

***Vibrio parahaemolyticus* Interim Control Plan For Oysters - 1999**
With 2000 addition unlined and in bold.

A. Contingency Plan

(1) If the waters of a state have been confirmed as an original source of oysters associated with two or more confirmed V.p. illnesses within the past 3 years, the Authority shall develop and adopt a V.p. contingency plan.

(2) The plan shall define the administrative procedures and resources necessary to accomplish the following:

- (a) Identify and define growing areas in the state affected by V.p. based on hydrographic and geographic parameters and other considerations relevant to control of a naturally occurring pathogen.
- (b) Conduct an oyster meat sampling and assay program in those areas which have been associated with a V.p. illness;
- (c) Close affected oyster growing areas;
- (d) Prevent harvesting of affected oysters ; and
- (e) Provide for oyster recall if the oyster growing area is closed as a result of illness;
- (f) Notify the shellfish industry and the local health jurisdictions in the state of the potential for illnesses due to *V. parahaemolyticus* prior to historical times of onset or at a minimum of once a year;

(g) Issue a health advisory to the public about the potential problem and advise the industry to educate wholesalers, retailers, and consumers about the potential problem, with recommendations that the product not be consumed raw during periods historically affected by V.p.

(3) The plan may include agreements or memoranda of understanding between the Authority and individual oyster harvesters and processors to allow harvesting of oysters from growing areas which have been placed in the closed status, as specified in C. for:

- (a) post-harvest treatment by a process which has been demonstrated to reduce V.p. levels to non-detectable or;
- (b) shucking and labeling "for cooking only"; or
- (c) under specific circumstances, as approved by the Authority, where the oyster shellstock will be sold to a retailer or food service establishment, food processor, or to a shucker-packer and labeled in accordance with (3)(b) or.;
- (a) under specific circumstances, as approved by the Authority, where the oyster shellstock will be cooked and controls exist to ensure cooking.

B. *Vibrio parahaemolyticus* Monitoring

(1) In all areas where confirmed V.p. illnesses have occurred within the last 3 years, representative samples of oysters shall be collected monthly during harvest periods (as determined by the Authority) and analyzed, using the direct plating procedure and gene probe methods for total (tlh+ colonies) V.p. and virulent (tdh+) V.p. and other methods as determined by the Authority.*

(2) In all areas where a confirmed V.p. outbreak has occurred, representative samples of shellfish shall be collected during harvest periods as determined by the Authority. Samples shall be collected at intervals determined by the Authority (minimum weekly during months historically associated with an outbreak) and analyzed for total (tlh+ colonies) and virulent (tdh+) V.p. by the procedure and methods prescribed in B.(1) and other methods as determined by the Authority.

(3) In order to determine the number of samples that would be appropriate for V.p. monitoring, the following factors shall be considered:

- (a) the size of the growing area;
- (b) the amount of oyster shellstock typically harvested from the area;
- (c) the sensitivity of the methodology;
- (d) the size of the oyster meat samples being analyzed.

(4) In the event that emerging technologies and research identify pathogenic strains other than or in addition to tdh+, the Authority may adopt and FDA may approve other or additional monitoring and control methods for preventing V.p. illnesses.

C. Closed Status of Growing Areas Based On Monitoring Results.

(1) The growing area as defined in accordance with A.(2)(a), shall be placed in the closed status for oyster harvest, except as allowed under A.(3), if any virulent (tdh+) V.p. as confirmed by replicate analysis are found in any oyster sample from the harvest area. **A replicate is defined as two filters for the tdh analysis from the same homogenate at the same dilution.** If any sample shows total V.p. counts above 10,000 CFU/g then additional samples (twice the number collected as determined by the Authority) shall immediately be collected and analyzed for virulent (tdh+) V.p. Should any of these additional samples show virulent (tdh+) V.p., the area will be placed in the closed status for oyster harvest, except as allowed under A.(3).

(2) The closed status shall remain in effect until two consecutive representative samples of oyster meats, collected a minimum of four days apart, show no tdh+ samples. If any sample shows total V.p. counts above 10,000 CFU/g then additional samples (twice the number collected as determined by the Authority) shall immediately be collected and analyzed for virulent (tdh+) V.p.

(3) The analysis leading to a decision to return a growing area to the open status shall be adequately documented.

D. Illness Outbreak

(1) When a growing area is implicated in a V.p. illness outbreak, the Authority shall follow the procedures prescribed in Chapter II. Section @.01A through E. If a growing area is closed due to an illness outbreak, the closed status shall remain in effect until two consecutive representative samples of oyster meats, collected not less than 4 days apart, show no tdh+ samples and no samples with total V.p. counts above 10,000 CFU/g.

(2) If additional confirmed V.p. illnesses occur within 2 weeks of re-opening, they should be considered a continuation of the illness outbreak. The growing area shall immediately be placed in the closed status, and re-opening may only occur when environmental conditions shift to those unfavorable to the growth of V.p., or the Authority, in conjunction with the state epidemiologist, develops and implements a sampling plan.

E. Records.

The Authority shall maintain a copy of all of the following records:

(1) All information, including monitoring data, relating to the levels of V.p. in the shellfish growing areas;

(2) Copies of notices placing growing areas in the closed status;

(3) Evaluation reports; and

(4) Copies of notices returning growing areas to the open status.

*[Direct plating procedure by Cook, D.W. et al 1999. Procedure for enumeration of *Vibrio parahaemolyticus* in shellfish meats. A collaborative study by shellfish producing states, FDA and the ISSC; gene probe methods, for total (tlh + colonies) V.p. (McCarthy, S.A. et al 1999. TRS. Appl. Microbial. 28:66-70.); and virulent (tdh+) V.p. (McCarthy, S.A. et al 1999. Abstracts of the 99th General Meeting of the American Society for Microbiology, p.512].