Proposal No. **13-200**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Reducing the Risk of Vibrio Illnesses
Specific NSSP Guide Reference	NSSP Guide for the Control of Molluscan Shellfish
Text of Proposal/ Requested Action	A Vibrio workshop was held in Dauphin Island, Alabama in November 2012 to discuss possible solutions for addressing illness risks. State Shellfish Control Authority representatives, Vibrio researchers, and the USFDA participated in the two-day workshop. The participants identified several topics (listed below) that are related to Vibrio controls. These topics should be addressed by the collective participants of the ISSC. The purpose of this proposal is to request the ISSC Executive Board work collaboratively with the USFDA to address the information gaps that are obstacles to identifying effective control strategies for reducing the risk of illness associated with Vibrioses. Requested Action Items: Rewrite Chapter II. Risk Assessment *V.p.* (section 05). Incorporate salinity (and other environment factors?) into *V.v.* and *V.p.* risk calculators. Develop protocol for validating the effectiveness of non-labeling PHPs Develop protocol for ensuring that growing/harvest/handling (production) practices do not increase risk of Vibrio illness. Request FDA to develop sampling protocol for closing versus reopening growing areas after outbreaks including the development of resources to sustain the present capabilities Develop new labeling/tagging system for oysters produced under conditions achieve equivalent levels as validated PHP (for labeling), including validation protocol ISSC request FDA to reexamine risk assessments and risk calculators (*V.p.* and *V.v.*) ISSC request FDA to reexamine illness and landings data to determine observed risk per serving Develop the process for using local data to refine calculators to more accurately reflect risk in the region or state Determine how best to estimate national consumption patterns for molluscan bivalves Mega study ISSC request FDA technical assistance for enhancing state vibrio programs (data management, laboratory support, think tank, BMPs, evaluation of effectiveness of new controls, statistical support) States request FDA assistance with developing approved method(s) to temper clams Draft proposal for acceptance of laboratory methods validated by other accrediting bodies
Public Health	The ISSC continues to struggle with identifying practical cost effective strategies for

Significance	reducing the risk of Vibrio illnesses associated with the consumption of molluscan shellfish. This proposal identifies information needs that are obstacles to the development of control strategies.
Cost Information	
Research Needs Information Proposed (specific research need/problem to be addressed)	1. Is total *V.v.* a valid indicator of risk? 2. Are there differential effects of validated PHP on virulent subpopulations? 3. How do environmental factors affect levels of virulent subpopulations? 4. Compile collection of *V.v.* for future virulence research. 5. Do other species react to controls the same as *V.v.* and *V.p.*? 6. Determine relative virulence of *V.p.* subpopulations. 7. What are Vibrio (total and virulent) levels at harvest (in oysters and clams)? 8. How much Vibrio (total and virulent) growth results from the current time/temperature controls (in oysters and clams)? Priorities: 1. What information is needed to supply more tools to the "toolbox"? 2. What regional information is needed to refine risk assessments and risk calculator tools for implementation of effective control plans? 3. What is the significance of salinity to Vibrio levels in shellfish? 4. Is there a salinity/temperature matrix that determines Vibrio levels? 5. What are the key virulence factors (or combination thereof) for *V.v.* and *V.p.*? 6. Need to know dose response of different Vibrio strains and populations 7. What are the regional differences in pathogenic strains of *V.v.* and *V.p.*? 8. What is the percentage of pathogenic strains of Vibrio in growing waters? 9. Should the "viable but not culturable" state in pathogenic Vibrios be a concern?
Explain the relationship between proposed research need and program change recommended in the proposal	
Estimated cost	
Proposed sources of funding	
Time frame anticipated	
For Research Guidance Committee Use Only	Relative priority rank in terms of resolving research need ☐ Immediate ☐ Required ☐ Valuable ☐ Important ☐ Other
Action by 2013 Task Force II	Recommended referral of Proposal 13-200 to an appropriate committee as determined by the Conference Chairman with instructions to the committee as follows: 1. Request that FDA reexamine its risk assessments and risk calculators (*V.p.*) and (*V.v.*) and present the results to ISSC, including the factors and methodology used to calculate risk per serving. 2. Develop a process for using local data including regional or state illness and landings information, to more accurately reflect risk in a region or state. 3. Determine how best to estimate consumption patterns, including collection data regarding the number of shellfish consumed per serving, through market research, end-point consumer data, or other information gathering methods. 4. Evaluate existing NSSP regulations to reduce risk of Vibrio illness caused

	by improper handling, storing, or transportation of shellstock and the effectiveness of existing enforcement mechanisms. 5. Provide recommendations to ISSC based on the results of the above study and evaluation.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 13-200.
Action by FDA May 5, 2014	FDA concurred with Conference action on Proposal 13-200 with the following comments and recommendations. FDA concurs with ISSC referral of Proposal 13-200 to Committee. As appropriate, FDA will provide support to the Committee via participation of Agency Vibrio research and risk assessment experts to assist in addressing Committee charges as set forth in Proposal 13-200. The Agency will look to the Conference to advance recommendations made by the Committee for purposes of implementing appropriate controls to reduce the Vibrio risk. Results of ISSC actions in response to Proposal 13-204 will be integral to answering key questions associated with the Committee's charges.
Action by 2015 Vibrio Management Committee	Recommended the following action on Proposal 13-200: That the ISSC recognize the new *V.v.* and *V.p.* calculators as a tool available to calculate the actual risk and assess the effectiveness of state controls. Continue to monitor the activities addressed in items 2 & 3 and report annually to the VMC regarding progress. That a workgroup be formed to evaluate the effectiveness of existing NSSP regulations to reduce risk of Vibrio illnesses caused by improper handling, storing, or transportation of shellstock; to identify areas within the NSSP needing improvement; and make recommendations to the ISSC. The workgroup will consist of FDA, state and industry representatives.
Action by 2015 Task Force II	Recommended adoption of VMC recommendations 2. And 3. with referral of Proposal 13-200 to an appropriate committee with a recommendation that States be allowed to pilot the new *V.v.* and *V.p.* calculators and to provide input to the FDA and report back to VMC prior to the next ISSC meeting.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 13-200.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-200.