

SUPPORTING STATEMENT A

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 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. The reauthorization in 2018 emphasized the role of aquaculture and called for aquaculture expansion in order to meet domestic seafood demand. This will require improving the economic viability of aquaculture ventures and mitigating risk in starting a new business, both of which *Vibrio* affects. In addition, estimating the costs associated with *Vibrio* illnesses outside a hospital setting is a demand expressed in a number of industry settings. Washington State Department of Health expressed desire for this information in order to more accurately plan their budgets.

- 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 module of questions for each group parallels each other for ease of comparison, 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 as they arise to ensure no duplication in question topics. Possible follow up questions are listed for some questions to make sure we have information for each part of the conceptual model. Some questions ask for 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, and Pacific Coast Shellfish Growers Association. They will use the cost

estimates to help in budgeting future operations for disease management and response. The research community 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. This will be especially helpful in areas where *Vibrio* illness rates are expected to increase due to warming water conditions.

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. The question is broken out by categories of expenses we know from talking to our partners at the Department of Health 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

Since food safety for shellfish is a stakeholder-driven process, a high level of participation is expected from shellfish managers and growers to ensure representation. 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. We will account for time and money separately, as we understand this is not a direct conversion¹.

- 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

¹ Foley, D. 1982. The Value of Money, the Value of Labor Power, and the Marxian Transformation Problem. *Review of Radical Political Economics* 14(2): 37-47.

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 time².

- 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 don't 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.

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 time
 - 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.

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

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 need an estimate of variation to be able to generalize to an annual resources dedicated to investigations.

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, so this will be used to check non-response bias (see part B, question 2).

Part A: Surveillance and Prevention

² Freitag, A. Vogt, B. Hartley, T. 2018. Breaking Stereotypes Through Network Analysis of the Chesapeake Oyster Community. *Marine Policy* 90:146-151.

- 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 industry. 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] 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.

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]

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.

- 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?

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.

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 requirements, 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.

- 1) During times of increased Vibrio cases, have you noticed any change in 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.)

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.

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.**

This interview is designed to 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, an e-mail first contact may be used. Based on this first contact, if respondents indicate they want questions in another language, we may 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 project³.

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.

A literature review on Vibrio and economics revealed one study that 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 menus⁴. 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 Northwest⁵. 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.

Many studies (e.g. Scharff 2012⁶, Todd 1989⁷, Hoffman et al 2012⁸, and Raston et al 2011⁹) 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. Recognizing this body of work is vast, we will not directly ask about these costs and instead perform a meta-analysis of the literature to estimate average cost of a Vibrio case in health care terms.

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 acid¹⁰. 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

³ De Leeuw, E. 2005. To Mix or Not to Mix Data Collection Modes in Surveys. *Journal of Official Statistics* 21(2): 233-255.

⁴ 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.

⁵ 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.

⁶ Scharff. 2012. Economic Burden from Health Losses Due to Foodborne Illness in the United States. *Journal of Food Protection*. 75(1): 123-131.

⁷ Todd, E. 1989. Preliminary Estimates of Costs of Foodborne Disease in the United States. *Journal of Food Protection* 52(8): 595-601.

⁸ 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.

⁹ 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.

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 large¹¹. 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 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 and 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 expanding¹², 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.

¹⁰ 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.

¹¹ Van Senten, J., C. R. Engle. 2018. Economic Effects of Regulations on West Coast Shellfish Farms. Presentation at PCSGA 2018, Blaine WA.

¹² 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.

- 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. 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 someone for each of the modules who works in that field as part of the interview guide creation process. Two staff from the Phillips Wharf Environmental Center (who help with a 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.

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 48 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.

The draft products will be presented at the Pacific Coast Shellfish Growers Association meeting in September of 2019, and all respondents will be invited to attend. After this, 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. The data collection will ideally happen in summer 2019 (off-season for the producers), and completion of the reports is expected throughout the fall and winter of 2019.

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.