

**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.)

THOMAS J. VILSACK, in his official capacity as)
U.S. Secretary of Agriculture,)
U.S. Department of Agriculture)
1400 Independence Avenue SW)
Washington, DC 20250,)

Civil Action No. 14-895

U.S. DEPARTMENT OF AGRICULTURE,)
1400 Independence Avenue SW)
Washington, DC 20250,)

ALFRED V. ALMANZA, in his official capacity)
as Administrator of the Food Safety and Inspection)
Service,)
Food Safety and Inspection Service)
U.S. Department of Agriculture)
1400 Independence Avenue SW)
Washington, DC 20250-3700,)

FOOD SAFETY AND INSPECTION SERVICE,)
U.S. Department of Agriculture)
1400 Independence Avenue SW)
Washington, DC 20250-3700,)

Defendants.)

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiff Center for Science in the Public Interest (CSPI) brings this action pursuant to the Administrative Procedure Act (APA), 5 U.S.C. §§ 702 and 706, to compel

agency action unreasonably delayed. Specifically, CSPI seeks to compel defendants the U.S. Department of Agriculture (USDA), Secretary of Agriculture Thomas Vilsack, the Food Safety and Inspection Service (FSIS), and its Administrator Alfred Almanza to act on CSPI's May 2011 petition requesting that they declare certain strains of antibiotic-resistant (ABR) *Salmonella* in ground meat and poultry to be adulterants under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA).

2. On May 25, 2011, pursuant to 9 C.F.R. § 392 and 7 C.F.R. § 1.28, CSPI petitioned FSIS—a component agency of USDA—to issue an interpretive rule declaring certain strains of ABR *Salmonella*, when found in ground meat and poultry, to be adulterants under the FMIA and PPIA. Meat and poultry products for human consumption may not be sold in commerce in the United States if they are adulterated.

3. Ample scientific and medical research demonstrates that ABR *Salmonella* in meat and poultry products poses grave public health dangers. However, more than three years after CSPI's petition, FSIS has neither granted nor denied the petition, and it has taken no action to declare ABR *Salmonella* an adulterant. Therefore, to protect public safety and prevent needless death and injury, CSPI seeks a declaration that defendants have acted unlawfully by withholding action on CSPI's petition and an order requiring defendants to act thereon.

PARTIES

4. Plaintiff CSPI is a national nonprofit organization founded in 1971. With approximately 843,000 members in the United States, CSPI is an advocate on issues of nutrition and health, food safety, alcohol policy, and sound science. CSPI and its members have been, and continue to be, injured by defendants' failure to act on CSPI's petition and to declare ABR *Salmonella* to be an adulterant when found in ground meat and poultry. As long as ABR

Salmonella is not considered an adulterant when found in such food, CSPI's members are at risk of suffering infection from dangerous bacteria and of experiencing other physical harm, including death.

5. Defendant Thomas Vilsack is the Secretary of Agriculture, and defendant Alfred Almanza is the Administrator of FSIS. Both are sued in their official capacities. Defendant USDA is a federal government agency, and defendant FSIS is a component agency within USDA. USDA has delegated to FSIS the responsibility of administering, to the extent relevant here, the FMIA and PPIA. 7 C.F.R. § 2.53(a)(2)(i), (ii). FSIS is thus responsible for ensuring that the United States' commercial supply of meat and poultry products is safe, wholesome, and correctly labeled and packaged.

6. As set forth in more detail below, defendants have violated the law by failing to act on CSPI's petition seeking a rule declaring that specific strains of ABR *Salmonella* are adulterants under the FMIA and PPIA.

JURISDICTION

7. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

FACTS

8. Antibiotics are critical to the treatment and control of infectious diseases, including salmonellosis. Salmonellosis is an infection caused by *Salmonella* bacteria, the most common culprit of foodborne illness in humans.

9. In recent years, many bacteria—including some types of *Salmonella*—have become resistant to one or more existing antibiotic treatments. One cause of the emergence of ABR bacteria is the widespread use of antibiotics in food-producing animals, such as cattle and chickens. Food producers frequently administer antibiotics to animals to prevent or treat disease.

They also administer antibiotics for long periods of time at low levels to promote growth or to compensate for unsanitary and crowded conditions on farms or feedlots that would otherwise breed disease. Over time, some bacteria to which the animals are exposed become resistant to antibiotics and can be passed to humans by way of contaminated meat and poultry products.

10. The human health consequences of infection by ABR pathogens are severe. They include more serious and prolonged infections, lengthier hospitalizations, increased frequency of bloodstream infections, and increased mortality.

11. Certain strains of ABR *Salmonella* are of particular concern to consumers of meat and poultry products. Specifically, ABR *Salmonella* Hadar, ABR *Salmonella* Heidelberg, ABR *Salmonella* Newport, and ABR *Salmonella* Typhimurium in such products have resulted in outbreaks of illness, hospitalizations, and deaths. For example, in 2009, Beef Packers, Inc., owned by Cargill, recalled over 825,000 pounds of ground beef products due to concerns over contamination by ABR *Salmonella* Newport. See Press Release, USDA, California Firm Recalls Ground Beef Products Due to Possible *Salmonella* Contamination (Aug. 6, 2009), available at <http://1.usa.gov/S6SxzU>. In the recall release, FSIS noted that the bacteria were “resistant to many commonly prescribed drugs,” which could “increase the risk of hospitalization or possible treatment failure in infected individuals.” *Id.*

12. Similarly, in 2011, FSIS oversaw a recall of nearly 55,000 pounds of frozen, raw turkey burger products due to a documented association between the products and contamination by ABR *Salmonella* Hadar. See CDC, Multistate Outbreak of *Salmonella* Hadar Infections Associated with Turkey Burgers (2011), <http://www.cdc.gov/salmonella/hadar0411/040411/index.html>. The outbreak of *Salmonella* Hadar sickened at least 12 people. *Id.*

13. Despite the serious consequences of infection by ABR *Salmonella*, and the demonstrated health risks of exposure to this bacteria in ground meat and poultry products, FSIS has not declared the aforementioned ABR *Salmonella* strains to constitute adulterants under the FMIA and PPIA. A declaration of this kind would have the effect of barring affected meat and poultry products from entering commerce. It would also confirm the agency's authority to request without evidence of illness that a company recall products containing ABR *Salmonella*, or—in the absence of a company's voluntary compliance—to detain and seize those products. See 21 U.S.C. §§ 467b, 673; FSIS, FSIS Food Recalls, available at http://www.fsis.usda.gov/wps/wcm/connect/27fbd74b-3d95-4f6a-b19a-1f6da6d4e835/FSIS_Food_Recalls.pdf?MOD=AJPERES.

14. On May 25, 2011, pursuant to 9 C.F.R. § 392 and 7 C.F.R. § 1.28, CSPI filed a petition with FSIS requesting that the agency declare that ABR *Salmonella* Hadar, ABR *Salmonella* Heidelberg, ABR *Salmonella* Newport, and ABR *Salmonella* Typhimurium, when found in ground meat and poultry products, are adulterants under the FMIA and the PPIA. CSPI moved for expedited review of its petition under 9 C.F.R. § 392.8, which provides that FSIS will review a petition “ahead of other petitions” where the requested action “is intended to enhance the public health by removing foodborne pathogens or other potential food safety hazards that might be present in or on meat . . . [or] poultry” products. *Id.* § 392.8(a), (c). CSPI discussed scientific evidence demonstrating the serious adverse health effects of ABR *Salmonella* and the presence of such bacteria in ground meat and poultry products.

15. On July 26, 2013, defendant Secretary of Agriculture Thomas Vilsack wrote to CSPI “apologiz[ing] for the delayed response” and stating that “review of the petition is continuing.”

16. FSIS has posted CSPI's petition, along with selected comments from the public, on its website. *See* FSIS, Petitions, <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/petitions> (last visited May 23, 2014).

17. CSPI's petition provides sufficient grounds, including citation to scientific evidence, for FSIS to determine whether to adopt a rule declaring the four types of ABR *Salmonella* identified in CSPI's petition to be adulterants under the FMIA and PPIA.

18. To date, despite the significant public health consequences of ABR *Salmonella* infection documented in CSPI's petition, FSIS has not issued a decision on the petition.

19. In the years since CSPI's petition, evidence demonstrating the dangers of ABR pathogens, including ABR *Salmonella*, has only grown. For example, beginning in 2012, an outbreak involving ABR *Salmonella* linked to Foster Farms resulted in 134 illnesses in 13 states. CDC, *Outbreak of Salmonella Heidelberg Infections Linked to a Single Poultry Producer — 13 States, 2012–2013*, Morbidity and Mortality Weekly Report (July 12, 2013), *available at* <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6227a3.htm>. Beginning in 2013, another outbreak of ABR *Salmonella* in poultry products linked to Foster Farms caused more than 520 illnesses in 25 states. CDC, *Multistate Outbreak of Multidrug Resistant Salmonella Heidelberg Infections Linked to Foster Farms Brand Chicken*, <http://www.cdc.gov/salmonella/heidelberg-10-13/index.html> (last visited May 23, 2014). And in 2012, then Director-General of the World Health Organization warned of a “post-antibiotic era” if current trends involving drug-resistant pathogens continue, stating that “the pipeline” for replacement antibiotics “is virtually dry.” Statement of Dr. Margaret Chan, Director-General of the World Health Organization, *Antimicrobial Resistance in the European Union and the World* (Mar. 14, 2012), *available at* http://www.who.int/dg/speeches/2012/amr_20120314/en/.

20. The considerable danger to public health caused by the presence of ABR *Salmonella* in ground meat and poultry products counsels in favor of expeditious action on CSPI's petition, as FSIS's own regulations providing for expedited review recognize. *See* 9 C.F.R. § 392.8(a), (c). The pace of defendants' decisional process has lagged unreasonably in light of the nature and extent of the public health interests at stake.

CLAIMS FOR RELIEF

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

22. Defendants' 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 defendants' failure to act on CSPI's petition;
- B. Order defendants 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,

/s/ Julie A. Murray

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