ISSC COMMITTEE REPORT

Vp Subcommittee
Date: 08-03-03
Chair: Paul Comar

August 2003 Committee Meeting Attendees:

Paul Comar	Angela Ruple
Bob Connell	Brett Bishop
Klaus Schallie	Robin Downey
William Hastback	Bob Collette
William Watkins	Jennifer Tebaldi
Kathy Brohawn	Bill Kramer

2001 – 2003 Committee Charges:

1. 98-107 – Vp Control Strategy
2. Review the 2002 state reports required under Chapter II@01 to assess whether future changes to the Vp interim guidance document and Satisfactory Compliance are needed.
3. Appoint a Vp Research Workgroup to develop a prioritized preliminary report listing research needs.
4. The Vp Subcommittee Chairman and the ISSC Executive Director will establish a workgroup to enhance the CDC report form to include the additional epidemiological and environmental information. The CDC form will be used in the interim.

Charge 1:

Proposal 98-107 Vp Control Strategy

Findings: (Opinion of the Committee as to the validity of the problem.)

1a. V. parahaemolyticus illnesses present a health concern that requires control measures. Several states and British Columbia follow the Vp Interim Control Plan, some voluntarily now, i.e., lack of outbreaks puts them outside the Guidance Document recommendations.

1b. Sporadic cases have been reported when Vp monitoring levels do not indicate a problem; and conversely, there have been instances of high tlh or even high tdh V.p. levels found during monitoring with no or low illness reports. There was just one 2-case OUTBREAK in 2003.

1c. A few states are using SEASONAL harvesting and handling advice or requirements or such advice or requirements based on Vp MONITORING results.

1d. Monitoring can be very costly to states, and negative "outbreak" findings may be inconclusive or inadequate to address a broader safety concern of sporadic cases.

Conclusions: (Opinion of the Committee as to whether the proposed action is appropriate.)

1a. The FDA presented a summary of its Draft V.p. Risk Assessment (January 2001 report) and other related imporovements to their risk assessment models. The FDA will be finalizing that report by the end of 2003. The FDA also presented a Discussion Paper developed before the meeting that estimates there are roughly 100 times more actual Vp illnesses than are reported. It is suggested that V.p. illnesses are underreported due to the relatively mild, self-correcting nature of the gastrointestinal illness. Among other findings and recommendations, the report will include 24 different risk region/season models with analyses of several different mitigation scenarios.

1b. The models are based on various assumptions and come, as all models, with estimates and characterizations of variabilities and uncertainties. Also, as with all mathematical models, they will improve with more data on the host of factors involved in the risk model, such as Vp levels, percent of pathogenic strains, rates of growth under various conditions, shellfish consumption patterns, etc.

1c. The models are proposed by FDA as " tools not answers" to help reduce the risk of V.p. illness. FDA committed to assist states in using the models to help determine which control strategies might best help lower the risk of illness, with perhaps different controls working better in different areas of the state.

1d. FDA presented its V.p. discussion paper previously sent to the ISSC Office and the subcommittee. It asks the subcommittee to consider developing new Vp illness control measures to reduce the risk of illness from CASES, recognizing that the current V.p. Interim Control Plan (ICP) was established and refined since 1998 to help reduce the risk of OUTBREAKS of Vp. This concept and rationale was discussed by the subcommittee in the context of the current ICP and the FDA overview of its V.p. risk models.

Recommendations: (Include recommended language of submitter or amended languages of the committee, no action, or other action deemed appropriate by the committee.

1a. Retain the current interim guidance for two more years and charge the V.p. subcommittee to identify and evaluate alternative control strategies, with a goal of making a recommendation at the 2005 ISSC biennial meeting. The FDA's V.p. risk assessment report with its models will be one important tool in this evaluation of methods to reduce the risk of illness from sporadic cases.

1b. Request FDA to continue to analyze the costs and benefits associated with different illness control strategies, in additon to those contained in the 2000 Research Triangle Institute study. ISSC assistance in those analyses is important.

1c. Recommend the addition of additional Gulf and East Coast state and industry personnel to the subcommittee to better balance the representation. This is very important as any new control measures recommended and approved would affect states and industry nationwide.

1d. Recommend the subcommittee meet at upcoming scheduled ISSC Executive Board times and places and continue to act on these recommendations via phone calls and e-mail as needed prior to the 2005 meeting. Further recommend that FDA and ISSC help support travel and expenses of state and industry to such meetings.

Charge 2:

Appoint a Vp Research Workgroup to develop a prioritized preliminary report listing research needs.

Discussion: (Summary of discussion)

2a. The subcommittee acknowledged the need to identify research needs to ultimately assist in reducing the risk of V.p. illness.

Recommendations: (Include recommended language of submitter or amended languages of the committee, no action, or other action deemed appropriate by the committee.

2a. The following is a list of research needs which will be prioritized as the subcommittee continues its work on a schedule to be determined:

1. Determine whether the gene sequence tdh is the best indicator of virulence.
2. Determine if nutrient levels influence the level of V.p.
3. Determine if dissolved oxygen is a factor in the level of V.p.
4. Determine if the "condition" of shellfish (spawning or prevalence of disease such as MSX or dermo) is a factor in the level of V.p.
5. Determine (through survey, observation or other means) the post harvest handling practices being used by the industry to control the level of V.p. This may include on boat and dockside shellstock temperature control procedures, mandatory or voluntary seasonal harvest restrictions, and other product holding or treatment methods. It is critical to describe and quantify such control steps to ultimately determine what impact they may have on reducingV.p. illnesses. (Possible graduate student survey work.)
6. Determine the impact that various on board control measures may have on level of V.p., such as shielding from sun, evaporative cooling, icing, and other techniques.
7. Catalog the methods that each state is using to quantify V.p. as total (tlh) and pathogenic (tdh and/or trh). Include the reason for quantifying pathogenicity using tdh, trh or both. Include not only the basic technique (gene probe vs pcr), but detail any modifications to the techniques by individual states and the rationale and improvements found in selecting or modifying methods. This could be done through survey of the states.

8. Determine if total and pathogenic V.p. increase and decrease at the same rate with temperature changes, both in the environment and post harvest.

Charge 3:

The Vp Subcommittee Chairman and the ISSC Executive Director will establish a workgroup to enhance the CDC report form to include the additional epidemiological and environmental information. The CDC form will be used in the interim.

Discussion: (Summary of discussion)

3a. This task has not been done. It was acknowledged by most subcommittee members that securing accurate environmental data for the CDC report was not possible in most instances.

3b. It was felt that the ISSC's V.p. illness report form collects most epi data needed for its purpose.

Recommendations: (Recommendations as appropriate)

3a.

3b. Some modifications to that form are recommended. See Charge 4 below.

Charge 4:

Review the 2002 state reports required under Chapter II@01 to assess whether future changes to the Vp interim guidance document and Satisfactory Compliance are needed.

Discussion: (Summary of discussion)

4a. It was felt that the ISSC's V.p. illness report form collects most epi data needed for its purpose. However, several states did not summarize their V.p. Reportng Procedures. Further, some additional data was requested to be collected and added to the form.

4b. There were some states whose V.p. illnesses were not included in the final Vp. illness table prepared July 29, 2003, and a number of reports were received in the ISSC Office very late. Each state must report, and that data must be compiled for review under Chapter II@01. From discussion, it appeared that most, if not all, states did report to their FDA specialists. But there was likely a lack of submission of the data to the ISSC or other misconnection which resulted in the incomplete illness summary table.

Recommendations: (Include recommended language of submitter or amended languages of the committee, no action, or other action deemed appropriate by the committee.)

4a. Some clarifications are recommended to the instructions for the data collection form to help ensure that all states report in a complete and standard manner. The changes will be made, reviewed, and finalized prior to the March 2004 Executive Board meeting. Further, Paul Comar will work with the Specialists and ISSC Office to complete the 2002 table and send to the subcommittee by September 15, 2003.
Also, it was recommended to add harvest location and date to the Vp In-State Report column. This may be useful in investigations to link environmental measures with the reported illness.

4b. Require states to submit their V.p. annual illness data in the approved format to their FDA specialist by March 1 of the following year (2003 data will be reported by March 1, 2004). Cases confirmed after March 1 will be submitted to the FDA specialist as completed. FDA specialists will verify that all data is received by March 1 and notify and rapidly follow-up with any state not providing the information. FDA specialists will provide the illness data for all states in their Region to the ISSC Office no later than May 1. Further, FDA will submit supplemental data of cases confirmed by the states later than May 1 to the ISSC Office as it is submitted to them by states. ISSC will compile and finalize the report no later than July 1 for review by the subcommittee.

Recorder: Kathy Brohawn

Report Approved By: Paul Comar