Proposal 13-204

PUBLIC HEALTH RATIONALE

The ISSC stakeholders have worked hard since the 1990s, using a number of science and policy tools to mitigate the public health effects associated with *Vibrio* species, most notably *Vibrio vulnificus* (Vv) and *Vibrio parahaemolyticus* (Vp). As a result, the Model Ordinance has slowly evolved with different requirements for Vv and Vp. These controls include the use of Vv Control Plans (VVCP) and Vp Control Plans (VPCP) which vary from state to state. States requiring Vv controls generally must implement more restrictive harvest controls than states which only require Vp control plans. Additionally, risk per serving standards associated with VVCP require corrective actions that are absent in VPCP. This disparity creates an economic advantage for industry in states with less stringent requirements and potentially favors higher exposure to more risky product. This proposal will provide a level playing field for the shellfish industry by unifying the controls for Vp and Vv.

To-date, the Model Ordinance requirements have not been effective in reducing the number of cases of Vv and Vp. FoodNet data (Figure 1 below) indicates that vibriosis has more than doubled since the baseline years of 1996-98 while illnesses from all other major foodborne pathogens have either been stable or in most cases decreased during this same period [3]. COVIS data provided to ISSC supports similar increases in vibriosis in the US as observed with FoodNet. Vv and Vp Control Plans are not achieving expected illness reductions. In fact, Vv illnesses have exceeded the ISSC baseline each of the three years since the VVCP was implemented in 2010 and reported Vp illnesses have increased four of the five years since implementation of the VPCP in 2008. There have also been 49 deaths due to Vv since 2010 and 21 due to Vp since 2008 [8, 11].

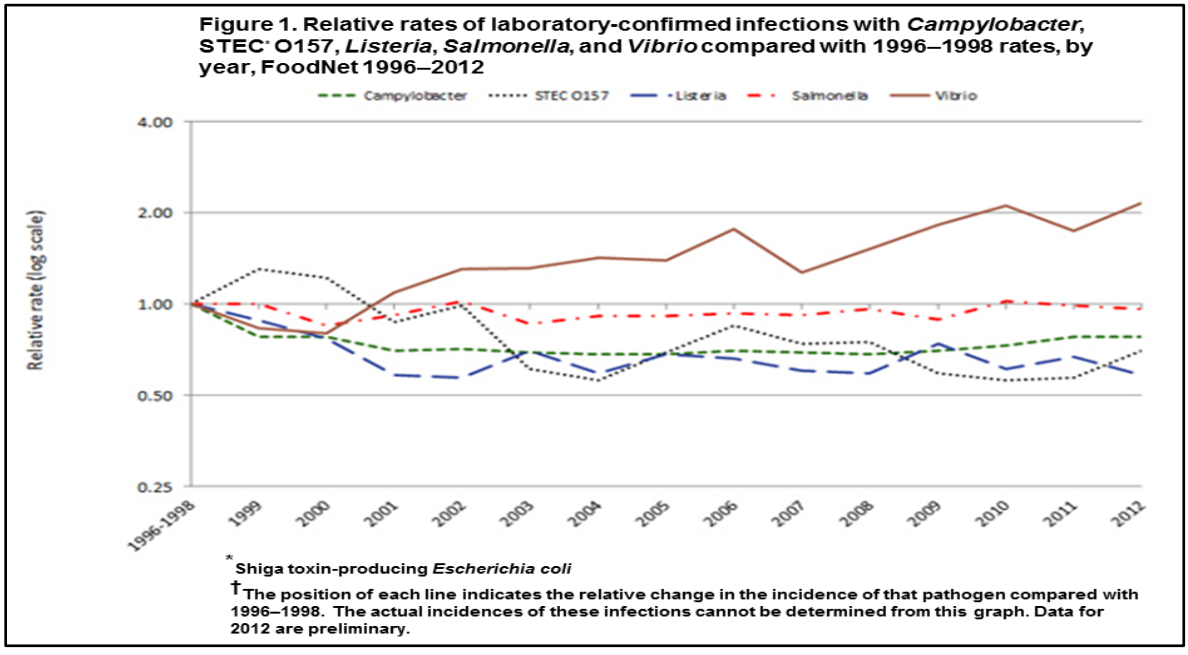


Figure 1. Relative rates of laboratory-confirmed infections with *Campylobacter*, STEC* O157, *Listeria*, *Salmonella*, and *Vibrio* compared with 1996–1998 rates, by year, FoodNet 1996–2012

*Shiga toxin-producing *Escherichia coli*

†The position of each line indicates the relative change in the incidence of that pathogen compared with 1996–1998. The actual incidences of these infections cannot be determined from this graph. Data for 2012 are preliminary.

The cost of vibriosis to society is significant. Economists and epidemiologists can provide formulas for estimating the acute health costs of morbidity and mortality factors (human illness and deaths). There are also significant costs associated with the public health responses required; case investigations, trace back to harvest areas, closure and opening protocols and product recalls. However, the costs to the oyster and clam industries also include the loss of customer and consumer confidence, both in the US and export markets such as the European Union. The efforts by the ISSC to date to control vibriosis have been unsuccessful. This evidenced by petitions from consumer advocates, audits by GAO and refusal of product by international trading partners [2, 4, 9].

There are likely several reasons for the increasing incidence of vibriosis, including improved clinical diagnosis and illness surveillance systems, increased raw shellfish consumption patterns, expanded seasonal and geographical range of illness and the emergence of highly virulent strains. For example, the introduction of the US West Coast outbreak strain of Vp into the Long Island Sound in 2012 caused the largest oyster-associated outbreak ever reported along the Atlantic Coast, tripling 2012 Atlantic Vp cases relative to the previous 5-year mean [10, 12] . This outbreak strain re-emerged in the same area in 2013 and illnesses expanded geographically from MA to VA by July [12]. The 2013 Vp case count to-date far exceeds 2012 figures for the entire season and is likely to increase considering the long lag between harvest and illness reporting and because the 2013 season continues. Numerous outbreaks, area closures and recalls have disrupted the industry and brought negative publicity about deteriorating shellfish safety.

Figure 2. Estimated Atlantic (North and Mid-Atlantic States) servings for summer (July-Sept) season assuming 50% raw consumption and 200g per serving. Imputed serving estimates for 2012 and 2013 are estimates based on recent (5 years) of data and considering early season closures due to Vp outbreaks.

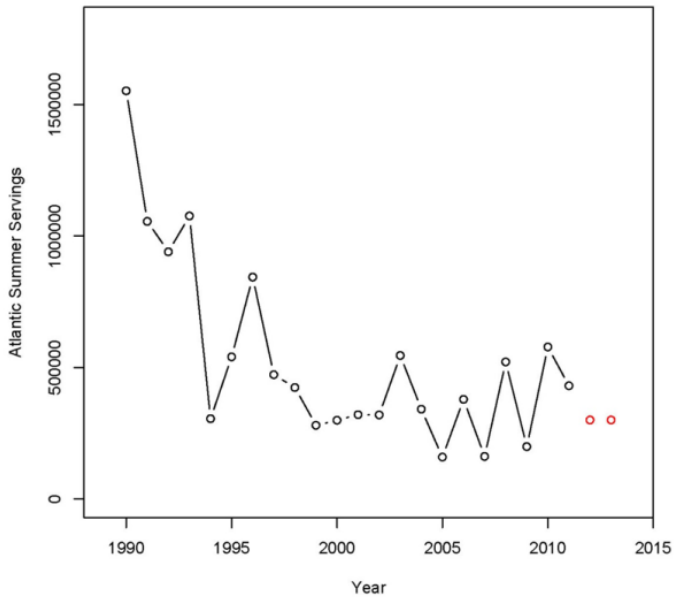


Figure 2 indicates relatively stable shellfish production in the Atlantic region since 2000 and projects 2012 and 2013 servings based on average harvest from 2007-2011. Figures 3 and 4 highlight the increase in illnesses and risk since 2012 after the introduction of the Pacific NW outbreak strain.

Figure 3: Oyster Associated Vp illnesses associated with summer (July – Sept) harvest from Atlantic (North and Mid-Atlantic) States from 1997 to the present. Vp Illnesses for 2012 and 2013 estimated to be 28 and 54, respectively. Estimates for 2013 are based on incomplete data.

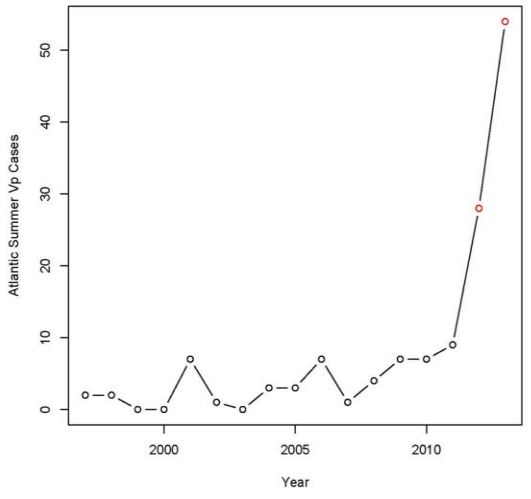
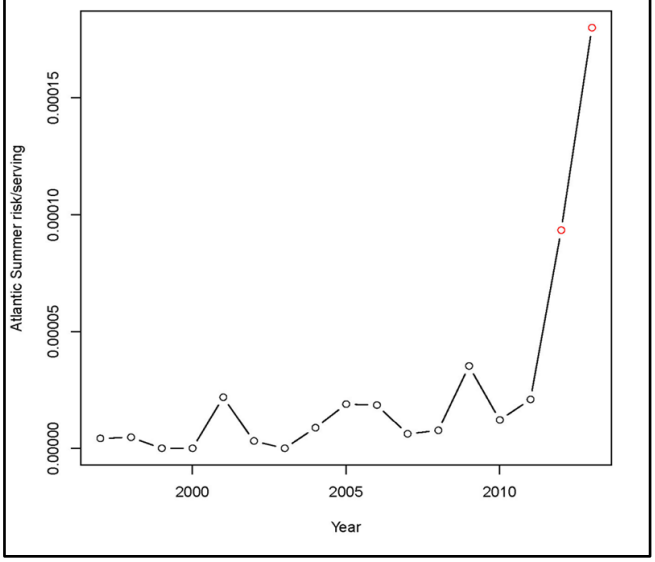


Figure 4. Estimated Risk per serving for Atlantic summer oysters assuming no under-reporting or under-diagnosis.



Sound scientific information is available on the conditions required to prevent growth of the vibrio pathogens: Vv ≤55°F and Vp ≤50°F [5]. As with other foodborne pathogens, the risk of vibrio illness increases relative to the exposure to the organism. In other words, the more vibrio bacteria consumed the higher the chance the shellfish consumer will become ill. For example, FDA and FAO/WHO risk assessments for Vp assume a doubling of risk each time the bacteria doubles [1, 7]. The FAO/WHO Vv risk assessment assumes that the risk increases about 1.5-fold for each doubling [6]. Generation times for Vp can be as fast as one hour when ambient temperatures are around 90°F and almost as fast for Vv.

Immediate cooling upon harvest would prevent post-harvest vibrio growth, maintain levels present at the time of harvest, and provide enhanced public health protection relative to the current VVCPs and VPCPs. This approach is consistent with the international guidance put forward in the Codex Alimentarius guidance for bivalve molluscs[5] and industry cooling practices with other seafood products that are inherently less risky. Immediate cooling at the time of harvest is considered to be the best management practice, offering significant risk reduction, which can be used in the process of harvesting shellfish that are to be consumed raw.

While exploring the practicality of immediate cooling, FDA has undertaken field studies on board small harvesting vessels. These studies demonstrated that oysters coming from warm harvest waters (80-90°F) can be cooled to less than 50°F within 30 minutes using an ice slurry system without significant hindrance of crew harvesting activity. Frequently asked questions regarding the cost, risks and benefits of using ice are listed in Appendix A.

The public health benefit from immediate cooling at harvest time would be significant. Tables 1 and 2 depict the estimated benefits of cooling for Vp and Vv, respectively.

Table 1. Estimated Benefits of Rapid Cooling *Vibrio Parahaemolyticus* based on reported and laboratory confirmed illnesses without the adjustments for under-reporting or under-diagnosis.

Region	Reported Illnesses/year (Baseline 2008-2011)	Predicted # of Reported Illnesses/year(Rapid Cooling)	Predicted %-Reduction in Reported Illness	Predicted Cost* of Reported Illness (Baseline) (Millions)	Predicted Cost* of Reported Illness (Rapid Cooling) (Millions)
Atlantic	20.1	1.0	95%	0.95	0.047
Gulf	16.4	1.6	90%	0.78	0.076
PNW	131	7.9	94%	6.22	0.38
TOTAL	**167.5**	**10.5**	**94%**	**7.95**	**0.50**

*Cost per reported illness determined as $47,500 by combining Ralston's cost estimates for each of 3 illness severity classes (2=seek physician ($500), 3=hospitalization ($10,000), 4=death ($5,000,000)) with probabilities of each severity class among reported illnesses (2=seek physician (77.8%), 3=hospitalization (21.3%), 4=death (0.9%) as determined by Scallan et al.

Table 2. Estimated Benefits of Rapid Cooling *Vibrio vulnificus* based on reported and laboratory confirmed illnesses without the adjustments for under-reporting or under-diagnosis.

Gulf State	Predicted # of reported Illness (Baseline)	Predicted # of reported Illness (Rapid Cooling)	Predicted % Reduction in Reported Illness	Predicted Cost* of Reported Illness (Baseline) (Millions)	Predicted Cost* of Reported Illness (Rapid Cooling) (Millions)
Texas	4.1	3.0	27%	7.2	5.3
Louisiana	11.7	9.3	20%	20.6	16.4
Florida	2.3	1.3	41%	4.0	2.4
TOTAL	**18.1**	**13.6**	**25%**	**31.8**	**24.1**

*Cost per reported illness determined as 1.76 million by combining Ralston's cost estimates for each of 3 illness severity classes (2=seek physician ($500), 3=hospitalization ($10,000), 4=death ($5,000,000) with probabilities of each severity class among reported illnesses (2=seek physician (8.7%), 3=hospitalization (56.3%), 4=death (35%) as determined by Scallan et al.; predicted number of reported cases for baseline and immediate cooling scenarios in selected states (TX, LA, FL) were determined using the Vv calculator assuming: (a) baseline time-to-refrigeration, cooldown time and oyster temperatures at harvest equal to that specified in Vv management plans in effect in each state (TX, LA, FL); (b) 1.46 million Gulf oyster servings per year consumed by at risk individuals distributed by month as specified in Vv management plans; (c) 21% of Gulf servings attributed to TX, 57% attributed to LA, and 10% attributed to FL (based on NMFS landings data).

The FDA Dauphin Island scientific team is currently working on a number of projects associated with oyster cooling practices. At the time of writing this rationale the results and conclusions from these projects are not available. This information will be available at the 2013 ISSC meeting.

Aside from the projected reduction in morbidity and mortality numbers, there will be further positive effects associated with acceptance of this proposal. This proposal would unify and simplify the controls for Vp and Vv and provide a level playing field for all of industry. There likely also would be a gain in trust by national and international customers and consumer advocacy groups. While immediate cooling is not as effective as Post Harvest Processing (PHP) or closures, it is far less disruptive to the nation's commercial shellfish industry than those approaches and offers a control strategy generally available to all the shellfish industry.

As with any regulatory policy, implementation will be critical for success. There will need to be ownership by the industry and verification by State regulators that the policy is being actively implemented. To implement this proposal, if adopted, industry will be required to make some changes to their harvesting vessels and ensure that they have access to the resources that enable immediate cooling such as containers to maintain shellfish at cooled temperatures. Additional obstacles, such as the availability of "approved" ice supplies may need to be overcome. Therefore, it may be appropriate for the ISSC to consider a stepped process to allow industry to achieve full compliance over 2 years.

Reference List

1. Anonymous. *Quantitative risk assessment on the public health impact of pathogenic Vibrio parahaemolyticus in raw oysters*. Washington, DC: U.S. Food and Drug Administration; 2005.

2. CEFAS. Equivalence negoatiations on trade of bivalve molluscs between USA and EU: outcome of discusstion of electronic working group on marine vibrios. 2013 Jul 12.

3. Center for Disease Control and Prevention. Incidence and trends of infection with pathogens transmitted commonly through food - foodborne diseases active surveillance network, 10 U.S. sites, 1996-2012. *MMWR* 2013;65(15):277-287.

4. Petition for regulatory action to establish a performance standard of non-detectable levels for *Vibrio vulnificus* in molluscan shellfish: Center for Science in Public Interest, (Feb 9, 2012).

5. FAO. Guidelines on the application of general principles of food hygiene to the control of pathogenic *Vibrio* species in seafood. GAC/GL 73-2010. 2010. Rome, Italy.

6. FAO, WHO. Risk assessment of *Vibrio vulnificus* in raw oysters: Interpretative summary and technical report. 2005. Rome, Italy, FAO. Microbiological Risk Assessment Series No. 8.

7. FAO, WHO. Risk assessment of *Vibrio parahaemolyticus* in seafood: Interpretive summary and technical report. 2011. Microbial Risk Assessment Series 16.

8. Glatzer M. *Vibrio vulnificus* shellfish cases file from 1989 to 2012. 2001. U.S. Food and Drug Administration.

9. Government Accountability Office. FDA Needs to reassess its approach to reducing an caused by eating raw oysters. 2011. Report No.: GAO-11-607.

10. Martinez-Urtaza J, Baker-Austin C, Jones JL, Newton AE, Gonzalez-Aviles G, DePaola A. Transoceanic spread of Pacific Northwest *Vibrio parahaemolyicus* strain. *New Engl J Med* 2013;In Press.

11. Newton A. CDC *Vibrio parahaemolyticus* database. 2013.

12. Newton A. COVIS Summary Data. 2013.

Appendix A
On Board Oyster Icing: Frequently Asked Questions

What are vibrios and why are they a problem?

- Vibrios are naturally occurring bacteria commonly found in oysters during warm months
- Vibrios can cause diseases ranging from diarrhea to death

Why is rapid cooling of oysters needed?

- Vibrios present at harvest can grow until oysters are cooled to 50F
- As the vibrios double so does the risk of illness

Is it feasible to cool oysters rapidly on small harvest boats?

- Ice is the most effective means for rapid chilling of oysters on-board small boats
- Either layering ice with oysters or dipping in ice slurries are effective cooling methods

How much ice is needed and what is the cost?

- One bushel of ice in a slurry produced with 90°F seawater can cool 2 bushels of oysters
- Reuse of the ice slurry can reduce ice usage to 1 bushel of ice for 4 bushels of oysters
- The additional cost for purchase of ice is approximately $1/bushel or 80# sack

Is it safe to reuse ice slurries for repeated dipping of oysters?

- FDA research indicates that dipping oysters for 10-20 minutes does not allow any bacteria from the ice slurries to enter the shell and contaminate the meats

Will ice slurries kill oysters?

- Oyster dipped in ice slurries survive over a 2-week period as well as with conventional refrigeration

What new equipment and boat modifications are needed?

- Dipping container (5-gallon bucket, ice chest, plastic drum)
- Cold storage container (external ice chest, insulated hull with lid)

What are the benefits from rapid cooling?

- Reduced risk of illness
- Fewer closures from outbreaks
- Potentially higher prices for oysters produced under best management practices
- Longer harvest periods
- Prevents delays for out of state shipments