Courses in risk management and consumer education are more difficult to find. We will request assistance from FDA shellfish specialists in identifying appropriate training courses in these areas if none are identified during calendar year 2005.

- (B) Data Collection Data collection is the basis for determining appropriate control measures for disease prevention. ADPH staff will:
- (1) Continue to assist the ADPH Bpidemiology Branch in collecting the following information, as practicable, using the approved CDC form or other form as required by the ISSC on each person who is diagnosed with exposure to *Fibrio valnificus* from raw cysters:
  - a. underlying medical conditions;
  - b. icnowledge of disease status;
  - c. preexisting knowledge of risk associated with eating raw cysters;

- d. existence of consumer advisories at point of purchase or consumption;
- e. patient level of awareness and understanding of advisories;
- prior counseling on avoidance of high risk foods, including raw oysters.

ADPH Epidemiology Division is aware of, and has copies of, the supplemental Vv form. No cases originating from shellfish commercially harvested in Alabama were identified in 2004 necessitating ADPH Seafood Branch assistance with use of the form.

- (2) In conjunction with ADPH Epidemiology Branch, maintain a record of Vibrio vulnificus illnesses from 1995 to the present;
- Continue to trace back each disease incident to the place of harvest;

No cases originating from commercially harvested oysters in Alabama were identified in 2004 necessitating traceback.

(4) Continue to collect routine samples of both growing waters and shellfish for analysis of Vibrio vulnificus levels;

#### (C) Controls and Treatment

(1). In order to determine the capacity for post harvest treatment in the State of Alabama as required by the ISSC, the ADPH Seafood Branch will send out a survey each year in January to the shellfish processors certified under Alabama Administrative code 420-3-18 (Shellfish Sanitation Rules) to determine each processor's capacity for post harvest treatment of oysters intended for the raw and/or half-shell market. ADPH will collect the information from the surveys and calculate the total post harvest treatment capacity for the state for that calendar year.

The survey, at a minimum, will collect the following information:

 a. processor's capacity for post harvest treatment of oysters intended for the raw and/or half-shell market;

b. the total number of oysters sold for the raw or half-shell trade for the surveyed year;

(2) Since the shellfish industry in Alabama shucks ca. 95 % of their shellstock there is little incentive for the firms to implement post harvest treatment. This fact was confirmed after the results of the first survey were reviewed. The post harvest treatment capacity goals, 25 % by December 31, 2004 and 50 % by December 31, 2006, were set up as a means of reducing the number of V. vulnificus illnesses associated with raw oyster consumption. As an alternative to post harvest treatment we feel that pre harvest time to temperature controls in combination with current processing techniques will be sufficient to assist with the national illness reduction goals.

ADPH in conjunction with the Alahama Department of Conservation and Natural Resources limits harvesting to six hours (6:00 AM to 12:00 PM) during the months of May through September. This requirement is more stringent than the current Model Ordinance requirement of 10 hours. The Alabama shellfish industry traditionally shucks approximately 95 % of the oysters processed by certified dealers. ADPH believes that the stricter harvest time requirement in conjunction with current processing practices by the shellfish industry in Alabama will serve to reduce/maintain the number of illnesses associated with oysters harvested in AL or processed by AL processors. At the current time ADPH does not believe that post harvest processing by the Alabama shellfish industry will be required.

#### Alabama Administrative Code Chapter 220-3-.15 states:

Oyster Season And Sack Limit Regulation. All public water bottoms of Alabama not closed by the Department of Public Health, shall be opened for the taking of oysters; provided, however, that those public water bottoms opened to bystering shall be opened to the Laking of cysters only from 6:00 a.m. to 3:00 p.m. Monday through Fridgy of gash work and also from 6:00 a.m. to 3:00 p.m. for the next six Saturdays on which public roofs are open by the Department of Public Health, following the effective date of this regulation: except however that each Saturday from the first Saturday in October through the last Saturday in December of each year, those public water bottoms opened to eyatering shall be opened to the taking of ovators only from 6:00 a.m. to 12:00 moon; and further provided, that from the first Monday in June through the last Priday in September of each year, those public water bottoms opened to oystering shall be opened to the taking of oysters only from 6:00 a.m. to 12:00 Noon Monday through Friday of each week. The commercial harvest of ovaters by licensed oyster catchers shall be limited to eight (8) sacks per licensed byster catcher per day [according to the standard Alabama measure of one-quarter (1/4) Alabama barrel per sack) or sixteen (16) sacks per boat per day regardless of the number of licensed dyster catchers on board the boat; provided further, no licensed ovster catcher may move to another boat or transfer his catch to, or place his catch in, another boat for purposes of avoiding the requirements of this regulation. A boat towed to or from the public byster reefs and upon which dysters are transported from the public byster reefs shall be considered as part of the towing boat for the purposes of the daily limit of sixteen (16) sacks per boat, unless a licensed byster catcher or catchers remains on board the boat at all times while on the public cyster reefs or transporting cysters from the public ovater reefs.

(3) Should the yearly compilation of *Vibria valnificus* illness data for the years 2005 and 2006 (averaged) demonstrate that the average illness rate for 2005 and 2006 meets the 40 percent reduction, then ADPH will continue with the plan outlined above.

ADPH Scafood Branch proposes to continue the plan as outlined above through calendar year 2005.

(4) If the ISSC goal of *Vibrio valnificus* illness reduction of 40 percent nationally is not met by December 31, 2006, then ADPH will require each certified dealer to implement one of the following controls:

NOTE: The following provisions are a restatement of portions of Alabama Administrative Code Chapter 420-3-18-409, adopted effective December 25, 2003.

- (a) Labeling all oysters, "For shocking 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) I abeling all oysters, "For shucking by a certified dealer", during the months of May through September, inclusive;
- (c) 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 valnificus* levels to SMPN/g or less 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.
- (5) If the ISSC goal of *Vibrio vulnificus* illness reduction of 60 percent nationally is not met by December 31, 2008, then ADPH will require each certified dealer to implement one of the following controls:

NOTE: The following provisions are a restatement of portions of Alabama Administrative Code Chapter 420-3-18-,09, adopted effective December 25, 2003.

- (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-barvest treatment that reduces the *Vibrio valnificus* 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 shocking by a certified dealer", during the months of May through September, inclusive;
- (e) Subjecting all oysters intended for the raw, balf-shell market to a post-harvest treatment that is both approved by the Authority and reduces the Vibrio valnificna levels to 3MPN/g or less during the mouths of May through Soptomber, 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.
- (D) Regulatory Framework ADPH believes the regulatory framework is adequate to implement the risk management plan as written.

Alabama Administrative Code Chapter 420-3-18-.09, adopted effective December 25, 2003, adopts the NSSP Program Guide. 2001 revision:

- (1) Adoption by reference The document entitled National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2001 Revision, promulgated by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, is hereby incorporated by reference and made a part of this rule as if set out in full and all provisions thereof are adopted as a rule of the State Board of Health.
- (2) Availability Said document is available at the office of Director, Division of Food, Milk, and Lodging, RSA Tower Suite 1250, 201 Monroe Street, Montgomery, Alabama 36104.
- (3) Control Where there is consistency between Chapter 420-3-18 and the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2001 Revision, these rules control. Where these rules are silent, the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, 2001 Revision, controls.
- (E) Plan Modification Each case of foodbome Vibrio valuificus illness attributed to oysters harvested from approved harvest areas in Alabama will be reviewed with FDA shellfish specialists to determine the appropriateness of additional management plan elements and Model Ordinance applications.

No cases of Vv originating from commercially harvested shellfish in Alabama have been reported in 2004.

(F) <b>Progress Report</b> An annual progress report under each lettered point will be made a part of ADPH's <i>Vibrio vulnificus</i> management plan file.
Done on January 24, 2005.
APPROVED:
Lewis A. Byrd, Ph.D. Director, Scafood Branch

#### VIII. APPENDICES

- 1. State Vv Management Plans
- c. Louisiana

#### Louisiana Vibrio vulnificus Management Plan for Oysters

The purpose of the oyster program in Louisiana is to encourage improving water quality for oyster growing areas, to increase the population of oysters on the seed grounds, provide responsible sanitation practices at oyster processing plants and on oyster harvesting vessels, and promote the importance of the culture of the oyster industry in Louisiana and as well as the United States. The purpose of the National Shellfish Sanitation Program, (NSSP), is to set uniform guidelines for shellfish that are harvested, processed, and transported into interstate commerce. The NSSP is revised bi-annually at the Interstate Shellfish Sanitation Conference, (ISSC), whose members include federal and state shellfish control agencies as well as the shellfish industry. Federal and State shellfish control agencies will provide the greatest level of public health protection as possible by managing the shellfish growing areas and processing facilities with the understanding that complete elimination of shellfish-borne illness is impossible to attain under any program. The "Louisiana Vibrio vulnificus Management Plan" is designed to assure a significant reduction in Vibrio vulnificus illnesses through a combined effort involving consumer education, processing incentives and, if necessary, harvest and/or processing controls.

#### Louisiana Vibrio vulnificus Risk Management Plan for Oysters:

This Plan implements the Interstate Shellfish Sanitation Conference requirement that states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw oysters that originated from the waters of this state. This Plan will focus on the administrative procedures, responsibilities, and goals to be achieved in the State of Louisiana.

- (A) The goal of the Louisiana *Vibrio vulnificus* Risk Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses reported from the consumption of commercially harvested raw oysters in 1) Louisiana; 2) from oysters processed by Louisiana certified processors. Louisiana will evaluate each illness to determine if a) the vibrio illness is associated with eating raw oysters; b) the requirements for oyster harvesting and handling were met under the NSSP and Model Ordinance; and c) those identified as "at-risk" consumers were properly advised of the risk of eating raw shellfish as required under the Louisiana Sanitary Code.
- (B) "Etiologically confirmed" is defined as those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met. The Louisiana Department of Health and Hospital's disease surveillance data will be used to identify cases reported in Louisiana. The U. S. Food and Drug Administration data will be used for cases reported in the identified core states. The baseline rates of illness will include the years 1995 through 1999. Illnesses will also be evaluated according to each source state. The State of Louisiana's baseline rate of illness for *Vibrio vulnificus* is an average of 0.644 per million population) during the 1995-1999 baseline period.

- (C) The ISSC has established rates of reduction for *Vibrio vulnificus* in each of the source states. These rates of reduction are 40 percent for years 2005 and 2006 (average) and 60 percent for years 2007 and 2008 (average). For the State of Louisiana, the average *Vibrio vulnificus* case rates in Louisiana for years 2005 and 2006 will be estimated to be less than 0.644 per million population [Note: Louisiana Department of Health and Hospitals reserves the right to set guidelines for determining if each *Vibrio vulnificus* case meets the criteria for the reduction requirement, i.e., the vibrio illness was determined to be associated with eating raw oysters, were the oysters harvested and handled under the requirements of the NSSP and Model Ordinance, were those identified as "at-risk" consumers properly advised of the risk of eating raw shellfish as required under the Louisiana Sanitary Code] The ISSC has reserved the right to reevaluate the reduction goal prior to 2006 and adjust it in the event that new science, data, or information becomes available. If the ISSC does reevaluate the reduction goal, the State of Louisiana's goals may be adjusted to conform to the new ISSC goal.
- (D) The State of Louisiana believes that consumer education is the first and foremost tool to reduce oyster-associated *Vibrio vulnificus* illnesses to "at-risk" consumers. As the cornerstone of this plan, the State of Louisiana will:
  - (1) Assess and improve the requirements for retail establishments that sell raw oysters to provide educational information to their patrons through notices, tent cards, placards, etc., regarding the risks associated with eating raw oysters;
  - (2) Continue to provide educational workshops and materials to the Louisiana medical community and high risk individuals regarding the risks associated with eating raw oysters, identifying signs and symptoms of *Vibrio vulnificus* infection and appropriate treatment;
  - (3) Continue to provide educational workshops and materials to the Louisiana registered dieticians regarding the risks of eating raw oysters for the identified population "atrisk" and provide appropriate counseling;
  - (4) Continue to provide educational materials to the general public regarding the risks of consuming raw oysters via advisories, public service announcements, pamphlets and workshops on request.
  - (5) Continue to collect the following information using the approved CDC form or other form as required by the ISSC on each case diagnosed with *Vibrio vulnificus* as a result of exposure to raw oysters by consumption:
    - a. Underlying medical conditions;
    - b. Knowledge of disease status;
      - 1. Was the person aware he/she had liver disease?
      - 2. Was the person seeing a physician for the liver problem?
    - c. Pre-existing knowledge of risk associated with eating raw or improperly cooked oysters; did the patient receive counseling on avoidance of high-risk foods such as raw shellfish prior to raw oyster consumption?
    - d. Did the case's physician warn him/her about eating raw oysters?
    - e. Existence of consumer advisories at point of purchase or consumption;
      - 1. If oysters were eaten in a restaurant, did the case observe the posting of the oyster advisory?
      - 2. If so, did the patient have full understanding and acknowledgement of the warning?

- f. Did the raw shellfish product consumed originate from an approved post-harvest treatment source or was it the natural raw product?
- g. Place and date of purchase.
- (6) Continue to conduct trace-back investigation related to each case report including the distribution process down to identifying the site of oyster harvest and report the information to the Louisiana Department of Health and Hospitals and Louisiana Oyster Task Force;
- **(7)** In order to determine the capacity for Post-Harvest Processing in the State of Louisiana as required by the ISSC, the Louisiana Department of Health and Hospitals will survey each certified shellfish processor to determine each processor's capacity for Post-Harvest Processing of oysters intended for the raw and/or half-shell market. The Louisiana Department of Health and Hospitals will collect the survey results and estimate the total Post-Harvest Processing capacity for the state. By December 31, 2004 a Post-Harvest Processing capacity of 25 percent of all oysters intended for the raw, half-shell market during the months of May through September is required by the ISSC. If the survey indicates that the state does not meet the ISSC required 25 percent Post-Harvest Processing capacity, then those resources approved by the ISSC for achieving the required goal may be used. Capacity is defined for this plan to include all operational plants as well as those under construction. The survey will collect the following information: a) the total number of oysters sold in Louisiana for the raw or half-shell trade for the surveyed time period from May through September; and b) each processor's capacity for Post-Harvest Processing of ovsters intended for the raw and/or half-shell market.
- (E) The Louisiana Department of Health and Hospitals will provide a comprehensive summary report including an estimate of the Post-Harvest Processing capacity, the total number of oysters sold for the raw or half-shell trade within Louisiana for the surveyed time period, and the annual total of *Vv* oyster-associated cases. This information will be compared to the objectives set by the ISSC.
- (F) The yearly compilation for the years 2005 and 2006 (averaged) must demonstrate that the average *Vibrio vulnificus* illness rate be at a 40 percent reduced level from the base number, which is estimated to be less than 0.644 per million population for Louisiana. [Note: Louisiana Department of Health and Hospitals reserves the right to set guidelines for determining if each *Vibrio vulnificus* case meets the criteria for the reduction requirement, i.e., the vibrio illness was determined to be associated with eating raw oysters, were the oysters harvested and handled under the requirements of the NSSP and Model Ordinance, were those identified as "at-risk" consumers properly advised of the risk of eating raw shellfish as required under the Louisiana Sanitary Code]
- (G) Should the yearly compilation for the years 2005 and 2006 (averaged) demonstrate that the average case rate for 2005 and 2006 meets the 40 percent reduction, then the Louisiana Department of Health and Hospitals will continue to adopt the plan as outlined above and modify as needed.
- (H) If the ISSC goal of *Vibrio vulnificus* illness reduction of 40 percent in Louisiana is not obtained by December 31, 2006, then the Louisiana Department of Health and Hospitals will immediately notify all shellfish processors to implement the requirement for Post-Harvest

Processing for 50 percent for all oysters going to the raw or half-shell market. Capacity is defined for this plan to include all operational plants as well as those under construction. If Louisiana cannot obtain the 50 percent capacity requirement, each certified dealer will be required to implement one of the following or equivalent measures:

- (1) Label all oysters, "For shucking by a certified dealer," or "For cooking only" when the Average Monthly Maximum Water Temperature exceeds 75°F;
- (2) Subject all oysters intended for the raw, half-shell market to a department-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) Label all oysters, "For shucking by a certified dealer," or "For cooking only" during the months of May through September, inclusive; or
- (4) Subject all oysters intended for the raw, half-shell market to a post-harvest treatment that is both approved by the department and reduces the *Vibrio vulnificus* levels to 3 MPN/g or less during the months of May through September, inclusive. The temperature, *Vibrio vulnificus* levels and months of the year parameters can be adjusted as needed to achieve the established illness reduction goal. Upon notification by the department of the above illness rate which does not meet the goal, each certified dealer will in writing notify the department which measure the certified dealer has chosen.
- (I) The yearly compilation for the years 2007 and 2008 (averaged) must demonstrate that the average *Vibrio vulnificus* illness rate be at a 60 percent reduced level from the base number, which is estimated to be less than 0.644 per million population for Louisiana. [Note: Louisiana Department of Health and Hospitals reserves the right to set guidelines for determining if each *Vibrio vulnificus* case meets the criteria for the reduction requirement, i.e., the vibrio illness was determined to be associated with eating raw oysters, were the oysters harvested and handled under the requirements of the NSSP and Model Ordinance, were those identified as "at-risk" consumers properly advised of the risk of eating raw shellfish as required under the Louisiana Sanitary Code]
- (J) If the ISSC goal of *Vibrio vulnificus* illness reduction of 60 percent in Louisiana is not achieved by December 31, 2008, then the Louisiana Department of Health and Hospitals will immediately notify all shellfish processors to implement the requirements under the ISSC and Model Ordinance. On January 1, 2009, if Louisiana cannot obtain the 100 percent capacity requirement, each certified dealer will be required to implement one of the following or equivalent measures:
  - (1) Label all oysters, "For shucking by a certified dealer," or "For cooking only" when the Average Monthly Maximum Water Temperature exceeds 75°F;
  - (2) Subject all oysters intended for the raw, half-shell market to a department-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) Label all oysters, "For shucking by a certified dealer," or "For cooking only" during the months of May through September, inclusive; or
  - (4) Subject all oysters intended for the raw, half-shell market to a post-harvest treatment that is both approved by the department and reduces the *Vibrio vulnificus* levels to 3MPN/g or less during the months of May through September, inclusive. The temperature, *Vibrio vulnificus* levels and months of the year parameters can be

adjusted as needed to achieve the established illness reduction goal. Upon notification by the department of the above illness rate which does not meet the goal, each certified dealer will in writing notify the department which measure the certified dealer has chosen.

- (K) In addition, the State of Louisiana will continue to work with the federal government and Congress to further develop Post-Harvest Processing technology; compile analytical data concerning *Vibrio vulnificus* levels in Louisiana waters and Louisiana oysters; and increase harvester education with current harvesting requirements-shading, time to refrigeration and other current control measures.
- (L) Louisiana Department of Health and Hospitals in conjunction with the Louisiana Oyster Task Force will meet at least annually to review the Plan and review progress. The work group will deliver a written annual progress report.

Performance Based Incentives: To be developed.

#### VIII. APPENDICES

- 1. State Vv Management Plans
- d. Texas

#### Texas Vibrio vulnificus Management Plan

#### Introduction/Background

*Vibrio vulnificus* is a naturally occurring bacterium that can be found in temperate marine waters. It is commonly found in oysters harvested from Gulf of Mexico bays and estuaries. Highest numbers occur in oysters harvested April thru November.

Concern for *Vibrio vulnificus* exists because certain people who eat raw molluscan shellfish can develop a severe and potentially fatal infection. Most people's immune systems are able to ward off these infections; however certain conditions put some individuals in a high risk category if they consume raw or inadequately cooked oysters. Conditions for high risk category:

- Diabetes
- Liver impairment (from hepatitis, cirrhosis and alcoholism)
- Cancer
- Low gastric acid
- Immunocompromise
- Hemochromatosis / hemosiderosis

In healthy individuals self limiting gastroenteritis can result from consumption of raw oysters. In contrast, immunocompromised individuals infected with *Vibrio vulnificus* can develop severe infections. Infections in such individuals can be complicated by bacteremia, resulting in septic shock. For those individuals, the fatality rate is greater than 50%. Fortunately, vibriosis related to raw oyster consumption is rare. Nationally, 30-35 illnesses related to shellfish can be expected resulting in 15-20 deaths annually. In 2000, Texas reported 11 cases resulting in 5 deaths. In 2001, Texas reported 6 cases resulting in 2 deaths. Virtually all cases of shellfish related *Vibrio vulnificus* cases have occurred from oysters harvested from states bordering the Gulf of Mexico.

In 2001, delegates at the Interstate Shellfish Sanitation Conference (ISSC) voted to implement a plan to reduce *Vibrio vulnificus* infections related to consumption of raw oysters. The plan establishes goals for illness reduction. The plan requires a 40% reduction of *Vibrio vulnificus* related illnesses in 5 years and a 60% reduction in 7 years in cases reported from Texas, Louisiana, Florida and California. If the goals are not met after 7 years, states must implement controls on harvest or processing to ensure that the goals are attained.

The State of Texas is required to prepare and implement a *Vibrio vulnificus* management plan. Based upon the National Shellfish Sanitation Program (NSSP) requirements passed at the 2001 ISSC conference the plan must contain the following required elements:

- 1. Education Program.
- 2. Process to collect standardized information and tracking of products.

- 3. Prepare for achieving a goal of Post-Harvest Processing capacity of 25% of all oysters intended for raw consumption harvested during the months of May through September by December 31, 2004.
- 4. Prepare for achieving a goal of Post-Harvest Processing capacity of 50% of all oysters intended for raw consumption harvested during the months of May through September by December 31, 2005.
- 5. Identification and preparation for implementing additional controls should the 60% reduction in the rate of illness not be achieved collectively by 2008. The controls will need to be implemented to achieve the required 60% reduction in the rate of illness. Control measures include requiring shucking, requiring Post-Harvest Processing, closing shellfish waters above 75 degrees, and closing waters for half shell oysters during certain months.

Authority to implement the *Vibrio vulnificus* Management Plan is contained in Chapter 436 of the Health and Safety Code.

#### **Required Elements:**

#### 1. Education Program

It is hoped that an effective ongoing education program can achieve the required illness reductions of 40% in five years and 60% in 7 years. The Texas Department of Health (TDH) as the Authority for the processing and sale of oysters, and the ISSC has conducted educational efforts for many years in Texas. On-going efforts have included yearly press releases warning at-risk consumers not to consume raw oysters, piloting a health care provider education effort in Travis County, airing of television public service announcements in the Houston area, regular articles in Disease Prevention Newsletters to health care professionals around the state and distributing educational pamphlets in Spanish and English at various events in the state.

For an educational program to be effective, we must rely on partnerships to be able to maximize our efforts. The ISSC has developed tools for use in the educational efforts. These tools include educational pamphlets in Spanish and English, physician fact sheets, education videos for clinicians, public service announcements and media press sets. Wherever possible, Texas should use the tools provided by the efforts of the ISSC. Within TDH, partnerships will be developed between associateships that deal directly with risk groups such as those involved in diabetes, hepatitis and HIV education and with any continuing education activities for physicians, nurses, epidemiologists or other health care professionals. Continued partnership with Infectious Disease Epidemiology and Surveillance Division is essential to a successful program. Outside of TDH, partnerships will be arranged with Texas Department of Agriculture (TDA) to include the warning to at-risk individuals in their promotional efforts. Additionally, Texas A&M Extension is adding oyster information into their food safety program used by home demonstration agents around the state.

The ISSC *Vibrio vulnificus* Management Committee has provided guidance on what program elements should be contained in a state education program. Elements should address education to high risk consumers, health professionals and broader consumer audience. Attachment 1 lists proposed Texas educational activities in the three categories. It is expected that the plan will change as more opportunities become available to reach populations at-risk or to educate health care professionals.

Educational activities will be required to be sustained for the full 7 years of the management plan. Long term funding should be sought to implement the *Vibrio vulnificus* Management plan.

#### 2. Process to collect standardized information and tracking of product.

A workgroup of the *Vibrio vulnificus* subcommittee is developing an addendum to the CDC Vibrio investigation form. The form and addendum will be used by the core states (TX, LA, FL, CA) to gather standardized information on *Vibrio vulnificus* infections.

In order to answer questions regarding the handling of the product at all points between harvest and final consumption, additional efforts by local and regional sanitarians will be needed to document holding conditions at each step. Investigations will include inspections of certified dealers, all wholesalers that handle the product and the final retailer before consumption.

3. Prepare for achieving a goal of Post-Harvest Processing capacity of 25% of all oysters intended for raw consumption harvested during the months of May through September by December 31, 2004.

Several Post-Harvest Processing processes have been demonstrated to significantly reduce *Vibrio vulnificus*. It is thought that increasing the percentage of post-harvest treated oysters in the market place will result in a decrease in illnesses.

However, this logic is based on the assumption that the Post-Harvest Processing reduces the *Vibrio vulnificus* levels significantly and requires market acceptance to replace fresh caught warm weather oysters. Several types of Post-Harvest Processing processes have demonstrated the ability to significantly reduce *Vibrio vulnificus*. High pressure treatment, mild heat pasteurization and low temperature treatment with extended frozen storage have demonstrated significant *Vibrio vulnificus* level reductions in oysters. Market acceptance of post-harvest treated product is essential if these processes are to be effective in reaching the illness reduction goal.

The purpose of promoting Post-Harvest Processing is to prepare the industry for required Post-Harvest Processing of oysters intended for raw or half-shell consumption in case educational efforts fail to achieve the required illness reduction goals. The 25% capacity must be in place by December 21, 2004.

The Texas Department of Health will gather information needed to determine the percentage capacity of Post-Harvest Processing plants in Texas. At time of certification, starting in 2002 each licensed facility will need to determine the Post-Harvest Processing capacity of the facility. The data will be retained in central office files. Harvest figures for oysters harvested from Texas waters from May - September will be obtained from Texas Parks and Wildlife. An estimate will be made to determine the percentage of oysters that will be shucked. Once this data is gathered, capacity percentage will be determined for compliance.

TDH will facilitate meetings with industry to discuss Post-Harvest Processings. Texas A&M Galveston and Sea Grant could work with industry in discussing technical aspects of available Post-

Harvest Processing. The ISSC will provide information regarding financing of opportunities for Post-Harvest Processing. ISSC will develop criteria for post-harvest validation verification studies.

4. Prepare for achieving a goal of Post-Harvest Processing capacity of 50% of all oyster intended for raw consumption harvested during the months of May through September by December 31, 2005.

All elements of #3 apply to this required element. The percentage capacity must be 50% by 12-31-05. If the 40% reduction in the rate of illness is not met by December 2006, the states must implement Post-Harvest Processing or implement other controls to sufficiently reduce illnesses.

5. Identification and preparation for implementing additional controls should the 60% reduction in the rate of illness not be achieved collectively by 2008. The controls will need to be implemented to achieve the required 60% reduction in the rate of illness. Control measures such as requiring shucking, requiring Post-Harvest Processing, closing shellfish waters above 75 degrees and closing waters for half shell oysters during certain months.

The state of Texas will need to evaluate the percentage of illness reduction needed to achieve the collective reduction. Specific actions will need to be assessed as to their ability to achieve the desired decrease. The actions should be taken from the list provided in the issue:

- (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 Treatment 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 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.

#### **Conclusions:**

Implementation of Issue 00201 passed at the July 2001 ISSC meeting will be phased in over a number of years. Texas must begin educational efforts and implementing Post-Harvest Processing incentives in order to accomplish the illness reduction rate goals of 40% by 2006 and 60% by 2008. The evaluation of the plan will be conducted by the US Food and Drug Administration. The ISSC *Vibrio vulnificus* Management Plan will be updated yearly to make needed changes in state actions.

### **Attachment 1**

Texas Vibrio vulnificus Education Plan

Target Audience	Education Plan Activity	Measure of Performance
High-Risk Consumers	Distribute consumer brochures (Spanish and English)	# distributed, identify at-risk group
	Partner with health & advocacy groups & organizations with membership of those at-risk	Type and number of activities to be conducted, e.g. materials distributed, internet postings, newsletters sent, presentations given, etc.
	Place articles on <i>Vv</i> in publications oriented towards those at-risk	Circulation and # of persons reached
Health Professionals	Conduct educational programs for clinicians, such as nurses, county health personnel, physicians' grand rounds, medical association meetings, in-service training for ER doctors, etc.	# of clinicians reached through presentations
	Develop & implement CME (Continuing Medical Education) program for clinicians	# of clinicians receiving CME units for inservice training
	Distribute fact sheets  Distribute videos & accompanying	# fact sheets distributed
	materials  Develop yearly DPN articles to distribute to health care providers	# video packets distributed
D 1 G 1 H		# of DPN distributed
Broader Consumer Audience	Placement of articles on <i>Vv</i> prevention in print media to general audiences	Estimated circulation
	Disseminate press kits to media outlets  Distribute press releases to news outlets	# of media outlets reached; # of broadcasts, estimated viewers
	Broadcast 60-second TV spot on Vv prevention	Outlets reached
	Distribute educational materials at community health fairs and events	Estimated # of viewers
	Work with Texas A&M Extension to include oyster education in food safety program	# of demonstration / people
	Include education materials with Texas Department of Agriculture demonstration / promotion events	# of events / people in attendance
	Distribute Oyster handling requirements to retail establishments in Texas	# of handling posters, brochures, promotion events/# of people
		# of materials distributed

- 2. Vv Education
- a. ISSC Executive Office

The adoption of Proposal 00-201 by the ISSC in July, 2001 meant that now the Model Ordinance requires that each state with two or more etiologically confirmed cases of *Vibrio vulnificus* develop and implement a *Vibrio vulnificus* Education Program which will be reviewed annually under FDA Evaluation Criteria. Each program must address the following populations and evaluate their progress: At-risk population, Medical/Health Community and Physicians and other Health Care Professionals and the General Population.

In 2001 the ISSC began the following activities to address education of at-risk consumers.

- 1. Provided partial funding for a facilitator to assist states in developing and implementing *Vibrio vulnificus* illness reduction as outlined by the Conference. These state programs utilize a comprehensive network of regulatory, advocacy groups, industry and public health professionals to accomplish education of high-risk consumers and other illness reduction strategies. Materials developed funding from other sources and provided it to states in the implementation of their state plans.
- 2. Provided funding for distribution of educational materials in workshops and outreach projects. The ISSC worked with the states of Florida and Mississippi to conduct educational workshops for licensed physicians. Additional efforts to educate clinicians will be held in Alabama, Mississippi, Louisiana and Texas. The workshops addressed diagnosis, treatment, and other educational information related to *Vibrio vulnificus*. The location of the workshops was determined by identifying areas reporting higher numbers of *Vibrio vulnificus* illnesses.
- 3. Provided funding for conduction of outreach projects and other proposal, which offer innovative opportunities to reach the at-risk population. This project proposed to underwrite the cost of conducting outreach projects and other workshops as deemed necessary by individual Gulf States.
- 4. Assisted in funding state pre and post-assessment of *Vv* educational program. ISSC provided partial funding for evaluation of various state and advocacy group education efforts.

In 2001 and 2002 the ISSC accomplished the following tasks:

- Developed educational materials for presentation to the Florida Medical Association. These materials will also be used for other states as they conduct their outreach projects.
- Provided state facilitator to meet with states and assist in the organization of their outreach programs.
- The ISSC State Facilitator began working on state voluntary *Vibrio vulnificus* disease reduction strategies. Letters were sent to each state by the ISSC Executive Director requesting cooperation in anticipation of ISSC Issue 00-201. Meetings were held with Florida, Alabama, Mississippi, and Louisiana with an addition meeting in Louisiana focused on the development of an education program scope of work.

- Met with Texas Department of Health to address the state epidemiological reporting requirements, a Consumer Education Program, a plan for reaching the Post-Harvest Processing 2004 and 2006 goals and/or equivalent goals as spelled out in Issue 01-201 as adopted by the 2001 ISSC Conference.
- Began developing contracts with States to provide funding for each state's *Vv* Education Programs.
- Provided materials for Florida Medical Association Meeting. Materials were distributed to participants.
- Participated in a panel discussion on *Vibrio vulnificus* and its effect on the at-risk consumer at the Florida Medical Association Meeting.
- Provided *Vibrio vulnificus* Educational Display for exhibition at the Florida Medical Association Meeting.
- Reviewed participants' feedback from Florida Medical Association Meeting to determine the effectiveness of materials provided.
- Met with state education coordinators as a group to discuss educational activities to accomplish illness reduction strategies for their respective state.
- Worked with each state to develop the educational component of their illness reduction strategy management plan. These plans incorporate physician and health care provider workshops.
- Requested Gulf States identify opportunities to conduct workshop for physicians and other health care personnel.
- Florida agreed to work with the ISSC to conduct a *Vibrio vulnificus* workshop for food handlers and inspectors at the retail level and to seek a speaker's slop and space for the ISSC display of *Vv* education materials at the annual meetings of the Florida Nursing Association and Florida Dietetic Association.
- Began development of educational kits for workshop distribution.
- Began gathering information on the use of web-based training for health care professionals seeking continuing education credits.
- Received guidance from the VMC and *Vibrio vulnificus* Subcommittee which is continuing to develop implementation strategies for the ISSC *Vibrio vulnificus* illness reduction program. The VMC has adopted interim criteria for evaluation of state education programs. The criteria include physician and other health care provider workshops.

In October 2003, ISSC requested a redirection to address the following. Develop an online education module for physicians on *Vibrio vulnificus* that satisfies state requirements for continuing medical education (CME) units. This course is intended to enhance physicians' ability to prevent, diagnose and treat patients exposed to *Vibrio vulnificus* and to improve overall competency in this area.

The ISSC has developed the course curriculum, including setting objectives and determining educational content. The ISSC also provides oversight to the educational software development firm with expertise in this area. This firm will also maintain records of those that have successfully completed the training and send them written confirmation of completion.

The ISSC will provide funds for states to promote the online program to physicians through associations, meetings, journals etc.

In November 2004, the Interstate Shellfish Sanitation Conference (ISSC) launched "Vibrio vulnificus Diagnosis, Prevention and Treatment" an online education program for physicians and part of a national effort to prevent illness and death from Vibrio vulnificus. Tulane University approved the course as satisfying national requirements for continuing medical education (CME) units for licensed physicians. For 18 months, Tulane University has agreed to provide 1.0 CME units to medical doctors who complete the course with a passing score on the final exam.

This course prepares physicians to identify the clinical manifestations of *Vibrio vulnificus* infection, know current treatment guidelines, recognize groups at higher risk of infection and advise patients to avoid exposure to raw oysters. Modules on diagnosis, treatment and prevention address each of these areas in detail. Audio and visual input, combined with photographs, illustrations, graphics, and self-tests make the course interesting, engaging and effective.

In October 2004, the ISSC sent a letter to 15,141 licensed physicians in Texas, Florida and Louisiana informing them about the course. This letter resulted in the course enrollment to date. This is just the first step, however. Further promotion through state and regional physician associations, medical journals and websites is planned over the next few months. Promotion will intensify as warmer weather and the high-risk season approaches.

Flying Fish, the software firm who developed the course, is responsible for tracking course participants, including rates of completion, exam scores, evaluations and demographics. To date, 86 physicians have accessed the course and 73 have successfully completed it. These physicians include 42 from Florida, 26 from Texas and 10 from Louisiana. A handful of physicians from other states have taken the course as well—Mississippi (3), Georgia (1), New York (1) and Missouri (1). The course took participants an average of 15 minutes to complete.

### 2. Vv Education

### b. State Vv Education Programs

- 1. The ISSC State Facilitator has provided technical assistance to each of the source states, Florida, Alabama, Louisiana, and Texas, in development and implementation of Vv risk management plans. Additionally, Mississippi, Georgia and California were assisted in the development of their voluntary Vv education plans. Meetings were held in six of the states to form Vv education advisory committees and to select state education coordinators. ISSC funds partial salaries for Vv education coordinators in Louisiana and Georgia.
- 2. In some states the funding of a state coordinator has greatly expanded the *Vv* education activities. For example: ISSC has a contract with LSU to fund an education coordinator for Louisiana. The State Coordinator, hired under the contract has done extensive work with atrisk groups and partners such as Alcoholics Anonymous, American Liver Foundation, American Gastroenterological Association, and American College of Gastroenterologists. She has arranged media outlets for ISSC *Vv* press kits and developed distribution outlets for ISSC *Vv* education materials to the at-risk population. In addition, she identified opportunities for providing educational exhibits and materials on *Vv* at meetings and conventions of medical associations and other groups that target the at-risk consumer. The coordinator works closely with state agencies such as Louisiana Department of Health and Hospitals who develop and distribute *Vv* medical treatment information to emergency rooms for prevention, early detection, and treatment of *Vv* and are in the process of developing physician *Vv* education (CEU) programs.
- 3. Georgia began a voluntary program in 2002 when the Division of Public Health reported seven *Vv* cases, which resulted in four deaths. The ISSC facilitator developed a contract with the University of Georgia Marine Extension Service to fund a Georgia *Vv* education project beginning July 1, 2003. The Georgia Education Project is targeting four: health care professionals, at-risk consumers, general public, and seafood dealers who sell raw oysters.
- 4. Unfortunately, in 2003 California passed emergency regulations banning raw oysters from the Gulf of Mexico. Although there were numerous meetings with California Department of Health and elected officials the ban was made permanent and resulted in formal complaints by Louisiana, Florida and Alabama. This has caused a temporary halt in *Vv* education efforts. However, prior to the imposed ban the State Facilitator assisted California in developing and implementing a *Vibrio vulnificus* Education Program directed at Spanish-speaking Latino males with alcohol induced liver disease within southern California. The program was a collaborative effort of the California Department of Health Service, Food and Drug Branch, California Department of Alcohol and Drug Programs, FDA, Los Angeles, Orange and San Diego county health departments. The programs still have available the media program and materials developed by Magnet Communications, working closely with FDA. The resulting media campaign was conducted successfully in Miami and Houston in May 2003.

Listed below are a few highlights from the very active state programs. A cumulative summary can be found in the appendices.

### FLORIDA

- The *Vv* Risk Management and Education Plans were completed.
- The Vv training module to educate nurses and dieticians was completed and presented at over 20 seminars throughout the state.
- FL Dietetic Assoc. meeting (769 attendees)
- There is an on-going effort to place articles on Vv in dietetic, nursing and HMO newsletters.
- Training materials have been developed and distributed for food handlers and inspectors at the retail level, emphasizing time/temperature issues, tag retention and warning language. Classes have been conducted, using the materials, for restaurant inspectors. A training tape, developed within this timeframe, has been made available to restaurant inspectors statewide. Inspector's Guide-174 restaurant inspectors
- 20,000 food service industry brochures distributed
- Florida Department of Agriculture and Consumer Services (DACS) Agreement with Winn Dixie pharmacies to distribute *Vv* information to high risk patients with their prescriptions
- Florida began a successful program with pharmacies. 27,000(English) and 3000 (Spanish) brochures *Vv* educational materials are placed with prescriptions for at-risk patients. Other states have picked up on this opportunity and are contacting pharmacy chains
- Coordination with ALF Gulf Chap. Blue Cross/Blue Shield and other HMOs to distribute Florida *Vv* education materials, publish articles in leading journals, and state health newsletters

### ALABAMA

The Alabama Vv Risk Management Plan has an educational component as follows:

- Training seafood processors in the handling of seafood, which includes a *Vv* component, is an on-going project.
- Seafood Safety Awareness packet to agencies, media and private sector
- *Vv* education packets/toolkits are being distributed to county health departments.
- Training in Vv Education to new environmentalists & interested groups
- Provided forum for discussion of *Vv* related issues at the annual Gulf and South Atlantic States Shellfish Conference.

### LOUISIANA

- Developed a state *Vv* education plan.
- Prepared and presented CEUs for nurses and MDs via LA Public Health website
- Conducted an Oyster Food Safety Workshop at the library on the main campus of LSU.
- Held conferences with state specialists to plan statewide distance learning training of all LSU Ag Center Extension Agents.
- Staffed various educational booths and provided information on Vv to interested parties.
- Conducted an Oyster Food Safety Workshop that received coverage by local television stations.
- Conducted a 28-minute radio interview on oysters and the Vv issue. The station has 60 affiliated and 7.5 million potential listeners.
- Prepared news article for mass media distribution.
- Presentations to and materials distributed to 73 family consumer educators.

- Provided information on the risk of eating raw oysters to the attendees of the Grandparents Raising Grandchildren statewide conference. Information reached approximately 225 participants.
- Conducted consumer workshop for the elderly.
- Working with Health Systems Pharmacy and LA Pharmacy Association for distribution of *Vv* materials.
- Presented Serv-Safe Course to LA Restaurant Association.
- Conducted educational programs for the Louisiana Dietetic Association in nine districts and at statewide meeting.
- Attended US conference on Aids and worked with HIV Clinic Network.

### **TEXAS**

- The Seafood Safety Division of the Texas Department of Health developed a *Vv* education mobile display board.
- Distributed 1700 English and 600 Spanish brochures at 64 Methadone Clinics
- Distributed 800 brochures at Bi-National TB Conference.
- Educated 295 STD and 316 HIV contractors on Vv.
- Provided educational materials to participants of the Texas Medical Association Meeting, which had 4500 attendees. Educational materials were provided to medical schools and dietician societies.
- Texas A & M Extension Service distributed Spanish and English consumer information brochures in 20 coastal county offices and 12 statewide district offices.
- Texas Department of Agriculture included an "at-risk consumer message" in promotional presentations at various Food shows. Plans continue in the use of bilingual marketing specialists to reach the Hispanic population.
- The Texas Department of Health, Seafood Safety Division, is working with the ISSC to distribute educational materials to various sources. Distributed Reference material as follows:
  - Vv Reference materials distributed 255
  - Spanish/English *Vv* brochures more than 8450
  - (5000 additional to Tamalipus health officials)
  - Corpus Christi (100 English, 100 Spanish, 50 fact sheets)
  - Bacliff (500/500/50)
  - 67 Methadone clinics (1700/600/67)
  - 325 End Stage Renal facilities (24,000/17,000/2,000)
  - Physicians Fact sheet distributed 2650
  - Clinician Guide distributed 80 (60 to advocacy groups, local health clinics, medical and pharmaceutical contacts)
  - Video Press Kits 25 (ISSC sent these kits to Texas TV stations
  - Interviews for media re Vv 5 (Radio newspaper, television)

### **MISSISSIPPI**

- The Mississippi Department of Marine Resources has developed several *Vibrio vulnificus* educational efforts.
- Personnel Training Provided training courses on HACCP, Plant Sanitation, and other safety issues dealing with NSSP and state regulations and prevention of foodborne diseases Education-Printed 5000 Food Safety brochures titled "Raw Seafood"; compiled educations materials developed by the ISSC for distribution to the public; prepared sanitation labels and

posters in Spanish and Vietnamese for distribution to the industry; mailed out articles on industry concerns and food safety and ISSC Vv education materials to Seafood Dealers; coordinated with the MS Department of Health on the availability of Vv educational materials available through the ISSC; began a regular column on seafood safety in the DMR's newsletter including articles on seafood safety, cooking tips and Vv; and, submitted a report for media release to the local paper on Vv and the danger of eating raw oysters quoting the ISSC media release article on May 2002 (Sun Herald daily circulation average 50,000).

 Public Outreach – Conducted phone survey on technical assistance needs of oyster industry, participated in various public events to distribute food safety materials developed by the ISSC.

### **GEORGIA**

- Presentation at the Southern Medical Association annual convention in Atlanta Nov. 6-8, 2003
- Article, Vv Infections in At-Risk Patients, in Georgia ALF newsletter (circulation 3,000 A Vv
- Materials to doctors, diabetes educators and county extension agents (7500 brochures) and county health departments (200 brochures)
- Prepared *Vv* article for June 2003 "News for Family and Consumers" distributed to 70 extension agents (7,700 brochures.
- Article, Vv Infections in At-Risk Patients, in Georgia ALF newsletter (circulation 3,000 A Vv

### **CALIFORNIA**

- A Vv Education Program directed at Spanish-speaking Latino males with alcohol induced liver disease within southern California has been initiated. The Program is a collaborative effort of the California Department of Health Service, Food and Drug Branch, California Department of Alcohol and Drug Programs, and the FDA.
- Magnet Communications developed a short-term project, which includes key messages about oyster consumption and at-risk health conditions. The bilingual message reflects existing knowledge, understanding, and perceptions about oyster consumption and health conditions among Hispanic males with compromised immune systems.
- Further plans by Magnet Communications included:
  - Camera-ready article (taken from backgrounder)
  - Vv Fact Sheet
  - Pitch Letter
  - B-roll
  - Media Outreach/Spokesperson Media Tour
  - Public Service Announcements
- The Outreach programs were planned with Los Angeles, Orange, and San Diego counties.
   ISSC and Magnet communications would supply needed materials, the counties would distribute.

- 2. Vv Education
- d. Rx for Success

In 2002 the Florida Department of Seafood Marketing began an innovative collaboration with Winn-Dixie Pharmacies. By utilizing this chain of supermarket-based pharmacies, the Department disseminated over 30,000 brochures on Vibrio vulnificus directly to those most vulnerable to illness. The approach they used is easy, inexpensive and effective. The California Department of Health Services adopted a similar approach with pharmacies in Safeway supermarkets to prevent childhood lead poisoning.

Why would a retailer want to educate consumers about raw oysters? Because educating people about food safety fits with pharmacies' role as health promoters. Since physicians have less and less time to spend with patients, consumers turn increasingly to pharmacists for medical information and advice. They consider pharmacists to be trustworthy sources of information, and consumer confidence is for good business. Pharmacies build their reputation as good neighbors by providing health information to customers. It sends a positive message about the company's integrity and helps certain businesses stand out. A good reputation also promotes customer loyalty, communicating that the pharmacy cares about more than profits. The fact that consumers have confidence in pharmacies makes pharmacies desirable advisors about food safety. The strategy is simple: utilize a retail pharmacy chain to deliver information to those most susceptible to illness from raw oysters. Such adults often have health conditions requiring pharmacy medications. By including brochures about raw oysters with drugs prescribed to treat these conditions, the information is delivered to those who need it most. This targeted approach is efficient, reaching only those at-risk. Distribution costs are absorbed primarily by the pharmacy. With brochures currently subsidized by the ISSC, the only real cost to health programs is a few hours of staff time overseeing implementation with a pharmacy chain

### VIII. APPENDICES

### 3. Vv Illness Reports for 2000-2005 Illness Reporting

The goal of the *Vibrio vulnificus* Risk Management Plans is to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses from the consumption of commercially harvested raw or undercooked oysters by 40 percent as reported by core reporting states collectively, for years 2005 and 2006 (average), and by 60 percent for years 2007 and 2008 (average), from the current rate of 0.306/million. The core reporting states include Florida, Texas, California, and Louisiana. The illness rate shall be calculated as the number of illnesses per unit of population.

The goal may be reevaluated before the year 2006 and adjusted should new science, data, or information suggest a change is appropriate. For example, population adjustments can be made in consultation with statisticians and epidemiologists from core reporting states and federal agencies. The baseline data for measuring illness reduction shall be the reported illnesses in the core reporting states for the period 1995 to 1999, as compiled by the Southeast Regional Office of the FDA. The data used for measuring goal attainment shall begin with 2002 data.

The following information is a brief summary of illness data collected by FDA from 2000 to August of 2005. The full reports can be found in the appendices.

```
Number of cases reported, 1/1/00 to 12/31/00:
                                                  30
Number of Deaths:
                                                 18
                                                 29/18
Number of Males/Deaths:
Number of Females/Deaths:
                                                  1/0
States Involved (consumption):
                                                  11 (AR-1; CA-7; FL-6; LA-1; ME-1; MO-1; MS-1; NC-1; OH-
1; TX-9; VT-1)
Number of cases reported 1/1/01 to 12/31/01:
                                                   6
Number of Deaths:
                                                   5
Number of Males/Deaths:
                                                  5/4
Number of Females/Deaths:
                                                  1/1
States Involved (consumption):
                                                   4
                                                          (AR-1; FL-1; LA-3; TX-1)
Number of cases reported 1/1/02 to 12/31/02
                                                  35
Number of Deaths:
                                                  17
Number of Males/Deaths:
                                                 27/15
Number of Females/Deaths:
                                                  8/2
States Involved (consumption):
                                                   11
                                                          (CA-5; DC-1; FL-6; GA-4; LA-1; MD-1; ME-1; MO-1;
NC-1; SC-3; TX-4; UKN-7)
Number of Cases/Deaths Reported by CA, FL, LA and TX:
                                                          14/8
                                                                  (CA-6/5; FL-5/1; LA-1/0; TX-5/3)
Number of cases reported 1/1/03 to 12/31/03
                                                   35
Number of Deaths:
                                                   17
Number of Males/Deaths:
                                                  25/12
Number of Females/Deaths:
                                                   9/4
Number of Unknown/Deaths:
                                                   1/1
States Involved (consumption):
                                                   12
                                                          (AL-2; CA-1; FL-14; GA-5; IN-1; LA-1; NM-1; OK-1;
SC-1; TN-1; TX-4; VA-2; UKN-1)
Number of Cases/Deaths Reported by CA, FL, LA and TX:
                                                          20/9
                                                                  (CA-1/1; FL-12/3; LA-1/0; TX-6/5)
Number of cases reported 1/1/04 to 12/31/04
                                                   36
Number of Deaths:
                                                   20
Number of Males/Deaths:
                                                  32/19
Number of Females/Deaths:
                                                   4/1
States Involved (consumption)
                                                   13
                                                          (CO-2/1; GA-2/0; FL-12/5; LA-2/1; MD-2/1; MI-1/1;
                                                          NJ-1/1; NM-1/1; NY-2/2; OH-2/2; OK-1/0; SC-2/0; TX-
                                                          6/5)
Number of cases reported 1/1/05 to date:
                                                   6
Number of Deaths:
                                                   2
Number of Males/Deaths:
                                                   6/2
Number of Females/Deaths:
                                                   0/0
States Involved (consumption):
                                                    3
                                                          (FL-4/1; NJ-1/1, TX-1/0)
Number of Cases/Deaths Reported by CA, FL, LA and TX:
                                                          3/0
                                                                  (FL-2/0; TX-1/0)
```

### 4. Post-Harvest Processing Capacity Report

The NSSP requires that each source state achieve the 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) by December 31, 2004. The percentage of Post-Harvest Processing will include the capacity to produce post-harvest treated product of all operational plants as well as plants under construction. If disease reduction goals are still not met by December 31, 2006, the source state is required to meet a harvest treatment capacity of 50% of all oysters intended for the raw, half-shell market during the months of May through September. The ISSC has been working with participating states to promote and encourage voluntary industry adoption of Post-Harvest Processings where feasible by developing workshops and post-harvest education materials. The ISSC collected and evaluated the post-harvest capacity figures provided by each of the states. These data were compiled and presented to the *Vv* Subcommittee in August 2004 at the ISSC Executive Board Meeting in Las Vegas, Nevada to show the relationship to the PHP goals established by the Conference.

ISSC PHT Survey Results Data for Period of May 1 - September 30, 2004

			PHT Capacity	
State	Total	Half-Shell	(May-Sept)	% Half-Shell PHT
Florida*	4,333,204	3,604,396	22,032,000	611.00%
Alabama	490,554	0	0	N/A
Louisiana	62,236,423	16,192,605	12,852,000	79.00%
Texas	14,356,120	10,679,380	15,759,000	148.00%
TOTALS	81,416,301	30,476,381	50,643,000	166.00%
Florida Updated 10/5/04	4,333,204	3,604,396	11,610,000	322.00%

### VIII. APPENDICES

### 5. Task Force Report – Future Directions

The Vv Subcommittee presented the following questions to a Special Task Force at the March meetings in Point Clear, Alabama. The Task Force recommended the findings to the Subcommittee, which acted upon each.

- 1. The goals are collective, therefore, what does ISSC expect of the individual states? If the collective goals of the Vv Risk Management Plan are achieved, the source states are in compliance with the National Shellfish Sanitation Program.
- 2. Each state is being evaluated individually. How will the evaluation of the collective goals be conducted? Direct ISSC administration and staff to meet with states to discuss their *Vv* Risk Management Plans, individually and collectively, along with USFDA Shellfish Specialists and report back to the Committee at the August 2005 meeting.

- 3. What are the criteria for evaluating the goals? Committee members agreed that states will develop a collective plan and report to the Committee.
- 4. How and who will evaluate *Vv* State Plans and the achievement of goals?
- 5. Are the goals pass/fail or will additional illness reduction measures be based on percentage of goal not achieved? Committee members agreed that states will develop a collective plan and report to the Committee.
- 6. If core state cases are reduced and cases increase nationally, what is the process for modifying the Plan? Conference will have to change the Plan.
- 7. Can consideration be given to individual states that have had success in reducing illnesses? Committee can assess the success of a state's individual plan and make recommendations. The accomplishments of the states can/will be reflected in the FDA (Marc Glatzer's) report.
- 8. What tools can be used by states to evaluate the effectiveness of proposed strategy for illness reduction? The only tool available at this time is the FDA Vv Risk Assessment. Can the Consumer Education Survey results be used as a tool? The consumer education survey was developed only to measure the overall effectiveness of the Vv Education Program. In addition, environmental data along with illness data can be used. Should the assessment of tools be used to evaluate effectiveness of reduction of illness? How many states are using the addendum for reporting illness? The ISSC will contact the core states and encourage those states to use this reporting form.
- 9. Does goal setting end with achievement of the 60% goal? The ISSC Executive Office will reviews the Model Ordinance to propose language and to draft a proposal for the 2005 Biennial Meeting to clarify that long term illness reduction goals should be maintained after 2008.
- 10. Illnesses implicating non-Gulf states have occurred. It is the opinion of many that this could be the result of dealers tagging Gulf oysters as oysters of another state. How does the Conference address this problem? In light of market opportunities created by the Vv Risk Management Plan, the Vv Subcommittee (Vibrio Management Committee) requests the ISSC Executive Board ask sates and National Marine & Fisheries Service be more vigilant regarding potential tagging violations. Appoint a work group to explore possibilities of the Conference to work with states on the issue of mislabeling and report back to the Vv Subcommittee at the August 2005 meeting.
- 11. How do we address inter-state disagreements regarding individual state strategies that affect other states?

6. Requirements: Proposal 00-201 (NSSP Model Ordinance Requirements and Guidance Documents)

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

Additional Guidance - IV Guidance Documents

- 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, 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, and 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 State's *Vibrio vulnificus* management plan shall include, at a minimum:
  - 1. (1) The ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *vulnificus* illnesses;
  - 2. (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. (3) A standardized process for tracking products implicated in *Vibrio vulnificus* illnesses;
  - 4. (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. (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 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 processing 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; 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.

Responsible				
Agency/Contact	High Risk Consumers	Health Professionals	Broader Consumer Audience	Remarks
ISSC	Partnership:1) American Liver	At ALF Medical Advisory	New Revised Vv consumer	Produced and distributed
Ken Moore	Foundation (ALF), National Chapter,	Comm. 3,000 ISSC <i>Vv</i> brochures	brochures & distributed	educational materials,
Executive Director 803-788-7559	Gulf Coast, Los Angeles and San	to health care providers (incl.	>383,000(English) and >84,300	Catalon CV almotion materials
803-788-7339	Diego Chapters; ALF: mailing reached >50,000 by direct mail,	physicians). Distributed >59,539 health care	(Spanish).	Catalog of <i>Vv</i> education materials on web site.
Dorothy Leonard	20,000 in response to calls.	provider fact sheets.	30-second PSA (televised in	on web site.
State Facilitator	Articles in ALF newsletter	provider fact sheets.	GOM states 4,380 times in 2001	Expanded and updated shellfish
410-626-7206	(circ=45,000 households)	In cooperation with FL developed	GOW states 4,500 times in 2001	education section on the ISSC
410 020 7200	(ene 43,000 households)	"Clinicians Guide to Vibrio	Media kit developed and 274	web page
Michelle Bashin	Diabetes Digest Online (30,000	vulnificus Infection & Treatment	distributed in 2002 to outlets in 6	wee page
Education Coordinator	diabetics).	"(60 min video, journal articles,	states (approximately 25 TV	State facilitator assisted 7 states
510-223-3678		fact sheets, and brochures. (599	stations).	in the development of Vv Risk
	ALF Gulf Chapter mailings to 127	distributed)		Management Plans and/or Vv
Tom Herrington, Chair	vet organizations, 6 hospitals and	,	Conducted consumer survey	education programs. (Details
Vv Education Subcommittee	article in Veterans Post Newsletter.	List of published <i>Vv</i> reference	(contractor=Clearwater) 1,975	follow by state).
228-688-7941		materials (>207). Updated and	interviews with raw oyster	
	ALF Chapter newsletter (circ=2,500	available.	consumers. Results will be	Allocated funds to support state
	households) contained $Vv$ brochures.		compared with survey to be	activities (LA, FL, and GA).
			conducted 2 years after	Gave technical assistance and
	ALF San Diego distributed >4500 Vv	Continuing Medical Education	implementation of intense Vv	guidance to states applying for
	brochures to liver disease support	Program for doctors and nurses	education programs.	funds.
	groups and to 2 transplant centers &	accredited and available on-line.	- "	
	500 Vet organizations.		Follow-up consumer survey	New Vv exhibits available for
	I O I ID: D I I		which includes modifications	states and consumer education
	Iron Overload Disease Foundation,	Letters (approximately 15,000)	suggested by Vv Ed Comm.	groups, state medical assoc.
	International Hepatitis Foundation Multicultural Area Health Education	sent to all gastroenterologists and	completed by ORC Macro with	meetings.
		internists in the Gulf states	500 interviews, 115 Spanish speaking consumers in 4 states	Displayed at EDA Contaminants
	Center (Los Angeles County) Area Health Education Centers (LA)	announcing the program and	(FL,LA,TX,CA). Survey results	Displayed at EPA Contaminants in Fish Conference-8/2003)
	Area Hearth Education Centers (LA)	encouraging participation. 86 accessed, 73 completed course.	in April 2005.	III FISH Conference-8/2003)
	Produced Rx for Success-Teaming up	accessed, 75 completed course.	III April 2003.	ISSC web site expanded to
	with Walgreen's Pharmacies to			provide Vv Education reports and
	distribute Vv education materials.			downloadable publications.
	distribute / / oddomon materials.			assuddore publications.
				New harvester education video
				includes time and temperature
				controls to reduce levels of <i>Vv</i> .

Responsible				
Agency/Contact	High Risk Consumers	Health Professionals	<b>Broader Consumer Audience</b>	Remarks
Florida	Vv brochures to ALF Gulf Coast	Professional fact sheets and	"Pearls of Wisdom for Oyster	Developed Vv Risk Management
David Heil	Chapter. (See ISSC above). and	surveys and articles for	Lovers" distributed to county	Plan and Vv education program
FL Department of	Florida liver support groups	physicians, nurses, health	health departments. 9 regional	
Agriculture &Consumer		educators and dieticians (1300	food and waterborne disease	State laws require warnings at
Services	Coordination with Blue Cross/Blue	fact sheets, 10,000 patient	epidemiologists& health depts.	point of purchase.
850-488-5471	Shield and other HMOs.	education kits).		
			174 restaurant inspectors trained	Circulation of guidance re: Post-
Roberta Hammond	Agreement with Winn Dixie Drug	CME Workshop at FL Medical	w/1-hour video.	Harvest Processing (PHT) to
FL Department of Health	Chain (300 stores) to include Vv	Association (9/2001) 50 attended		retailers and processors
850-245-4116	brochures in prescription envelopes	workshop, 100 other individuals	20,000 food service industry	
	of immunocompromised patients.	received packets at/through info	brochures distributed.	
Paul Balthrop	(27,000 English, 3000 Spanish)	booth.	www.hospitalityeducation.org	
FL Department of	D' d'I d' CYV I I d' I'	D ( ) C FI D' ( )	D 1:: 27 1: 41:	
Agriculture &Consumer	Distribution of Vv brochures to liver	Presentation for FL Dietetic	Press kits to 37 media outlets,	
Services	support groups and one transplant	Assoc. 7/2002, 769 attendees and	press releases to 40 media outlets,	
850-488-0163	center (317 English, 126 Spanish.	7/2004.	67 county health departments.	
	Walling with Walanage to include	The Floride Names W. ontiels	Distribution of educational	
	Working with Walgreen's to include <i>Vv</i> brochures with prescriptions.	The Florida Nurse: Vv article		
	vv brochures with prescriptions.	(circ. 175,000)	materials at community health	
	December of El Liver Cumpart	Train the Trainer Westschen	fairs.	
	Recontact of FL Liver Support Groups & brochures sent:	Train-the-Trainer Workshop, 4/13/04 for Gulf Coast state and	Displays at professional	
	Liver support groups=267 English, 76	California health educators	associations	
	Spanish.	Camornia nearm educators	associations	
	Organ Transplant Centers = 50	Presentation for FL Academy of	Press release 5/28/04	
	English, 50 Spanish.	Physician Assistants, 8/6/04	110351010450 3/20/04	
	English, 50 Spanish.	1 Hysician 7 (3515tants, 6/6/64	Training of professional chefs	
	FL Hepatitis Program Council	Vibrio vulnificus Infection,	(01/05)	
	Meeting. They will include $Vv$	Prevention & Treatment for	(01/03)	
	materials in mail outs	Nurses presented at Hillsborough,	Overview of Vibrio vulnificus	
	materials in man outs	Cypress, and Broward County	issues, university classes:	
		Chapters.	Tallahassee Community College	
		C.1.up 1415.	Community Health class (2/2/05)	
		Infection, Prevention & Treatment	and University of Florida Food	
		for Dieticians presented at	Microbiology class (3/14/05);	
		Cypress, Broward, Pinellas,	County Extension Agents in-	
		Duvall, Manasota, Gainesville	service (5/19/05)	
		chapters& U of N. FL.		
		Ft. Lauderdale Culinary Institute		

Responsible				
Agency/Contact	High Risk Consumers	Health Professionals	Broader Consumer Audience	Remarks
Agency/Contact	High Risk Consumers	Infection, Prevention & Treatment for Health Care Professionals presented at FL Environmental Health Directors, Lakeland Reg. Medical Ctr., and St. Johns Co Health Dept.  Display, poster, materials at 2004 Symposium of Fl. Physician Assistants and presentation of Infection, Prevention & Treatment for Health Care Professionals  Display & Materials at FL Student Nurses Assoc. 2004 mtg.  Direct mailing of the availability of the free on-line CME credit for physicians and ISSC Vv fact sheet to licensed physicians in FL  1/4 page advertisement of the free on-line CME credit for physicians every issue of the Florida Medical Quarterly (circulation >17,000) from October 2005 through October 2008.  Vibrio vulnificus Infection, Prevention & Treatment for Health Care Professionals presented at Epidemiology Grand Rounds (teleconference, 6/25/05) and National Environmental Health Association (6/29/05)  Epidemiology of Vibrio	Vibrio vulnificus Infection, Prevention &Treatment for Health Care Professionals, County Extension Agents in- service (5/26/05)  Annual press release (5/27/05)	Remarks
		vulnificus, Viral Hepatitis Council (5/25/05)		

Responsible	W.I. D.I. G			
Agency/Contact	High Risk Consumers	Health Professionals	Broader Consumer Audience	Remarks
		Displays, posters and educational materials: Council for State and		
		Territorial Epidemiologists		
		Annual Meeting (6/6/05); Annual		
		Florida Dietetic Association		
		Meeting (7/11-7/12/05)		
		DACS and DOH are working		
		with USEPA GMP, Florida Sea		
		Grant Program, ISSC, Gulf and South Atlantic States Fisheries		
		Development Foundation, and		
		FDA to provide a direct mailing		
		to licensed physicians in AL, FL,		
		GA, LA, and TX (>118,000)		
		announcing the opportunity to		
		participate in the free on line $Vv$		
		CME course (letter with web link		
		and Vv fact sheet).		
		DACS and DOH are working		
		with Florida Sea Grant Program		
		and ISSC to provide		
		advertisement in all publications		
		of the Florida Medical		
		Association Quarterly		
		(circulation >17,000), the <i>Journal</i>		
		of the Louisiana State Medical		
		Society (circulation >7,000), and		
		the Texas Medicine (circulation		
		>34,000) beginning October 2005 through October 2008.		
		unough October 2008.		

Responsible				
Agency/Contact	High Risk Consumers	Health Professionals	<b>Broader Consumer Audience</b>	Remarks
Mississippi	Veterans Day events=400 Vv	Vv info presented at HACCP &	Jackson Co Fair	2003 Developed voluntary Vv
	brochures (Elderly)	sanitation courses for industry.	2002=5000 brochures/ fact sheets	Education Plan
Ruth Posadas			2003=300 brochures/fact sheets	
Bureau of Marine Resources	Celebrate the Gulf = $800 \ Vv$	Delivered <i>Vv</i> Education Toolkits	2004 = 300 brochures and fact	2003 Coordinated with MS
228-374-5022	brochures (2 events) and fact	including the video kit and the $Vv$	sheets	Health & Human Services on Vv
	sheets (Children)	brochures and Facts sheets to the Main		case reporting (Investigated 1 Vv
	2001=700 brochures	office of the MS Health & Human	Cajun Crawfish Festival	mortality case in NJ implicating a
	2003=450 brochures	Services for distribution to county	2002=1200 brochures	MS oyster as one of the oyster
	2004=>600 brochures /fact	health depts. other state and county	2003-250 brochures/fact sheets 2004=500 brochures/fact sheets	sources. On-going investigation
	sheets	agencies.	2004=300 brochures/fact sheets 2005= 100 brochures/ fact sheets	of a positive <i>Vv</i> mortality case in Biloxi, MS but uncertain whether
	2001/2003 Fishing Rodeo for	2 coastal hospitals& 2 branches of MS	2003–100 blochules/ fact sheets	it was a wound infection or oyster
	handicapped children=400 Vv	Health & Human Services received Vv	Fish &Wildlife Extravaganza	consumption
	brochures	Education Video kit for continuing	2003 = 500 brochures/fact sheets	Consumption
	ordenares	education of medical &health	2004 =150 brochures/fact sheets	2004 Assisted 1 certified and
	Presented a Vv Education	professionals.	Biloxi Seafood Festival	permitted seafood dealer develop
	seminar to 21 members of the	1	2002/2003= 800 Vv Brochures	a PHP facility for IQF
	Midway Methodist Men's	V 1 1 1 1 1 1	and fact sheets	2004 Assisted 1 certified and
	Thursday Club (Elderly and	Vv brochures and Facts sheets delivered to the three county health departments	2004 = 300 brochures/fact sheets	permitted facility develop a PHP
	retired) at the Jackson County,	in the coast.		HACCP Plan for freezing
	MS.	in the coast.	Printed and distributed 5000	
		2003 Vv brochures and Facts sheets	"Raw Seafood" brochures.	2003-2004 Providing information
	Classroom outreach=66 people.	delivered to the Training Department of	2003 Developed, printed and	to several certified and permitted
		the MS Restaurant Association.	distributed 5000 "Available PHP	seafood dealers on plans to put up
			Technologies for Oysters" and	a PHP plant and develop value
		Vv brochures and Facts sheets delivered	5000 Fact Sheets "Post-Harvest Oyster Processing Technologies"	added products of oysters.
		to a three Doctor's clinics and to two	Developed, printed and	2004 –2005 Conducted trace back
		Hospital Emergency lobby rooms.	distributed 5000 posters "Post-	investigation of a Vv case in
			Harvest Processing Technologies	Oklahoma City from a raw
		2005 Conducted Vv Health Education	for Oysters"	consumption of oysters.
		Workshop and distributed 9 Vv		
		education Toolkit and video to MS	2004 Reprinted another 5,000	Conducted another trace back
		Dept. of Agriculture and Commerce,	PHP brochures.	investigation of a Vv case in
		MS Dept. of Health, MS Restaurant Association. Fact sheets and brochures		Georgia from a raw consumption
		were given to 49 people from the state	2003 -2004 Prepared sanitation	of oysters.
		and federal regulatory agencies and the	labels & posters in Spanish&	
		MS Restaurant Association	Vietnamese.	2003 -2004 Conducted Consumer
		professionals.		and product profile survey In
1		Protestimis.		Coastal Counties of MS, one in

Responsible				
Agency/Contact	High Risk Consumers	Health Professionals		Remarks
Responsible Agency/Contact	High Risk Consumers	>500 ISSC Vv brochures given >250 PHP brochures given >250 Vv fact sheets given >250 PHP Fact sheets given  2005 Conducted a Vv and PHP display at the Regional Hospital Education seminar for a day.	Broader Consumer Audience  2002-2003- 2004 Vv article in DMR newsletter. (Circ=1000)  Vv media release May 2002(circ=50,000)  2003-2004-2005 Vv Education materials were inserted in the giveaways of the HACCP and Sanitation Training Course for MS Seafood Dealers and workers, ISSC Vv Video and Information Kit included.  2005 Printed 5000 copies and distributed some of the "Mississippi Oyster Seafood Safety" brochure with Vibrio vulnificus information inside.  2005 Vv education and seafood safety materials given away at St. Ann's Fishing Rodeo tournament. Est. > 100 people attended.	Jackson MS, and another at the International West Coast Seafood Show at Long Beach, CA and the Medical Community at Los Angeles CA.  2003-2004 Conducted PHP raw oyster sensory surveys among the Hispanic workers in Coastal MS.  2004 Collaborated with the MS Restaurant Association and MS Seafood Promotion & Marketing Bureau in showcasing Postharvest Processed oysters (IQF) to MS Legislature and the Governor serving over 11,000 guests in three occasions.  2003-2004 Contributed to the final report of the "Integrated Oyster Market Research, product development, Evaluation, Promotion and Consumer
			Est. > 100 people attended.	Promotion and Consumer Education for the Gulf of Mexico's Oyster Industry"  2003-2004 Compiled over a hundred titles of oyster PHP scientific journal articles for references  Attended the "Vv Train –the- trainer" workshop in New Orleans April, 2004  2005 Conducted a VV awareness survey among the members of the MS seafood industry and the business community

Responsible				
Agency/Contact	High Risk Consumers	Health Professionals	Broader Consumer Audience	Remarks
				2005 Approved the validation study of an oyster PHP using MS
				and LA oysters harvested from
				October till April only. The
				concurrence from FDA was
				received recently for the rapid
				freeze process of oysters.
				2005 Adapted new changes in
				2003 Model Ordinance to State
				Ordinance incorporated in Title 22 Part 17 (Regulation of
				Shellfish Landing, Unloading,
				Transporting, Processing,
				Buying, Selling, Opening, and
				Other Shellfish Related Activities
				in the State of Mississippi"
				2004-2005 Published printed and
				distributed 10,000 Oyster
				Cookbook with Vv warning
				information inside.
Louisiana	Vv article in AARP newsletter	Presentation/Vv materials @ 6 regional	News article, The Risk of Eating	Developed Vv Education Plan
Sally Soileau  Vv Education Coordinator	Booth/brochures at Grandparents Raising	LA Dietetic Assoc. statewide LDA meetings (>325 contacts) in 2003.	raw Oysters-Higher Levels of Vv in Warm Summer Waters (64	Employed Vv Education
LSU Ag Center	grandchildren Statewide Conf.,	meetings (> 323 contacts) in 2003.	parishes & web site)	Coordinator
225-389-3055	(3/2004) = 60 participants in	Developing web-based Vv module with	F	
	Hammond & 80 at Saint	CMEs for MDs and CEUs for nurses	Presentations and Vv materials to	Laws requires labeling on sacks
Susanne Straif-Bourgeois	Gabriel's Prison. Senior	via LA Public Health website.	73 family consumer educators,	of oysters and advisory to high
LA Public Health 504-568-5005	Nutrition at Scotlandville	Working w/Ochsner HMO for MDs and	in-service training of LSU extension agents, LSU's 1st	risk consumers posted at all retailers
304-308-3003	Community Center.	high risk patients	Mondays at the Market.	retariers
	5/2004 Senior Nutrition Food	mgn risk patients	iviolidays at the ividiret.	4/2004 LA Technical School
	Safety program=20 seniors & at	10 yr perspective for LA Morbidity	LA Restaurant Assoc. Serv-Safe	Wellness=25 students
	North Baton Rouge & ML King	Rpt. Dist=5000 physicians	course included Vv materials.	
	Community Center			Louisiana Restaurant Association
	Consumer workshop for the	LA Society of Health Systems	LA Food Service Expo >15,000	educational booth=6500
	elderly, health fairs		Workshop at American Wms Bus Assoc. and International	participants.
			Assoc. and international	1

Responsible Agency/Contact	High Risk Consumers	Health Professionals	Broader Consumer Audience	Remarks
	Working with 64 Councils on Aging-4500 brochures sent  2004 outreach to Diabetes Assoc., HIV clinics (HIV Ryan White sent 6000 brochures  9/2003 US Conf on Aidsdelivered 4000 brochures  DHH Office of Abusive Disorders Prevention (regional mgrs reach >30,000 clients.  Senior Food Safety Program at Mall of Louisiana for Walkers.  Senior Food Safety in Denham Springs Livingston Parish  Nutrition Education Workshop with Organ Wise Guys and Oyster Food Safety Vibrio vulnificus booth and workshop for audience  Senior Nutrition program: Senior food safety and Oyster Vv information  2 Main Street Market educational program for 1 <sup>St</sup> Monday at the Market Program on Blood Pressure-Hypertension/DASH Diet/ and Food safety Vibrio vulnificus	Louisiana Pharmacy Assoc. Annual Meeting # pharmacists, 1.5 CE hrs Oyster Vv Education Seminar & info shared w/175 contacts 4500 brochures Medical staff at Earl K. Long hospital (#dieticians, #physicians, nurses 4/2004 Ed booth at Food & Nutrition Program at LSU Ag Center = 125 participants  LA State Dietetic Assoc booth 175 participants.  Speaker at District LA Dietetic Assoc. & at Nicholls State in Thibodaux Regional  Booth & materials at Southern Medical Assoc. Meeting Nov.  11-13-2005 representing 41 states. Reached 633 physicians, 131 Residents and Fellows, 40 other health care professionals. Dr. Fred Lopez=speaker on Vv for CME credit. Co-authored SMA Journal article with Dr. Lopez, Dr. Sanders and Susan Wilson.  Provided 300 brochures for 2003 American Assoc of Office Nurses.  Conducted Nutrition/Food Safety for health care providers at Capital Area Agency=27 sites=3000 seniors  Direct mailing of the availability of the free on-line CME credit for physicians and ISSC Vv fact sheet to licensed physicians in LA	Association of Admin. Professionals.  Family Consumers Education and Nutrition Workshops  LA Restaurant Assoc trade show 16,000 attendees New Orleans  4/2004 Vv Ed booth at CAN DO in Baton Rouge=350 participants  5/2004 Booth at LA 4H Seafood Ambassadors-LSU=75 participants.  Conducted Food 7 Nutrition workshops at Baton Rouge & Thibodeaux  Louisiana Dietetic Association Oyster Food Safety Vibrio vulnificus educational booth at state meeting - 2005 Food and Nutrition Conference & Expo in Lafayette, LA with 300 participants reached with information and materials on Oyster Vv education.  Healthy Lifestyles 3 sessions; Jones Creek Library site for Town Hall public outreach Oyster Food Safety Vibrio vulnificus educational booth (75); Session 2 at Baton Rouge Parish  6 Main Street Market Calcium/Osteoporosis and Oyster Vv educational program for I <sup>St</sup>	VV Education outreach at Hispanic Festival 2004 in Baton Rouge =6000 participants.  "Serving Food Safely" at Main St Market.  Preparing for distribution of CD of Food Safety Information for nutrition educators.  Master nutrition volunteer curriculum.

VIII.

Responsible				
Agency/Contact	High Risk Consumers	Health Professionals	Broader Consumer Audience	Remarks
	Baton Rouge - In-service	Biomedical Conference Center site for	Monday at the Market Program	
	nutrition and food safety	LSU Food Science Food Processor	120 participants	
	workshop including Oyster	Conference with educational booth for		
	Food Safety Vv with Capital	Oyster Food Safety Vibrio vulnificus	Nutrition/wellness/food safety	
			Oyster Vv for 35 participants	
	Area Agency on Aging(13	Featured published article in <i>Advance</i>	Senior Wellness program with	
	parishes of health care	for Nurses serving RN's in Metro Areas	information on oyster Vv and	
	professionals/paraprofessionals	of Texas and Louisiana, Vol. 3, No. 8,	materials presented to 50	
	who work with seniors)– 145	pp.31-32, The Raw Truth on the	participants at. Baton Rouge, LA	
	participants	dangers of raw shellfish authored by		
		Susan Wilson and Karen Stassi and	Delmont Gardens Library	
		reaching a few thousand nurses in two	Healthy Bodies Program	
		states, Louisiana and Texas.	nutrition, food safety (Vv Oyster	
			education), 25 participants	
		May-June Louisiana Morbidity Report		
		OPH-DHH Newsletter, Vol. 16, No. 3,	Statewide news articles on	
		p. 3. Article advertising: <i>Online CME</i> -	Oysters Vv topic was prepared	
		Approved Course for Physicians –	and distributed statewide through	
		Deadly Delicacy: Vibrio vulnificus in	LSU AgCenter Communications	
		Raw Oysters	to 26 daily newspapers (741,269	
			total circulation) and 81 weekly	
		Educational in-service on Food Safety	newspapers (295,329 total	
		and Oyster Food Safety Vibrio	circulation)	
		vulnificus with Baton Rouge Regional		
		Louisiana Dietetic Association, 35	Vibrio power point at public	
		participants	website with statistical data	
		LA State Pharmacy Association Oyster	5-8 2005 Louisiana Restaurant	
		Food Safety Vibrio vulnificus education	Association (LRA) annual	
		booth (reached 125 pharmacists)	meeting with Food Safety	
			educational booth in New	
		Provided in-service training for	Orleans, Morial Convention	
		Southeast Louisiana Regional Dietetic	Center, featuring Serving Food	
		Association in Ponchatoula on topics of	Safety & Oyster Food Safety	
		Oyster Food Safety Vibrio vulnificus	Vibrio vulnificus—reached 3000	
		and Fetal Alcohol Syndrome	participants	
			• •	

Responsible				
Agency/Contact	High Risk Consumers	Health Professionals	Broader Consumer Audience	Remarks
		DHH Louisiana Sanitarian public		
		power point on Vv with food		
		code/training for state sanitarians		
		information/available for		
		retail/restaurant		
Texas	Methadone clinics (67):	Vv materials distributed at TX Medical	25 press kits to TX TV stations.	Developed VV Education
Kirk Wiles	brochures (1700 Eng., 600	Association. Meeting >4500 physicians	Bacliff (500/500/50)	program with TDOH, TDA,
TX Department of Health	Span. 6750 fact sheets)	registered. Educational materials sent	Interviews w/media re: Vv 5	TF&W, A&M Extension
504-719-0215	,	to medical schools and dietetic assns.	(newspaper, radio, TV)	
	BiNational TB Conference (800		Developed Vv education mobile	
Russ Miget	brochures)	-500 brochures to Tamalipus health	display.	
TX A&M Extension	·	officials		
361-980-3460	Dialysis & Transplant Centers	2650 physician fact sheets distributed	Consumer info brochures to 20	
	Licensed by TDH)(1700 Span.,	-80 clinician guides to advocacy	coastal county offices.	
	24,000 Eng., 2000 fact sheets)	groups, health clinics, medical &		
		pharmaceutical contacts	Vv instructional videos to Family	
	TX Alcohol & Drug	-STD Counselors (295)	Consumer agents in 20 counties-	
	Commission (info placed in	-HIV contractors (316)	info distributed through local	
	training manuals)	-TX Society of Medical	media	
	Diabetes Education (10,000	Assistants(presentation)	Local health fairs in multiple	
	tool kits )		locations	
		Nurses Statewide Conf(1200 brochures,		
		500 clinician guides)	Speaking with Health TDH radio	
		2 county medical societies	shop (distributed to 600 radio	
			outlets)	
		Clinician guides and information to <u>all</u>		
		local health departments and all	Buccaneer Days in Corpus Christi	
		epidemiological personnel in TX	(100 fact sheets, 100 brochures in	
		TTY 16 1: 1 4 2000 :: (7000	English, 100 brochures in	
		TX Medical Assoc. 2003 meeting (5000	Spanish)	
		registered physicians) mail outs to all	Au 1 1T B 1 0 Writes	
		members of TX Medical Assoc.	Attended Texas Parks & Wildlife	
		Description of TV C	Expo. Set up Vv display and	
		Presentation at TX Society of Medical	distributed brochures.	
		Assistants 2003	Attendance=44,000.	

Responsible				
Agency/Contact	High Risk Consumers	Health Professionals	Broader Consumer Audience	Remarks
		Presentation at National Hepatitis Direct mailing of the availability of the free on-line CME credit for physicians and ISSC Vv fact sheet to licensed physicians in TX	Materials included in all Food Safety sessions through Extension personnel.	
		1/3 page advertisement of the free on- line CME credit for physicians every issue of the <i>Texas Medicine</i> (circulation >34,000) from October 2005 through October 2008.		
California Michael Hernandez CA Health Services 916-327-8037 Orange Co, Patricia Gentry 714-667-3755 San Diego County Vickie Church 619-338-2274 MAHEC, Franco Reyna 323-780-7640			FDA is working w/Magnet Communications to get key messages to Latino males in 5 SO CA counties through press releases, camera-ready articles, Vv fact sheet, PSAs and B-roll for media	ON HOLD  Vv voluntary education program is under development using ISSC and FDA materials-outreach by OR & SD counties and Multicultural Health Education Center in LA CO.
Georgia Tori Stivers University of Georgia Marine Extension 770-460-2506	Article "Liver Disease & Raw Oysters" in ALF GA Chapter. newsletter (3,000 circulation)  Brochures to Diabetes Educators & physicians  Presentation to Atlanta/Grady Hospital ALF Support Group (100 brochres,100 fact sheets)  Mailed 25 Vv consumer brochures & 6 physician fact sheets to Tucker/DeKalb Co	Abstract accepted for SO Medical Assoc poster session  Presentation to Clayton Co Health Dept. 200 brochures  Conf call to state public health epidemiologists =30 participants)  Presentation (Vv Impact on Public Health) @ quarterly epidemiology training session in Macon=40 attendees.  Vv exhibit @ GA/SC Dietetic	Article in "News for Families & Consumers" GA Coop. Ext.  7500 brochures to 70 Coop. Ext. agents Article in "Salty Dog", for commercial & recreational fishing industry	Based on 7 Vv illnesses and 4 deaths to GA residents in 2002 GA is developing a voluntary VV Education Plan

### 7. Vv Education Summary

### Multi-Year Results of ISSC and State Vibrio vulnificus Consumer Education Programs

Responsible	H. I B. I C	H M D 6 : 1	D I C A I	D 1
Agency/Contact	High Risk Consumers	Health Professionals	Broader Consumer Audience	Remarks
	ALF Support Group	Assoc.=430 Vv publications		
		Article about Vv cases in News for		
		Families and Consumers 70 Ext. agents		
		6/2004 Presentation Vv Ed in GA @		
		Interstate Environmental Health		
		Seminar in AL		
		Semmar in 742		
		Direct mailing of the availability of the		
		free on-line CME credit for physicians		
		and ISSC Vv fact sheet to licensed		
		physicians in GA		

Date	State	Contact Person	Brochure Risk of Eating Raw Oyster - English	Brochure Risk of Eating Raw Oyster - Spanish	Health Care Provider Fact Sheet	Published V. vulnificus Reference Materials	Video: Clinicians' Guide of Vv Infection & Treatment	Video: Illegal Shellfish Harvesting	Illegal Shellfish Harvesting Brochure	Foodborne illness table
01/06/03	SC	Iron Disorders Institute	200							
01/22/04	МО	Schnock Markets, Inc.		200						
02/03/04	GA	Tori Stivers UGA	500							
02/03/04	LA	Susan Wilson, LA DHH					22			
02/17/04	IL	Greene Co. Health Dept.	100		100	10	1			
02/17/04	AL	Wintzell's Oyster House	400							
03/05/04	OR	Pat Byttner (Individual)	4							
03/05/04	LA	Susan Wilson, LA DHH	6000		3000		12			
03/17/04	LA	St. Tammany Parish Hospital	200		100		1			
03/17/04	MS	Department of Marine Resources	1000	300	500		15			
03/22/04	PA	Henry's Seafood	100							
03/22/04	GA	Division of Public Health (Lagrange)	100		50					
03/22/04	LA	West Jefferson General Hospital	500		500					
03/22/04	GA	East Health District	2000	200	1000					
03/22/04	GA	South Central Health District	4500	2300	500	1	1			
03/31/04	LA	LSU HSC Leonard Chaberb Medical Center	300		200					
03/31/04	TX	Department of Health	6000	6000	6000					
04/01/04	GA	Dept of Agriculture Seafood Safety Office	300	300				4	4	
04/01/04	GA	Northeast Health District CHASE Unit	200	100	50					
04/08/04	GA	GA Division of Public Health	100	100						
04/09/04	GA	Dougherty County Environmental Health	200	200	200					
04/15/04	LA	Barksdale Air Force Base Pharmacy	2600							
04/15/04	LA	LSU HSC Leonard Chaberb Medical Center	700	200						
04/15/04	GA	Fulton County Epidemiology	200		100					
05/11/04	GA	UGA Marine Extension Service	100				12			

Date	State	Contact Person	Brochure Risk of Eating Raw Oyster - English	Brochure Risk of Eating Raw Oyster - Spanish	Health Care Provider Fact Sheet	Published V. vulnificus Reference Materials	Video: Clinicians' Guide of Vv Infection & Treatment	Video: Illegal Shellfish Harvesting	Illegal Shellfish Harvesting Brochure	Foodborne illness table
05/20/04	GA	District 2 Health Office Gainesville	2000	200	15	13	1			
05/20/04	LA	Public Health Infectious Disease Epidemiology	2800		1200					
05/20/04	GA	Dialysis / ADA	100	100	100	1	1			
05/20/04	GA	South Health District 8-I Valdosta	2600	200	300	1	1			
05/20/04	OR	Multnomah Co Environmental Health	100	100						
05/20/04	GA	UGA Shellfish Research Lab	200							
05/20/04	LA	St. Tammany Parish Hospital Cancer Ctr	100							
05/24/04	CA	University of CA Seafood Extension					1			
06/01/04	LA	West Jefferson Medical Center Pre-Admit	300	100						
06/10/04	FL	Gulf & South Atlantic Fisheries Foundation	500							
06/10/04	SC	Pee Dee Dietetics Association	100		50	2	1			
06/22/04	GA	North Central Health District	500	500	500		2			
07/07/04		American Hemochromatosis Society	8,100		600					
07/12/04	FL	Bureau of Community Environmental Health	750							
09/10/04	LA	LSU Ag Center (Sally Soileau)	1000	500						
09/10/04	LA	St. Tammany Parish Hospital Oncology Program	100							
09/16/04	ОН	Columbus Health Department Food Safety	500	200	500	1	1			
10/04/04	FL	Gulf & South Atlantic Fisheries Foundation	100	100						
11/15/04	FL	Florida Medical Clinic Tampa	50	50						
11/19/04	LA	St. Tammany Parish Environ Health (Slidell)	300			1				1
12/06/04	LA	Tulane University School of Public Health	100				1			1
		TOTALS	46604	11950	15565	30	73	4	4	2

Date	State	Organization	Brochure Risk of Eating Raw Oyster - English	Brochure Risk of Eating Raw Oyster - Spanish	Health Care Provider Fact Sheet	Published V. vulnificus Reference Materials	Video: Clinicians' Guide of Vv Infection & Treatment	Video: Illegal Shellfish Harvesting	Illegal Shellfish Harvesting Brochure	Foodborne illness table	Baseline Survey of Raw Oyster Consumers	R <sub>x</sub> for Success Pharmacies	Vv & Liver Disease	Vv & Diabetes	Vv for Immuno Compromised
1/10/2005	HI	American Liver Foundation	200		200										
1/31/2005	GA	UGA Shellfish Research Lab	500										500	500	500
02/10/05	FL	Nassau County Health Department	200	200		5	2			5	2	2	50	50	50
03/08/05	MD	Digital Harbor High School	100	100	1	1	1	1	1	1	1	1	1	1	1
03/15/05	NC	Occupational & Environmental Epidemiology	1	1	1		1								
04/12/05	LA	Office of Public Health	100		30					1					
04/12/05	FL	Seminole County Epidemiology	300	300											
05/03/05	FL	Florida Department of Health	2000	500	500								500		
05/19/05	IN	Regional Diabetes Center	100							1				1	
05/19/05	ОН	Alliance Community Hospital			1		1			1			1	1	1
05/19/05	NJ	St. Peters Hospital Diabetes Care Center for Diabetes, Endocrinology												200	
05/19/05	WV	and Metaboism	100	100	5									25	
05/19/05	FL	Florida Department of Health	2000	500	500								500		
05/19/05	LA	Pennington Biomedical Research Ctr	100	100	1	1	1							1	
05/19/05	TX	Texas Sea Grant	100		100										
06/08/05	AZ	Banner Good Samaritan Hospital	100	100	3								25	75	
06/24/05	MO	Schnuck Markets, Inc.	2000	400											
06/24/05	DE	Delaware Department of NREC	1500	500	1000								100	100	100
08/02/05	CA	CA Department of Fish & Game	100			1	1						1	1	1
08/08/05	PA	John Herr's Village Market	200												
08/23/05	AL	George Kiracafe, MD	40	20	2		1			1					
09/19/05	FL	Rodolfo Corona, MD		100			1						1	1	1
09/27/05	FL	Cesar O'Phelan, MD	100	100											
10/12/05	TX	Richard S. Burnham, DDS	100							1					

Date	State	Organization	Brochure Risk of Eating Raw Oyster - English	Brochure Risk of Eating Raw Oyster - Spanish	Health Care Provider Fact Sheet	Published V. vulnificus Reference Materials	Video: Clinicians' Guide of Vv Infection & Treatment	Video: Illegal Shellfish Harvesting	Illegal Shellfish Harvesting Brochure	Foodborne illness table	Baseline Survey of Raw Oyster Consumers	R <sub>x</sub> for Success Pharmacies	Vv & Liver Disease	Vv & Diabetes	Vv for Immuno Compromised
10/13/05	FL	Robert A. McCarron, MD	50												
10/13/05	GA	Joseph W. DeHaven, MD	100												
10/13/05	GA	L. J. Carter, MD	100		100					1					
10/13/05	TX	Texas Health Care	100	100	100					1					
10/13/05	TX	James W. Henry, MD								1	1				
10/13/05	GA	David McCann, MD	100	100		1				1			1	1	1
10/13/05	TX	Philip Wisiackas, MD	100	100											
10/13/05	TX	Sergio Mercado, MD	50	50											
10/13/05	AL	Jack Thompson, MD	20												
10/13/05	FL	Richard Baney, MD	25												
10/13/05	GA	John Onderkirk, MD	100		1					1	1	1	10	10	20
10/18/05	GA	Atlanta Pediatric Partners	100		1					1					
10/20/05	LA	LSU Ag Center (Sally Soileau)	1500	400	400	10	11			10	2	5	150	150	150
10/20/05	FL	Collier County Health Department Mississippi State University	400	400	50		2						150	50	500
10/24/05	MS	Coastal Research & Extension Ctr.	100	100	100	100	11			100			100	100	
11/02/05	TX	Michelle Cummins, MD	100												
11/02/05	TX	Carmen Cawley	400	400											
11/02/05	FL	Women's Health Associates	100		1	1									
11/04/05	MO	Schnuck Markets	2400	1200											
		TOTALS	15086	5871	2897	120	33	1	1	127					

### 8. Raw Oyster Consumer Survey 2002

In 2002, the ISSC adopted new National Shellfish Sanitation Program Guidelines for reducing illness from *Vibrio vulnificus*. These standards require states with two or more reported cases of *Vibrio vulnificus* from raw oysters to implement a *Vibrio vulnificus Risk Management Plan* for oysters. Educating raw-oyster consumers is a mandatory element of state plans.

The new National Shellfish Sanitation Program (NSSP) defined two success criteria for consumer information programs:

- 1) Increase raw-oyster consumer awareness of the risks of eating raw shellfish 40 percent above baseline levels; and,
- 2) Increase the proportion of high-risk consumers who stop eating raw oysters 20 percent above baseline levels

The purpose of this survey is to establish a baseline for consumers' beliefs, consumption patterns and knowledge of risks before states intensify *Vibrio vulnificus* education activities. The ISSC contracted with Clearwater Research Inc. to conduct telephone interviews in California, Florida, Louisiana and Texas. Between September 27, 2001 and February 28, 2002 Clearwater Research completed 1,963 interviews with raw oyster consumers. A follow-up survey will be conducted in 24-months. Changes from baseline levels will reflect state's progress toward meeting these objectives.

Key Findings - The following results pertain to raw oyster consumers in all four states.

### Awareness of Who Should Not Eat Raw Oysters

- Nearly half (43 percent) of all consumers are unfamiliar with any at-risk group; 23 percent know of one; 20 percent know of two; and 14 percent know of all three groups.
- Consumer awareness that people with liver disease are at higher risk of illness is moderate.
   Half of raw oyster consumers in all four states are aware that people with liver disease should not eat raw oysters.
- Consumer awareness that people with diabetes are at higher risk of illness is minimal. Only 19 percent know that diabetics should not eat raw oysters.
- Consumers with any risk factor are significantly aware of who should avoid raw oysters than consumers with no known risk factor.

### Risk Reduction Measures

- One in three consumers are eating raw oysters less often—primarily for health reasons.
- Half of all raw oyster consumers are doing "nothing" to reduce their risk of illness.
- Those at-risk were more likely to report doing *something* to reduce their risk of illness, but that action was usually an ineffective one.
- Misconceptions about how to reduce one's risk of *Vibrio vulnificus* infection are widespread.

### Conclusions

• Consumer awareness of who should not eat raw oysters is moderate at best. Half of all consumers do not know about liver disease and raw oysters. Very few know that diabetic

- consumers are at high risk of *Vibrio vulnificus* infection. This limited awareness is particularly worrisome with the accelerating rates of diabetes and liver disease in America.
- Many of those at-risk are already taking some action to avoid illness. These actions, however, are usually ineffective ones. By emphasizing effective risk reduction measures and debunking popular misconceptions, state programs can persuade at-risk consumers to adopt more effective behaviors.
- One in three consumers are eating raw oysters less often. There is no statistically significant difference between those at-risk and those with no known risk factors. Programs face the challenge of reducing raw oyster consumption among those at-risk, while maintaining overall consumer demand.
- Key messages should address 1) which groups are at-risk; 2) *effective* actions to prevent illness; 3) popular myths about preventing illness.
- Health care providers such as diabetes care managers; dieticians and nurses offer another avenue for reaching those at-risk. Educational efforts should address a broad range of professionals with direct contact with those at

### 9. Raw Oyster Consumer Survey 2004

This report presents the results for the 2004 Raw Oyster Consumer Survey. The 2004 Raw Oyster Consumer Survey was conducted for comparison with baseline survey measures of consumers' beliefs, consumption patterns and knowledge of risks collected in 2002, before states intensified their Vibrio vulnificus education activities.

In 2002, the Interstate Shellfish Sanitation conference (ISSC) adopted new National Shellfish Sanitation Program Guidelines for reducing illness from *Vibrio vulnificus* in raw oysters. These standards required states with two or more cases of *Vibrio vulnificus* from raw oysters to implement a Vibrio Risk Management Plan for oysters. Educating raw oyster consumers is a mandatory element of state plans.

The National Shellfish Sanitation Program (NSSP) defined the success criteria for consumer education programs as:

- Increased raw oyster consumer awareness of the risks of eating raw shellfish 40 percent above baseline levels; and;
- Increased proportion of high-risk consumers who stop eating raw oysters 15 percent above baseline levels.

Overall, this survey detected little or no change in awareness or risk reduction behavior among At-Risk and Not At-Risk consumers between 2002 and 2004.

General findings, using the weighted data, are presented in the following section. It should be noted that for the purpose of analysis, any responses given of Don't Know or Refused by a respondent were not used in the calculations for the Results section. This same method was utilized in the 2002 Report, and to make the percentages comparable, we employed the same method.

Complete report available on ISSC Website at www.issc.org.

### 10. Overview of "Diagnosis, Treatment & Prevention of Vibrio vulnificus" Physician On-Line CME Course

In November 2004, the Interstate Shellfish Sanitation Conference (ISSC) launched "Vibrio vulnificus Diagnosis, Prevention and Treatment" an online education program for physicians and part of a national effort to prevent illness and death from Vibrio vulnificus. Tulane University approved the course as satisfying national requirements for continuing medical education (CME) units for licensed physicians. For 18 months, Tulane University has agreed to provide 1.0 CME units to medical doctors who complete the course with a passing score on the final exam.

This course prepares physicians to identify the clinical manifestations of *Vibrio vulnificus* infection, know current treatment guidelines, recognize groups at higher risk of infection and advise patients to avoid exposure to raw oysters. Modules on diagnosis, treatment and prevention address each of these areas in detail. Audio and visual input, combined with photographs, illustrations, graphics and self-tests make the course interesting, engaging and effective.

Flying Fish, the software development firm behind the course, is responsible for tracking course participants, including rates of completion, exam scores, evaluations and demographics. To date, 86 physicians have accessed the course and 73 have successfully completed it. These physicians include 42 from Florida, 26 from Texas and 10 from Louisiana. A handful of physicians from other states have taken the course as well—Mississippi (3), Georgia (1), New York (1) and Missouri (1). The course took participants an average of 15 minutes to complete.

In October 2004, the ISSC sent a letter to over 15,000 licensed physicians in Texas, Florida and Louisiana informing them about the course. This letter resulted in the course enrollment to date. This is just the first step, however. Further promotion through state and regional physician associations, medical journals and websites is planned over the next few months. Promotion will intensify as warmer weather and the high-risk season approaches.

### New! Free! Online CME-Approved Course for Physicians *Vibrio vulnificus* in Raw Oysters

Vibrio vulnificus in raw oysters is among the most virulent food-borne pathogens. The case fatality rate is 53 percent and prompts physician diagnosis and treatment is critical to patient survival. "Diagnosis, Treatment and Prevention of Vibrio vulnificus Infection" is an innovative, online course that gives physicians concise, practical information on this topic. Developed in consultation with CDC, EPA's Gulf of Mexico Program and Tulane University's Health Sciences Center, this online course is interactive, informative and engaging. The course is available to licensed physicians at no cost for a limited time only.

Access the course online at <u>www.carreermap.net</u>. Enter "vibrio" in the user name, leave the password blank, and click on "submit" to launch the course. After you completing the course, fill out the Verification Form and send it to the Tulane University Health Sciences Center. CME credit will be emailed or faxed to you.

This course has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of Tulane University Health Sciences Center and Interstate Shellfish Sanitation Conference (ISSC). Tulane University Health Sciences Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians and has designated this educational activity for a maximum of 1 Category 1 credit toward the AMA Physician's Recognition Award.

Tulane University Health Sciences Center presents this activity for educational purposes only and does not endorse any product or content of presentation. Participants are expected to utilize their own expertise and judgment while engaged in the practice of medicine. The content of the presentations is provided solely by presenters who have been selected because of their recognized expertise.



Every year millions of Americans consume raw molluscan shellfish, especially oysters and clams. For some people, however, eating raw or undercooked molluscan shellfish can cause serious illness or death from Vibrio vulnificus.

Vibrio vulnificus is a gram-negative bacterium and is considered the most lethal of the vibrios inhabiting brackish and salt water. This bacterium is not the result of bacteriological or chemical pollution of marine waters, but occurs naturally in warm, coastal areas, such as the Gulf of Mexico. V. vulnificus is found in higher concentrations from April through October when coastal waters are warm.

### AT-RISK POPULATION

Most healthy individuals are not at risk for *V. vulnificus* infection. Persons at high-risk include those with liver disorders, including hepatitis, cirrhosis and liver cancer; hemochromatosis; diabetes mellitus; and those with immunocompromising conditions, such as HIV/AIDS, cancer, or undergoing their treatments. Individuals who take prescribed medication to decrease stomach acid levels or who have had gastric surgery are also at risk.

### INFECTION

Filter-feeding shellfish, such as oysters and clams, concentrate V. vulnificus in their tissues. When a person eats these shellfish raw or undercooked, the bacteria enter the digestive tract and multiply rapidly. In addition to ingestion, high-risk individuals can become infected when cuts, burns or sores come in contact with seawater containing V. vulnificus.

### RESULTING ILLNESS

V. vulnificus infections are associated with three distinct clinical syndromes:

- Primary septicemia occurs after food containing V. vulnificus is consumed and the bacteria invade the bloodstream via the digestive tract. The illness is characterized by fever and chills, and is usually accompanied by nausea, vomiting and diarrhea. A sharp drop in blood pressure commonly occurs, with possible outcomes of intractable shock and death. The majority of patients also develop painful skin lesions. The skin initially appears red. Blisters develop quickly and erode into necrotic ulcers.
- Gastroenteritis occurs after ingestion of food containing V. vulnificus. Patients with gastroenteritis have a relatively milder syndrome consisting of vomiting, diarrhea and abdominal cramps. Patients with gastroenteritis may require hospitalization, but rarely die.
- Wound infection results when skin lacerations or abrasions come in direct contact with seawater containing V. vulnificus. Additionally, wound infections can occur during acute, penetrating marine injuries. These infections typically begin with swelling, redness, and intense pain around the infected site. Fluid-filled blisters often develop and progress to tissue necrosis in a rapid and severe process resembling gas gangrene. Fifty percent of patients with V. vulnificus infected wounds require surgical debridement or amputation. In some patients, infection spreads to the bloodstream, and in such cases death commonly occurs.



### DIAGNOSIS

Although *V. vulnificus* infection is diagnosed by routine stool, wound or blood culture, laboratories should be notified when this infection is suspected so that a special growth medium can be used to increase the diagnostic yield.

### TREATMENT

The mainstays of medical treatment for *V. vulnificus* infections are prompt antimicrobial therapy and supportive care. The American Medical Association and the Centers for Disease Control and Prevention recommend treating the patient with tetracycline and intravenous doxycycline with ceftazidime.

### LONG-TERM SEQUELAE

V. vulnificus infection is usually an acute illness in healthy persons. Those who recover should not expect long-term consequences. Infection in high-risk individuals, however, has a 50 percent case fatality rate. High-risk individuals who recover from wound infection often develop necrosis that frequently requires skin grafting or limb amputation.

### CASE REPORTING

Requirements for disease reporting are mandated at the state level. For current and complete information on *V. vulnificus* reporting requirements in your state, consult your state health department or their website.

### REDUCING THE RISK OF INFECTION

V. vulnificus infection case reviews have indicated a median time period of 48 hours or less from hospital admission to death. This underscores the limited effectiveness of treatment and the importance of prevention.

High-risk individuals should abstain from eating raw oysters or clams. *V. vulnificus* infection can also be avoided by eating only thoroughly cooked shellfish. High-risk persons may also prevent *V. vulnificus* infection by avoiding contact of cuts, burns or sores with marine waters.

### PREVENTION RECOMMENDATIONS

- Instruct high-risk patients not to eat raw oysters or clams.
- Encourage high-risk patients to eat well-cooked oysters and clams.
- Provide high-risk patients, including immunocompromised individuals, with information about the risk of eating raw oysters or clams. Free copies of the brochure "The Risk of Eating Raw Oysters: Advice for Persons with Liver Disease, Diabetes and Weakened Immune Systems" are available through the ISSC website (www.issc.org) or by calling 1-800-416-4772.

### References

 American Medical Association, Centers for Disease Control & Prevention, US Food & Drug Administration (2001): Diagnosis and Management of Foodborne Illnesses, A Primer for Physicians

Daniels N and Shafaie A (2000): A Review of Pathogenic Vibrio Infections for Clinicians, J Infectious Medicine 17(10):965-685.

 U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition (2000): Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, Bad Bug Book





The information contained in this fact sheet is provided for information only. This information does not constitute medical advice, and it should not be relied upon as such.

The American Liver Foundation (ALF) does not engage in the practice of medicine. ALF, under no circumstances, recommends particular treatments for specific individuals, and in all cases recommends that you consult your physician before pursuing any course of treatment.

## WHAT ARE THE

Symptoms usually occur within 24-48 hours, and may include:

- Fever / Chills
- Skin lesions
- Stomach pain / Nausea
- Diarrhea Vomiting
- Shock

and have any of these symptoms, seek medical attention immediately If you have consumed raw shellfish

most effective therapy. aggressive antibiotic treatment is the to death within two days. Early, For those at risk, infection can lead

are mild and temporary individuals. When it does, symptoms Vibrio vulnificus rarely affects healthy

# FOR MORE INFORMA

Contact the following:

- FDA website: www.cfsan.fda.gov

Foundaidon

7.67

1-800-GO-LIVER (465-4837)

www.uverfoundanon.org

heury

For information on liver disease and hepanins, contact

### IN THE SHELL

Cook live oysters or clams in small pots so those in the middle are cooked thoroughly.

U

- BOILING: After the shells open, boil live oysters or clams for another 3-5 minutes
- STEAMING: In a pot that is already steaming, cook live oysters or clams for another 4-9 minutes

- BAKE at 450°F for 10 minutes
- SHUCKED OYSTERS
- BOIL or SIMMER for at least 3 minutes or until edges curl
- FRY at 375°F for at least 3 minutes
- BROIL 3 inches from heat for 3 minutes

Containing Vibrio vulnificus

diabetes, or weakened Advice for persons with liver disease ımmune systems



- ISSC website: www.issc.org

# DID YOU KNOW...?

containing the bacteria Vibrio especially oysters and clams. But if enjoy eating raw molluscan shellfish--Each year millions of Americans vulnificus can make you seriously ill. weak immune system, raw shellfish ou have liver disease, diabetes, or a

shellfish. Eat only shellfish that have been thoroughly cooked. abstaining from consumption of raw You can avoid illness simply by

### VIBRIO VULNIFICUS? WHAT IS

at-risk people who eat raw shellfish. cause severe illness or death to Vibrio vulnificus is a bacteria that can

are infrequent, about half (179) have raw oysters with 2% associated with been associated with consumption of percent (98%) of these illnesses have oysters and clams containing the associated with consumption of raw recorded 341 serious illnesses and Drug Administration (FDA) From 1989 to 2002, the U.S. Food resulted in death. Eastern Hard Clams. While illnesses Vibrio vulnificus bacteria. Ninety-eight

# WHERE IS IT FOUND?

summer months. Vibrio vulnificus is or odar of shellfish. bacteria are elevated during the warm coastal waters, such as the NOT a result of pollution, and can be Gulf of Mexico, where levels of the NOT change the appearance, taste, harvesting. Vibrio vulnificus does found in waters approved for shellfish Vibrio vulnificus is found naturally in

# ARE YOU AT RISK?

of these health conditions: you eat raw shellfish and have any You are at risk of serious illness if

- Liver disease (from hepatitis) cirrhosis, alcoholism, or cancer,
- Iron overload disease 'hemochromatosis,
- Diabetes
- Cancer (including lymphoma) leukemia, Hodgkin's disease,
- Stomach disorders
- Or any illness or medica body's immune system treatment that weakens the

Unsure of your risk? Ask your doctor.

Healthy people are not at risk of serious intection.

### **AVOID INFECTION?** HOW CAN YOU

shellfish containing Vibrio vulnificus open wound while swimming. bacteria enter your body through an You can also become infected if these can make you sick. If you are at risk, raw or undercooked

To safeguard your health, take these

precautions: SEMO

- Physicians recommend that raw animal protein origin. This those at risk not eat any food of includes raw shellfish.
- FEAT oysters or clams that have destroys the bacteria been THOROUGHLY COOKED--heat
- NEVER swim or wade in seawater when you have sores or open wounds

# **CUALES SON LOS**

entre otros: en un período de 24 a 48 horas, y son, Los síntomas aparecen por lo general

- Fiebre / Escalofríos
- Lesiones en la pie
- Náusea / Dolor de estómago
- Vómitos

### SIN CONCHA

ricen los bordes

obtenga atención medica inmediatamente.

después de comer ostiones crudos Si tiene cualquiera de estos síntomas

Shock Diarrea

Para los que están en un grupo de

- FRIA a 375°F por lo menos tres minutos
- minutos

cuando lo hace, los síntomas son

quienes gozan de buena salud, y Vibrio vulnificus pocas veces afecta a

leves y temporales.

precoz y agresivo con antibióticos.

muerte en un periodo de dos días.

La

riesgo la infección puede causar la

terapéutica más eficaz es el tratamiento

SANITATION CONFERENCE (803) 788-7559 · www.issc.org INTERSTATE SHELLFISH

follero y apopa for esfirerzos de la ISSC por educar a los construidanes esta riesgo. Para mayor información solve las enfermedades del higado y la La American Liver Foundation ha examinado in información en este dwgase a



nstituciones:

FDA Food Safety hotline:

1-888-723-3360

FDA website: www.cfsan.fda.gov

ISSC website: www.issc.org

Puede comunicarse con los sigientes

ARA MAYOR INFORMACION

1-800-GO-LIVER (465-4837) нячи: (тефацикалюн. org

### ARA COCINAR OSTIONES CONSEJOS PRACTICOS

### EN SU CONCHA

- Cueza los ostiones en cazuelas pequeñas para que los que estén en medio se cuezan totalmente.
- entre tres y cinco minutos más después HERVIDOS: Siga hirviendo los ostiones de que las conchas se abran.
- AL VAPOR: Cocine los ostiones entre quatro y nueve minutos más en una cazuela que ya esté hirviendo.

HIERVA los ostiones a fuego lento por lo menos tres minutos o hasta que se

ASE a 3 pulgadas del fuego durante tres

HORNEE diez minutos a 450°F

Consejos para las personas higado, diabetes o con las con entermedades de defensas bajas



## USTED...?

causarle una enfermedad grave mejillones y las almejas podrian bacterias en los ostiones, los tiene las defensas bajas, ciertas Unidos disfrutan los ostiones crudos padece del hígado, de diabetes o si cada año. Sin embargo, si usted Millones de personas en los Estados

## Para evitar enfermarse:

- Jamás coma moluscos crudos
- Coma únicamente mariscos que estén completamente cocidos

## **VULNIFICUS?**

crudos que contengan esta bacteria gravemente o morir si come moluscos defensas baja puede enfermarse ostiones. La gente que padece de hígado, de diabetes o que tiene las se encuentra a menudo en los Vibrio vulnificus es una bacteria que

almejas duras del este (Eastern Hard crudos, y el dos por ciento al de detectó 341 casos de Vibrio vulnificus los afectados murieron Clams). Aproximadamente la mitad de ha vinculado al consumo de ostiones por ciento de estas enfermedades se causados por mariscos crudos desde La U.S. Food and Drug Administration 1989 hasta 2002. El noventa y ocho

## DONDE SE **ENCUENTRA?**

encuentra en aguas costeñas cálidas apariencia de las almejas. aguas que han sido aprobadas para la contaminación. Se encuentra en vulnificus N0 es producto de la como las del Golfo de México. Vibrio pesca de moluscos. Vibrio vulnificus NO cambia el color, el sabor, ni la bacteria Vibrio vulnificus se

### GRUPO DE RIESGO? **¿ESTA USTED**

herida abierta.

Los médicos les recomiendan a

crudos y padece de: enfermedad grave si come mariscos Usted corre peligro de contraer una

- Enfermedades del higado (a alcoholismo o cancer) causa de hepatitis, cirrosis,
- Enfermedades por depósitos de hierro elevados (hemochromatosis)
- Diabetes
- Cáncer (entre otros leucemia Hodgkin, linfoma o la enfermedad de
- Irastornos estomacales
- O cualquier enfermedad o tratamiento médico que debilite las defensas.

No está seguro de su riesgo? Consulte a su médico

corren riesgo de contraer una infeccion grave.

Las personas en buen estado de salud no

### COMO SE NFECCION? EVITA

entran a su cuerpo a través de una diabetes o si tiene las defensas bajas con Vibrio vulnificus pueden hacerle nadando en el mar, estas bacterias mucho daño si padece del hígado, de Los mariscos crudos o poco cocidos También puede infectarse si, al esta

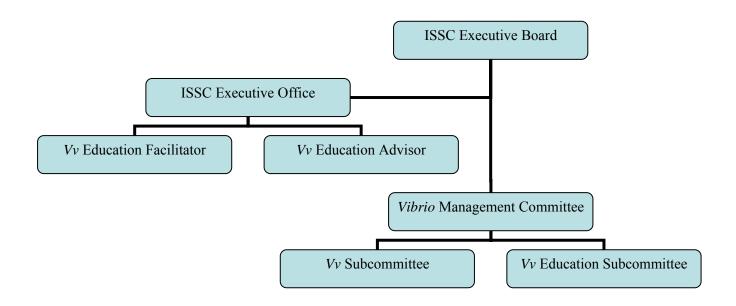
2

animal, entre otras, los moluscos ninguna proteina cruda de origen aquéllos en riesgo que no comar Si corre riesgo, tome estas

precauciones:

- JAMAS coma ostiones crudos. estén completamente cocidos--e calor destruye la bacteria Coma únicamente ostiones que
- JAMAS nade o se bañe en el si tiene lesiones o heridas abiertas mar

### 12. Organization Chart – Vv Coordination



### 13. Organization Chart – Vv Responsibilities

