

SUPPORTING STATEMENT
U.S. Department of Commerce
National Oceanic & Atmospheric Administration
Estimating the Economic Burden of *Vibrio parahaemolyticus* in Washington State
Aquaculture
OMB Control No. 0648-xxxx

JUSTIFICATION

- 1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.**

This project meets three of the strategic goals of the NOAA Office of Aquaculture: to advance understanding of the interactions of aquaculture and the environment; to increase the supply of nutritious, safe, high-quality domestic seafood; and to develop and use socioeconomic and business research to advance domestic aquaculture. These goals fit into the NOAA Aquaculture Policy Statement of Policy¹ to “encourage and foster sustainable aquaculture development that provides domestic jobs, products and services and that is in harmony with healthy, productive, and resilient marine ecosystems”. The NOAA Aquaculture Policy also prioritizes under Science and Research the need to “provide the necessary ecological, technological, economic, and social data and analysis to effectively and sustainably develop, support, manage, and regulate private and public sector marine aquaculture and species restoration” as well as “develop and evaluate the cost-effectiveness of methodologies to prevent, minimize, and mitigate potential adverse ecosystem and socioeconomic impacts of aquaculture”.

The Office of Aquaculture strategic goals and NOAA Aquaculture Policy serve in support of the Magnuson-Stevens Fisheries Conservation and Management Act, as aquaculture is a large and growing part of the domestic seafood supply. National Standard 7 of the Magnuson-Stevens Act states² “Conservation and management measures shall, where practicable, minimize costs and avoid unnecessary duplication”. Minimizing costs requires have estimates of the management options within for food safety, in the case of *Vibrio* management. National Standard 8³ states “Conservation and management measures shall, consistent with the conservation requirements of this Act (including the prevention of overfishing and rebuilding of overfished stocks), take into account the importance of fishery resources to fishing communities by utilizing economic and social data that meet the requirements of paragraph (2), in order to (A) provide for the sustained participation of such communities, and (B) to the extent practicable, minimize adverse economic impacts on such communities.” Meeting national standard 8 through aquaculture requires improving the economic viability of aquaculture ventures and mitigating risk in starting a new business, both of which *Vibrio* affects.

¹ Found online: <https://www.fisheries.noaa.gov/content/noaa-aquaculture-policy-summary-statements-policy-and-policy-priorities>

² The Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1851 § 301) (2007)

³ *ibid*

The economic study of *Vibrio* also fits into several of NOAA's programmatic missions. NOAA runs the National Seafood Inspection Laboratory, which services the Agricultural Marketing Act⁴ by working to ensure effective and efficient methods for ensuring seafood safety while supporting commerce and trade⁵. They are planning to increase attention to *Vibrio* safety in the future and the program officer administering the grant funding this research stated our results will be of interest in that planning.

In addition, NOAA is a founding member of the Interstate Shellfish Sanitation Conference, which is the rulemaking body for seafood safety standards for shellfish. The ISSC works to coordinate state rules and jurisdictions to provide a consistent and safe seafood supply across state lines⁶. *Vibrios*, including *parahaemolyticus*, is an issue in need of consistent management attention in order to reduce cases⁷. ISSC members strive to make regulations that are effective without being an undue burden on seafood producers and harvesters, but have expressed the need to quantify what that burden is in monetary terms.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

General Overview

This project will use semi-formal interviews with three main categories of stakeholders who have expenditures related to *Vibrio*: managers, growers, and restaurants/retail. The stakeholder-specific module of questions for each group parallels each other to allow for comparisons between stakeholder groups and aims to gather the labor time and direct costs associated with managing and responding to *Vibrio* concerns. The model is built to compare daily costs associated with surveillance and prevention programs (that are fixed, required costs) with those invoked once a *Vibrio* case is detected and reported.

This is a semi-formal interview, meant to be flexible to individual respondent answers in a conversational setting. Interviewers will record answers to items included on the interview guide as they arise in conversation to ensure that all items are covered and there is no duplication in question topics. Possible follow up questions are included for some questions to make sure we have information for each part of the conceptual model. Questions are included to collect expenditure estimates, and respondents will know from the invitation which kinds of expenditures they are expected to estimate.

Who will use this information?

The primary audiences for this information will be the Office of Aquaculture, Washington State Department of Health, the Interstate Shellfish Sanitation Conference (ISSC), and Pacific Coast Shellfish Growers Association (PCSGA). The Office of Aquaculture will use the information to better understand the capital requirements of starting and maintaining an aquaculture business,

⁴ Agricultural Marketing Act of 1946 (7 U.S.C. 1621-1638) (2014)

⁵ Seafood Commerce & Certification [online: <https://www.fisheries.noaa.gov/topic/seafood-commerce-certification#seafood-inspection>]

⁶ Conference Administration [online: <http://www.issc.org/conference-administration>]

⁷ *Vibrio* Management Committee Charge 2018-2019 [online: <http://www.issc.org/Data/Sites/1/media/2018-2019-committee/vmc-draft-charge-memo.pdf>]

which will help structure programs to encourage growth of the industry. The Department of Health and the ISSC will use the information to better understand the economic implications of their rules and help choose regulations for food safety that have the least burden for the most vulnerable types of producers. The PCSGA and individual grower members will use this information to plan farm budgets and ensure farms have enough money banked to deal with traceback investigations and triggered Vibrio control rules when they occur. The secondary audience of the Vibrio and food safety research community (including NOAA's food safety inspection team) will also use the conceptual model of when and where costs are incurred to structure future studies of other related diseases.

For what purpose will the information be used?

This information will primarily be used to help plan future disease response and management budgets both within state agencies and on aquaculture farms, as described for each primary user above. This will be especially helpful in areas where Vibrio illness rates are expected to increase due to warming water conditions⁸. It will help regulators evaluate the costs between different Vibrio control options. Better budget planning can help reduce the risk associated with starting or maintaining an aquaculture business, ultimately encouraging more domestic producers to join the market and invest capital in their businesses to expand production.

Summary of Interview Items

Module 1: Managers

Part A: Surveillance and Prevention

- 1) Please describe the size and scope of your surveillance monitoring program for Vibrio. [ensure each of the following topics is addressed; if not, ask a follow-up question]
 - a) Number of staff assigned to this task for 2018, seasonally/interns or full-year and level of position (in hours)
 - b) Lab capacity – number of samples tested per week, which markers tested for, cost of supplies
 - a. Lab training – FDA certification, HACCP training
 - c) Sample collection – vehicle and gas, overtime hours, boats, cost of supplies and shipping
 - d) Research above and beyond required monitoring – supplies and staff time; in-kind time and other leveraged resources

The surveillance monitoring program is the bulk of the costs for managers in the prevention side of the equation, according to Washington Department of Health project partners. The question is broken out by categories of expenses we know from talking to our partners at the Department of Health (Erika Atherly and Clara Hard) are part of a typical surveillance program.

- 2) What is your level of involvement with the ISSC, state legislature, and other rulemaking bodies?
 - a. Staff time and level of staff involved

⁸ Hard, Clara. 2017. Update: Vibrio parahaemolyticus in the Pacific Northwest. ISSC/FDA National Vibrio parahaemolyticus workshop. Available online: <http://www.issc.org/issc-fda-national-vibrio-parahaemolyticus-workshop>

Since food safety for shellfish is a stakeholder-driven process, a high level of participation is expected from shellfish managers and growers to ensure representation⁹. Labor time across all categories is expected to be a significant portion of the overall economic burden, so we want to be sure to account for time spent in these stakeholder processes as well.

- 3) What resources are directed to communications about Vibrio prevention with industry members?
 - a. Informally answering questions about the surveillance program? – staff time
 - b. Marketing proper certifications and compliance? – staff time and budget

The managers, especially those who issue official food safety warnings, face the challenge of getting the word out about their findings. They also serve as an integrator for the shellfish community, answering calls from individual growers with questions and concerns, a role that takes significant time¹⁰.

- 4) What research projects with academics are you involved with to assess questions focused on Vibrio in your state? Are you receiving additional funding for participation in these projects?

This question reflects findings from our grower workshop at the Pacific Coast Shellfish Growers Association (which included some managers), where participants discussed the need to account for the fact that we do not know everything we need to about Vibrio in order to prevent Vibrio outbreaks, therefore research is still a very active field, and stakeholder participation is expected. This participation can be a significant cost in provision of product or labor time.

Part B: Traceback and Investigation

- 1) What is your agency's plan for responding to a reported Vibrio illness?
 - a. What is your capacity for following this plan, in terms of staff and lab resources?

Each region in the state (based on local ecological conditions) will have slightly different procedures for responding to Vibrio, so we will clarify which sets of rules a manager is responsible for and if they have the capacity to follow that control plan.

- 2) Describe your last traceback investigation. What was involved?
 - a. Site visits – staff time
 - b. Sample testing – staff time, lab supplies
 - c. Attorney fees
 - d. Paperwork and recordkeeping – staff time

This question will gather the cost data for the manager part of the cost model for when Vibrio cases are present. The cost categories listed as follow-up questions were developed with Department of Health partners. Civil servant salaries are public, so we will convert staff time to a dollar value by multiplying by salary.

- 3) Is this a representative traceback case? If not, please describe a more typical case.

⁹ ISSC Constitution & Bylaws [available online: <http://www.issc.org/constitution-bylaws-procedures>]

¹⁰ Freitag, A. Vogt, B. Hartley, T. 2018. Breaking Stereotypes Through Network Analysis of the Chesapeake Oyster Community. *Marine Policy* 90:146-151.

This question was added by Department of Health partners who suggested that once a business goes through an investigation, additional investigations in the same year are likely to go more smoothly. Investigations also vary in intensity by how much information the sick person remembers (i.e., the number of leads the investigation must follow), so we will use answers to this to estimate variation in traceback costs.

Module 2: Growers and Processors

Classification: So we get an idea of the size of your operation, how many acres do you have under production?

We are stratifying our sample by farm size, which we are confirming with this question. We will also follow up with nonresponders with this question to check non-response bias (see part B, question 2).

Part A: Surveillance and Prevention

- 1) Walk me through what you do regularly on your growing operation to prevent Vibrio.
[ensure each of the following topics is addressed; if not, ask a follow-up question]
 - a. HACCP training – staff time, annual fees
 - b. WDOH/ISSC contributions – conference attendance, staff time
 - c. Samples for surveillance testing – staff time, value of product
 - d. Reduced efficiency of harvest – staff time
 - e. Keeping things cold – equipment costs and replacement schedule
 - f. Recordkeeping – staff time and thermometers/equipment

Based on our workshop with growers (described in section B, question 5), these are the categories of labor time and monetary cost that are required to comply with Vibrio food safety measures. These form the bulk of our economic model and this question is designed to get numbers for that model.

- 2) Have you done anything differently [or are you considering doing anything differently] after a year of high Vibrio cases?

After a Vibrio outbreak, the food safety standards and guidelines are revisited both by state regulators and by industry¹¹. People are likely to remember – or still be in the midst of reacting to – the 2018 Vibrio season, so will be able to give details about minor changes in practice they began.

- 3) [If they have processing/distribution parts of the business, as determined by state permit] What do you do regularly in your processing/distribution operation to prevent Vibrio?
[ensure each of the following topics is addressed; if not, ask a follow-up question]
 - a. HACCP training – staff time, annual fees
 - b. Keeping things cold – equipment costs and replacement schedule
 - c. Recordkeeping – staff time and thermometers/equipment

This question pairs with question 1 to account for costs in a different branch of the business (if applicable). Processing and distribution have many requirements for food safety that are strengthened in warm seasons. Answers to this question will contribute to the economic model in a similar fashion to question 1.

¹¹ ISSC Constitution & Bylaws [available online: <http://www.issc.org/constitution-bylaws-procedures>]

Part B: Case Investigations and Reactions

- 1) Have you had to deal with a Vibrio illness traced back to your farm? [if no, skip rest of section]
 - a. If yes, what year?

Screening question in order to determine who has the expertise to answer questions on the side of the model calculating costs after a Vibrio case is reported. The year will be to determine whether there might be recall bias.

- 2) Think back to the last time you had to deal with Vibrio traced back to your farm. What did you have to do in response?

[ensure each of the following topics is addressed; if not, ask a follow-up question]

- a. Harvest disruption – pauses in production, use of other leases, or both?
- b. Labor costs due to harvest disruption
- c. Investigation – staff time
- d. Recalls – lost product, staff time, relationship with buyers
- e. Keeping things cold changes – equipment purchases
- f. Attorney fees
- g. When was it?

These answers will directly contribute to our cost model (see section B, question 5, figures 1 and 2). Participants in our grower workshop said it would be easier to think back to a single case and walk through what they had to do in response, rather than try to generalize across many experiences.

- 3) Is this case representative of a typical Vibrio traceback for your farm? If not representative, what costs were atypical and what would be a more typical response?

We want an idea of the variance in traceback resources, and if the example they just walked us through is representative enough to generalize to other similar cases.

- 4) On average, how many Vibrio tracebacks do you respond to each year?

This will produce a multiplier value to be able to estimate annualized costs.

- 5) What would be the worst case scenario for you in a Vibrio traceback?

Since most people have not experienced all possible results of a traceback that cost money, we want a way to estimate the upper end of costs. According to the workshop, this is likely to be product recall with associated legal fees.

- 6) [if a processor/distributor] In what ways does a Vibrio case change your processing/distribution practices?
 - a. What does investigation look like in terms of staff time and recordkeeping?
 - b. Are there any new equipment purchases or change in handling procedure as a result?

This question pairs with question 1 to account for costs in a different branch of the business (if applicable). Processing and distribution have many requirements for food safety that are strengthened in warm seasons. Answers to this question will contribute to the economic model in a similar fashion to question 1.

Module 3: Restaurants and Retail

Classification: So we get an idea of the size of your oyster-related business, about what volume of oysters do you sell annually?

This will be used to extrapolate costs to the oyster-related restaurant industry for the surveillance and prevention values, since we are only interviewing businesses that have direct experience with Vibrio. Costs scale by size of seafood service.

Part A: Surveillance and Prevention

- 1) Walk me through what you do regularly in your restaurant/store to prevent Vibrio.
[ensure each of the following topics is addressed; if not, ask a follow-up question]
 - a. Food safety training and plan creation – staff time
 - b. Recordkeeping – staff time and equipment

Based on Department of Health food safety requirements¹², we know what restaurants are required to do for food safety protocols, but we need to find out what labor time is required to meet compliance. These answers will form the bulk of the restaurant/retail portion of our cost model.

- 2) Are there specific changes that you've made that you think would be helpful for other restaurants/retail shops to prevent Vibrio?

This question parallels #2 for the growers (Module 2), capturing informal changes to standard practice. Wording was suggested by reviewers from the restaurant trade.

Part B: Case Investigations and Reactions

- 1) Think back to a time you had to deal with Vibrio traced back to your restaurant/store. What did you have to do in response?
[ensure each of the following topics is addressed; if not, ask a follow-up question]
 - a. Investigation – staff time
 - b. Recalls – lost product, staff time
 - c. Keeping things cold changes – equipment purchases
 - d. Attorney fees
 - e. Changes in practices or menus – staff time, supply cost
 - f. Consumer purchases – lost customers, differences in purchases
 - g. When was it?

These answers will directly contribute to our cost model. The question format parallels the one for growers to be comparable.

- 2) During times of increased Vibrio cases, have you noticed any change in the seafood purchasing habits of your customers?
 - a. If so, would you characterize it as a 10/20/30/etc% decrease?
 - b. For how long do you observe this effect? (a week, a month, etc.)

¹² Washington State University Extension. Hazard Analysis Critical Control Point – HACCP. [available online: <https://foodprocessing.wsu.edu/extension/training/haccp/>]

This question addresses the consumer component of our cost model. Since most oyster sales are at raw bars in Washington State, the answer to this question will serve as a means of incorporating lost sales in the cost model due to decreased consumer demand. A review of news articles about *Vibrio* in the area yielded no recent mentions of *Vibrio* cases specifically, so we expect consumers would be responding to general status of *Vibrio* for the season, not an individual case.

It is anticipated that the information collected will be disseminated to the public or used to support publicly disseminated information. NOAA Office of Aquaculture will retain control over the information and safeguard it from improper access, modification, and destruction, consistent with NOAA standards for confidentiality, privacy, and electronic information. See response to Question 10 of this Supporting Statement for more information on confidentiality and privacy. The information collection is designed to yield data that meet all applicable information quality guidelines. Prior to dissemination, the information will be subjected to quality control measures and a pre-dissemination review pursuant to Section 515 of Public Law 106-554.

- 3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.**

The interview guide will be delivered via phone or in person so that follow-up questions are possible. However, in order to respond to respondent preferences and comfortable communication styles, first contact may be made via e-mail. Based on this first contact, if respondents indicate they want questions in another language, we will e-mail translated versions of our interview guide ahead of time. Mixed-mode contact is becoming more common and addresses concerns of falling response rates and differential access to technology across a respondent pool, both of which are concerns for the target audience of this project¹³.

The results will also be distributed through the Pathogens program website (<https://products.coastalscience.noaa.gov/vibrioforecast/>), where stakeholders regularly visit for *Vibrio* forecasts and other scientific information.

- 4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in item 2, above.**

Literature on Vibrio parahaemolyticus economics:

A literature review was conducted on the search terms “*Vibrio parahaemolyticus* economic burden”. Of the 99 most relevant articles (see Appendix), only 3 addressed economics of the seafood supply chain. The first (Muth et al 2000) investigated the economic impacts to the oyster industry of three proposed safety procedures for the Interstate Shellfish Sanitation Conference: individual quick freezing, cool pasteurization, and hydrostatic pressure¹⁴. They

¹³ De Leeuw, E. 2005. To Mix or Not to Mix Data Collection Modes in Surveys. *Journal of Official Statistics* 21(2): 233-255.

¹⁴ Muth, M., D. Anderson, S. Karns, B. Murray, J. Domanico. 2000. Economic Impacts of Requiring Post-Harvest Treatment of Oysters. RTI Project Number 7466.000.

modeled changes in supply and demand as a result of these post-harvest treatments based on case studies from large oyster companies in the Gulf of Mexico region and consumer taste tests of treated oysters. In the intervening decades, these methods of post-harvest treatment have not been required for all oysters and have fallen out of favor with the growing raw market because the treatment kills the oysters. The methods, however, provide a useful model for accounting the different types of costs associated with seafood safety treatments in general in terms of both capital and labor costs.

The second study (Bartsch et al 2018) accounted for the costs to a restaurant in the case of a foodborne illness outbreak, of which *Vibrio* is a possible cause¹⁵. The study accounted for lost revenue, lawsuits, legal fees, fines, and insurance premium increases associated with different sized outbreaks traceable to a single restaurant. Lawsuits and legal fees were, by orders of magnitude, the largest cost associated with an outbreak, and all costs increased with larger numbers of outbreak victims. The study modeled restaurant industry data, but collected no primary information on how restaurants respond to individual illness reports in terms of future prevention measures, but pointed out this would be a useful area of future study.

The final study (Cato 1998) is a Fisheries and Agriculture Organization report that reviews worldwide literature, industry studies, and government records on the costs associated with implementing a seafood safety program like HACCP (in the US)¹⁶. At the time, there was only one study related to oysters in which they determined the costs of depuration (relocating oysters until they purge illness-inducing toxins and bacteria) were too high for fishermen to accept given the associated price increase of safer oysters. The global perspective offered by FAO also identified research gaps, including the need for primary data collection of seafood safety costs across a variety of seafood safety methods, especially for oysters.

By far the largest number of studies on the economic burden of *Vibrio* focus on the clinical costs incurred in treating a *Vibrio* infection – 13 focus on the direct cost of care, 11 on the costs associated with lost productivity of victims, and 22 on estimating infection rates in a population (see Appendix). These studies (e.g. Scharff 2012¹⁷, Todd 1989¹⁸, Hoffman et al 2012¹⁹, and Raston et al 2011²⁰) have documented the healthcare and labor costs associated with the victims of *Vibrio* illness – their direct hospital and health expenses, as well as the costs of days missed from work. Another 13 recognize the clinical costs but do not attempt an economic estimate.

Recognizing this body of work is vast, we will not directly ask about these costs and instead

¹⁵ Bartsch, S., L. Asti, S. Nyathi, M. Spiker, B. Lee. 2018. Estimated Cost to a Restaurant of a Foodborne Illness Outbreak. *Public Health Reports* 133(3): 274-286.

¹⁶ Cato, J. 1998. Economic values associated with seafood safety and implementation of seafood Hazard Analysis Critical Control Point (HACCP) programmes. *FAO Fisheries Technical Paper* No 381. Rome, FAO. 70p.

¹⁷ Scharff. 2012. Economic Burden from Health Losses Due to Foodborne Illness in the United States. *Journal of Food Protection*. 75(1): 123-131.

¹⁸ Todd, E. 1989. Preliminary Estimates of Costs of Foodborne Disease in the United States. *Journal of Food Protection* 52(8): 595-601.

¹⁹ Hoffman, S., M. Batz, J.G. Morris. 2012. Annual Cost of Illness and Quality-Adjusted Life Year Losses in the United States Due to 14 Foodborne Pathogens. *Journal of Food Protection* 75(7): 1292-1302.

²⁰ Ralston, E., H. Kite-Powell, A. Beet. 2011. An estimate of the cost of acute food and water borne health effects from marine pathogens and toxins in the United States. *Journal of Water Health* 9(4): 680-694.

perform a meta-analysis of the literature to estimate average cost of a *Vibrio* case in health care terms.

The remainder of the research attention of the articles reviewed investigate the *Vibrio* bacterium itself – its genetics (8), ecology (11), medical effects (11), growth with climate change (12), legal cases (2), fishery gear development (15) (see Appendix). A handful (5) are about the economic burden of *Vibrio* in the aquaculture shrimp industry, where it causes mass mortality of shrimp in ponds. Out of all of these studies, but especially in the ones about *Vibrio* bacterial biology and ecology, 21 also mentioned the economic burden of *Vibrio* management as a justification for their research efforts. These mentions were unquantified but represent an understanding among *Vibrio* researchers of all topics of the importance of the costs of *Vibrio* management. See Appendix A for a table with references and classification of articles reviewed.

As a summary, the literature on the economic burden of *Vibrio parahaemolyticus* has yet to deal with *Vibrio* for the raw market. Many related research efforts have, however, identified the need for such data.

Literature on food safety economics:

This study methodology builds on work from both studies on the public health costs of *Vibrio* and supply chain-focused studies with other foodborne pathogens. Methods on the costs of food safety regulation were established as part of implementing the Hazard Analysis Critical Control Point program in the United States, when a more systematic food safety prevention system made the costs of such a program more apparent. In the late 1990's several reviews synthesized existing literature and methodology to help standardize evaluation metrics on food safety programs worldwide, including economic metrics. FAO's review for seafood specifically is discussed above, which notably left out oysters but focused on the sensitivities of food safety particular to high-risk seafood products that were increasingly shipped to a global market²¹.

A review of the methods to measure the costs and benefits of HACCP were summarized in a framework in which the costs to each separate firm in a supply chain are separately quantified and then added together to estimate total cost²². They also recommended performing studies where the quality is mandated to a performance standard (e.g. the beef and poultry industry's precedent of bacterial load low enough to prevent disease), which is the case for our study where *Vibrio* loads must be essentially nonexistent to prevent disease. A USDA report focused on this precedent also adds up all the costs associated with HACCP compliance but stresses that additional management capacity and costs should be included²³; they also establish a multiplier model to estimate how these costs are projected into the national economy. Finally, one of the highlighted studies from the founding members of the field set an example accounting for gear

²¹ Cato, J. 1998. Economic values associated with seafood safety and implementation of seafood Hazard Analysis Critical Control Point (HACCP) programmes. *FAO Fisheries Technical Paper* No 381. Rome, FAO. 70p.

²² Antle, J. 1999. Benefits and costs of food safety regulation. *Food Policy* 24; 605-623.

²³ Golan, E., S. Vogel, P. Frenzen, K. Ralston. 2000. Tracing the Costs and Benefits of Improvements in Food Safety: The Case of the Hazard Analysis and Critical Control Point program for Meat and Poultry. Food and Rural Economics Division, Economic Research Service, US Department of Agriculture. Agricultural Economic Report No 791.

and labor costs per firm stratified by firm size, since larger firms are expected to be able to take advantage of more means of meeting HACCP requirements²⁴.

Later studies expanded the approach from pork/beef HACCP focus to vegetables, as they became a more prominent source of disease. A case from fruits and vegetables serves as another good model, as they respond to new illness contexts, using a similar approach of measuring per firm costs of gear and labor necessary for compliance versus the cost of dealing with an illness. They suggest watching changes in surveillance costs after illnesses as a means of measuring the cost of a single cause of illness²⁵. Together, these precedents from the early days of HACCP implementation led us to a cost accounting approach adding both equipment and labor costs throughout the supply chain, stratified by size of firm, and including management capacity, and restaurants.

Related and regional studies and our coordination:

There are a handful of studies that address the demand for oysters related to *Vibrio* risk. For example, researchers found a 50% decrease in consumer demand in summer and 30% in winter for oysters in California once the health warning for *Vibrio* became required on menus²⁶. The same team found that when the menu warning specified Gulf of Mexico oysters, demand dropped for oysters from the Gulf of Mexico and Chesapeake, but increased for oysters from the Pacific Northwest²⁷. These address general consumer patterns and determine the elasticity of prices of oysters, including in the Pacific Northwest. We will not interview consumers directly, so are directly relying on these studies to address that stakeholder group. They did not document how these changes in demand impact the restaurants and retailers that sell oysters, which is where our study picks up this chain of cost effects.

In the region, two recent studies are slightly related. The first, by NOAA colleague Stephanie Moore, looked at the seafood industry's resilience after a harvesting closure due to domoic acid²⁸. This closure primarily affected crabbers and wild-harvest fishermen, whom we are not including in the study. We are also working with Stephanie to make sure our approaches will work with fishery culture in the northwest, and relying on her study for background information about how growers respond to closures in general. The other, by Jonathan van Senten (Virginia Tech), asked growers to evaluate the economic impact of regulations in their industry writ large²⁹. While food safety was included in his survey, it was a minor cost compared to permitting and environmental regulations, so was not covered in detail. We are collaborating with Jonathan

²⁴ Roberts, T., Buzby, J.C. and Ollinger, M., 1996. Using benefit and cost information to evaluate a food safety regulation: HACCP for meat and poultry. *American Journal of Agricultural Economics*, 78(5), pp.1297-1301.

²⁵ Ribera, L., M. Palma, M. Paggi, R. Knutson, J. Masabni, J. Anciso. 2012. Economic Analysis of Food Safety Compliance Costs and Foodborne Illness Outbreaks in the United States. *HortTechnology* 22(2): 150 - 156.

²⁶ Keithly Jr, W.R. and Diop, H., 2001. The Demand for Eastern Oysters, *Crassostrea virginica*, from the Gulf of Mexico in the Presence of *Vibrio vulnificus*. *Marine Fisheries Review*, 63(1), pp.47-53.

²⁷ Dedah, C., Keithly Jr, W.R. and Kazmierczak Jr, R.F., 2011. An analysis of US oyster demand and the influence of labeling requirements. *Marine Resource Economics*, 26(1), pp.17-33.

²⁸ Ritzman, J., A. Brodbeck, S. Brostrom, S. McGrew, S. Dreyer, T. Klinger, S.K. Moore. 2018. Economic and sociocultural impacts of fisheries closures in two fishing-dependent communities following the massive 2015 US West Coast harmful algal bloom. *Harmful Algae* 80: 35-45.

²⁹ Van Senten, J., C. R. Engle. 2018. Economic Effects of Regulations on West Coast Shellfish Farms. Presentation at PCSGA 2018, Blaine WA.

to make sure we are not asking the same questions, and have adopted his sampling scheme based on grower acreage in order to directly compare results and put *Vibrio* costs in perspective with other common expenses.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

This collection impacts aquaculture farms, restaurants, and the state Department of Health. Since the Department of Health is a partner on this study, they have expressed willingness to invest time in gathering data from their agency for the analysis. Since they were also party to the proposal very early in the research process, they will have ample time to gather this data (up to 18 months) at their discretion.

For the aquaculture farms and restaurants, we will offer them the option to answer our questions in person or over the phone – whichever is easiest for them and their daily habits. In our experience working with aquaculturists and restaurateurs, the in-person and phone options are desired so that they can continue with daily activities and answer questions at the same time. In addition, we will ask them to pick a representative to speak for the whole business in order to minimize burden to the busiest members of that business. We will also tell them the topics of the questions in the invitation to participate so that they can spend time collecting their memories and possibly records to best answer the questions and are not surprised when we ask about specific costs.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If the study is not conducted, the aquaculture program will still have no estimates of the cost of *Vibrio* to many businesses in the oyster production chain. As these costs are expected to rise as the range of the *Vibrio* bacteria is expanding³⁰ and the risky season is becoming longer³¹, this lack of information could lead to budget shortfalls across the production chain if costs are underestimated.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

Data collection will be consistent with OMB guidelines.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission by OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

³⁰ Martinez-Urtaza, J., J.C. Bowers, J. Trinanes, A. DePaola. 2010. Climate anomalies and the increasing risk of *Vibrio parahaemolyticus* and *Vibrio vulnificus* illnesses. *Food Research International* 43(7): 1780-1790.

³¹ Muhling, B.A., Jacobs, J., Stock, C.A., Gaitan, C.F. and Saba, V.S., 2017. Projections of the future occurrence, distribution, and seasonality of three *Vibrio* species in the Chesapeake Bay under a high-emission climate change scenario. *GeoHealth*, 1(7), pp.278-296.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

A Federal Register Notice published on October 17, 2018, (83 FR 52416) solicited public comment.

No comments were received.

Consultation

We consulted with experts for each of the modules who works in that field as part of the interview guide creation process. Two Pacific Northwest growers (one small and tribal, one medium sized), staff from the Phillips Wharf Environmental Center grower's education program), one restaurant manager from a seafood restaurant, one former restaurant supplier, and one member of a surveillance program laboratory all reviewed the interview guide. Each suggested minor wording changes to the relevant portion of the interview guide, confirmed the timing was reasonable, and that the topic was relevant to current concerns.

In addition to the literature review, we briefed colleagues at the NOAA/FDA pathogens team about the project, soliciting feedback on our approach in order to best meet the needs of the program and to ensure no duplication of effort. We specifically reached out to Erin Stokes with the enteric epidemiology program at CDC and Stacey McLeroy with the Center for Food Safety and Applied Nutrition at FDA, both of whom assured us that no similar studies were performed by their agencies.

We also requested external review of the draft interview guide and this supporting statement by two methods experts. Jonathan van Senten, PhD (Virginia Tech) has direct experience with our desired respondent pool, as he has conducted a survey in the region on the economic burden of regulation. His review suggested a number of wording changes to help with specificity of answers as well as emphasizing the importance of the flexibility in the question order in order to accommodate non-sequential lines of thought. The second reviewer, Luke Fairbanks, PhD (Colorado State University), has a research portfolio focusing on aquaculture policy and economic development. His biggest overall comment was about the level of recall required for a few of the questions, and that a heads up that we'll be asking such things might be useful in the invitation so they can be prepared. Other comments were about question specificity and possibly breaking them apart to be several, shorter, questions rather than one bigger one. Both thought expected burden seemed reasonable, given options for response format and promises of confidentiality. We made the requested revisions.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

No payments or gifts will be given to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

We will emphasize that given the small nature of the community, only aggregated results will be shared (i.e., 'small farms spend x dollars on Vibrio-related equipment'). Only the interviewer will know the individual answers to any particular question, and part of the reason we are conducting these interviews one-on-one is to help build trust in that relationship. We will also assure that answers used for our cost model will be under a pseudonym (case number), and the raw data protected on federal computers with strict IT protection.

The information collection will be considered confidential as required by [NOAA Administrative Order 216-100](#).

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

No questions of a sensitive nature will be asked during this data collection.

12. Provide estimates of the hour burden of the collection of information.

From our project partners, we have developed a contact list of 90 growers, 18 managers (including project partners), and 20 restaurants, for a total of 128 people. This is all oyster growers registered with either or both Pacific Coast Shellfish Growers Association or the Department of Natural Resources, all managers that deal with Vibrio as part of their job description, and all restaurants who have had Vibrio traceback investigations in the last year.

The interview is estimated from time tests in Maryland to take about 15-30 minutes to talk through all the questions, so we are using the upper end of the range to estimate burden. We expect a 75% response rate, which yields a request of 49 burden hours.

13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information.

No additional cost burden will be incurred by respondents beyond response time.

14. Provide estimates of annualized cost to the Federal Government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses, and any other expense that would not have been incurred without this collection of information.

The project is budgeted for \$61,000, which breaks down into contractor salary, travel to meet with respondents at two annual industry meetings (\$7000), and supplies (\$1000). The contractor salary covers 1/3 of salary of one of the primary investigators and a summer stipend for a student.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I.

This is a new collection.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time

schedule for the entire project, including beginning and ending dates of the collection of information, completion of the report, publication dates, and other actions.

The conceptual model and cost estimates will be analyzed using Mental Modeler, a software program frequently used to help quantify chains of effects, such as what happens after a Vibrio illness is reported. The conceptual model (shown in part B, question 5, figures 1 and 2) will be additive, so as we collect data on the different cost categories depicted in the model, we can sum the costs by different stakeholder groups. The final calculation will be a comparison between the costs in model 1 (figure 1) and model (figure 2), which will show what an increase in reported Vibrio cases will add to the costs from existing food safety practices. In short, the total costs and confidence intervals will be calculated as follows for each surveillance/prevention scenario and for traceback case present scenario:

Average costs of equipment = gear purchases * average cost + recurring expenses * average cost

[exact equipment to be solicited in the interview; for example, refrigeration costs = freezer * cost of industrial freezer + annual maintenance and recordkeeping for refrigerator]

Average labor hours = time spent on food safety practices + time in training for food safety + time spent on traceback investigations + time spent on recordkeeping

Total cost for each size class/stakeholder group = (Average costs of equipment + average labor hours*industry wage estimates) * number of firms in size class

Extra small total + small total + medium total + large total = total cost for growers

Management + growers + restaurant = Total cost to oyster aquaculture industry

The project timeline will begin upon OMB clearance and extend six to twelve months depending on the season. Data collection will take three months, targeting the summer months, when demand for oysters is lowest and concern about Vibrio highest. After collection, we will pick an industry meeting in the region to report results back (options include Pacific Coast Shellfish Growers Association, HACCP training workshops in King County, or an ISSC regional meeting), depending on timing. Following report-out, the results will be finalized in the form of an academic journal publication, a section of the Pathogen program website, and an infographic for distribution. If stakeholders and respondents request additional products, we will consider those as needed.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

Not applicable.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-1.

Not applicable.