

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

Petition for Regulatory Action to Establish)
a Performance Standard of Non-detectable)
Levels for *Vibrio vulnificus* in Molluscan)
Shellfish)
_____)

Docket No. _____

Submitted by the

Center for Science in the Public Interest

February 9, 2012

Michael F. Jacobson, Ph.D.
Executive Director

David W. Plunkett, J.D., J.M.
Senior Staff Attorney

1220 L Street, N.W.
Suite 300
Washington, D.C. 20005
202-332-9110

CONTENTS

A. ACTION REQUESTED	1
B. STATEMENT OF GROUNDS	1
1. Factual Grounds	1
a. <i>Vibrio vulnificus</i> is a Significant Threat to Public Health	1
i. <i>V. vulnificus</i> Causes Serious Illnesses and Death	2
ii. <i>V. vulnificus</i> Causes a Significant Number of Illnesses	4
iii. FDA Acknowledges <i>V. vulnificus</i> is a Significant Hazard	6
b. Control of <i>V. vulnificus</i> is a Federal Responsibility	6
c. FDA Has Already Called for Action Relevant to this Petition	8
2. Legal Grounds	9
a. Authority to Establish Performance Standard for <i>V. vulnificus</i>	9
b. Authority to Enforce a Performance Standard	14
i. <i>V. vulnificus</i> is an Adulterant Under Section 402(a)(1)	14
ii. Enforcement of Tolerance Levels Under Section 402(a)(2)(A)	18
iii. Insanitary Conditions Under Section 402(a)(4)	18
iv. Prevention of Communicable Diseases Under the PHSA	19
c. Section 114 of FSMA Does Not Bar Action on This Petition	21
C. ENVIRONMENTAL IMPACT	22
D. ECONOMIC IMPACT	22
E. CERTIFICATION	22
FIGURE	
Figure 1. Reported <i>Vv</i> Illnesses and Deaths 1989 to 2010	4
ATTACHMENT	
Letter from FDA Denying CSPI's 1998 Petition	

February 9, 2012

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

CITIZEN PETITION

The Center for Science in the Public Interest (“CSPI”) submits this petition pursuant to 5 U.S.C. §553(e) and 21 C.F.R. §§10.20 and 10.30 to request the Commissioner of Food and Drugs to issue a performance standard under section 104 of the FDA Food Safety Modernization Act (“FSMA”) (21 U.S.C. §2201) for *Vibrio vulnificus* in molluscan shellfish.

A. ACTION REQUESTED

CSPI requests that the Food and Drug Administration (“FDA”) 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* in molluscan shellfish intended for raw or processed raw consumption.

B. STATEMENT OF GROUNDS

1. Factual Grounds.

a. *Vibrio vulnificus* is a Significant Threat to Public Health.

Vibrio vulnificus (“*V. vulnificus*”) is the most important of the pathogenic *Vibrio* species because its invasiveness and high fatality rate place it as the leading cause of seafood-associated deaths in the United States.¹

¹ Nicholas A. Daniels & Alireza Shafaie, *A Review of Pathogenic Vibrio Infections for Clinicians*, 17 INFECT. MED. 665 (2000).

i. *V. vulnificus* Causes Serious Illnesses and Death.

V. vulnificus is a gram-negative, curved, rod-shaped bacterium that inhabits marine environments. When ingested with food, *V. vulnificus* causes mild gastroenteritis in the general population and primary septicemia (blood poisoning) in susceptible populations.² These illnesses are most often associated with consumption of raw shellfish harvested from the Gulf of Mexico, primarily in the months of April through November.³ The reason for that association is believed to be seasonal changes in temperature and salinity in Gulf waters that favor the growth of *V. vulnificus* during warmer months.⁴

Gastroenteritis from eating raw shellfish contaminated with *V. vulnificus* can strike healthy individuals but is rarely severe enough to require hospitalization.⁵

Primary septicemia, conversely, is a serious illness that accounts for most of the 91 percent hospitalization rate associated with infection.⁶ Primary septicemia attacks persons with hepatic disorders, immuno-compromising conditions, and stomach disorders.⁷ Rare cases occur in persons with no pre-existing medical condition.⁸ Serious

² WHO/FAO, RISK ASSESSMENT OF *VIBRIO VULNIFICUS* IN RAW OYSTERS, at 17 (2005); Daniels *supra*, note 1. A person may also contract an infection through open wounds. This type of infection is known as secondary septicemia.

³ Where the source state is known, 98 percent of cases (308/315) reported to the Centers for Disease Control and Prevention (“CDC”) come from a Gulf Coast State. Shellfish-Related *Vibrio vulnificus* Cases and Deaths, Reported by Marc B. Glatzer, Senior Shellfish Specialist, Southeast Region, Food and Drug Administration (“FDA”). See also, Angelo DePaola, et al., *Bacterial and Viral Pathogens in Live Oysters: 2007 United States Market Survey*, 76 APPL. ENVIRON. MICROBIOL. 2754, (2010).

⁴ C.W. Kaspar & M.L. Tamplin, *Effects of Temperature and Salinity on the Survival of Vibrio vulnificus in Seawater and Shellfish*, 59 APPL. ENVIRON. MICROBIOL. 2425, (1993).

⁵ Ozlem Uluarac & Elliot Carter, *Varied Clinical Presentations of Vibrio vulnificus Infections: A Report of Four Unusual Cases and Review of the Literature*, 97 SOUTH. MED. J. 163, 164 (2004); Stephenie L. Drake, et al., *An Overview of Vibrio vulnificus and Vibrio parahaemolyticus*, 6 COMPREHENSIVE REV. IN FOOD SCI. AND FOOD SAFETY 120, 124 (2007).

⁶ Elaine Scallan, et al., *Foodborne Illness Acquired in the United States—Major Pathogens*, 17 EMERG. INFECT. DISEASES 7, 12, (2011). Table 3 shows the hospitalization rate for *V. vulnificus* as 91.3 percent.

⁷ FDA, *Raw Oysters Contaminated With Vibrio vulnificus Can Cause Illness and Death: Understanding the Risks*, at <http://www.fda.gov/Food/ResourcesForYou/HealthEducators/ucm085365.htm> (last accessed Jan. 23, 2012) (Noting, importantly, that some “health conditions may be present without any symptoms so people may not know they are at risk”).

illness from an infection sets in quickly and death may occur within hours of onset of infection.⁹ Mortality rates increase from 33 percent to 53 percent if treatment is delayed for as little as 24 hours. The rate increases to 100 percent for patients who delay treatment by 72 hours.¹⁰ Death occurs in at least half the cases.¹¹ Where death does not occur, infection may impact a survivor's future quality of life. Treatment of primary septicemia can require disfiguring skin debridement or amputation.¹² *V. vulnificus* has also been associated with other clinical syndromes, including pneumonia, osteomyelitis, spontaneous bacterial peritonitis, eye infections, and meningitis.¹³

⁸ INST. OF FOOD TECH., *Scientific Status Summary: Bacteria Associated with Foodborne Disease*, at 12, (2004) (citing D.L. Tison & M.T. Kelly, *Vibrio Species of Medical Importance*, 2 DIAG. MICROBIOL. INFECT. DIS. 263 (1984) as source for statement that cases of primary septicemia from a *V. vulnificus* infection have been observed in healthy individuals); W. Gary Hlady & Karl C. Klontz, *The Epidemiology of Vibrio Infections in Florida, 1981-1993*, 173 J. OF INFECT. DIS. 1176, 1179 (1996) (Describing a case of fatal *V. vulnificus* septicemia in a patient whose only pre-existing condition was pernicious anemia.); WHO/FAO *supra*, note 2 at 43 (noting that <5% of reported cases occur among otherwise "healthy" individuals).

⁹ "The clinical course of *V. vulnificus* bloodstream infections may be fulminant and result in death within hours." Daniels *supra*, note 1. Of the 21 major bacterial pathogens associated with food, the average number of estimated deaths (36) from *V. vulnificus* each year outpaces all but three. Only *Campylobacter* spp., *Listeria Monocytogenes*, and *Salmonella* spp. cause more deaths on an annual basis. Scallan *supra*, note 6.

¹⁰ Michael Bross, et al, *Vibrio vulnificus Infection: Diagnosis and Treatment*, 76 AM. FAMILY PHYSICIAN 539, 540, 543 (2007).

¹¹ FDA, *Raw Oysters Contaminated With Vibrio vulnificus Can Cause Illness and Death: Understanding the Risks*, *supra*, note 7; Martha Iwamoto, et al., *Epidemiology of Seafood-Associated Infections in the United States*, 23 CLINICAL MICROBIOLOGY REV. 399, 400 (2010); Hlady *supra*, note 8 at 1178.

¹² Daniels *supra*, note 1; Bross *supra*, note 10 at 542-43.

¹³ Daniels *supra*, note 1 (citing: M.T. Kelly & D.M. Avery, *Lactose-positive Vibrio in Seawater: A Cause of Pneumonia and Septicemia in a Drowning Victim*, 11 J. CLIN MICROBIOL. 278 (1980); C.V. Vartian & E.J. Septimus, *Osteomyelitis caused by Vibrio vulnificus*, 161 J INFECT DIS. 363 (1990); D.J. Holcombe, *Vibrio vulnificus Peritonitis. A Unique Case*, 143 J. LA STATE MED SOC. 27 (1991); M. DiGaetano, et al., *Vibrio vulnificus Corneal Ulcer*, Case reports, 107 ARCH OPHTHALMOL 323 (1989); and B.Z. Katz, *Vibrio vulnificus Meningitis in a Boy With Thalassemia After Eating Raw Oysters*, 82 PEDIATRICS 784 (1988). Some of the cases described involved wound infections.)

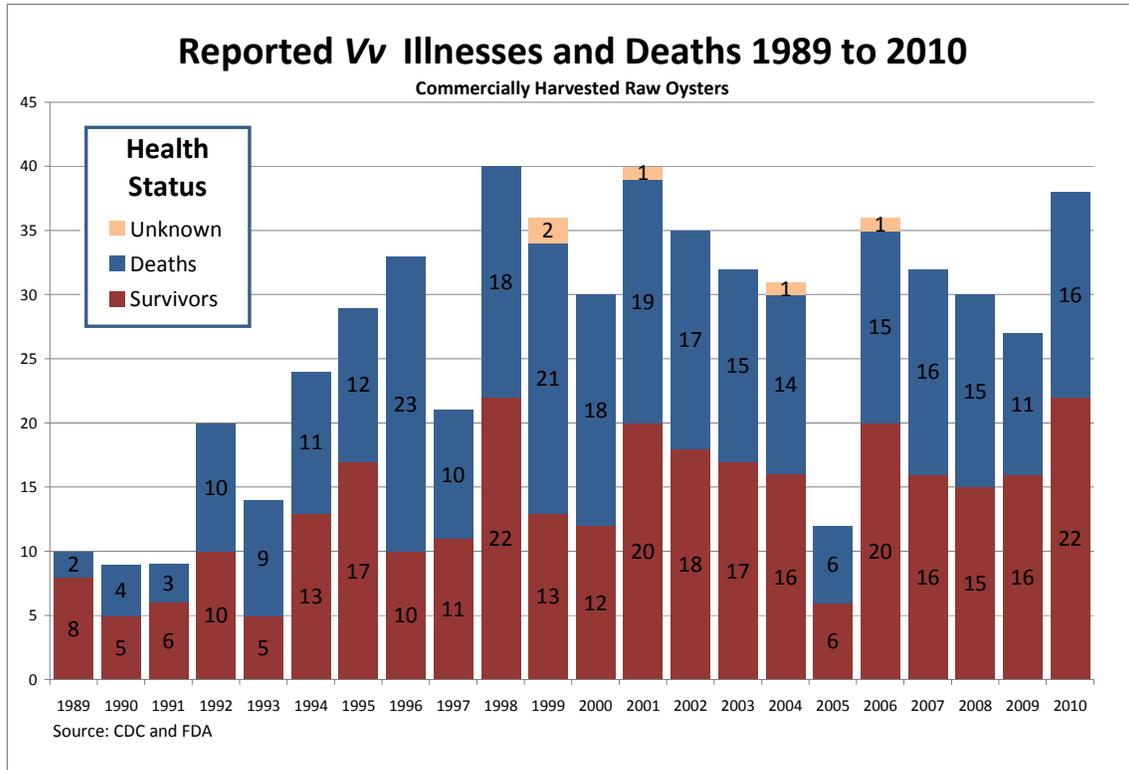


Figure 1. Since 1989, *V. vulnificus* has caused a significant number of illnesses and deaths each year.

ii. *V. vulnificus* Causes a Significant Number of Illnesses.

The number of *V. vulnificus* cases each year is high enough to warrant vigorous FDA action. State health departments and the Centers for Disease Control and Prevention (“CDC”) have collected and reported data on illnesses and deaths from *V. vulnificus* infections since 1989.¹⁴ In that time, there have been 616 recorded illnesses associated with shellfish consumption, of which 301 ended in death.¹⁵ (See Figure 1) CDC recognizes that the number of “reported cases” fails to capture the full extent of

¹⁴ CDC, *National Notifiable Diseases Surveillance System*, at http://www.cdc.gov/osels/ph_surveillance/nndss/phs/infdis2011.htm (last accessed Nov. 3, 2011); It is reportable in 36 states and the District of Columbia. See, CDC, *Vibriosis, Number of reported cases – United States and U.S. territories, 2008*, at http://www.cdc.gov/osels/ph_surveillance/nndss/annsum/2008/08graphs.htm (Last accessed Nov. 3, 2011).

¹⁵ The total is for all reported illnesses and deaths associated with eating *V. vulnificus* contaminated shellfish.

human suffering caused by *V. vulnificus*.¹⁶ Serious infections may be undercounted due to misdiagnosis.¹⁷ Also, cases of gastroenteritis are under-recognized, because the person may not seek medical attention and clinical laboratories do not routinely check for *V. vulnificus* in stool samples.¹⁸ Accounting for misdiagnosis and under-reporting, CDC estimates the total number of foodborne cases at between 60 and 139 resulting in 19 to 57 deaths annually.¹⁹ Based on CDC's estimate, since 1989 there have likely been between 1,300 and 3,000 cases of foodborne *V. vulnificus* infection, or two to five times the number of reported cases.

The large number of illnesses and deaths occur even though raw shellfish is eaten infrequently and by only a small segment of the population. Surveys find that only 10 to 20 percent of the total population eats raw shellfish.²⁰ Even along the Gulf Coast less

¹⁶ CDC uses a multiplier of 1.7 to account for under diagnosis of *V. vulnificus* infections. Scallan *supra*, note 6 at 11 (Jan. 2011); *See*, Jeffrey M. Johnston, et al., *Vibrio vulnificus: Man and the Sea*, 253 J. AMER. MEDICAL ASSN. 2850, 2852 (1985) (“Although less common than such enteric illnesses as shigellosis and salmonellosis, these incidence figures suggest that *V. vulnificus* infections may be more common than other unusually diseases, such as typhoid fever and cholera, in southern Louisiana.”).

¹⁷ Bob Thomas, *Flesh-eating Bacteria: Coastal Scourge (V. vulnificus) is Lurking in Estuaries*, Center for Environmental Communication, Loyola University New Orleans, Oct. 5, 2011. (Citing Dr. Charles Sanders, Edgar Hull Professor and Chair of Internal Medicine at the LSU School of Medicine, as stating “the most dangerous aspect of *Vibrio* infections is misdiagnosis, usually based on lack of experience with the organism and its manifestation.”) at <http://www.loyno.edu/lucec/natural-history-writings/flesh-eating-bacteria-coastal-scourge-vibrio-vulnificus-lurking-estuaries> (Last accessed Dec. 1, 2011).

¹⁸ Ullasac *supra*, note 5; Daniels *supra*, note 1; WHO/FAO *supra*, note 2 at 7 (“Because of the severity of the septicaemia, under-reporting is not as substantial a consideration (2:1) as with gastrointestinal illnesses, which the Centers for Disease Control (CDC) estimates to have a 20:1 under-reporting ratio (Mead et al., 1999). However, various sources of under-reporting of *Vibrio vulnificus* septicaemia have been identified. Historically, FDA has only recorded cases where patients admitted eating oysters. Patients who ate oysters may have denied oyster consumption, may not have been willing to answer questions, or may have deceased before a food history could be obtained. Another source of under-reporting is the failure to capture all the cases in different reporting systems. Adjusting for such under-reporting indicate that there may be up to 2.5 times more *Vibrio vulnificus* septicaemia cases associated with raw Gulf Coast oysters.”).

¹⁹ CDC estimates an average of 96 illnesses resulting in 36 deaths annually. Scallan *supra*, note 6 at 11-12.

²⁰ CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, INTERPRETIVE SUMMARY: QUANTITATIVE RISK ASSESSMENT ON THE PUBLIC HEALTH IMPACT OF PATHOGENIC *VIBRIO PARAHAEMOLYTICUS* IN RAW OYSTERS, at 8 (2005).

than one in five adults eats raw oysters.²¹ This reduces the potential for exposure far below the levels of exposure to foodborne pathogens in commonly consumed foods. Additionally, the risk of exposure to *V. vulnificus* from Pacific and Atlantic shellfish, while not zero, is much lower than the risk of exposure from Gulf of Mexico shellfish.

iii. FDA Acknowledges *V. vulnificus* is a Significant Hazard.

FDA already acknowledges that *V. vulnificus* is a significant hazard that must be controlled. FDA established a zero tolerance for *V. vulnificus* in ready-to-eat fishery products as early as 2001²² and has since added a level of non-detectable (less than 30 MPN/g) for shellfish that is labeled as post-harvest processed.²³ FDA's guidance for its Seafood Hazard Analysis Critical Control Points program ("Seafood HACCP") identifies *V. vulnificus* as a significant hazard in raw molluscan shellfish.²⁴ In response to comments on the 1995 Seafood HACCP final rule, FDA agreed that effective controls are needed to protect consumers from the hazard posed by *V. vulnificus*.²⁵

Taken together, the factors discussed above support identifying *V. vulnificus* as a significant foodborne pathogen for which the agency should implement and enforce a performance standard to protect public health.

b. Control of *V. vulnificus* is a Federal Responsibility.

FDA's primary mission is protection of public health. As section 903 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") (21 USC §393) makes clear:

²¹ INTERSTATE SHELLFISH SANITATION CONFERENCE, RAW OYSTER CONSUMER FOLLOW-UP SURVEY: 2004 TECHNICAL REPORT, at 15 (2004). The survey reported that 19.8 percent of adult Louisianans, 19.5 percent of adult Floridians, and 16.2 percent of adult Texans eat oysters at least once during the year.

²² FDA, FISH AND FISHERIES PRODUCTS HAZARDS AND CONTROLS GUIDANCE 3^D ED., Table A-5 (2001).

²³ FDA, FISH AND FISHERY PRODUCTS HAZARDS AND CONTROLS GUIDANCE 4TH ED., Table A-5 (2011).

²⁴ *Id.* at 79.

²⁵ Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, Final Rule, 60 Fed. Reg. 65096, 65168 (Dec. 18, 1995).

(a) IN GENERAL.—There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the “Administration”).

(b) MISSION.—The Administration shall –

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner; (2) with respect to such products, protect the public health by ensuring that (A) foods are safe, wholesome, sanitary, and properly labeled;... and

(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

The statute’s mission statement is supported by authority granted under the FFDCA to control adulterated foods and the Public Health Service Act (“PHSA”) to control communicable diseases. The agency may not prioritize an industry’s interest in selling a particular product over the interests of the consuming public in accessing safe food. The juxtaposition of 21 U.S.C. §393(b)(1) and (4) makes it clear that FDA must rely on the science supporting regulatory action in making decisions. The Federal court affirmed the priority of public health in *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C., 1987). There the court rejected FDA’s effort to protect businesses engaged in the interstate sale of certified raw milk. It found FDA’s explanation for not regulating raw milk did not advance a “specific competing policy which outweighs its primary responsibility to protect public health and welfare.”²⁶ (Emphasis added) The potential impact of a regulatory decision on product marketing or jobs is a secondary concern that FDA may only consider through equitable consultations with experts, consumers and industry.

²⁶ *Public Citizen v. Heckler*, 653 F. Supp. 1229, 1239 (D.D.C., 1987).

Since it is FDA's primary duty to protect public health, where there is clear evidence of an ongoing public health threat, the agency has a statutory responsibility for establishing a performance standard for *V. vulnificus*.

c. FDA Has Already Called for Action Relevant to this Petition.

The Center for Science in the Public Interest first petitioned FDA to set a performance standard for *V. vulnificus* in raw oysters in 1998.²⁷ On Oct. 21, 2002, FDA denied CSPI's petition in favor of working with the Interstate Shellfish Sanitation Conference ("ISSC") in the implementation of a control strategy for *V. vulnificus* in raw or undercooked oysters.²⁸ The denial letter from Associate Commissioner John Taylor agreed with CSPI that prior control efforts by FDA and the ISSC had failed.²⁹ The denial stated that if the ISSC's new control plan failed to achieve a 60 percent illness reduction by 2008, "the source states would be required to ensure that their oysters are not marketed for raw consumption during the key illness associated months without first being subjected to a post-harvest treatment designed to reduce *V. vulnificus* to nondetectable levels."³⁰ (Emphasis added) The ISSC effort, in fact, did fail, but to date FDA has not imposed the requirement for processing of raw oysters to reduce *V. vulnificus* levels.³¹

²⁷ Citizen Petition for Regulatory Action to Establish a Standard for *Vibrio vulnificus* in Raw Molluscan Shellfish of Undetectable Levels from Michael F. Jacobson, executive director of the Center for Science in the Public Interest, (June 29, 1998).

²⁸ Letter from John M. Taylor, Senior Associate Commissioner for Regulatory Affairs at FDA to Michael F. Jacobson, executive director of the Center for Science in the Public Interest 2 (Oct. 21, 2002)

²⁹ *Id.* at 4-5. (Furthermore, the letter recognized that the ISSC actively opposed after "considerable controversy and debate" a proposal from FDA to implement effective controls. "Considerable controversy and debate" is a veiled reference to the oysters industry's use of its political influence to have U.S. Senate and House offices pressure FDA to reverse its position on restricting harvests during warm water months. CSPI detailed the use of political pressure by the ISSC and industry to fend off effective controls its 2001 report "Death on the Half Shell.")

³⁰ Letter from John M. Taylor *supra*, note 28 at 5-6.

³¹ In 2009 FDA announced it would require post-harvest processing of Gulf Coast oysters shipped in interstate commerce, but has since placed any decision on requiring post-harvest processing in abeyance. Letter from Donald W. Kraemer, Deputy Director, Office of Food Safety in the Center for Food Safety and

Instead, FDA cooperated with the ISSC on new time-and-temperature controls that permit the industry to continue marketing infected oysters.³²

While CSPI supports post-harvest processing as an effective control for *V. vulnificus*, this petition does not request that specific action.³³ Instead, it calls on FDA to issue and enforce a performance standard that the industry may achieve by any validated method it chooses.

2. Legal Grounds

FDA has clear legal authority to establish a performance standard of non-detectable levels of *V. vulnificus* in molluscan shellfish intended for raw or processed raw consumption under section 104 of the FSMA (21 U.S.C. §2201). Furthermore, FDA has authority to enforce such a performance standard because molluscan shellfish contaminated with *V. vulnificus* are adulterated under sections 402(a)(1), 402(a)(2)(A) and 402(a)(4) of the FFDCa (21 U.S.C. §§342(a)(1), 342(a)(2)(A) and 342(a)(4)), and are infected with a communicable disease that is subject to control under section 361 of the PHSA (42 U.S.C. §264). Authority to issue regulations as necessary to enforce the performance standard is provided in section 701(a) of the FFDCa (21 U.S.C. §371(a)).

a. Authority to Establish Performance Standard for *V. vulnificus*.

FDA has an explicit mandate to establish performance standards for significant foodborne contaminants such as *V. vulnificus*. Section 104 of the FSMA directs FDA to identify significant foodborne contaminants based on an evaluation of “relevant health data and other relevant information, including from toxicological and epidemiological studies and analyses, current Good Manufacturing Practices... and relevant

Applied Nutrition, to J. Michael Hinchey, Chairman, Interstate Shellfish Sanitation Conference (Apr 6, 2010).

³² Interstate Shellfish Sanitation Conference Board Action of June 5, 2008. GAO, FDA NEEDS TO REASSESS ITS APPROACH TO REDUCING AN ILLNESS CAUSED BY EATING RAW OYSTERS at 9 (2011).

³³ Pasteurization, process treatment, and other approaches are all highly effective and commercially viable.

recommendations of relevant advisory committees.”³⁴ Once identified, FDA is required to establish a performance standard if doing so will “reduce the risk of serious illness or death... prevent adulteration of food... or ...prevent the spread by food of communicable disease.”³⁵ Adequate data and information exist to identify *V. vulnificus* as a significant foodborne contaminant for which a performance standard is necessary to reduce the risk of serious illness or death from food that is contaminated by the organism.

Section 104 applies because relevant health data and studies support a determination that *V. vulnificus* is a significant foodborne contaminant.³⁶ The discussion in the Factual Grounds above establishes that *V. vulnificus* is a serious threat to health that is poorly controlled.³⁷ Over the past decade, an average of 33 illnesses occurred annually from infected shellfish. By comparison, FDA enforced a performance standard for *Clostridium botulinum* in smoked white fish even though there had been only eight cases reported between 1899 and 1964.³⁸ The case-fatality ratio for *V. vulnificus* is higher than any other foodborne pathogen, including *Clostridium botulinum*.³⁹ Of the 21 major

³⁴ 21 U.S.C. §2201(a).

³⁵ 21 U.S.C. §2201(b).

³⁶ See, Michael R. Taylor, Senior Advisor to the Commissioner of FDA, Remarks at the ISSC Biennial Meeting (Oct. 16, 2009) <http://www.fda.gov/NewsEvents/Speeches/ucm187012.htm> (last accessed Nov. 11, 2011) (referring to *Vibrio vulnificus* as a “significant hazard”); Ulusarac *supra*, note 5 at 167 (“[T]he significant mortality rate associated with these infections makes this an important public health issue”).

³⁷ Infection rates for *Vibrio* have been increasing since 2001 and currently the rate is 85 percent above the 1996-98 baseline for FoodNet data. CDC, *Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – 10 States, 2009*, 59 MORBIDITY AND MORTALITY WEEKLY REP. 418, 420 (2010).

³⁸ See, *United States v. Nova Scotia Food Products, Inc.*, 568 F.2d 240, 250 (2nd Cir. 1977).

³⁹ The case-fatality rate for *Clostridium botulinum* is 17.3 percent. The case-fatality rate for *Listeria monocytogenes* is 15.9 percent. The case-fatality rate for *V. vulnificus* infections, including wound infections, is 34.8 percent or twice the rate for either *Clostridium botulinum* or *Listeria monocytogenes*. Scallan *supra*, note 6 at 12. FDA maintains a zero growth/toxin policy for *Clostridium botulinum* in smoked fish. Seafood Guidance, p. 440. FDA has a zero tolerance policy for *Listeria monocytogenes* in ready-to-eat food. FDA, QUANTITATIVE ASSESSMENT OF RELATIVE RISK TO PUBLIC HEALTH FROM FOODBORNE *LISTERIA MONOCYTOGENES* AMONG SELECTED CATEGORIES OF READY-TO-EAT FOODS (Technical document) at 4 (2003). Additionally, FDA will consider unprocessed and minimally processed foods contaminated with *Listeria monocytogenes* to be adulterated and seek their recall. See, Letter from La Tonya M. Mitchell, Denver District Director, FDA, to Ryan D. Jensen and Eric S. Jensen, Co-Owners/Partners of Jensen Farms (Oct. 18, 2011) (stating that cantaloupe contaminated with *Listeria Monocytogenes* are adulterated under section 401(a)(1) & (4) of the Federal Food, Drug, and Cosmetic Act.

bacterial pathogens associated with food, the average number of estimated deaths (36) from *V. vulnificus* each year outpaces all but three.⁴⁰

There have been many relevant recommendations for stronger controls to prevent *V. vulnificus* infections. Concern based on the prevalence of *V. vulnificus* illnesses was sufficient for Washington State to urge seasonal harvest restrictions in the Gulf of Mexico and California to adopt emergency regulations targeting Gulf Coast oysters in 1991.⁴¹ The Institute of Medicine in 1991 also recommended efforts to limit pathogenic *Vibrio* species in shellfish by developing new diagnostic methods and improved processing technology.⁴² In 1994, FDA recommended cooking oysters harvested from the Gulf of Mexico between April 1 and October 31 and proposed that Gulf States restrict harvests during these months.⁴³ In 1997, Dr. Eric Mouzin of the Los Angeles Department of Health, reviewed efforts by the ISSC to educate at-risk consumers and concluded that education was “insufficient to prevent *V. vulnificus* infections.” He recommended “enhanced preventive efforts.”⁴⁴ In 2010, a CDC survey of the epidemiology of seafood-associated infections noted:

Messages warning consumers of the potential risks of infection associated with raw oyster consumption are posted in restaurants in states where illnesses caused by *V. vulnificus* are prevalent; however, cases continue to occur, suggesting that these educational strategies by themselves may not prevent all cases and that additional regulatory measures, as well as more

⁴⁰ See, Scallan *supra*, note 6 at 12. Only *Campylobacter spp.*, *Listeria Monocytogenes*, and *Salmonella spp.* cause more deaths on an annual basis.

⁴¹ Richard E. Thompson, *Evolution of the Vibrio vulnificus Issue* (Dec. 1995) (manuscript, on file with the Center for Science in the Public Interest).

⁴² SEAFOOD SAFETY, COMMITTEE ON EVALUATION OF THE SAFETY OF FISHERY PRODUCTS, NATIONAL INSTITUTE OF MEDICINE 31, National Academy Press (Farid E. Ahmed (ed)) (1991).

⁴³ Letter from Thomas J. Billy, Director of Seafood, Center for Food Safety and Applied Nutrition, to Ken B. Moore, Executive Director, Interstate Shellfish Sanitation Conference (July 1, 1994); Letter from Patricia S. Schwartz, Acting Director of Seafood, Center for Food Safety and Applied Nutrition, to Ken B. Moore, Executive Director, Interstate Shellfish Sanitation Conference (June 27, 1995); Thompson *supra*, note 41.

⁴⁴ Eric Mouzin, et al., *Prevention of Vibrio vulnificus Infections: Assessment of Regulatory Educational Strategies*, 278 J. AMER. MEDICAL ASSN. 576, 578 (Aug. 20, 1997).

effective consumer education, may be needed to further reduce the incidence of illness.⁴⁵ (*Emphasis added*)

These recommendations from State and Federal government agencies as well as professionals in the health field, combined with the public health data, are sufficient to establish that *V. vulnificus* is a significant contaminant in food for which a performance standard of non-detectable is required.

Furthermore, FDA has effectively agreed that *V. vulnificus* is a significant contaminant. As discussed above, FDA already maintains a zero tolerance for *V. vulnificus* in cooked ready-to-eat fishery products and a level of non-detectable in post-harvest processed shellfish.⁴⁶ More recently, in announcing that it would no longer accept control measures that fall short of eliminating the bacteria in oysters, FDA Deputy Commissioner Michael Taylor referred to *V. vulnificus* as a “significant hazard.”⁴⁷ The announcement specifically pointed to the severity of the hazard and the availability of effective controls as reasons for FDA’s action.⁴⁸

The language of section 104 provides FDA with broad authority to issue a performance standard for *V. vulnificus* based on the characteristics of the contaminant, regardless of its status as an adulterant. Once a contaminant is identified as significant, the agency is mandated by the terms of section 104 to establish a performance standard if doing so will “reduce the risk of serious illness or death... or to prevent adulteration of food... or to prevent the spread by food of communicable disease.”⁴⁹ If FDA finds a performance standard would accomplish any of these three objectives, the agency must issue one.

⁴⁵ Iwamoto *supra*, note 11 at 409. Data showing essentially no reductions in *V. vulnificus* illnesses or deaths in States the permit sale of untreated raw oysters during warm months demonstrates that “sustained education efforts ... have not had the intended public health results.” *See*, footnote 74.

⁴⁶ FDA, FISH AND FISHERY PRODUCTS HAZARDS AND CONTROLS GUIDANCE, 4TH ED. 440, (2011).

⁴⁷ Michael R. Taylor, Senior Advisor to the Commissioner of FDA, Remarks at the ISSC Biennial Meeting (Oct. 16, 2009) (transcript available at <http://www.fda.gov/NewsEvents/Speeches/ucm187012.htm>) (last accessed Nov. 11, 2011).

⁴⁸ *Id.*

⁴⁹ 21 U.S.C. §2201(b).

The requirement for a performance standard to reduce the risk of serious illness or death means that FDA must adopt a meaningful safety standard. For *V. vulnificus* there is no established level at which illness will not occur. The infective dose for *V. vulnificus* is unknown but FDA assumes septicemia can occur with a dose of less than 100 organisms.⁵⁰ This is supported by studies that “indicate that high-risk individuals are susceptible to relatively low concentration of *V. vulnificus*.”⁵¹ For the purpose of reducing illnesses, this petition proposes a standard of non-detectable because that standard has been demonstrated to be reasonable and effective. California adopted regulations in 2003 that require oysters harvested from the Gulf of Mexico in warmer months to be post-harvest processed to a level of less than 3 MPN/g, which it defines as a non-detectable level.⁵² This action reduced *V. vulnificus* illnesses in the State from an average of 5 a year to 0.4.⁵³

Having established that *V. vulnificus* is a significant foodborne contaminant for which relevant advisory bodies have recommended effective controls, the terms of section 104 mandate issuance of a performance standard if doing so will reduce or prevent illnesses. Action taken by California in 2003 demonstrates that a level of non-detectable is effective for achieving the purpose of section 104. Therefore, CSPI is asking FDA to act in conformance with its statutory duties by issuing a performance standard of non-detectable for *V. vulnificus* in molluscan shellfish intended for raw or processed raw consumption.

⁵⁰ FDA, BAD BUG BOOK: FOODBORNE PATHOGENIC MICROORGANISMS AND NATURAL TOXINS HANDBOOK *VIBRIO VULNIFICUS*, at <http://www.fda.gov/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/ucm070473.htm> (lasts accessed Dec. 3, 2011). Animal studies support this, finding a dose as small as one cell was fatal in mice treated to induce iron-overload. Paul A. Gulig, et al., *Molecular Pathogenesis of Vibrio vulnificus*, 43 J. OF MICROBIOL. 118, 120, (Feb. 2005).

⁵¹ J. Keith Jackson, et al., *Evidence that Mortality from Vibrio vulnificus Infection Results from Single Strains Among Heterogeneous Populations in Shellfish*, 35 J. OF CLINICAL MICROBIOL. 2098, 2100, (Aug. 1997).

⁵² CAL. CODE REGS. TIT. 17 §13675 (2011).

⁵³ California has reported only three cases of *V. vulnificus* associated with oysters consumed in the State in the seven years since the 2003 rule went into effect.

b. Authority to Enforce a Performance Standard.

FDA may enforce the performance standard, once issued, under any of four authorities for controlling adulteration of food and foodborne communicable diseases. Shellfish contaminated with *V. vulnificus* when harvested commercially and shipped in interstate commerce are adulterated under sections 402(a)(1), 402(a)(2)(A) and 402(a)(4) of the FFDCFA. Delivering or introducing adulterated food into interstate commerce is a prohibited act that is punishable by fines and/or imprisonment.⁵⁴ Alternatively, *V. vulnificus* may be controlled as a communicable disease under section 361 of the PHSA. Violation of a regulation issued under section 361 is punishable by a fine or imprisonment.⁵⁵

i. *V. vulnificus* is an Adulterant Under Section 402(a)(1).

The FFDCFA describes seven circumstances under which food may be considered adulterated. The first of three that are applicable to enforcement of the performance standard sought by this petition is section 402(a)(1). It defines food as adulterated if “it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.”⁵⁶ In general, this means that any added substance that may cause injury is a per se adulterant under section 402(a)(1).⁵⁷ But a naturally occurring substance is only an adulterant if it is present in amounts that would ordinarily render the food injurious to health.⁵⁸ *V. vulnificus* is an adulterant under either analysis, satisfying section 402(a)(1) by being both added and present naturally in quantities that ordinarily render raw shellfish injurious to health.

⁵⁴ 21 U.S.C. §331(a); 21 U.S.C. §333(a).

⁵⁵ 42 U.S.C. §271.

⁵⁶ 21 U.S.C. §342(a)(1).

⁵⁷ *United States v. Twenty Kegs of Coca Cola*, 241 U.S. 265, 284, (1916).

⁵⁸ *Continental Seafoods, Inc. v. Schweiker*, 674 F.2d 38, 40 (D.C. Cir., 1982).

FDA can apply section 402(a)(1) to enforce a performance standard for *V. vulnificus* because Federal courts have interpreted the statute in a way that places *V. vulnificus* within the definition of added substances.

V. vulnificus is added because the human contribution to climate change, oil spills, and handling after harvest constitute intervening acts that result in increased levels of the bacteria in shellfish. In *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157 (5th Cir., 1980) the court found mercury in swordfish was an added substance based on its increased presence in the ocean environment due to humans dumping mercury waste into rivers.⁵⁹ This same reasoning would apply to *V. vulnificus*, the presence of which is increased by the effects of human activities on nutrient levels and seawater temperatures.⁶⁰ It is exactly analogous to the situation with oil spills where tar balls from the BP Deepwater Horizon oil spill in 2010 have been shown to provide a reservoir for *V. vulnificus* growth in the Gulf of Mexico.⁶¹ After harvest, *Anderson* would apply if the shellfish are not immediately refrigerated because harvesting and storage without

⁵⁹ *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157, 162 (5th Cir., 1980). The court found the link between mercury dumped with other pollutants into rivers that washed into the ocean, where it was methylated by bacteria, taken up by plankton that were eaten by fish, that were in turn eaten by larger fish, concentrating the mercury to hazardous levels before it entered the human food supply, sufficient to rule that FDA could regulate mercury as an “added” adulterant in seafood. 622 F.2d at 162.

⁶⁰ D. Jay Grimes, *Sources, Distribution, and Conveyance of Opportunistic Pathogens in Estuaries and the Oceans*, Paper 53rd Gulf and Caribbean Fisheries Institute (2002) (noting that since the mid-1900s *Vibrio* species have replaced *Pseudomonas* species as the dominant culturable bacterial communities in the world’s oceans, linking this to anthropogenic inputs, such as petroleum wastes, and climate change); Chaeshin Chu, et al., *Mathematical Modeling of Vibrio vulnificus Infection in Korea and the Influence of Global Warming*, 2 PUBLIC HEALTH RES. PERSPECT. 51 (2011) (Linking a 0.7°C increase in average water temperature during the last 35 years to an increased spread of *V. vulnificus*); Craig Baker-Austin, et al., *Environmental Occurrence and Clinical Impact of Vibrio vulnificus and Vibrio parahaemolyticus: a European Perspective*, 2 ENVIRON. MICROBIOL. REP. 7 (2010) (Noting the link between even small increases in water temperature from climate change events to increased infectivity of *vibrios*, and citing cases of outbreaks of *V. vulnificus* in Israel and Denmark that followed warming trends); See, Drake *supra*, note 5 at 124 (speculating that climate events that warmed Gulf waters are the cause of an increase since 2000 in *V. vulnificus* cases occurring in November).

⁶¹ Zhen Tao, et al., *High Numbers of Vibrio vulnificus in Tar Balls Collected from Oiled Areas of the North-Central Gulf of Mexico Following the 2010 BP Deepwater Horizon Oil Spill*, ECOHEALTH (published on line Nov. 23, 2011); See, Paul Voosen, *Will Bacterial Plague Follow Crude Oil Spill Along Gulf Coast?*, N.Y. TIMES, June 17, 2010 (quoting University of North Carolina *Vibrio* specialist Jim Oliver anticipating an increase in *Vibrios* (including *V. vulnificus*) as a direct result of oil degradation or as a side effect of added nutrient levels).

immediate refrigeration would constitute an intervening human act. *V. vulnificus* can increase almost 10-fold in three and a half hours at ambient summer temperatures in the Gulf.⁶² Since there is no known safe dose, any increase in the number of *V. vulnificus* bacteria increases the risk to consumers.⁶³

Even without the precedent of *Anderson*, FDA would still be able to apply section 402(a)(1) because *V. vulnificus* ordinarily renders shellfish injurious to health. The Gulf Coast oyster industry argues that because *V. vulnificus* occurs naturally in the environment and causes relatively few reported illnesses annually it is not an adulterant under section 402(a)(1).⁶⁴ Conducting a body count, however, is not the approach FDA and the Federal courts have traditionally followed for establishing whether a pathogen ordinarily renders food injurious to health. In *Seabrook Internat'l Foods, Inc. v. Harris*, 501 F.Supp. 1086, 1092 (D.D.C., 1980) the court recognized that a low rate of reported cases did not foreclose FDA's discretion to determine a pathogen may be injurious to health.⁶⁵

FDA's failure to protect consumers from *V. vulnificus* in the food supply is inconsistent with its treatment of other naturally occurring pathogens. Like *V. vulnificus*, the environmental pathogen *Listeria monocytogenes* targets an at-risk group for more severe symptoms while causing few serious illnesses relative to the population. Yet, FDA considers it an adulterant in raw and minimally processed food.⁶⁶ Eight instances of illnesses over a 65-year period attributable to naturally occurring *Clostridium botulinum*

⁶² David W. Cook, *Refrigeration of Oyster Shellstock: Conditions Which Minimize the Outgrowth of Vibrio vulnificus*, 60 J. FOOD PROTECTION 349, 351 (1997).

⁶³ *Id.* at 352.

⁶⁴ The Gulf Oyster Industry Council ("GOIC") argued this position in its comments on CSPI's 1999 Citizens Petition without explaining why the number of illnesses was an appropriate measure of "ordinarily" for purposes of section 402(a)(1). GOIC instead argued its position by pointing to State court cases applying the foreign-natural test and consumer expectation test. Comments submitted by the Gulf Oyster Industry Council in regard to a Petition for Regulatory Action to Establish A Standard for *Vibrio vulnificus* in Raw Molluscan Shellfish of Undetectable Levels (Apr. 20, 1999).

⁶⁵ This holding was affirmed in *Continental Seafoods, Inc.*, 674 F.2d at 44.

⁶⁶ Letter from La Tonya Mitchell *supra*, note 39.

in whitefish were sufficient to support issuing regulations for controlling its outgrowth.⁶⁷ These two instances are clear examples that FDA does not rely solely on the number of illnesses or deaths when establishing that a naturally occurring pathogen is an adulterant.

An appropriate definition of “ordinarily” would consider whether there are intervening actions that eliminate the risk. Where the food is eaten raw or might be under-cooked, the Federal courts have consistently found naturally occurring bacteria to be an adulterant. In *Texas Food Ind. Assn, v. Espy*, 870 F.Supp. 143, 148-49 (W.D. Tx, 1994) the court held that naturally occurring *E. coli* O157:H7 is an adulterant because people do not cook ground beef thoroughly enough to kill it. The court in *Continental Seafoods, Inc. v. Schweiker*, 674 F.2d 38, 44 (D.C. Cir., 1982) accepted FDA’s interpretation of “ordinarily injurious” as meaning the danger can be averted by proper cooking or storage. In the one case often cited for the proposition that naturally occurring pathogens are not adulterants, *American Public Health Ass’n v. Butz*, 511 F.2d 331 (D.C. Cir., 1974), the deciding factor was that housewives knew to cook the chicken, thus killing the *Salmonella*. Under the reasoning in these cases, raw shellfish is ordinarily rendered injurious to health by *V. vulnificus* because without an intervention to reduce or eliminate it, the pathogen causes illnesses that sicken and kill consumers on a regular basis.

V. vulnificus is an adulterant under section 402(a)(1) because human acts that increase its presence in the oceans make it a per se adulterant as an added substance. Even if it were not an added substance, naturally occurring *V. vulnificus* would

⁶⁷ *Nova Scotia Food Products*, 568 F.2d 240. In the similar situation of determining when a State may apply the doctrine of parens patriae to protect a public interest the Federal courts have found as few as eight affected persons to be a sufficient number to establish standing. *Alfred L. Snapp & Son, Inc., v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 607 (1982) (“The Court has not attempted to draw any definitive limits on the proportion of the population of the State that must be adversely affected by the challenged behavior.”); See, *People v. Peter & John’s Pump House, Inc.*, 914 F. Supp. 809 (N.D.N.Y., 1996) (Citing *Snapp v. Puerto Rico ex rel. Barez* for the proposition that, “[t]here is no numerical talisman to establish parens patriae standing.” *Id.* at 812. The court found that eight group home residents, .00004 percent of New York’s total population, was a substantial segment sufficient for parens patriae standing because future group home residents would be similarly affected.)

nonetheless be an adulterant under section 402(a)(1) since it ordinarily renders raw shellfish injurious to health. Therefore, FDA may enforce a performance standard under this section.

ii. Enforcement of Tolerance Levels Under Section 402(a)(2)(A).

As discussed above, *V. vulnificus* is an added poisonous or deleterious substance. Food is adulterated under section 402(a)(2)(A), “if it bears or contains any added poisonous or added deleterious substance... that is unsafe within the meaning of section 406.” Section 406 gives FDA authority to promulgate tolerances for added poisonous or deleterious substances.⁶⁸ In establishing a performance standard of non-detectable issued under section 104 of the FSMA, FDA may also issue a tolerance under section 406 of the FFDCa for purposes of enforcing the standard.

iii. Insanitary Conditions Under Section 402(a)(4).

Once FDA has set a performance standard, it may also enforce it under section 402(a)(4). This section provides that food is adulterated if it is “prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.”⁶⁹ Federal courts construe the adulteration provision in section 402(a)(4) liberally to give FDA wide authority to require public health measures that reduce naturally-occurring pathogens in food during processing.⁷⁰ The section is the legal basis of the seafood HACCP regulation.⁷¹

While the seafood HACCP regulation applies to shellfish, it contains no mandatory control for *V. vulnificus* in raw shellfish beyond existing post-harvest

⁶⁸ 21 U.S.C. §346. The section provides this authority even though *V. vulnificus* is naturally occurring in all oceans and may be said to be unavoidable in shellfish production. See, *Young v. Community Nutrition Inst.*, 476 U.S. 974 (1986) (“...although aflatoxin is naturally and unavoidably present in some foods, it is to be treated as ‘added’ to food under §346.”).

⁶⁹ 21 U.S.C. §342(a)(4).

⁷⁰ See, e.g., *Nova Scotia Food Products*, 568 F.2d 240.

⁷¹ Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule, 60 Fed. Reg. 65096, 65098 (Dec. 18, 1995).

refrigeration requirements. However, harvest-to-refrigeration time controls have proven to be woefully ineffective in preventing *V. vulnificus* deaths and illnesses.⁷²

Requiring stronger controls is clearly justified by controlling precedent. In *United States v. Nova Scotia Food Products, Corp.*, 568 F.2d 240 (2nd Cir, 1977), a smoked fish processor challenged FDA’s regulation establishing good-manufacturing-practice requirements for the hot processing of smoked fish. FDA took the position that failure to eliminate naturally-occurring bacterial spores in fish through an adequate brining, thermal, and refrigeration process created “insanitary conditions” that rendered the fish adulterated under section 402(a)(4).⁷³ The court agreed, holding that the section must be read broadly in order to effectuate the FFDCA’s overriding purpose to protect public health.⁷⁴ The holding serves as well-established precedent for enforcing a performance standard under section 402(a)(4).

iv. Prevention of Communicable Diseases Under the PHSA.

Section 361 of the PHSA also provides a basis for enforcing a performance standard for *V. vulnificus* in shellfish. It gives FDA broad authority to issue regulations to prevent the spread of communicable diseases upon a determination that doing so is necessary “to prevent the introduction, transmission, or spread of communicable

⁷² “Recent CDC data show there has been essentially no change in the number of *Vibrio vulnificus* infections or deaths resulting from consumption of raw oysters in those states that permitted the sale of untreated Gulf Coast oysters during the warm months. These data clearly demonstrate that sustained education efforts and voluntary adoption of PHP have not had the intended public health results.

“There is evidence that controls that were designed to reduce, but fall well short of eliminating, the risk of *Vibrio* illness such as implementation of a five-hour time from harvest to refrigeration also have not been effective. While such controls were in effect for most of the 2008 *Vibrio* risk season, there has not been a significant decline in the numbers of *Vv* illnesses reported in that year as compared to previous years.” FDA, BACKGROUND ON MEASURES TO ELIMINATE RISK CAUSED BY VIBRIO VULNIFICUS INFECTION FROM CONSUMPTION OF RAW MOLLUSCAN SHELLFISH (2009) at <http://www.fda.gov/NewsEvents/Speeches/ucm187014.htm> (last accessed Jan. 25, 2012); See, Mark Tamplin, *The Ecology of Vibrio Vulnificus*, PROCEEDINGS OF THE 1994 VIBRIO VULNIFICUS WORKSHOP at 77-78 (1994) (Tamplin cites studies that indicated *V. vulnificus* levels in oysters taken straight from the water may be sufficient to infect at-risk individuals and temperature abuse and growth after harvest may be less a contributing factor in illnesses than suspected. This would lead to the conclusion that time-and-temperature controls will not be effective.).

⁷³ *Nova Scotia Food Products*, 568 F.2d at 243-44.

⁷⁴ *Id.* at 246-48.

diseases... from one State or possession into any other State or possession.”⁷⁵ A communicable disease includes one that can be transmitted directly from an infected animal to a person.⁷⁶ *V. vulnificus* is transmitted from infected shellfish directly to people and, therefore, falls under the definition of a communicable disease.

FDA has already used its authority under section 361 to address the problem of communicable diseases associated with raw molluscan shellfish. FDA recognized it as the legal basis for its role in the National Shellfish Sanitation Program.⁷⁷ FDA also cites it in the Seafood HACCP regulation where it is the legal authority for 21 C.F.R. §1240.60, which states in part:

A person shall not offer for transportation, or transport, in interstate traffic any molluscan shellfish handled or stored in such an insanitary manner, or grown in an area so contaminated, as to render such molluscan shellfish likely to become agents in, and their transportation likely to contribute to the spread of communicable disease from one State or possession to another.

The provision goes on to require tagging of shellstock to identify its place of harvest and other identifying information. Although tagging has proven inadequate, FDA at the time estimated this practice would reduce illegal harvesting and avert between 12 and 30 illnesses a year.⁷⁸ FDA has used its authority under section 361 in other situations, as well. In 1987, FDA issued a rule requiring pasteurization of milk and milk products before they can be sold in interstate commerce.⁷⁹ It also banned the sale of small turtles associated with cases of salmonellosis in both intrastate and interstate commerce in

⁷⁵ 42 U.S.C. §264(a).

⁷⁶ 21 C.F.R. §1240.3(b).

⁷⁷ Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule, at 65163.

⁷⁸ Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule at 65185. Recordkeeping alone does not appear to have been as effective as FDA anticipated since there is no evidence of a reduction in illnesses following implementation of the requirement.

⁷⁹ 21 C.F.R. §1240.61.

1972.⁸⁰ That action was upheld in Federal court after Louisiana challenged the intrastate ban.⁸¹ These examples demonstrate that FDA has broad authority under section 361 to enforce a performance standard for *V. vulnificus*.

c. Section 114 of FSMA Does Not Bar Action on This Petition.

The ISSC has put forward an argument that section 114 of the FSMA (21 U.S.C. §342 note) in some way controls implementation of effective measures to address *V. vulnificus*.⁸² Section 114 requires FDA to report to Congress 90 days prior to issuing any guidance, regulation, or suggested amendment to the NSSP relating to post-harvest processing of raw oysters.⁸³ However, the reporting requirement is waived if the guidance is adopted as a consensus agreement between FDA, the States, and the oyster industry acting through the ISSC.⁸⁴ The language of the section does not prohibit action by FDA or the ISSC to control *V. vulnificus* through effective means. Furthermore, the section is directed specifically toward actions related to post-harvest processing, so it does not apply to the request made in this petition. That is because CSPI only requests that FDA issue a performance standard as required under section 104 of the same statute. The petition does not address specific methods or technologies by which the industry may meet that performance standard.⁸⁵

⁸⁰ Turtles, Tortoises, Terrapins; Prohibition of Importation; Bacteriological Testing and Certification for Interstate Shipment, 37 Fed. Reg. 24670 (Nov. 18, 1972); 21 C.F.R. §1240.62.

⁸¹ *Louisiana v. Mathews*, 427 F.Supp. 174, 176 (E.D.La. 1977). (“[T]he intrastate ban is not only authorized by the law, but, under modern conditions of transportation and commerce is clearly reasonable to prevent the interstate spread of disease.”).

⁸² INTERSTATE SHELLFISH SANITATION CONFERENCE, SUMMARY OF ACTIONS 2011 BIENNIAL MEETING, at 328, submitted to FDA Nov. 18, 2011.

⁸³ 21 U.S.C. §342(a) note.

⁸⁴ 21 U.S.C. §342(d) note.

⁸⁵ For example, flow through depuration is demonstrated to be effectively at reducing *V. vulnificus* concentrations from 110,000 MPN/g to 3 MPN/g in six days. Matthew Lewis, et al., *Evaluation of a Flow-Through Depuration System to Eliminate the Human Pathogen Vibrio vulnificus from Oysters*, 1 J. AQUAC RES. DEVELOPMENT 103 (2010). Relaying has been demonstrated to reduce *V. vulnificus* concentrations from 10⁴ MPN/g to <10 MPN/g within 7 to 17 days. Miles Motes & Angelo DePaola, *Offshore Suspension Relaying to Reduce Levels of Vibrio vulnificus in Oysters (Crassostrea virginica)*, 62 APPL. ENVIRON. MICROBIOL. 3875 (Oct. 1996).

FDA should act quickly on this petition and issue a performance standard of non-detectable as determined by the best available method of detection for *V. vulnificus* in molluscan shellfish intended for raw or processed raw consumption.

C. ENVIRONMENTAL IMPACT

The action requested is subject to a categorical exclusion in 21 C.F.R. §§25.30(j), 25.32(g) and 25.32(m) and therefore does not require the preparation of an environmental assessment or an environmental impact statement.

D. ECONOMIC IMPACT

No statement of the economic impact is presented because none has been requested by the Commissioner.⁸⁶

E. CERTIFICATION

The undersigned party certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



David W. Plunkett, J.D., J.M.
Senior Staff Attorney, Food Safety Program

⁸⁶ 21 C.F.R. §10.30(b)