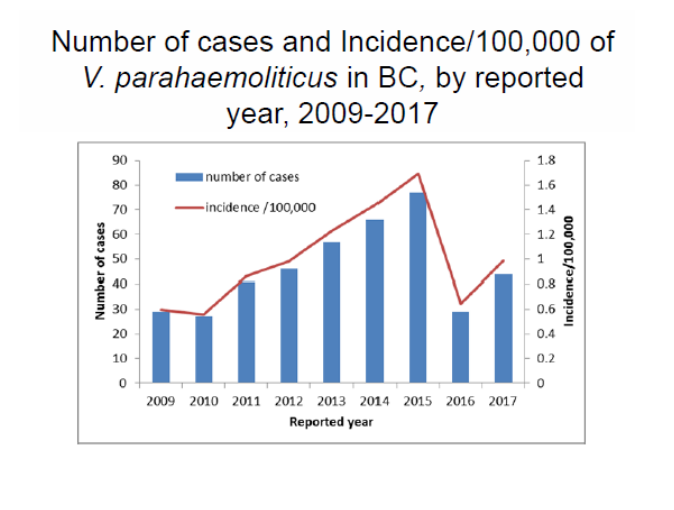
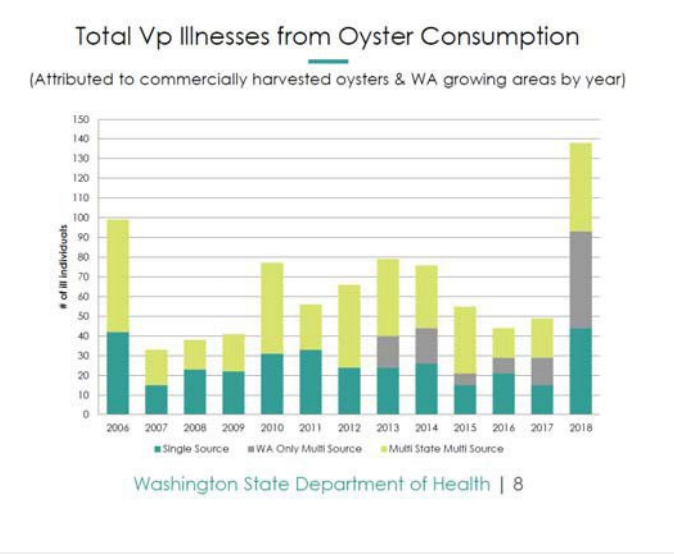
Submitter	Bill Dewey
Affiliation	Taylor Shellfish Farms
Address Line 1	130 SE Lynch Rd
City, State, Zip	Shelton, WA 98584
Phone	360-790-2330
Email	billd@taylorshellfish.com
Proposal Subject	Alternative for allowing harvest for raw consumption from a growing area closed due to *V.p.*
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (*V.p.*), Section A. (6)
Text of Proposal/ Requested Action	(6) Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one (1) or more of the following controls: (a) PHP using a process that has been validated to achieve a two (2) log reduction in the levels of total *V.p.* for Gulf and Atlantic Coast oysters and/or hard clams and a three (3) log reduction for Pacific Coast oysters and/or hard clams; (b) Implementing a process that has been validated to achieve <100 mpn/gram total *V.p.*; ~~(b)~~(c) Restricting oyster and/or hard clam harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing; ~~(c)~~(d) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.
Public Health Significance	The Center for Disease control estimates 45,000 people get ill each year in the United States from *V.p.*. In an effort to reduce *V.p.* illnesses SSCAs have developed and implemented vibrio control plans and industry has diligently implemented strict temperature controls and harvest practices. Despite these efforts *V.p.* illnesses persist. There are several possible explanations for this. It could be the result of more oysters being produced for raw consumption and therefore greater exposure or because the adopted controls are ineffective or because of improper handling during retail distribution and sale at facilities beyond the authority of ISSC to control or because of increased reporting of illnesses because of improved awareness or changes in reporting procedures. Regardless of the reason, the fact is consumers continue to get ill from eating raw shellfish contaminated with *V.p.* bacteria and it is incumbent on the ISSC to consider all options for reducing *V,p.* illnesses. With this proposal we hope to enlighten ISSC participants to the apparent efficacy of utilizing a < 100 MPN/gram tlh standard to reduce V.p. illnesses and establish the standard as an option for states to use.

While based in Washington State, Taylor Shellfish Farms has farms, a processing facility and oyster bar in British Columbia. Because of this we are familiar with Canadian *V.p.* regulations. Following a *V.p.* outbreak in 2015 Canada implemented a requirement for processors to reduce total V.p. (tlh) levels below 100 MPN/gram prior to sale or distribution. This new regulation appears to have been effective at reducing *V.p.* illnesses while adjacent Washington State continues to see significant *V.p.* illnesses despite a vibrio control plan updated in 2015 with stringent harvest controls and time to documented temperature reduction.





On Taylor Shellfish farms in British Columbia (d.b.a. Fanny Bay Oyster) we can

	predictably achieve the < 100 MPN/gram Canadian standard by holding oysters in culture trays at growing densities in 12-15 C water for 5 to 7 days. In Washington, we are achieving similar results after holding shellfish in a chilled recirculating wet storage system at 15 C for 3 days. The current Chapter II. Risk Assessment and Risk Management @.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (*V.p.*), Section A. (6)(c) allows for harvest from areas closed due to *V.p.* with "Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority". This could provide the opportunity for a SSCA to allow the use of the < 100 MPN/gram to permit harvest. We are submitting this proposal to draw attention to the effectiveness of the < 100 MPN/gram tlh standard and clearly state that it is an option for inclusion in state vibrio control plans. As proposed, it is our understanding and intent that this would be an option and not mandatory. If adopted it would provide companies with an option to continue harvesting and distribution of a reduced risk product during V.p. closures. The International Commission on Microbiological Standards for Foods (ICMSF) advises that < 100 MPN/gram would be of acceptable quality in live bivalve Mollusca. Other countries, including Japan for fresh/frozen fish and shellfish and Hong Kong, Australia, New Zealand in Ready to Eat (RTE) foods and Russia (for imported shellfish) have adopted the 100 MPN/gram standard. U.S. companies exporting live shellfish to countries that have adopted this standard already have to demonstrate their product achieves the standard. This is yet another reason we feel it makes sense for the U.S. to consider including it as an option in the Model Ordinance. As a major seafood and shellfish consumer Japan has had a history of large numbers of *V.p.* illnesses. Their response warrants review as it appears to have been very effective at reducing illnesses. Following a peak in 1998 with 839 outbreaks and 12,318 cases, Japan's Ministry of Health, Labor and Welfare (MHLW) instituted a series of regulations from production through consumption including adoption of a ≤ 100 MPN/gram standard. Subsequently, the number of cases and out- breaks of *V. parahaemolyticus* infections decreased by an unprecedented 99- and 93-fold, respectively, from 1998 to 2012. The 2014 paper: Impact of seafood regulations for *Vibrio parahaemolyticus* infection and verification by analyses of seafood contamination and infection by Kara-Kudo and Kumagai reviews Japan's response including an explanation of how they arrived at the ≤ 100 MPN/gram tlh standard while considering various serotypes and pathogenic thermostable direct haemolysin (TDH) and/or TDH-related haemolysin (TRH)-positive strains. Further, according to Kara-Kudo and Kumagai's review article total V.

	parahaemolyticus levels in seafood associated with 11 outbreaks from 1998 were analyzed. The contamination levels in 8 out of 11 outbreaks were >100 V. parahaemolyticus MPN/g food, suggesting that the regulatory level of ≤100 V. parahaemolyticus MPN/g is effective for food control. Taylor Shellfish Farms is confident based on recommendations from the International Commission on Microbiological Standards for Foods (ICMSF), that results seen in BC and documented in Japan that the < 100 MPN/gram tlh standard provides considerable *V.p.* illness risk reduction. So much so that we have begun construction of a 90,000 gallon chilled live holding system at our Shelton, Washington processing facility with the goal of ensuring all our shellfish destined for raw consumption meets this standard.
Cost Information	If adopted as intended, it would be optional for states to include it in their vibrio control plans and for companies to pursue validation of a process to achieve the standard. It is anticipated that the tests associated with the validation process and periodic verification would be at the expense of the participating company. The costs would only be incurred if a company opted to pursue validation of their process. It is anticipated that states would recoup the cost of the validation tests if they were performed at a state operated laboratory. Presumably SSCAs could also impose fees to cover cost associated with overseeing validation of a company's process and periodic verification. Costs incurred by companies would theoretically be recouped by having the advantage of continued sales when growing areas might otherwise be closed due to *V.p.*.
Action by 2019 Task Force II	Recommended referral of Proposal 19-240 to the appropriate committee as determined by the Conference Chair.
Action by 2019 General Assembly	Adopted recommendation of Task Force II on Proposal 19-240.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-240.
Action by *V.p.* Illness Response Committee, 2023	Recommendation: Refer proposal 19-240 to the appropriate committee as determined by the conference chair. The committee further recommends the Conference consider the development of additional language related to the design of appropriate scientific studies and control measures allow the harvest of shellstock from areas closed as a result of *V.p.* illness.
Action by Task Force II, 2023	Recommends accepting *V.p.* Illness Response Committee's recommendations on Proposal 19-240.
Action by 2023 General Assembly	Adopted recommendation of Task Force II on Proposal 19-240.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-240