



NOV 30 2016

Michael F. Jacobson
Executive Director
Center for Science in the Public Interest
1275 Connecticut Ave, N.W.
Suite 300
Washington, DC 20009

Re: Docket No. FDA-2012-P-0146

Dear Dr. Jacobson:

This letter responds to the citizen petition submitted by the Center for Science in the Public Interest (CSPI) dated February 9, 2012. In that petition, CSPI requested that the Food and Drug Administration (FDA or we) “take regulatory action to issue and enforce a performance standard of non-detectable as determined by the best available method of detection for *Vibrio vulnificus* (*V. vulnificus*) in molluscan shellfish intended for raw or processed raw consumption” (see Citizen Petition from Center for Science in the Public Interest at page 1 (hereinafter referred to as “Petition”)).

In accordance with Title 21 of the Code of Federal Regulations (CFR), section 10.30(e)(3)(21 CFR §10.30(e)(3)), we are denying the petition for the reasons discussed more fully below. We have determined that a performance standard of non-detectable for *V. vulnificus* in raw or processed raw molluscan shellfish is not warranted at this time. Identification and implementation of control measures that are effective in managing the risk of *V. vulnificus*, increased focus on adherence to the control measures by the shellfish industry and states, and increased oversight by FDA have resulted in a significant reduction in oyster-associated *V. vulnificus* illnesses since 2013.

I. Discussion

A. *Vibrio vulnificus*

V. vulnificus is a gram negative, aquatic bacterium that inhabits coastal ecosystems where filter-feeding bivalve mollusks, such as oysters, grow.¹ It is a naturally occurring organism. Proliferation of *V. vulnificus* in aquatic ecosystems is affected by environmental conditions,

¹ For a fuller discussion of *V. vulnificus*, please see Food and Drug Administration. Bad Bug Book, Foodborne Pathogenic Microorganisms and Natural Toxins. Second Edition. [pp. 46-49]. 2012., at <http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM297627.pdf>.

including water temperature and salinity; other environmental factors are less well established.^{2,3} Illnesses associated with *V. vulnificus* tend to follow warm weather seasonal trends in aquatic environments where salinities are favorable, such as the Gulf Coast, which is the source of oysters most commonly associated with illnesses caused by *V. vulnificus*.^{3,4,5,6}

V. vulnificus is a pathogen of public health concern. The infectious dose of *V. vulnificus* in both healthy and immunocompromised persons is unknown.⁷ Healthy individuals are susceptible to wound infection from skin exposure to *V. vulnificus* and to gastroenteritis from consumption of the bacteria. Severe *V. vulnificus* illness occurs most often in individuals whose immune systems have become compromised through one or more medical conditions, particularly liver disease. Symptoms from severe *V. vulnificus* can be extremely rapid and dramatic, and include shock, cellulitis, nausea, fever, multiple organ failure, and bullous lesions on the extremities, a distinguishing characteristic of sepsis.^{8,9,10} The hospitalization rate for immunocompromised individuals developing primary septicemia is over 90 percent, with a mortality rate ranging between 35-50 percent.^{6,10,11} Given the severity of the symptoms, and the need for immediate medical attention, while there may be some underreporting of illness associated with *V. vulnificus*, this is not as great a concern as is the case with some other foodborne pathogens, such as *Salmonella spp.*¹¹

B. CSPI 1998 Petition and FDA's Response

² De Paola A., G.M. Capers, D. Alexander. Densities of *Vibrio vulnificus* in the intestines of fish from the U.S. Gulf Coast. *Appl. Environ. Microbiol.*, 60 (1994), p. 984.

³ Motes M.L., A. De Paola, D.W. Cook, J.E. Veazey, J.C. Hunsucker, W.E. Garthright, R.J. Blodgett, S.J. Chirtel. Influence of water temperature and salinity on *Vibrio vulnificus* in Northern Gulf and Atlantic Coast oysters (*Crassostrea virginica*) *Appl. Environ. Microbiol.*, 64 (1998), p. 1459

⁴ Kaspar, C. W., and M. L. Tamplin. 1993. Effects of temperature and salinity on the survival of *Vibrio vulnificus* in seawater and shellfish. *Appl. Environ. Microbiol.* 59:2425–2429.

⁵ DePaola, A., J. L. Nordstrom, J. C. Bowers, J. G. Wells, and D. W. Cook. 2003. Seasonal abundance of total and pathogenic *Vibrio parahaemolyticus* in Alabama oysters. *Appl. Environ. Microbiol.* 69:1521–1526.

⁶ *V. vulnificus* illnesses linked to molluscan shellfish are almost exclusively associated with oysters. Horseman MA1, Surani S., A comprehensive review of *Vibrio vulnificus*: an important cause of severe sepsis and skin and soft-tissue infection. *Int J Infect Dis.* 2011 Mar;15(3):e157-66. doi: 10.1016/j.ijid.2010.11.003. Epub 2010 Dec 21.

⁷ The Petition at page 13, n. 50, cites FDA's Bad Bug Book for the assertion that "FDA assumes septicemia can occur with a dose of less than 100 organisms." While that statement appears in the first edition of the book, FDA's revised version, released in 2012 (after the Petition was submitted) (see Ref 1) states: "The FAO/WHO *V. vulnificus* Risk Assessment (VVRA) provides a dose response based on U.S. epidemiologic data and estimates . . . that a dose of 1,000 organisms can cause illness...."

⁸ Shapiro, R.L., et al., The role of Gulf Coast oysters harvested in warmer months in *Vibrio vulnificus* infections in the United States, 1988-1996. *Vibrio Working Group. J Infect Dis*, 1998. 178(3): p. 752-9.

⁹ Howard, R.J. and S. Lieb, Soft-tissue infections caused by halophilic marine vibrios. *Arch Surg*, 1988. 123(2): p. 245-9.

¹⁰ Blake, P.A., M. H. Merson, R. E. Weaver, D. G. Hollis, and P. C. Heublein., Disease caused by a marine *Vibrio*. Clinical characteristics and epidemiology. *N Engl J Med* 1979. 300(1-5).

¹¹ Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M.-A., Roy, S. L., ... Griffin, P. M. (2011). Foodborne Illness Acquired in the United States—Major Pathogens. *Emerging Infectious Diseases*, 17(1), 7–15.

<http://doi.org/10.3201/eid1701.P11101>

In 1998, CSPI submitted a citizen petition (Docket No. 98P-0504/CSPI), asking that we adopt a performance standard for *V. vulnificus*. In 2002, we denied the petition based on the fact that the Interstate Shellfish Sanitation Conference (ISSC) had recently (in 2001) adopted a requirement for states to develop and implement *V. vulnificus* management plans that focused on the use of education of immunocompromised consumers and post-harvest processing for purposes of achieving a targeted illness rate reduction goal of 60 percent.¹²

We stated in our response that “...participation in the ISSC program is the optimal course of action at the present time,” recognizing in the letter that since its establishment, the ISSC had proven effective in preventing illnesses associated with sewage-borne bacterial pathogens and our expectation for similar success with *V. vulnificus*. We have been working with the ISSC to provide guidance and counsel on matters for the sanitary control of shellfish and have mutually agreed to recognize the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish (NSSP Guide) as the set of principal standards and procedures for the sanitary control of shellfish.^{13,14} Control measures established under the NSSP are enforced by the states.

C. Control Efforts for *Vibrio Vulnificus*

Since our 2002 response to CSPI, federal oversight of State controls and partnership within the framework of the ISSC has allowed for continued progress towards effective management of *V. vulnificus*.¹⁵ The goal of the ISSC’s 2001 *V. vulnificus* risk management plan was to reduce the rate of *V. vulnificus* septicemia illnesses from the consumption of commercially harvested raw or undercooked oysters by 40 percent as reported by four “core” reporting states (California, Louisiana, Texas, and Florida) collectively for years 2005 and 2006 (2-year average), and by 60 percent for years 2007 and 2008 (2-year average), as compared to the annual average rate for the years 1995-1999 for those states (3 illnesses per 10 million people).¹⁶ ISSC’s plan to achieve these goals focused on educating the immunocompromised population. In addition to its education efforts, the ISSC prepared to implement a required post-harvest processing capacity of

¹² The ISSC is a voluntary organization of federal and state regulatory officials and the shellfish industry. ISSC provides a formal structure for state regulatory authorities to create legal requirements, guidelines, and procedures for managing the safety of shellfish. The ISSC-adopted control measures are published in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish (NSSP Guide), which contains a model ordinance that is incorporated into state law.

¹³ Memorandum of Understanding Between the Interstate Shellfish Sanitation Conference and The Food and Drug Administration:
<http://www.fda.gov/aboutfda/partnershipcollaborations/memorandaofunderstandingmous/othermous/ucm118388.htm>

¹⁴ NSSP Guide for the Control of Molluscan Shellfish: 2015 Revision:
<http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.htm>

¹⁵ The Petition argues that control of *V. vulnificus* is a federal responsibility. We do not disagree with this assertion. We regulate shellfish under a range of federal authorities. Our participation in the ISSC provides a formal structure for state regulatory authorities to create legal requirements, guidelines, and procedures for managing the safety of shellfish that incorporate the federal requirements and may also contain the state’s own, more stringent, standards.

¹⁶ NSSP Guide for the Control of Molluscan Shellfish, 2007 Revision. Section II. Model Ordinance, Chapter II. Risk Assessment and Risk Management@.04 *Vibrio vulnificus* Risk Management for Oysters B:
<http://www.fda.gov/downloads/Food/GuidanceRegulation/FederalStateFoodPrograms/UCM241512.pdf>.

50 percent of all Gulf of Mexico oysters intended for the raw half-shell market if the illness reduction goal was not achieved. Between 2001 and 2010 data from the “core” states showed a measurable reduction in the rate of severe illness from *V. vulnificus*,¹⁷ but the rate of illness at the national level did not change significantly. Furthermore, much of the reduction in the “core” state data was directly attributable to a 2003 California ban (California Code of Regulations Title 17, Section 13675) on the sale of raw Gulf oysters that have not been subjected to a post-harvest process to reduce *V. vulnificus* to non-detectable levels.¹⁸ In 2011, the ISSC adopted a new risk per serving approach to be achieved through implementation of stringent post-harvest time-to-temperature controls and other control measures; FDA concurred with the new approach in 2012. The new approach shifted from an illness rate reduction goal of 60 percent based on illnesses counted in the four core states to a three-tiered risk per serving goal, i.e. reducing the risk of illness for every 100,000 oyster servings, based on illnesses occurring nationally. The three tiers are defined as: (1) less than 1.75 illnesses per 100,000 servings when the water temperature exceeds 70 degrees Fahrenheit and is less than 75 degrees F, (2) no more than 2.5 illnesses per 100,000 servings when the water temperature exceeds 75 degrees F and is less than 80 degrees F, (3) less than 3 illnesses per 100,000 servings when the water temperature exceeds 80 degrees F.¹⁹ This approach more accurately assesses the national incidence of *V. vulnificus* illness associated with raw oyster consumption, by counting illnesses occurring nationally as opposed to illnesses occurring only within the four core states. The new NSSP approach placed accountability on individual states to meet risk per serving goals while providing for a cumulative measure of illness reduction at the national level.

In 2012, following adoption of the new NSSP control plan, states revised their *V. vulnificus* control plans for implementation by harvesters and processors of oysters intended for the raw half-shell market to include strict time-to-temperature and other control measures when the average monthly maximum water temperature exceeds 70° (these other control measures include labeling oysters "For shucking by a certified dealer"; subjecting all oysters intended for the raw, half-shell market to a state authority-approved post-harvest processing; and/or the state authority may implement alternative controls that will reduce the risk to a level comparable to these time-

¹⁷ For example, a 49.4% illness reduction was determined by the ISSC in 2007. March 2007 ISSC Vibrio Management Committee Report:
http://www.issc.org/client_resources/committe%20reports/vmc%20report%20march%2028%202007.pdf.

¹⁸ On April 3, 2003, the California Department of Health Services (CDHS) announced an emergency ban on the sale of oysters harvested in Gulf states during the months of April through October, unless the oysters had undergone a post-harvest treatment approved by CDHS. Florida, Louisiana and Mississippi separately challenged California's rule, arguing its implementation violates the Interstate Shellfish Sanitation Conference reciprocity policies. California was censured and was not able to vote for violation of the reciprocity policies of the ISSC until 2015 when the California Department of Public Health, Food and Drug Branch (CDPH-FDB), adopted a new standard for the level of *V. vulnificus* for post-harvest processed raw Gulf Oysters. The level of 3 MPN per gram was revised to 30 MPN per gram which harmonized California's Molluscan Shellfish Program standard for post-harvest processed raw Gulf Oysters with the other participating states of the National Sanitation Shellfish Program. The censure was subsequently dropped.

¹⁹ NSSP Guide for the Control of Molluscan Shellfish, 2011 Revision; Section II. Model Ordinance, Chapter II. Risk Assessment and Risk Management @.05 *Vibrio vulnificus* Control Plan.
<http://www.fda.gov/downloads/Food/GuidanceRegulation/FederalStateFoodPrograms/UCM350344.pdf>.

to-temperature control measures).²⁰ . The new controls, underpinned by a *V. vulnificus* illness risk calculator developed by FDA with recognition by the ISSC, are intended to reduce exposure of oysters to time-to-temperature regimes known to promote the post-harvest growth of *V. vulnificus* bacteria.²¹ This predictive *V. vulnificus* risk calculator provides states with an effective tool for defining the required time-to-temperature controls specific to product harvested within their state that are necessary to achieve the NSSP risk per serving goals adopted by the ISSC in 2011.

FDA's annual assessment of state compliance with NSSP requirements found the state shellfish control authorities have demonstrated increased efforts to monitor the shellfish industry, particularly at the point of harvest, and to enforce State mandated time-to-temperature controls set in accord with the NSSP. As part of our effort to ensure State compliance with NSSP requirements and to better manage the risk of *V. vulnificus*, we have incorporated a focused *Vibrio* component into our Molluscan Shellfish Compliance Program, which directs FDA activities in the evaluation of state shellfish sanitation programs.²²

In addition, we have developed a second risk calculator that states can use to define the actual per serving risk of *V. vulnificus* based on a State's individually reported oyster production and number of illnesses attributed to oysters harvested from the State. The ISSC will test the new calculator in the upcoming year. We also have established a Workgroup on Ecological Forecasting for *Vibrio*.²³ The workgroup's goal is to coordinate, plan, prioritize, and communicate ecological forecasting activities related to *Vibrio* within and beyond FDA. Specifically, we are collaborating with the National Oceanic and Atmospheric Administration (NOAA) under NOAA's Ecological Forecasting Roadmap to develop experimental *Vibrio* forecast products (among others) using FDA's risk models and NOAA's environmental data and hydrodynamic models. The FDA-NOAA collaboration, with the engagement of other key federal, State, industry, and academic partners, will result in enhanced and regionally-specific forecasting tools for *Vibrio* risk assessments.

We have also established a program to extend research and technical assistance on *Vibrio* to states and industry through our *Vibrio* Assessment Review Board (VARB). States and industry can submit VARB requests to us for research and technical assistance aimed at improving the science and control of *Vibrios* in molluscan shellfish. Through the VARB, we offer assistance, such as laboratory support, technical expertise, and statistical application, to help states and industry as they undertake independent *Vibrio* projects to better assess control measures intended to reduce risk. The VARB also ensures that the collaborative efforts undertaken will support the NSSP's intended risk reduction goals.

²⁰ NSSP Guide for the Control of Molluscan Shellfish, 2013 Revision; Section II. Model Ordinance, Chapter II Risk Assessment & Risk Management @.06 *Vibrio vulnificus* Control Plan E.(b)

²¹ FDA Vv Risk Calculator and Explanation, 9-18-2008: <http://www.issc.org/committees/VibrioManagement.aspx>.

²² Food and Drug Administration Compliance Program Guidance Manual, Chapter 18 Technical Assistance; The Molluscan Shellfish Compliance Program:
<http://www.fda.gov/downloads/Food/ComplianceEnforcement/ucm073326.pdf>.

²³ NOAA Ecological Forecasting: *Vibrio* Guidance Models:
<https://coastalscience.noaa.gov/products/vibrioforecast/default>.

In sum, FDA continues to work on innovative ways to further improve *Vibrio* management. The risk assessments discussed in this section will help states craft *Vibrio* management plans tailored to the specific risk factors in their regions; such as whether illnesses rise early or late in the growing season. Understanding populations and predictive modeling will allow states to use resources more wisely and further reduce illnesses by minimizing post-harvest *Vibrio* growth.

D. Recent Data on Illnesses from *V. vulnificus*

Beginning with the 2013 *V. vulnificus* risk season (April through October), as part of our annual assessment of State shellfish programs under the terms of the FDA Molluscan Shellfish Compliance Program (7318.004), we began to evaluate the implementation of the stricter time-to-temperature controls and of compliance by State regulatory officials and the shellfish industry.²²

During 2013, 2014 and 2015, we found that the shellfish industry has increased compliance with state-mandated, enforceable time-to-temperature control measures.²⁴ Those efforts resulted in a greater than 30 percent reduction in illnesses reported nationwide, and as much as a 40 percent reduction in deaths for 2013 and 2014—22 illnesses were reported for each year and 10 and 9 deaths respectively.²⁵

The petition cites an average number of 33 illnesses occurring annually from infected shellfish over the past decade (Petition at page 10). We do not believe that the use of these averages is appropriate in understanding the current risk associated with *V. vulnificus* from oysters. We believe that the 2013 and 2014 data are evidence of a significant risk reduction that can be attributed to improved intervention in terms of time-to-temperature controls.

The decrease in illnesses during 2013 and 2014 is not linked to any known decrease in raw oyster consumption. While the National Marine Fisheries Service shellfish landings data indicate some year to year fluctuation, oyster landings in the Gulf of Mexico, the source of almost all oysters associated with *V. vulnificus* illness, have remained relatively stable.²⁶ In combination, these facts demonstrate that the 2013 and 2014 reduction in *V. vulnificus* illnesses associated with Gulf oysters cannot be linked to a reduction in oyster production.

E. *V. vulnificus* and FDA Authorities

Your petition states that section 104 of FSMA explicitly requires us to establish performance standards for significant foodborne contaminants such as *V. vulnificus*. We disagree. Section 104 of FSMA states that, “when appropriate to reduce the risk of serious illness or death to

²⁴ Evaluations for 2016 are not yet complete, but there is no indication that the most recent data are inconsistent with the trend, as reported by the FDA in *Vibrio* Program Element Evaluation Reports.

²⁵ See Appendix I and also *Shellfish-Related Vibrio vulnificus Cases/Deaths, 2013*: http://www.issc.org/client_resources/publications/2013%20v.v.%20illness%20table.pdf and *2014*: http://www.issc.org/client_resources/2014%20v.v.%20illness%20table%20.pdf. Illness data for 2015 has not yet been finalized by CDC.

²⁶ National Marine Fisheries Service Annual Commercial Landings Statistics: <https://www.st.nmfs.noaa.gov/commercial-fisheries/commercial-landings/annual-landings/index>

humans or animals, or to prevent adulteration of the food... or to prevent the spread by food of communicable disease...,” FDA, working in coordination with the U.S. Department of Agriculture, must issue contaminant-specific and science-based guidance documents or regulations. Section 104 of FSMA states that the guidance documents may include guidance documents regarding action levels, but nowhere does the text of section 104 of FSMA require us to set a performance standard for significant foodborne contaminants that must be followed by the food industry.

Your petition also states that we have the authority to enforce a non-detectable performance standard under sections 402(a)(1), 402(a)(2)(A) and 402(a)(4) of the FD&C Act, because you assert that shellfish contaminated with *V. vulnificus* would be considered adulterated under those provisions. Additionally, your petition states that we have the authority to control *V. vulnificus* as a communicable disease under section 361 of the Public Health Service Act (the PHS Act). While section 402 of the FD&C Act, combined with other sections of the FD&C Act, could give us the authority under certain circumstances to enforce a performance standard designed to stop a food from being adulterated, there is no statutory mandate for FDA to establish a performance standard for *V. vulnificus* in molluscan shellfish, and at this time FDA is not establishing one. Therefore, we decline to fully address the scope of FDA’s authority to enforce such a performance standard in this response. Further, we note that at this time we are not prepared to state that any level of *V. vulnificus* above non-detectable levels renders molluscan shellfish adulterated. We recognize the dose response value cited in FDA’s Bad Bug Book which originated from the FAO/WHO Risk Assessment of *Vibrio vulnificus*. This level was derived from the best data available at the time; however, the model used to determine that value was developed with known caveats primarily linked to data limitations.²⁷ Thus, there is currently no known infectious dose of this naturally occurring aquatic bacterium. Furthermore, as discussed above, over the last few years increased compliance with state-mandated, enforceable time-to-temperature control measures has resulted in a decrease in the number of illnesses and deaths from *V. vulnificus* associated with molluscan shellfish consumption. With respect to your statement that section 361 of the PHS Act gives FDA the authority to control for *V. vulnificus* in molluscan shellfish, while we agree that the section gives us the authority to promulgate certain requirements to control communicable diseases, and that infections with *V. vulnificus* are “communicable” because they are transmitted from animals to humans (see 21 CFR 1240.3(b)), for the reasons stated above, at this time we are not establishing a non-detectable performance standard for *V. vulnificus* in molluscan shellfish.

Your petition also asserts that section 114 of FSMA does not bar action on your petition, in part because section 114 of FSMA is directed towards actions related to post-harvest processing. The language of section 114 speaks for itself with respect to what procedures FDA would have to follow were we to determine, now, or at some future time, that there is a need to set a performance standard for *V. vulnificus*. As this response to your petition states, we do not agree that a performance standard of non-detectable levels of *V. vulnificus* is warranted at this time.

²⁷ Risk assessment of *Vibrio vulnificus* in raw oysters: interpretative summary and technical report. Published jointly with the World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO). 2005. <http://www.fao.org/docrep/008/a0252e/a0252e00.htm>.

Furthermore, while your petition is correct that section 114 of FSMA specifically concerns regulatory action that “relates to post harvest processing for raw oysters,” we note that while setting a performance standard of non-detectable for *V. vulnificus* itself would not expressly create a requirement for the post-harvest processing of oysters, the standard would relate to post-harvest processing of raw oysters because the practical effect of the standard would be to require post-harvest processing of oysters intended for raw consumption. We are not aware of any method that ensures a non-detectable level of *V. vulnificus* in oysters intended for raw consumption that would not involve some form of post-harvest processing.

II. Conclusion

Combining the revised ISSC *V. vulnificus* control plan with our increased oversight as part of a focused approach to conducting annual assessments of state and industry compliance with *V. vulnificus* control plan requirements, we have seen a significant reduction in oyster-associated *V. vulnificus* illnesses. In addition, to enhance FDA oversight of state and industry compliance with the control plan requirements, we work closely with the Centers for Disease Control and Prevention and the ISSC’s Illness Review Committee, a standing committee that examines information related to *V. vulnificus* illnesses, to ensure that all *V. vulnificus* illnesses attributable to oyster consumption have been counted appropriately and accurately for use in assessing illness reduction.

Improving food safety by fostering implementation of preventive controls to prevent foodborne illness is a priority for FDA. In acting on these responsibilities, we will continue to seek the advice and support of all interested parties, including the ISSC members. With the reduction of oyster-associated *V. vulnificus* illnesses in 2013 and 2014 and the effort of states and industry to work with us to achieve risk management strategies that are measurably effective, we decline to establish a performance standard of non-detectable for *V. vulnificus* at this time. We have determined that the most appropriate course of action is to work cooperatively with the ISSC to assess and refine NSSP controls that are shown to be effective in managing the risk of *V. vulnificus*. Because we are making this determination, based on the data and information discussed in this letter, we are not addressing in detail the arguments in the petition concerning FDA’s legal authority to set such a standard. We have determined that our decision to continue working with the states and industry to implement *V. vulnificus* risk reduction measures is the most appropriate use of the agency’s limited resources. FDA is currently engaged in developing, completing, and implementing several significant rulemakings regarding food safety and nutrition. Given the scope of FDA’s responsibilities regarding the food supply, we must make difficult choices regarding how to use our limited resources. In light of the agency’s many competing priorities, and based on our careful consideration of the information you submitted and of the information presented in this letter, we have determined that the action you requested is not the best use of agency resources at this time.

Page 9 – Michael F. Jacobson:

In conclusion, for the reasons described above, we are denying your petition.

Sincerely,

A handwritten signature in black ink, appearing to read "Nega Beru". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Nega Beru, Ph.D.
Director,
Office of Food Safety
Center for Food Safety
and Food Safety

Appendix I – Shellfish consumption illnesses and deaths reported by states to CDC and FDA by year

Year	Illnesses from consumption of raw molluscan product	Deaths from consumption of raw molluscan product
1998	40	19
1999	29	16
2000	30	18
2001	32	16
2002	35	17
2003	34	16
2004	39	20
2005	15	8
2006	39	16
2007	33	16
2008	33	17
2009	41	15
2010	38	16
2011	27	14
2012	36	17
2013	22	10
2014	22	9