Name of Committee: *Vibrio parahaemolyticus (Vp)* Subcommittee

Chairperson: Paul Comar

Date of Meeting: Sunday, August 14, 2005

There were six charges to the *Vp* subcommittee, some of which have previously been met. Most of the deliberation focused on the second charge: *Identify and evaluate alternate controls that would address sporadic cases of Vp illness. Develop recommendations for the 2005 Biennial Meeting.*

Charge 1: Proposal 98-107 *Vp* Interim Control Plan

Findings: There may be methods other than those in *Vp* ICP guidance that may reduce the risk of *Vp* illnesses.

Recommendations:

Retain the current *Vp* ICP Interim Guidance until the 2007 ISSC biennial meeting. States should continue to evaluate which controls and monitoring may work best at limiting the occurrence of illnesses under various regional and seasonal harvesting and handling practices.

Charge 2: Identify and evaluate alternate *(to those in place under the Vp Interim Control Plan – Vp ICP)* controls that would address sporadic cases of *Vp* illness. Develop recommendations for the 2005 biennial meeting.

Findings: The Subcommittee began considering this charge in 2004, based on an FDA discussion paper developed and presented by the agency at the ISSC 2003 annual meeting and based on its unreleased *Vp* Risk Assessment. At subsequent meetings, including May 2005, FDA has presented data in tables and other forms from the draft risk assessment. FDA has described how the CDC illness estimate and a variety of other time/temperature and *Vp* monitoring data were used to estimate *Vp* illness risk under a variety of regional and seasonal conditions, with risk linked primarily to shellstock temperatures post-harvest. The agency has also prepared and presented models to show how various shellstock cooling control measures might limit increases in *Vp* levels post-harvest caused by a rise product temperature.

In prior meetings as well, the Subcommittee has acknowledged that *Vp* illnesses are a concern and noted that specific shellstock temperature control measures might be helpful as a "tool box" to be considered for application as determined in various regions and seasons. However, a number of Subcommittee members have voiced comments and questions about the illness data and other information used

in the risk assessment, the resultant models developed, performance criteria to measure effects of implementing any new harvest/handling practices, and costs for the controls.

To help with deliberation, the Subcommittee asked that FDA make its *Vp* Risk Assessment public and that FDA provide cost/benefit analyses on the implementation of various shellstock temperature controls on selected regional and seasonal bases. Without that information, the Subcommittee reached no conclusion or consensus about the need for or scope of additional guidelines or mandatory controls for reducing *Vp* sporadic cases. (See full reports of *Vp* meetings of March 2004, August 2004, and May 2005 for more detail of prior discussions and findings).

In addressing these requests, the FDA publicly released and published its *Vp* Risk Assessment at the end of July. FDA economists also collected information on regional shellfish harvesting and handling practices and projected costs and benefits of reductions in *Vp* illness associated with various controls put in place regionally and seasonally. That information was provided to the Subcommittee in early August.

During the August 14 meeting, FDA presented its cost/benefit analyses of implementing selected controls to more rapidly cool shellstock post-harvest. Costs were estimated for capital investments and operational expenditures for more rapid cooling of shellstock on a regional and seasonal basis. Costs were not projected for the additional resources of state regulators to ensure controls would be put in place and adhered to. Benefits were shown as illnesses (both *Vp* and V. vulnificus) estimated to be prevented times a societal cost in dollars per illness. Additional benefits that might accrue to the shellfish industry from new harvest/handling practices were not estimated.

Subcommittee members acknowledged and thanked FDA for this information, and much discussion focused on the estimates. Several members indicated they desired more time to review the full set of materials presented just prior to the meeting. FDA agreed to provide information on the derivation of the estimated $18,000 cost per *Vp* illness used as one component in the cost/benefit analyses. FDA, as in prior meetings, solicited more participation from the industry on current harvesting/handling practices and costs of implementing new practices to control shellstock temperature. Costs to state regulatory programs should be gathered and projected, and estimates of impacts on tribal and small, single boat harvesters should be provided. The full Subcommittee agreed that these more complete and improved cost/benefit analyses can be prepared only through cooperation of states and industry.

Finally, the potential new shellstock control measures would result in major changes in harvest and handling in some segments of the shellfish industry.

Workshops with industry were recommended to share information about *Vp* illness risk, potential control measures and cost/benefit analyses.

Recommendations:

1. Retain the current *Vp* ICP Interim Guidance until the 2007 ISSC biennial meeting.

2. Charge the *Vp* Subcommittee to identify and evaluate control strategies that could be implemented on a regional basis to reduce the risk of *Vp* illnesses from both sporadic cases and outbreaks. The approach will encompass the following steps:

   i. In concert with the FDA, the Subcommittee will evaluate and provide information to improve the FDA's *Vp* Risk Assessment and cost/benefit analyses on a regional basis.
   ii. The Subcommittee will work through the ISSC Office to structure, schedule and ensure the conduct of regional meetings to include the shellfish industry, economists, state regulators and others as determined by the Subcommittee. Regions will be those projected in the *Vp* Risk Assessment to account for the large majority of *Vp* illnesses.
   iii. The purpose of the meeting is to: 1) exchange information on *Vp* illnesses, 2) evaluate costs and benefits of various controls if implemented, specific to practices of the industry in that region, and 3) discuss the need to implement such controls.
   iv. Reports findings and recommendations from those meetings to the regional participants, *Vp* Subcommittee, Vibrio Management Committee, and Executive Board.
   v. Receive and review comments and modify reports as needed.
   vi. Complete a consolidated report and recommendations for the 2007 biennial meeting.

Charge 3: Finalize the prioritized list of research needs

Findings: Completed. This list was prepared and finalized on April 5, 2004 and attached as an addendum to the March 2004 Subcommittee report.

Charge 4: Continue efforts to enhance the CDC report form to include additional epidemiological and environmental information. Include harvest location and date of harvest.

Findings: None. Action deferred due to concentration on Charge 2.

Recommendation:

Consider at next Subcommittee meeting.

Charge 5: Provide clarification to instructions for *Vp* illness data collection

Findings: Completed. The Subcommittee's August 10, 2004 report indicated no further need to revise these instructions.

Charge 6: Complete the 2002 illness data summary table

Findings: None. Action deferred due to concentration on Charge 2.

Recommendation:
Consider at next Subcommittee meeting.
