UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR SCIENCE IN THE PUBLIC INTEREST, 1220 L Street NW, Suite 300, Washington, DC 20005, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, White Oak Building 1, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Defendant.	)	Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. If past experience holds true, this year an estimated thirty Americans will become seriously ill, and half of those people will die, from consuming raw shellfish contaminated with a bacteria called *Vibrio vulnificus* (*V. vulnificus*). *V. vulnificus* is the leading cause of deaths linked to seafood consumption in the United States.

2. Plaintiff Center for Science in the Public Interest (CSPI) brings this action pursuant to the Administrative Procedure Act (APA), 5 U.S.C. §§ 702 & 706, to compel defendant U.S. Food and Drug Administration (FDA), the federal agency responsible for the safety of oysters and other shellfish, to act on CSPI's February 2012 citizen petition asking FDA to establish a "performance standard" requiring companies to ensure that *V. vulnificus* levels are nondetectable in oysters and other molluscan shellfish sold for raw consumption. *See* CSPI

Citizen Petition, *available at* https://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0146-0001.

3. A performance standard measures outcomes—here, whether *V. vulnificus* levels are below a mandatory ceiling—while allowing companies to determine for themselves the best way to meet that standard.

4. In the four years since receiving CSPI's petition, FDA has neither granted nor denied the requested action. To protect public safety and prevent needless death and serious illness, CSPI seeks a declaration that defendant has acted unlawfully by withholding action on CSPI's petition and an order requiring defendant to act.

PARTIES

5. Plaintiff CSPI is a national nonprofit organization founded in 1971. With approximately 610,000 members and subscribers in the United States, CSPI is an advocate on issues of nutrition and health, food safety, and sound science. CSPI and its members have been, and continue to be, injured by defendant's failure to act on CSPI's petition. So long as FDA fails to require companies to bring *V. vulnificus* to nondetectable levels in molluscan shellfish intended for raw consumption, CSPI's members will continue to be exposed to bacteria that can result in serious illness or death or, to avoid such exposure, must avoid eating molluscan shellfish altogether.

6. Defendant FDA is a federal government agency within the U.S. Department of Health and Human Services and is responsible for implementing the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 et seq., and section 104 of the Food Safety Modernization Act (FSMA), 21 U.S.C. §§ 2201.

JURISDICTION

7. This Court has jurisdiction pursuant to 28 U.S.C. § 1331. *See In re Natural Resources Def. Council*, 645 F.3d 400, 407 (D.C. Cir. 2011).

FACTUAL BACKGROUND

I. *V. Vulnificus* as a Recognized Public Health Hazard

8. *V. vulnificus* is a naturally occurring bacterium in coastal waters. It is present in some molluscan shellfish, particularly from the Gulf of Mexico. *V. vulnificus* levels in shellfish peak during warm-weather months—from April to November—when water temperatures are higher than at other times of the year.

9. Individuals infected by *V. vulnificus* often become ill within one or two days of consuming the bacteria. In otherwise healthy people, *V. vulnificus* may cause vomiting, diarrhea, and abdominal cramps.

10. *V. vulnificus* is particularly dangerous for people with certain underlying health conditions, including diabetes, liver disease, cancer, iron overload disease (hemochromatosis), hepatitis, and HIV/AIDS. These individuals are at greatest risk of contracting *V. vulnificus*-related septicemia (blood poisoning), although otherwise healthy individuals may also contract septicemia from *V. vulnificus*. Citizen Petition at 2.

11. According to FDA, between twelve and thirty million Americans have health conditions that put them at risk of septicemia from *V. vulnificus*. FDA, Notice: Performance Standard for Vibrio Vulnificus; Request for Comments, 64 Fed. Reg. 3,300, 3,300, Jan. 21, 1999. Some of these conditions—such as iron-overload disease—can have few or no symptoms. As a result, affected individuals, even those who receive specific warnings, may not know they are at greater risk of serious illness or death from eating raw shellfish.

12. Individuals with septicemia related to a *V. vulnificus* infection can experience high fever, swelling and blistering wounds on the legs, vomiting and diarrhea, a sharp drop in blood pressure, and severe pain.

13. At least one-half of all victims of *V. vulnificus*-related septicemia die. Citizen Petition at 3. The mortality rate increases to 100 percent for individuals who delay treatment by 72 hours. *Id.*

14. Between 1989 and 2010, there were 616 reported cases of individuals who suffered a *Vibrio*-related illness from shellfish consumption, and 301 of those illnesses ended in death. *Id.* at 4 (relying on data from the U.S. Centers for Disease Control and Prevention (CDC)). However, reported cases capture only 20 to 50 percent of all foodborne *V. vulnificus* infections. *See id.* at 5. The CDC estimates that 96 individuals become ill from *V. vulnificus*-infected shellfish each year and that 36 of those individuals die. *Id.* at 5 n.19.

15. Even individuals who survive *V. vulnificus* infections may suffer serious, long-term health effects. Treatment of *V. vulnificus*-related septicemia can require disfiguring skin debridement or the amputation of limbs. *Id.* at 3. In addition, *V. vulnificus* infections have been associated with pneumonia, bone infection (osteomyelitis), and meningitis. *Id.*

II. FDA's Failure to Adequately Regulate *V. Vulnificus* in Raw Shellfish

16. FDA has been aware of the public health threat posed by *V. vulnificus* in Gulf Coast shellfish since at least the 1980s. Letter to CSPI from John M. Taylor, III, FDA, Denying CSPI 1998 Petition 4 (hereinafter, Taylor Letter), *available at* https://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0146-0001.

17. By 1995, FDA had publicly acknowledged that "effective controls are needed to protect consumers from the hazard posed by *V. vulnificus* in Gulf Coast oysters during certain times of the year." FDA, Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65,096, 65,168 (Dec. 18, 1995) (final rule) (italics added).

18. FDA has recognized that the presence of any *V. vulnificus* in cooked, ready-to-eat shellfish is unsafe. *See* FDA, Fish and Fishery Products Hazards and Controls Guidance 440, Table A-5 (4th ed. 2011), *available at* http://www.fda.gov/downloads/Food/Guidance Regulation/UCM251970.pdf.

19. However, to date, FDA has not adopted a performance standard for raw shellfish that would require companies to ensure that *V. vulnificus* levels are sufficiently low as to be nondetectable.

20. In 1994, FDA requested that the Interstate Shellfish Sanitation Conference (ISSC), a public-private entity made up of shellfish industry representatives, state shellfish control agencies, and several federal agencies, including FDA, consider prohibiting oysters harvested in Gulf Coast waters from April through October from being sold for raw consumption. Taylor Letter at 4. The ISSC adopts shellfish safety procedures that member states implement. *Id.* at 2.

21. The ISSC rejected FDA's proposal and instead developed a two-year plan to place "limits on the time that oysters could remain without refrigeration or ice after harvest." *Id.* at 4. FDA later concluded that these controls "did not result in any measurable reduction in the number of *V. vulnificus* illnesses." *Id.*

22. In 1998, CSPI submitted a citizen petition to FDA seeking the adoption of a regulation to require molluscan shellfish harvested in waters linked to *V. vulnificus* infections

and sold for raw consumption to have nondetectable levels of *V. vulnificus*. That petition described the failure of refrigeration controls, consumer education, and product labeling to reduce significantly deaths and illnesses from *V. vulnificus*.

23. FDA published a notice in the Federal Register seeking public comment on the petition's request. Performance Standard for Vibrio Vulnificus; Request for Comments, 64 Fed. Reg. at 3,300. It stated that its policy since 1993 had been that "at-risk individuals should only consume molluscan shellfish that ha[d] been adequately cooked." *Id.* Although FDA asked the public for additional information about promising post-harvest technologies to reduce or eliminate *V. vulnificus*, it acknowledged that one post-harvest process of which the agency was aware was "capable of reducing [the bacteria] in oysters to nondetectable levels." *Id.* at 3,301.

24. In 2001, the ISSC voted to require member states to develop and implement management plans for the control of *V. vulnificus* if two or more confirmed *V. vulnificus* illnesses had been traced to raw or undercooked oysters from those states' waters since 1995. Taylor Letter at 5. The plan called for a 40 percent reduction in the average rate of illness in 2005 and 2006, and an 60 percent reduction for 2007 and 2008. *Id.*

25. Under the ISSC plan, if the states failed to achieve collectively the 60 percent reduction goal by the end of 2008, "the source states [would] be required to ensure that their oysters [were] 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." *Id.* at 5-6. Such steps could have included "implementing seasonal closure of waters for all oysters intended for the raw market; implementing seasonal post-harvest treatment of all oysters intended for the raw market; or implementing seasonal labeling of all oysters to require shucking." *Id.* at 6.

26. In 2002, FDA denied CSPI's petition. FDA acknowledged that "[s]ince the mid-1990s, there ha[d] averaged approximately 30 annual reported cases of septicemia, about half causing death, from raw oysters containing *Vibrio vulnificus* bacteria." *Id.* at 3. It also stated that it "agree[d] with CSPI that *Vibrio vulnificus* represents an important public health issue that needs to be addressed" because the "consequences of septicemia from this organism can be severe, even for those who survive (e.g. loss of limb, long convalescence)." *Id.* at 3-4. However, FDA stated that it had concluded that "the best course of action" was to work with the ISSC to implement the 2001 control strategy adopted by the group. *Id.* at 2.

27. The ISSC's control plan did not meet its goal to reduce illnesses by 60 percent. *See* GAO, FDA Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Oysters 2 (2011) (hereinafter, GAO Report), *available at* http://www.gao.gov/products/GAO-11-607. FDA recognized in 2009 that there had "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." FDA, Backgrounder on Measures to Eliminate Risk Caused by *Vibrio vulnificus* Infection from Consumption of Raw Molluscan Shellfish, *available at* http://www.fda.gov/NewsEvents/Speeches/ucm187014.htm. It stated that these "data clearly demonstrate[d] that sustained education efforts and voluntary adoption of [post-harvest processing techniques to reduce or eliminate *V. vulnificus*] ha[d] not had the intended public health results." *Id.*

28. In May 2009, "[i]nstead of imposing the illness reduction strategies specified in the [2001] guidelines if the illness rate reduction goals were not met, . . . the ISSC approved, with FDA concurrence, new more stringent time and temperature controls." GAO Report at 2.

29. In 2011, the President signed the Food Safety Modernization Act (FSMA), a landmark food safety statute. The FSMA includes a provision entitled "Performance standards," which requires FDA, "not less frequently than every 2 years, [to] review and evaluate relevant health data and other relevant information . . . to determine the most significant foodborne contaminants." 21 U.S.C. § 2201(a). That provision also mandates:

> Based on [this] review and evaluation . . . , and when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent adulteration of the food under section 342 of this title or to prevent the spread by food of communicable disease under section 264 of Title 42, the Secretary *shall* issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels, or regulations.

Id. § 2201(b) (emphasis added).

30. On February 9, 2012, the Center for Science in the Public Interest filed a second citizen petition with FDA regarding *V. vulnificus*. This petition asked the agency to establish a performance standard of nondetectable for *V. vulnificus* in raw molluscan shellfish. *See generally* Citizen Petition. It emphasized that the FSMA now mandated that FDA determine whether a performance standard was appropriate to reduce the risk of illness and death from *V. vulnificus*.

31. To date, four years after CSPI's petition and three years after the FSMA's first deadline for the review and evaluation of significant foodborne contaminants, FDA has neither granted nor denied CSPI's petition.

32. FDA has authority to adopt and enforce the performance standard requested by CSPI. *See* Citizen Petition at 9-21.

33. CSPI's petition and subsequent submissions to FDA in support of the petition provide sufficient grounds, including citation to scientific evidence, for FDA to determine whether to adopt a rule setting a performance standard that requires non-detectable levels of *V. vulnificus* in molluscan shellfish sold for raw consumption.

34. The considerable danger to public health caused by *V. vulnificus* counsels in favor of expeditious action on CSPI's petition. The pace of defendant's decisional process has lagged unreasonably in light of the nature and extent of the public health interests at stake and the defendant's obligation under 21 U.S.C. § 2201 to determine every two years the most significant foodborne contaminants and to adopt appropriate standards based on that determination.

CLAIMS FOR RELIEF

35. FDA's failure to act on CSPI's 2012 citizen petition constitutes agency action unlawfully withheld or unreasonably delayed, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(1).

36. Defendant's failure to act on CSPI's petition is not in accordance with law and violates the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

WHEREFORE, plaintiff requests that this Court

A. Declare unlawful defendant's failure to act on CSPI's petition;

B. Order defendant to issue a decision on CSPI's petition within 30 days of the Court's order;

C. Award CSPI its reasonable costs and attorney's fees under 28 U.S.C. § 2412; and

D. Grant all other appropriate relief.

Respectfully submitted,

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