

**Florida Department of Agriculture and Consumer Services**  
**Charles H. Bronson, Commissioner**

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**Florida *Vibrio vulnificus* Risk Reduction Plan For Oysters**

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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, 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 dietitians 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 traceback 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 treatment 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 treatment 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 treatment capacity for the state for that calendar year. A post harvest treatment 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 treatment 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 treatment 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 treatment 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 to 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, 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 treatment 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 treatments, 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 treatments, 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 treatment 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.