Vibrio **Evaluation Reference**

The following outline provides a reference for conducting and compiling reports of annual state *Vibrio* evaluations. Every state requiring a *Vibrio* risk management plan, whether for *V. vulnificus (Vv)* or *V. parahaemolyticus (Vp)*, is evaluated annually. Annual evaluations include a review of *Vibrio* control plans developed by the state shellfish control authority(s) and their implementation by state authorities and the shellfish industry. Although all items contained within may not be applicable to a given state, this reference provides detail regarding state and industry requirements and activities necessary for FDA to evaluate and report on their implementation and compliance with *Vibrio* control efforts by states and industry. It also provides FDA with an overall assessment of compliance at the national level. Finally, this comprehensive evaluation and reporting effort is essential to FDA's responsibility to inform the ISSC regarding state and industry measures to control the risk of *Vibrio* and whether or not more effective controls may be necessary.

If, prior to completion of a Vibrio evaluation, a state is determined to have significant deficiencies with either state or industry compliance, the Shellfish and Aquaculture Policy Branch (SAPB) at CFSAN should be notified for possible follow-up with the Shellfish Specialist and the ISSC.

Evaluation Outline:

1) Has the NSSP state conducted an annual assessment of *Vv* and *Vp* illnesses associated with consumption of shellfish? Does the assessment include the required record of illnesses reported within the state and from receiving states, the number of illnesses per event, and actions taken in response to the illnesses?
2) If the shellfish producing state is not currently on a *Vv* control plan, has it conducted an annual *Vv* risk evaluation?
3) Has the NSSP shellfish producing state conducted an annual *Vp* risk evaluation? Did the evaluation include consideration of the factors as required under the NSSP Model Ordinance *Vp* Control Plan (Chapter II. @.06)?
4) What was the status of the previous FDA *Vibrio* evaluation? Have previously identified deficiencies been adequately addressed? What actions were taken to address previously identified deficiencies?
5) What is the status of the current *Vibrio* evaluation?
    A. Does the state have a *Vibrio* Risk Management Plan? Explain if this plan is a stand-alone document or an administrative strategy. Explain what types of information and supporting documents are used to make the assessment and implement the plan.
    B. When did the state last conduct an evaluation of the effectiveness of its *Vibrio* Management Plan and what were the results? Were there any changes from the previous year? If yes identify the changes.

C. Does the plan meet NSSP-MO requirements (NSSP MO Chapter II @.06 for *V. parahaemolyticus* and NSSP MO Chapter II @.05 for *V. vulnificus*)? If not, explain. Include a copy of the state's current control plan, explain the administrative strategy, or include policy documentation as an attachment to the Annual *Vibrio* Evaluation Report.
D. Has the state used the *Vibrio vulnificus* risk calculator to determine the risk per serving for each harvest month as required by MO Chapter II @.05? Does the state use the *Vibrio vulnificus* risk calculator to establish time and temperature controls in their *Vibrio vulnificus* control plan? Does the state use the *Vibrio parahaemolyticus* risk calculator to establish time and temperature controls in their *Vibrio parahaemolyticus* control plan? If the state does not use the calculator, but has implemented time and temperature controls, explain how the state established the appropriateness of those controls.
E. Has the state adopted state laws and/or regulations necessary to enforce the current control plan? Cite those laws and/or regulations.
F. For states required to implement a *Vibrio vulnificus* Control Plan, is the state meeting the required risk per serving standards set forth in MO Chapter II @.05? What control or combination of controls have been implemented to achieve the risk per serving standards (e.g. time-temperature restrictions, harvest closures, PHP, labeling for shucking, etc.).
G. For states not yet required to implement a *Vibrio vulnificus* Control Plan has the state developed a *Vibrio vulnificus* Contingency Plan when required in accordance with NSSP MO Chapter II @.05.D.
H. In field industry compliance review:
    i. Based on attachment D of the 2011 Shellfish Compliance Program (CP), indicate how many harvest vessels and landing locations were recommended for evaluation. How many harvest vessels and landing locations or combination thereof were examined for compliance with state *Vibrio* control requirements? Were multiple visits made to any vessel or location? Did the number of harvest vessels and/or landing locations visited/examined comprise a representative number in order to verify compliance? If circumstances prohibited a representative sample based on CP attachment D please explain.
    ii. Where applicable, check harvester records and internal product temperatures for compliance with the state's *Vibrio* Risk Management Plan and with NSSP-MO requirements. Has industry complied with time to refrigeration and internal product temperature requirements of the state's *Vibrio* control plan and the NSSP MO?
    iii. How many Post Harvest Processing (PHP) plants currently operate in the state? How many are processing for purposes of added safety labeling? Visit all PHP plants that are presently using safety added labeling and verify operation under a validated PHP process approved by the state with FDA concurrence. Verify that the facility is conducting the required PHP process verification. Review records and labeling to verify compliance with HACCP plans and NSSP-MO requirements.

iv. Indicate the number of primary processers that process shellstock intended for raw consumption, thus requiring *Vibrio* time/temperature controls. Visit a representative number of those processors based on CP attachment D. If circumstances prohibit visiting a representative sample based on CP attachment D please explain.

v. Summarize the results of in-field evaluations and identify areas of compliance and noncompliance with the state's *Vibrio* Risk Management Plan and other applicable NSSP requirements. What percentage of plants visited were in compliance?

I. Time temperature controls.
   i. List and describe the activities that the state employs to verify industry compliance with time/temperature controls.
   ii. What actions are taken by the state in response to industry noncompliance?
   iii. Are state efforts adequate to ensure industry compliance with the state *Vibrio* Risk Management Plan, HACCP plans, and NSSP-MO requirements?

J. *Vibrio* illnesses/outbreaks.
   i. In the past year have there been *Vibrio* outbreaks caused by shellfish harvested from the state? How many? Did the state conduct an investigation and take actions in accordance with NSSP MO Chapter II? Describe.
   ii. In the past year have there been individual *Vibrio* illnesses associated with shellfish harvested from the state? Describe
   iii. Did the state notify CDC of illnesses and/or outbreaks as they occurred?
   iv. Are there persistent occurrences of sporadic *Vibrio* illnesses? Has the state adjusted its *Vibrio* Risk Management Plan accordingly?

K. Are there exemptions to the state's *Vibrio* Risk Management Plan? Explain. Is industry complying with exemption requirements?

L. Does the State have a *Vibrio* education program? Describe the program and cite what audiences are targeted (i.e., harvesters, transporters, processors, consumers, medical community, at-risk population, etc.). Has the state made an effort to determine the effectiveness of educational efforts? Describe.

M. Summarize the state's program accomplishments and future goals related to controlling the risk of *Vibrio* spp.

N. Describe any new or emerging issues/concerns associated with *Vibrio* spp. (e.g. *Vibrio* illnesses associated with clams, *Vibrio cholerae*, etc.)

O. Summarize technical assistance and training requests made by the state.

P. Summarize the state's responses to FDA's evaluation, including corrective actions taken.

Q. List conclusions regarding state efforts to effectively address and control the risk from *Vibrio* spp.

R. Describe in detail recommendations, including requests for Action Plans, made to the state.