

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

Petition for an Interpretive Rule)
Declaring Specific Strains of)
Antibiotic-Resistant)
Salmonella in Ground Meat and Poultry)
to be Adulterants)
Within the Meaning of 21 U.S.C. §601(m)(1))
and (2)(A) and 21 U.S.C. §453(g)(1) and)
(g)(2))
_____)

Docket No. _____

CITIZEN PETITION

Submitted by:

Center for Science in the Public Interest

May 25, 2011

May 25, 2011

FSIS Docket Clerk
Department of Agriculture
Food Safety and Inspection Service
Room 2534 South Building
1400 Independence Avenue, S.W.
Washington, DC 20250-3700

I. REQUESTED ACTIONS

A. Issuance of an Interpretive Rule

Pursuant to 5 U.S.C. § 553(e), 9 C.F.R. § 392, and 7 C.F.R. § 1.28, we submit this petition requesting the administrator of the Food Safety and Inspection Service (FSIS) to issue an interpretive rule declaring certain delineated strains¹ of antibiotic-resistant *Salmonella* (hereinafter “ABR” and “ABR-*Salmonella*”), when found in ground meat and ground poultry, to be adulterants within the meaning of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).² Both the FMIA and the PPIA definitions, found at 21 U.S.C. § 601(m)(1) (hereinafter “§ 601(m)(1)”) and 21 U.S.C. § 453(g)(1) (hereinafter “§ 453(g)(1)”) state in pertinent part that a carcass, part thereof, meat, or meat food product, or poultry product is adulterated “if it bears or contains any poisonous or deleterious substance which may render it injurious to health.” A second basis for finding ABR-*Salmonella* an adulterant is found at 21 U.S.C. § 601(m)(2)(A) and 21 U.S.C. § 453(g)(2)(A) which state that meat or poultry are adulterated “if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide

¹ Antibiotic resistant strains of *Salmonella* Hadar, *Salmonella* Heidelberg, *Salmonella* Newport, and *Salmonella* Typhimurium are the subject of this petition.

² As stated in the FMIA, “It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.” 21 U.S.C. § 602 (2004).

chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food.”

In 1994, FSIS interpreted § 601(m)(1) to declare *E. coli* 0157:H7 as an adulterant, indicating by its action that the agency has wide latitude to declare dangerous pathogens to be adulterants through interpretive rules. The 1994 interpretive rule—and its subsequent application and enforcement—applied the USDA’s strictest performance standard to protect consumers from the danger of *E. coli* 0157:H7. It is worth noting that although the agency might well have made the move to declare *E. coli* 0157:H7 an adulterant through rulemaking, it did not do so. Instead, an agency official simply announced the decision in a speech, and followed the announcement by publishing a final draft FSIS Notice in the Federal Register, describing in detail the new testing and sampling program.³ The agency has demonstrated its ability to work within its interpretive powers to protect the public from *E. coli* 0157:H7, and CSPI, after fully reviewing the legal precedents, concludes that the agency can use the same approach to address ABR-*Salmonella* strains that pose similar public health risks.

Scientific and medical research demonstrates that contamination of meat and poultry by ABR strains of *Salmonella* poses grave public health dangers that are comparable to those posed by *E. coli* 0157:H7 in 1994. Specifically, ABR *Salmonella* Hadar, ABR *Salmonella* Heidelberg, ABR *Salmonella* Newport, and ABR *Salmonella* Typhimurium in ground meat and poultry products have resulted in recalls, outbreaks, and deaths.⁴ Additionally, these strains have been found in meat in

³ FSIS NOTICE, Microbiological Testing Program for Escherichia coli in Raw Ground Beef (Final Draft, Oct. 11, 1994) (stating that “[t]o stimulate a reduction in the presence of [*E. coli*] 0157:H7 in raw ground beef, FSIS will commence on October 17, 1994, a microbiological testing program for *E. coli* 0157:H7.”)

⁴ DeWaal, C.S., Roberts, C.R., & Catella, C.M. (2011, January 25). *Antibiotic Resistance in Foodborne Pathogens: Evidence of the Need for a Risk Management Strategy*. Retrieved from Center for Science in the Public Interest website: <http://cspinet.org/new/pdf/abrfoodbornepathogenswhitepaper.pdf>; FSIS Recalls website: http://origin-www.fsis.usda.gov/Fsis_Recalls/Open_Federal_Cases/index.asp.

retail settings.⁵ Their resistance to antibiotics renders them capable of causing greater harm than non-resistant strains of *Salmonella*, and thus imposes an immediate and compelling burden on the agency to use its interpretive authority to declare them to be adulterants under the Act. While the number of documented outbreaks caused by ABR-*Salmonella* contamination of meat and poultry is small, the actual number is likely to be far greater. Moreover, USDA should adopt preventive measures to spare consumers of ground meat and poultry the increased physical harm (including potential death) and expense due to ABR foodborne illnesses.

Once adulterant status is declared, it is incumbent upon the agency to take steps to ensure adequate sampling and testing to detect the presence of the pathogens and remove contaminated meat from the food supply.⁶ CSPI expects that after the declaration of adulterant status, the agency would publish details of a testing program similar to the 1994 Notice. FSIS is already collecting *Salmonella* samples as part of its Pathogen Reduction Program, so developing a sampling program for specific ABR-*Salmonella* strains should not be unduly burdensome for the agency. Although CSPI has identified four specific strains as the subject of this petition, we note that other ABR pathogens are present in the food supply.⁷ The agency has the authority under FMIA and

⁵ *National Antimicrobial Resistance Monitoring System*. (2011, April). Retrieved April 2011, from U.S. Food and Drug Administration website:

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm>; DeWaal, C. S., Roberts, C. R., & Catella, C. M. (2011, January 25). *Antibiotic Resistance in Foodborne Pathogens: Evidence of the Need for a Risk Management Strategy*. Retrieved from Center for Science in the Public Interest website: <http://cspinet.org/new/pdf/abrfoodbornepathogenswhitepaper.pdf>; *Dirty Birds* (2007, January). Retrieved April 2011, from Consumer Reports website: http://www.consumerreports.org/cro/food/chicken-safety-1-07/overview/0107_chick_ov.htm.

⁶ Declaration of adulterant status is an interpretive rule, as will be discussed in detail later in this petition. Notably, initiating a corresponding testing and sampling program has also been held to be within the agency's discretion as a "procedural rule" and thus also does not require formal rulemaking. *Texas Food Industry Ass'n v. Espy*, 870 F.supp. 143, 147,(W.D. Tex. 1994).

⁷ For example, a study published in the April 2011 journal *Clinical Infectious Disease* found that nearly half of all meat and poultry samples were contaminated with *Staphylococcus aureus* bacteria. More than half of the bacteria were resistant to at least three classes of antibiotics. *S. aureus* is among the most prevalent causes of clinical infections globally and has gained public attention due to the increasing mortality associated with multidrug-resistant strains. The study examined 136 samples of meat and poultry from 80 brands in 26 retail grocery stores in five U.S. cities. Ninety-six percent of the *S. aureus* isolates found in the samples were resistant to at least one antimicrobial and multidrug resistance was found in 52 percent of the isolates. Waters, A.E., Contente-Cuomo, T., Buchhagen, J., Liu, C.M.,

legal precedent to act more broadly to regulate those pathogens in its products, and should consider any evidence on the public health impact of these strains.

B. A Grant of Expedited Review

Because this petition requests action intended to enhance the public health by reducing food safety hazards, the petitioners ask for expedited review. As stated in the recently amended FSIS petition procedures, 9 CFR § 392.8(a):

A petition will receive expedited review by FSIS if the requested action is intended to enhance the public health by removing or reducing foodborne pathogens or other potential food safety hazards that might be present in or on meat, poultry, or egg products.⁸

The interpretive rule requested in this petition would prompt better monitoring for specific strains of ABR-*Salmonella*, and, when they were found, result in product being withheld or recalled from commerce, thus reducing the risk to consumers. In accordance with 9 CFR § 392.8(b), the requested action is supported by scientific information that demonstrates that such an interpretive rule would reduce consumer exposure to foodborne pathogens capable of causing severe illnesses. For those reasons, the petitioners request that FSIS grant this petition expedited review.

II. ABOUT THE PETITIONERS

The Center for Science in the Public Interest (CSPI), founded in 1971 and located in Washington, D.C., is a nonprofit, non-governmental consumer advocacy organization focused primarily on nutrition, health and food safety issues.

CSPI has been working on food safety reform and enhanced public protection from contaminated food since the early 1990s, and has filed a number of petitions to improve U.S. food safety, including: Regulatory action requiring microbial testing by industry for *Listeria monocytogenes*

Watson, L., Pearce, K., Price, L. B. (2011, April 15). *Multidrug-Resistant Staphylococcus aureus in US Meat and Poultry. Clinical Infectious Diseases*, doi:10.1093/cid/cir181

⁸ 9 CFR § 392.8(a).

in ready-to-eat meat and poultry products (2000); Banning the use of spinal cord from cattle feed (2001); Posting *Salmonella* testing results (2001); and Setting a *Campylobacter jejuni* performance standard (2002). The Food Safety Program maintains a database of more than 6,600 U.S. foodborne outbreaks with both an identified food source and etiology, and publishes the annual *Outbreak Alert! Report* analyzing these outbreaks.

CSPI represents 750,000 American consumers.

III. FACTUAL GROUNDS FOR PETITION

A. Antibiotic-Resistant Pathogens Generally

Resistance is an inevitable consequence of antibiotic use; the more that antibiotics are used in animal production, the more bacteria will develop resistance. Scientists have documented sophisticated biochemical mechanisms that allow bacteria to fend off or neutralize antibiotics and have shown the correlation with use of antibiotics in animals.⁹ As the use of antibiotics in animals for non-therapeutic purposes has increased over the decades, resistant bacteria have emerged more rapidly.¹⁰ Resistance poses a major threat to the continued effectiveness of antibiotics used to treat human and veterinary illnesses. Further exacerbating the problem, fewer new antibiotics are being developed to replace those that are losing their effectiveness.¹¹ Although the use of antimicrobials in animals is not controlled by FSIS, consumer exposure to the increased risk of antibiotic-resistant pathogens in the meat supply can be mitigated by FSIS.

Numerous studies have documented direct transference of antibiotic-resistant bacteria from animals to humans, including studies showing that after antibiotics were administered to animals to treat infections, the prevalence of antibiotic-resistant *E. coli* and *Campylobacter* bacteria

⁹ Silbergeld, E.K., Price, L., and Graham, J. (2008). Industrial food animal production, antimicrobial resistance, and human health. *Annu Rev Public Health* 29, 151-69.

¹⁰ Whether the increase is due to increased use of antibiotics or to increased testing and reporting could not be determined.

¹¹ Silbergeld, E.K., Price, L., and Graham, J. (2008). Industrial food animal production, antimicrobial resistance, and human health. *Annu Rev Public Health* 29, 151-69.

also increased in humans.¹² Other studies have confirmed that antibiotic-resistant *Campylobacter*, *Salmonella* Typhimurium DT 104, and *Salmonella* Newport have moved from animals to humans through foods of animal origin.¹³ Reflecting the fact that bacteria can develop resistance to numerous antibiotics, one group of related antibiotic-resistant *Salmonella* Newport strains is resistant to most available antimicrobial agents approved for the treatment of salmonellosis.¹⁴

The human health consequences of these resistant organisms include more serious infections and increased frequency of treatment failures. Patients may experience prolonged duration of illness, lengthier hospitalizations, increased frequency of bloodstream infections, and increased mortality.¹⁵ Health care costs increase with longer hospital stays and the need for more expensive antibiotics to fight resistant pathogens. The antibiotics used to treat resistant pathogens can be more toxic, with more serious side effects, to the patients.

A. FSIS's Current Treatment of Products Contaminated with ABR-*Salmonella*

In 2009, the meat industry announced three significant recalls of meat and poultry products contaminated with ABR-*Salmonella*. In 2009, Beef Packers, Inc., owned by Cargill, recalled over 825,000 pounds of ground beef products due to contamination with ABR-*Salmonella* Newport, which resulted in 40 illnesses in four states. Later that same year, Beef Packers again recalled over 22,000 pounds of ground beef contaminated with the same strain of ABR-*Salmonella*

¹² Smith, K.E., Besser, J.M., Hedberg, C.W., Leano, F.T., Bender J.B., Wicklund, J.H., Johnson, B.P., Moore, K.A., and Osterholm, M.T. (1999, September). Quinolone-resistant *Campylobacter jejuni* infections in Minnesota, 1992-1998. *New England Journal of Medicine*, 340.; Ribot, E.M., Wierzbza, R.K., Angulo, F.J., and Barrett, T.J. (2002). *Salmonella enterica* serotype Typhimurium DT104 Isolated from Humans, United States, 1985, 1990, and 1995. *Emerging Infectious Diseases*, 8(4), 387-391; Gahart, M. T., & Lansburgh, J. E. (2004, January). *ANTIBIOTIC RESISTANCE: Federal Agencies Need to Better Focus*. Retrieved from U.S. Government Accountability Office website: <http://www.gao.gov/new.items/d04490.pdf>.

¹³ Id.

¹⁴ Gupta, A., Fontana, J., Crowe, C., Bolstorff, B., Stout, A., Van Duyne, S., Hoekstra, M.P., Whichard, J.M., Barrett, T.J., and Angulo, F.J. (2003). Emergence of Multidrug-Resistant *Salmonella enterica* Serotype Newport Infections. *Journal of Infectious Diseases*, 188, 1707-1716.

¹⁵ Angulo F.J., Nargund, V.N., and Chiller, T.C. (2004). Evidence of an Association Between Use of Anti-microbial Agents in Food Animals and Anti-microbial Resistance Among Bacteria Isolated from Humans and the Human Health Consequences of Such Resistance. *J. Vet. Med. B Infect. Dis. Vet. Public Health*, 51, 374-379.

Newport after two consumers became ill.¹⁶ In 2011, the agency oversaw a recall of nearly 55,000 pounds of frozen, raw turkey burger products contaminated with ABR-*Salmonella* Hadar, which sickened at least 12 people.¹⁷

Those recalls indicate that FSIS already considers meat and poultry products contaminated with ABR-*Salmonella* to be adulterants under FMIA once they cause illness; unfortunately, the agency is waiting for outbreaks to occur before removing the products from commerce. Sufficient data exist for the agency to take preventive steps—including initiating testing for ABR-*Salmonella* strains—to prevent entry into commerce of those especially dangerous bacteria. An interpretive rule declaring the specific strains of ABR-*Salmonella* as adulterants would thus formalize a policy that FSIS already implicitly recognizes, and could protect consumers from exposure to these pathogens.

Similar recalls linked to other strains of ABR-*Salmonella* and other antibiotic-resistant pathogens have also occurred in recent years. USDA has both the authority under FMIA and PPIA, and legal precedent to enact stricter regulatory protocol—including declaring these additional pathogens to be adulterants—without waiting for outbreaks to occur. Such an action could also help to mitigate the rise of antibiotic-resistance generally by encouraging livestock handlers toward more judicious use of antibiotics in animal husbandry to avoid producing adulterated product. Notably, decreasing the use of antibiotics generally in animal production could have a significant positive impact on the development of antibiotic-resistant pathogens. This preventive effect distinguishes antibiotic-resistant pathogens from *E. coli* O157:H7 in one

¹⁶ *California Firm Recalls Ground Beef Products Due to Possible Salmonella Contamination*. (2009, August). Retrieved April 2011, from USDA Food Safety and Inspection Service website: http://www.fsis.usda.gov/News_&_Events/Recall_041_2009_Release/index.asp; *California Firm Recalls Ground Beef Products Due to Possible Salmonella Contamination*. (2009, December). Retrieved April 2011, from USDA Food Safety and Inspection Service website: http://www.fsis.usda.gov/News_&_Events/Recall_065_2009_Release/index.asp.

¹⁷ *Investigation Announcement: Multistate Outbreak of Salmonella Hadar Infections Associated with Turkey Burgers*. (2011, April). Retrieved May 2011, from Centers for Disease Control and Prevention website: <http://www.cdc.gov/salmonella/hadar0411/040411/index.html>.

profound sense—the industry has a heightened ability and responsibility to control the emergence of additional strains because they are not, in fact, naturally occurring.

B. Data Indicate Continuing Outbreaks Linked to ABR-*Salmonella*

Outbreak data analyzed by CSPI provides a compelling scientific basis for this petition. Notably, the available data set is presumed to severely understate¹⁸ the actual number of outbreaks linked to ABR (and non-ABR) pathogens. In a review of 36 documented outbreaks linked to antibiotic-resistant bacteria since the 1970s, 42 percent (15 out of 36) occurred in the last decade. A total of 19,909 people were sickened from these 36 outbreaks, resulting in 3,064 hospitalizations and 26 deaths.¹⁹ Of the 36 outbreaks from antibiotic-resistant pathogens, 39 percent occurred in FSIS-regulated meat and poultry products.²⁰

An antibiotic-resistance pattern was reported for 25 of those 36 outbreaks.²¹ The responsible bacteria displayed resistance to a total of 14 different antibiotics and the entire sulfonamide class of antibiotics. Of those 14 antibiotics, six are classified by the World Health Organization (WHO) as “critically important” to human medicine and seven as “highly important” to human medicine.²²

Of the 36 documented ABR outbreaks, 29 were linked to strains of *Salmonella*. The most frequently identified bacterial pathogen was *Salmonella* Typhimurium, which was implicated in 14 outbreaks causing 17,808 illnesses (39 percent of all 36 outbreaks), followed by *Salmonella* Newport, which was implicated in nine outbreaks with 586 illnesses (25 percent of the 36

¹⁸ CDC estimates that for every documented case of *Salmonella*, an additional 29.3 *Salmonella* cases may be undiagnosed. Scallan, E., Hoekstra, R.M., Angulo, F.J., Tauxe, R.V., Widdowson, M.A., & Roy, S.L. (2011, January). Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis.*, 17, Retrieved from <http://www.cdc.gov/EID/content/17/1/7.htm>.

¹⁹ This includes one large *Salmonella* Typhimurium outbreak caused by milk in 1985 in which 16,659 were sickened, 2,777 were hospitalized, and 18 died. Petitioners recognize that regulation and oversight of pathogens in milk is not under the authority of USDA, but we include this data to illustrate the potential magnitude of harm.

²⁰ The other 61 percent are attributed to a range of foods regulated by FDA, including dairy, produce, seafood, and eggs.

²¹ An antibiotic-resistance pattern refers to the specific drug or class of drugs to which the bacteria displays resistance.

²² Trimethoprim-sulfamethoxazole and ceftiofur are not on WHO's list of antimicrobials used in human medicine.

outbreaks). Six other *Salmonella* subspecies were each implicated in one outbreak (with a total of 935 illnesses), including an outbreak attributed to *Salmonella* Hadar in ground turkey burgers in 2011, and an outbreak attributed to *Salmonella* Heidelberg in 1997, causing over 700 illnesses and 2 deaths.²³

CSPI identified a total of 14 outbreaks related to FSIS-regulated products: nine in beef, two in pork, and three in poultry, including one in ground turkey. All of the beef-related outbreaks were associated with ground beef, with *Salmonella* Newport implicated in seven outbreaks and *Salmonella* Typhimurium implicated in two. Meat and poultry outbreaks overall were associated with 1,388 illnesses, 93 hospitalizations and 5 deaths.

C. **ABR-*Salmonella* Have Been Found in Retail Settings**

Surveillance data tracking the prevalence of ABR pathogens in food indicate the urgency of the problem at hand, and lend support to CSPI's position that the presence of ABR-resistant pathogens in food requires decisive intervention from USDA.

The National Antimicrobial Resistance Monitoring System (NARMS) retail meat surveillance program monitors the prevalence of antimicrobial resistance in foodborne bacteria, specifically, *Salmonella*, *Campylobacter*, *Enterococcus*, and *Escherichia coli*.²⁴ The findings of the NARMS retail meat program serve as a reference point for identifying and analyzing trends in antimicrobial resistance among those organisms. *Salmonella* Heidelberg and *Salmonella* Typhimurium have been among the most frequent serotypes found in retail meats, occurring in the list of the ten most common serotypes from 2002 to 2008.²⁵ Those pathogens also were implicated in a number of

²³ Notably, though *S. Heidelberg* is only cited as the source of one major outbreak in the period studied, the strain appears in the top 10 serotypes identified by NARMS retail meat sampling data for every year since tracking began (2002-2008). Further discussion on this appears in the following subsection of this petition.

²⁴ NARMS defines "meat" as chicken breast, ground turkey, ground beef, and pork chop.

²⁵ *NARMS Methods and Data*. (2011, May). Retrieved April 2011, from U.S. Food and Drug Administration website: <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm059103.htm>.

human foodborne illnesses, as discussed above. Additionally, antibiotic-resistant *Salmonella* Newport is included in this petition because it has been implicated in at least seven outbreaks in ground beef products.

In a separate 2001 study of antibiotic-resistant pathogens found in ground chicken, turkey, beef, and pork purchased from supermarkets in the Washington, D.C., area, 20 percent of all samples contained *Salmonella*, with a total of 13 serotypes.²⁶ Eighty-four percent of the isolates were resistant to at least one antibiotic, and 53 percent were resistant to at least three antibiotics. Sixteen percent of the isolates were resistant to ceftriaxone, the drug of choice for treating salmonellosis in children.

III. LEGAL BASIS FOR DECLARING ABR-*SALMONELLA* AN ADULTERANT

The purpose of the FMIA and PPIA is clear: “It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.”²⁷ That objective is best met by a recognition that ABR-*Salmonella* is an adulterant.

ABR-*Salmonella* qualifies as an adulterant under either part of the relevant FMIA and PPIA definitions, §§601(m)(1) and 453(g)(1). Both definitions require that a substance either be added or, if natural, render the resulting food article ordinarily injurious to health. While FSIS does not classify *Salmonella* in raw meat as an adulterant, ABR-*Salmonella* has unique characteristics that justify stricter treatment. The chief characteristic is that it arises as a result of human intervention—namely, the administration of antibiotics in meat and poultry production.

Additionally, the fact that treatment for ABR-*Salmonella* infections is less effective and, therefore,

²⁶ White, D.G., Zhao, S., Sudler, R., et al. (2001, October 18). The Isolation of Antibiotic-Resistant *Salmonella* from Retail Ground Meats. *N Engl J Med*, 345, 1147 – 1154.

²⁷ 21 U.S.C. § 602 (2004).

presents a greater risk of injury to human health, lends further support to finding it an adulterant. FSIS has authority to proceed via an interpretative rule under the FMIA and past precedence.

In the alternative, FSIS may use its authority under §§ 601(m)(2)(A) and 453(g)(2) to declare food contaminated with ABR-*Salmonella* as unfit for human consumption.

1. **ABR-*Salmonella* is Adulterated Under 21 USC 601(m)(1) and 21 U.S.C. §453(g)(1)**

ABR-*Salmonella* is an added substance within the meaning of 21 U.S.C. § 601(m)(1) and 21 U.S.C. §453(g)(1), meaning that to declare it an adulterant under the law, FSIS must only show that it is injurious to health. The relevant definition states:

(m) The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) 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 article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;²⁸

The crucial legal difference between ABR-*Salmonella* and *Salmonella* that occurs naturally in the environment arises because ABR-*Salmonella* occurs due to an act of humans: the use of antibiotics on farms or feedlots.

FSIS has previously determined that *Salmonella* is not an added substance and, therefore, falls within the second part of the definition of adulteration. The first part of the definition is directed at poisonous or deleterious additives and not substances that may be inherent in the meat.²⁹ If a substance is not added, then the Agency must show that it would “ordinarily render [the meat] injurious to health.” It is in this second part of the definition that courts have used to compel FSIS to conclude that *Salmonella* is not an adulterant in raw meat because normal methods

²⁸ 21 U.S.C. § 601(m)(1) and 21 U.S.C. §453(g)(1)

²⁹ *Amer. Public Health Ass’n v. Butz*, 511 F.2d 331, 334, (U.S. App. D.C., 1974).

of preparing and cooking do not ordinarily result in salmonellosis.³⁰ While this reasoning has been narrowly construed by later courts and publicly criticized,³¹ FSIS has not to date reversed its position with regard to *Salmonella*. The same analysis does not apply to ABR-*Salmonella*.

ABR-*Salmonella* is rightly determined to be an adulterant under the first part of § 601(m)(1) and §453(g)(1), which addresses added substances. In the case of food adulteration, a substance is added if it is “artificially introduced or attributable in some degree to the acts of man.”³² Scientists have shown that resistant strains of ABR-*Salmonella* develop in part because industrial agriculture uses antibiotics in livestock.³³

The fact that ABR-*Salmonella* are not directly added through an act of man does not matter. In *United States v. Anderson Seafoods, Inc.*, 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

³⁰ 511 F.2d at 334.

³¹ *Continental Seafood v. United States*, 674 F.2d 38, 41, (rejecting the Butz position as “dictum uttered in a different legal and factual context”); *Texas Food Ind. Assn v. Espy*, 870 F. Supp. 143, 149, (W.D. Tex. 1994) (noting Butz referred to “proper” cooking while “thorough” cooking is necessary to protect consumers from *E. coli*); Dennis Stearns, *BPI Ground Beef Salmonella Recall: Will the Meat Industry Sue, and Who Will the USDA Stand Up For?*, FoodPoison Journal, (Aug. 6, 2009) at <http://www.foodpoisonjournal.com/food-poisoning-watch/bpi-ground-beef-salmonella-recall-will-the-meat-industry-sue-and-who-will-the-usda-stand-up-for/> (calling the USDA’s position in Butz as “nonsensical as it was sexist”).

³² *United States v. Anderson Seafoods, Inc.*, 662 F.2d 157, 160, (5th Cir. 1980), holding that “The Food and Drug Administration argues that there need not be any connection between man’s acts and the presence of a contaminant for it to be considered an added substance. The Agency points to the rule it recently promulgated interpreting § 342(a)(1), quoted above, which defines an added substance as one which is not “an inherent natural constituent of the food”, but is instead the “result of an environmental, agricultural, industrial, or other contamination”. 21 C.F.R. §§ 109.3(c), (d) (1977). Under the rule, mercury in swordfish tissue deriving from the mercury naturally dissolved in sea water would be an added substance, as would any substance not produced by or essential for the life processes of the food organism. In light of the legislative history and the *Coca Cola* case, however, we agree with the district court that the term “added” as used in § 342(a)(1) means artificially introduced, or attributable in some degree to the acts of man.” 447 F.Supp. 1151, 1155 (emphasis added).

³³ Gellin, G., Langlois, B.E., Dawson, K.A., & Aaron, D.K. (1989, September). Antibiotic Resistance of Gram-Negative Enteric Bacteria from Pigs in Three Herds with Different Histories of Antibiotic Exposure. *Applied and Environmental Microbiology*, 55(9), 2287-2292. Retrieved from: <http://aem.asm.org/cgi/reprint/55/9/2287.pdf>.

FDA could regulate mercury as an “added” adulterant in seafood.³⁴ It did not matter that mercury occurred naturally in the environment because an act of man was responsible for increasing and concentrating the substance in food fish.³⁵ Similarly, the use of antibiotics in meat production has been shown to increase the prevalence of antibiotic-resistant bacteria in farm animals.³⁶

Secondly, to be found an adulterant, a substance must be injurious to health.³⁷ That *Salmonella* is injurious to health is well-established: the pathogen causes over one million illnesses per year in the U.S.³⁸ In situations where the public is likely to consume food without cooking it (i.e., ready-to-eat foods) it is already treated as an adulterant. For ground meat and poultry products, the risk to consumers is particularly great, since even “proper” cooking often fails to reach the necessary temperature for lethality.³⁹ Further, even when a meat thermometer is used, it is difficult to measure internal temperature properly in ground products, resulting in inadvertent undercooking of these foods.⁴⁰

In addition to the normal risk associated with *Salmonella*, ABR-*Salmonella* poses an additional risk of injury because it is more difficult to treat.⁴¹ Patients stricken with antibiotic-resistant illnesses often suffer longer and more extreme forms of illness, longer hospitalizations,

³⁴ 662 F.2d at 162.

³⁵ 662 F.2d at 161-162.

³⁶ Siegel, D., Huber, W.G., & Enloe, F. (1974, December). Continuous Non-Therapeutic Use of Antibacterial Drugs in Feed and Drug Resistance of the Gram-Negative Enteric Flora of Food-Producing Animals. *American Society for Microbiology*, 6(6), 697-701.

³⁷ *United States v. Lexington Mill Elevator Co.*, 232 U.S. 399, 411 (1914).

Scallan, E., Hoekstra, R.M., Angulo, F.J., Tauxe, R.V., Widdowson, M.A., & Roy, S.L. (2011, January). Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis.*, 17, Retrieved from: <http://www.cdc.gov/EID/content/17/1/7.htm>.

³⁹ See *Texas Food Industry Ass’n v. Espy*, 870 F.supp. 143, 149, (W.D. Tex. 1994), stating, “However, unlike other pathogens, it is not ‘proper’ cooking but ‘thorough’ cooking that is necessary to protect consumers from *E. coli*. The evidence submitted by Defendants indicates that many Americans consider ground beef to be properly cooked rare, medium rare, or medium. The evidence also indicated that *E. coli* contaminated ground beef cooked in such a manner may cause serious physical problems, including death. Therefore, *E. coli* is a substance that renders ‘injurious to health’ what many Americans believe to be properly cooked ground beef.”

⁴⁰ *Meat Preparation: Color of Cooked Ground Beef as It Relates to Doneness*. (2011, May). Retrieved April 2011, from USDA Food Safety Inspection Service website: http://www.fsis.usda.gov/factsheets/Color_of_Cooked_Ground_Beef/index.asp.

⁴¹ Holmberg, S.D., Osterholm, M.T., Senger, K.A., & Cohen, M.L. (1984, September). Drug-Resistant *Salmonella* from Animals Fed Antimicrobials. *N. Engl. J. Med.*, 311(10), 617-22.

and serious side effects from alternative antibiotics available to treat them.⁴² This additional risk adds urgency to a determination that ABR-*Salmonella* is an adulterant.

2. ABR-Salmonella is Adulterated Under 21 USC § 601(m)(2)(A) and 21 U.S.C. § 453(g)(2)(A)

ABR-*Salmonella* may also be classified an adulterant because it is present as a result of antibiotics administered to a live animal. Under § 601(m)(2)(A) and § 453(g)(1) meat or poultry is adulterated “if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance... which may, in the judgment of the Secretary, make such article unfit for human food.”⁴³ As discussed above, the administration of antibiotics to live animals causes an increase in the level of antibiotic-resistant bacteria.

The determination that an item is unfit for human food is different from a determination that it is injurious to health,⁴⁴ but that difference is not detrimental to using § 601(m)(2)(A) and § 453(g)(1) to declare ABR-*Salmonella* an adulterant. The unfitness standard is one that an average person, under ordinary conditions, would use when finding food not suitable for chewing or swallowing, according to the court in *United States v. 24 Cases*.⁴⁵ That criterion does not mean a person must be able to detect the adulteration for the meat to be unfit for food. Instead, unfitness “is a broad general classification allowing the widest variety of reasons for condemning a food.”⁴⁶ To the extent that the resistant bacteria are present, they make the meat unfit for human food because a person would be unlikely to consume a food if he or she knew that it had the potential to cause severe illness with the potential for an untreatable infection.

⁴² Angulo F.J., Nargund, V.N., and Chiller, T.C. (2004). Evidence of an Association Between Use of Anti-microbial Agents in Food Animals and Anti-microbial Resistance Among Bacteria Isolated from Humans and the Human Health Consequences of Such Resistance. *J. Vet. Med. B Infect. Dis. Vet. Public Health*, 51, 374-379.

⁴³ 21 U.S.C. § 601(m)(2).

⁴⁴ *United States v. 24 Cases, Etc.*, 87 F.Supp. 826 (D. Me. 1949).

⁴⁵ 87 F. Supp. at 828.

⁴⁶ *United States v. 449 Cases*, 212 F.2d 567, 569, 570, (2nd Cir. 1954).

3. Declaring ABR-*Salmonella* Through an Interpretive Rule is Consistent with FSIS Authority and Past Practice.

Because CSPI requests that the agency declare ABR-*Salmonella* an adulterant via an interpretive rule, the agency need only consider—under the weight of the evidence of the public health concern—whether it has the authority to issue such an interpretation. We believe, under the FMIA and legal precedent, that it does.

The agency is not required to engage in substantive rulemaking to declare that a particular substance is an adulterant under the meaning of the FMIA.⁴⁷ This power was tested and confirmed in 1994, when the agency issued an interpretive rule declaring *E. coli* 0157:H7 an adulterant and initiated a sampling program to monitor for the pathogen. The meat industry challenged the interpretive rule and sought an injunction against the agency to prevent the declaration and to bar any sampling or monitoring programs that would follow from it. The resulting decision in *Texas Food Industry Association, et al. v. Espy* (hereinafter “*Texas Food Industry Ass’n*”) soundly and conclusively determined that the agency has the authority to issue interpretive rules of this nature, citing the Administrative Procedures Act (APA) and relevant precedent.

Pursuant to the APA, agencies may issue “interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice” without the notice and comment procedures that are required for formal, substantive rulemaking.⁴⁸ The key question arising from this explicit authority is what exactly constitutes an interpretive rule. The *Texas Food Industry Ass’n* court, relying on an earlier case, *American Mining Congress v. Mine Safety & Health Administration* (hereinafter “*American Mining*”), carefully delineates the criteria for an interpretive rule—and the action requested in this Petition fits within that definition.

⁴⁷ *Texas Food Industry Ass’n v. Espy*, 870 F.supp. 143, 149,(W.D. Tex. 1994).

⁴⁸ 5 U.S.C. § 533(b)(3)(A).

American Mining applies a legal effect analysis and lays out a four-part construction for determining whether a rule is substantive or interpretive:

(1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule. If the answer to any of these questions is affirmative, we have a [substantive] rule, not an interpretive rule.⁴⁹

If any of these factors are found, the resulting rule is substantive. An interpretive rule, however, is a rule or statement issued by an agency “to advise the public of the agency’s construction of the statutes and rules which it administers.”⁵⁰

Applying that construction to the *E. coli* interpretation challenged in *Texas Food Industry Ass’n*, the court held that the declaration of *E. coli* 0157:H7 as an adulterant was within the authority of the agency as interpretive—not substantive—rulemaking, and thus did not require notice and comment or other formal rulemaking action.

The same analysis can be applied to the action requested by this Petition, and will similarly and conclusively illustrate that the agency may use an interpretive rule to declare ABR-*Salmonella* an adulterant under the FMIA. First, *Texas Food Industry Ass’n* specifically upheld the authority of the agency to, in its “[discretion] . . . proceed through case-by-case adjudication and interpretive orders rather than through the rulemaking process.”⁵¹ Further, the statute provides the legislative basis and authority for the agency to bring an enforcement action based on the declaration that ABR-*Salmonella*, like *E. coli* O157:H7, is an adulterant. Moreover, in granting this Petition, the agency need not publish its rule in the Code of Federal Regulations or invoke its general legislative authority. Finally, the proposed interpretive rule does not amend a prior legislative rule. Instead, the requested declaration would only advise the public regarding ABR-*Salmonella*’s status as an

⁴⁹ *American Mining Congress v. Mine Safety & Health Administration*, 995 F.2d 1106, 1112(D.C. Cir. 1993).

⁵⁰ Id. (quoting the Attorney General’s Manual on the Administrative Procedures Act (1947)).

⁵¹ *Aroyelles Sportsmen’s League, Inc. v. Marsh*, 715 F.2d 897, 909 (5th Cir. 1983)

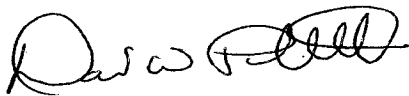
adulterant under existing statutes and regulations. Thus, based on the factors enumerated by *American Mining* and upheld in *Texas Food Industry Ass'n*, the agency may use an interpretive rule to declare ABR-*Salmonella* an adulterant under FMIA.

IV. CONCLUSION

In light of the evidence, which establishes that ABR-*Salmonella* is a serious health risk to consumers, the agency must act quickly and decisively to prevent the sale of meat contaminated with these dangerous pathogenic strains. While the number of documented outbreaks caused by ABR-*Salmonella* is small, the actual number is likely to be far greater. Moreover, USDA should adopt preventive measures to spare consumers of ground meat and poultry the increased physical harm (including potential death) and expense due to ABR foodborne illnesses. The agency has both the authority to issue an interpretive rule and the legal and scientific basis to support such an action, and we urge the agency to do so. To delay action on this critical public health issue would only further subject consumers to serious illnesses that cannot be properly and efficiently treated.

V. CERTIFICATION

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



David Plunkett
Senior Staff Attorney

Respectfully Submitted,



Sarah Klein
Staff Attorney