

SAFE FOOD COALITION

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April 27, 2016

The Honorable Thomas J. Vilsack
Secretary
U.S Department of Agriculture
1400 Independence Ave. SW.
Washington, DC 20250.

Re: Docket No. USDA-2016-0001, “Retrospective Review”

VIA ELECTRONIC SUBMISSION

Dear Secretary Vilsack:

The undersigned members of the Safe Food Coalition appreciate the opportunity to submit these comments regarding how the U.S. Department of Agriculture should modify, expand, streamline, or repeal regulations to make its regulatory program more effective or less burdensome in achieving regulatory objectives, consistent with Executive Orders 13563 and 13610. These comments focus on the regulatory activities of USDA’s Food Safety and Inspection Service.

FSIS performs a vital public health service. According to the Centers for Disease Control and Prevention, nearly 48 million Americans contract acute foodborne illnesses each year, which in turn cause 128,000 hospitalizations and 3,000 deaths, and an unknown number of long term health conditions including paralysis, mental illness, diabetes, and kidney failure.¹ CDC further estimates that contaminated meat and poultry cause 22% of foodborne illnesses and 29% of the deaths.² Outbreaks such as *E. coli* in Jack in the Box hamburgers in 1993, or antibiotic resistant *Salmonella* in Foster Farms chicken in 2013-2014, have not only devastated victims and their families, but also undermined confidence in the food system. Americans deserve a reasonable assurance that their food is safe, and not contaminated by dangerous microorganisms. The value of that peace of mind should not receive short shrift in any analysis that purports to weigh the full costs and benefits of proposed or existing regulations.

The latest CDC FoodNet data shows little progress on reducing infection rates from common foodborne illnesses, and a continuing pattern of little or no control over two particularly problematic pathogens: *Salmonella* and *Campylobacter*.³ Salmonellosis is the leading foodborne illness killer and campylobacteriosis, which has increased by 13% over 2006-2008 levels in recent years, is a

¹ See, e.g. Batz MB, Henke E, Kowalczyk B. (2013) “Long-term consequences of foodborne infections.” *Infect Dis Clin North Am* 27(3):599-616; Buzby, J.C., and Roberts, T. (1997). “Guillain-Barré Syndrome increases foodborne disease costs,” *FoodReview*, Washington, DC: US Department of Agriculture, Economic Research Service, 20 (3), pp. 36-42.

² Painter JA, Hoekstra RM, Ayers T, Tauxe RV, Braden CR, Angulo FJ, et al. Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998–2008. *Emerg Infect Dis* [Internet]. 2013 Mar [3/21/2016]. <http://dx.doi.org/10.3201/eid1903.111866>.

³ See CDC “FoodNet 2015 Preliminary Data” available at: <http://www.cdc.gov/foodnet/reports/prelim-data-intro.html>

common trigger for Guillain-Barre syndrome, a condition that causes temporary paralysis and requires intensive medical care.⁴ Antibiotic resistant strains of both *Salmonella* and *Campylobacter* have also become more prevalent.⁵ a troubling occurrence considering that children under the age of five suffer the highest incidence rates for the two pathogens.⁶ *Salmonella* and *Campylobacter* infection rates remain far from meeting the 2020 Healthy People targets.⁷ The latest data also shows the incidence of *Cryptosporidium* and non-O157 STEC infections was higher in 2015.⁸

Against this backdrop, FSIS should focus this review on making progress towards food safety goals rather than reducing costs to regulated industry. Toward that end, we request that the agency consider in its review the following proposals to modify, expand, streamline, or repeal regulations:

- Modify the agency’s inspection and recordkeeping systems to better promote continuous improvement towards reducing the incidence of foodborne illness;
- Expand the definition of “adulterant” to include, at a minimum, antibiotic resistant (ABR) *Salmonella Heidelberg*, ABR *Salmonella Hadar*, ABR *Salmonella Newport*, and ABR *Salmonella Typhimurium* when found in meat and poultry;
- Modify the HACCP rule so that establishments must consider certain commonly occurring pathogens as “reasonably likely to occur” in their HACCP plans;
- Modify testing regulations to reflect the latest science showing that some poultry rinses interfere with the detection of pathogens;
- Expand the use of data from USDA VetNet, the *Salmonella* Verification Testing Program, the CDC, and other sources, to reduce foodborne illness;
- Modify performance standards to bring them up-to-date across the board, for all pathogens and all products, starting with *Salmonella* in ground beef.
- Build a data-sharing platform to better monitor and control antibiotic resistant bacteria in meat and poultry products, from farm to fork.

As discussed further below, these regulatory changes will better align the incentives facing industry with consumers’ interests, and ultimately spare many families from the burden of suffering a foodborne illness.

FSIS should not invoke Executive Orders 13563 and 13610 to remove, or recommend removing, consumer protections without the data necessary to assess the impact of those changes. We believe the agency did just that in 2012, when it cited E.O. 13563, “Improving Regulation and

⁴ See CDC. “Trends in Foodborne Illness in the United States.” available at: <http://www.cdc.gov/foodborneburden/trends-in-foodborne-illness.html>

⁵ See, e.g. Huang JY, Henao OL, Griffin PM, et al. Infection with Pathogens Transmitted Commonly Through Food and the Effect of Increasing Use of Culture-Independent Diagnostic Tests on Surveillance — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2012–2015. MMWR 65(14);368–371, available at: <http://www.cdc.gov/mmwr/volumes/65/wr/mm6514a2.htm>; Food Safety News. “CDC: Antibiotic Resistance Increasing in Certain Salmonella Serotypes,” (June 9, 2015) available at: <http://www.foodsafetynews.com/2015/06/cdc-antibiotic-resistance-increasing-in-certain-salmonella-serotypes/#.VyDC0NqrKUK>

⁶ American Academy of Pediatrics, Center for Foodborne Illness Research & Prevention, and The Pew Charitable Trusts (2014) Young Children and Foodborne Illness Fact Sheet. Available at: http://www.foodborneillness.org/cfi-library/Children_and_Foodborne_Illness-FS-v10-110514.pdf

⁷ See “Trends in Foodborne Illness in the United States.” *supra* note 4.

⁸ See “FoodNet 2015 Preliminary Data” *supra* note 3.

Regulatory Review,” as the rationale for proposing its New Poultry Inspection System (NPIS) rule. We urge FSIS not to use this review to support similarly unproven policy reforms that would threaten public health, such as expansion of the Hazard Analysis and Critical Control Points (HACCP)-based Inspection Models Project (HIMP) program for hog slaughter facilities (“hog HIMP”), or relaxing requirements for inspection of foreign imports and the equivalency determination of foreign government’s food safety inspection. Nor should FSIS use the regulatory review to forego common sense rules that protect consumers, such as eliminating new labeling regulations for injected and mechanically tenderized meat and poultry products.

Our detailed comments – in response to the Department’s request for information – follow below.

I. Modify agency inspection and recordkeeping systems to achieve continuous improvement toward food safety goals

FSIS should use inspector-generated data to evaluate alternative inspection regimes and identify ways for the agency to make progress towards the Healthy People 2020 goals. On an ongoing basis, the agency should compare the results of microbiological sampling and other data from similar establishments under different inspection regimes, and make changes to improve food safety on the basis of these analyses. Such analyses should include comparisons of data from establishments operating under the New Poultry Inspection System (NPIS) with data from those operating under traditional inspection systems.

In 2014, FSIS issued a final rule establishing NPIS. NPIS expands the poultry HIMP pilot program and transfers online inspection tasks to company employees. Poultry plants may now choose to operate under NPIS or to continue under one of several preexisting inspection regimes: the Streamlined Inspection System (SIS), the New Line Speed Inspection System (NELS), the New Turkey Inspection System (NTIS), or Traditional Inspection. Presumably, using different inspection regimes imposes costs on FSIS by requiring increased training, recordkeeping, and other resources. On the other hand, the different systems present an opportunity for the agency to compare the efficacy of its inspection strategies in reducing the incidence of foodborne pathogens.

Thus far, FSIS has not gathered and analyzed the data necessary to take advantage of this natural experiment. In 2012, when FSIS first proposed NPIS, the agency analyzed data from 20 young chicken slaughter establishments participating in the poultry HIMP pilot program, which the rule sought to expand. Yet the agency’s data did not demonstrate that the pilot program performed better than, or even equivalent to, the traditional inspection regime in reducing pathogen contamination.⁹ Members of the Safe Food Coalition raised this concern, and in the final rule implementing NPIS, the agency justified its decision on the basis of modeling. Specifically, the agency concluded that NPIS would allow inspectors to perform more off-line inspection activities, which in turn “would likely result in a lower prevalence of carcasses contaminated with *Salmonella* and *Campylobacter*.”¹⁰ Now, with NPIS underway in some 56 establishments, FSIS has the opportunity to verify whether this “likely result” of reduced contamination has come to pass.

⁹ See FSIS. “Evaluation of HACCP Inspection Models Project (HIMP)” (Aug. 2011) at p. 26, Table 3-12 (indicating that a comparison group of establishments under traditional inspection had lower *Salmonella* rates for the most recent two years analyzed) available at: http://www.fsis.usda.gov/shared/PDF/Evaluation_HACCP_HIMP.pdf

¹⁰ 79 Fed. Reg. 49574 (August 21, 2014).

Specifically, the agency can analyze how the NPIS facilities' microbiological samples compare with those of similar establishments under traditional inspection. Currently, however, FSIS only looks at data at the "establishment level" to verify that each facility, whatever the inspection system, meets the minimum performance standards.

A comparative analysis would better comply with the Administration's regulatory review directives. In particular, E.O. 13563 directs agencies to "facilitate the periodic review of existing significant regulations." According to the Order, FSIS "shall consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome," and "such retrospective analyses, including supporting data, should be released online whenever possible." Consistent with the Order, FSIS should analyze data beyond the "establishment level" and give the public access to sufficient information to judge whether NPIS and other recent reforms have improved food safety.

II. Expand the definition of adulterant to include, at a minimum, antibiotic resistant (ABR) *Salmonella* pathogens

We continue to urge FSIS to issue an interpretive rule that at a minimum declares ABR *Salmonella* Heidelberg, ABR *Salmonella* Hadar, ABR *Salmonella* Newport, and ABR *Salmonella* Typhimurium (collectively "ABR *Salmonella*"), when found in meat and poultry, to be adulterants within the meaning of the Federal Meat Inspection Act and the Poultry Products Inspection Act, for the reasons explained in the Center for Science in the Public Interest' petition of October 2014.¹¹ FSIS took similar actions in 1994, declaring *E. coli* O157:H7 an adulterant, and in 2011, declaring six other serotypes of shiga-toxin producing *E. coli* to be adulterants. FSIS already treats ABR *Salmonella* as if it were an adulterant, however, the agency does so on a case-by-case basis only after an outbreak has occurred, prolonging the time that adulterated products sit on the shelves. This practice exposes consumers to unnecessary risk.

FSIS should use this regulatory review to evaluate the costs and benefits of classifying ABR *Salmonella* as an adulterant. Where appropriate, the agency should draw from the experience of its 1994 and 2011 interpretive rules on *E. coli* to estimate the costs and benefits of a similar ABR *Salmonella* rule. The agency's review should also take into account the growing threat of antibiotic resistance and the potential for salmonellosis cases to increase in severity under the status quo.

III. Modify the HACCP rule so that establishments must consider certain commonly occurring pathogens as "reasonably likely to occur" in their HACCP plans

Under the Pathogen Reduction/Hazard Analysis and Critical Control Points ("HACCP") rule, FSIS inspectors must verify the effectiveness of food safety systems employed by meat and poultry establishments. HACCP is a management system that addresses food safety through the identification and control of biological, chemical, and physical hazards all along the production process. Company managers design and deploy HACCP systems, and the HACCP rule has had the effect of shifting responsibility for food safety from government inspectors to the private sector.

¹¹ Center for Science in the Public Interest. Petition for an Interpretive Rule Declaring Antibiotic-Resistant *Salmonella* Heidelberg, *Salmonella* Hadar, *Salmonella* Newport, and *Salmonella* Typhimurium in Meat and Poultry to be Adulterants available at: <http://cspinet.org/images/ABR%20Salmonella%20Petition%20FINAL.pdf>

For years, however, USDA’s Office of Inspector General, the Government Accountability Office, and even FSIS itself, have recognized that many meat and poultry establishments stumble at the first HACCP hurdle: identifying and addressing common pathogen hazards.¹² For example, a pork producer may not recognize *Yersinia* as a relevant food safety hazard to control, and a poultry producer may not recognize *Salmonella* as a hazard to address in its HACCP plan. Such omissions are inconsistent with FSIS guidance, but the agency does not require companies to correct them.

FSIS should use the regulatory review process to evaluate the impact of requiring each establishment to identify all pathogens that typically affect the food under production, and to address those pathogens as hazards in the HACCP plan. This requirement would not preclude plants from identifying other hazards, but it would provide greater assurances that plants are at least addressing hazards that are generally known to occur in particular products. FSIS can draw from Centers for Disease Control and Prevention (CDC) studies to specify common pathogen hazards. In particular, drawing on outbreak data between 1998 and 2008, CDC researchers have indicated that the following pathogens on the following food types are important contributors to foodborne illness.

- Beef: *Campylobacter*, *Clostridium perfringens*, *Escherichia coli* sp.*, *E. coli* O157/STEC, *Listeria***, *Salmonella*, *Shigella*
- Pork: *Bacillus cereus*, *Listeria***, *Salmonella*, *Shigella*, *Yersinia*
- Poultry: *Bacillus cereus*, *Campylobacter*, *Clostridium perfringens*, *Escherichia coli* sp.*, *Listeria***, *Salmonella*¹³

The Safe Food Coalition supports a requirement that all beef, pork, and poultry slaughter and processing establishments at a minimum recognize as hazards the corresponding pathogens listed above.

Unfortunately, many establishments have only recognized common pathogens as hazards in their HACCP plans after an outbreak has occurred. Requiring establishments to recognize common pathogens before an outbreak will help to advance the transition to a preventive, rather than reactive, food safety regulatory system. All meat and poultry establishments, not just those that have experienced an outbreak, should exercise controls for the common pathogens associated with their products. Requiring HACCP plans to identify and address these pathogens is a clear, simple, and objective standard that should not tax FSIS’s enforcement resources significantly.

¹² See, e.g. U.S. Government Accounting Office, “Better USDA Oversight and Enforcement of Safety Rules Needed to Reduce Risk of Foodborne Illnesses.” GAO-02-902, August 2002; Office of Inspector General, “Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments.” Report No: 24601-07-Hy, December 2007.

¹³ See Painter et al. *supra* note 2. *Researchers have found an association between extraintestinal pathogenic *E. coli* (ExPEC) in poultry and human Urinary Tract Infections. See Racicot Bergeron C., Prussing C., Boerlin P., Daignault D., Dutil L., Reid-Smith R.J. (2012). Chicken as reservoir for extraintestinal pathogenic *Escherichia coli* in humans, *Canada. Emerg Infect Dis* 18(3), 415-421. ***Listeria* is primarily found in Ready-to-Eat meat and poultry products.

IV. Modify testing regulations to reflect the latest science showing that some poultry rinses interfere with the detection of pathogens.

In recent years, poultry processors have increased their use of antimicrobial rinses to kill pathogens, such as *Salmonella*, on poultry carcasses. USDA researchers have long recognized the risk that some rinses may appear effective but not actually kill the *Salmonella* on the carcass, leaving consumers vulnerable.¹⁴ FSIS should modify its testing regulations to the extent needed to address this concern.

USDA sampling procedures have changed little since 1998. A technician pulls a poultry carcass from the “chiller” at the end of the slaughter line, puts it into a sample bag filled with a buffered peptone solution, and then removes the carcass and sends the solution in the sample bag to the lab for testing. When USDA established this procedure in 1998, companies applied chemical interventions like chlorine earlier in the slaughter process. The solutions in the chillers would wash off and dilute the chlorine, or other anti-microbial agents, and the buffered peptone solution would neutralize any remaining chemicals. Now, however, processors apply antimicrobial agents later in the process, including post-chill interventions.¹⁵

In 2013, researchers presented FSIS with evidence that certain antimicrobial agents—in particular cetylpyridinium chloride (CPC)—may create false negatives when used in accordance with existing procedures.¹⁶ Use of these antimicrobials is widespread in poultry establishments.¹⁷ The researchers alleged that USDA significantly underestimates *Salmonella* contamination in poultry as a result of testing flaws, and they recommended that the agency “confirm our results,” and prescribe in detail how establishments should neutralize chemical interventions.¹⁸

Nearly three years have passed since these concerns were first brought to USDA’s and the public’s attention.¹⁹ The Safe Food Coalition has repeatedly asked FSIS officials what the agency is doing to address these concerns, and the agency has made references to research that ARS is

¹⁴ See, e.g., Transcript. USDA FSIS “Advances in Post-Harvest Interventions to Reduce *Salmonella* in Poultry,” pp. 267-285 (presentation of Stan Bailey, Microbiologist, Agricultural Research Service) (Feb. 23, 2005) (“We know from many of the early studies with some of the chemicals that looked particularly effective that what we were doing was not necessarily killing the *Salmonella* on the carcass. What we were doing was – that carcass carried some of the residual active ingredient of those chemicals with it. And when you did the rinse sample of the carcass to see if it had killed the *Salmonella*, you kept that residual chemical in your rinse water, and it would kill it there. It hadn’t killed it on the carcass.”).

¹⁵ See Presentation of Dr. Scott Russel and Dr. Jon Howarth. “Presence of Antimicrobial Compounds in Poultry Rinsate Samples” (June 5, 2013) (available on file with the Safe Food Coalition) (hereinafter “Russel presentation”).

¹⁶ *Id.* The researchers argued that cetylpyridinium chloride (CPC) is not neutralized by peptone broth or activated carbon, the neutralizing agents typically used, and that USDA should require the use of an effective neutralizer. They further argued that USDA labeling regulations should require disclosure of CPC residue that remains on chicken after normal industry rinsing processes.

¹⁷ See, e.g., National Chicken Council “Questions & Answers about Processing Aids Used in Chicken Production” (April 13, 2013) available at <http://www.nationalchickencouncil.org/questions-answers-about-antimicrobial-use-in-chicken-processing/> (“Common antimicrobial interventions when processing chickens include the use of paracetic acid (PAA), chlorinated water, cetylpyridinium chloride (CPC), acidified sodium chlorite (ASC), organic acid rinses, bromine and others.”) (emphasis added).

¹⁸ Russel presentation at 60.

¹⁹ See, e.g., Kimberly Kindy. “USDA reviews whether bacteria-killing chemicals are masking *Salmonella*.” *The Washington Post* (Aug. 3, 2013) available at: https://www.washingtonpost.com/politics/usda-reviews-whether-bacteria-killing-chemicals-are-masking-salmonella/2013/08/02/da88238e-ee9e-11e2-a1f9-ea873b7e0424_story.html

carrying out to develop a new neutralizing agent. The agency has not, however, directly refuted the claims that antimicrobials are skewing test results. Such testing inadequacies raise serious concerns. The agency should use this review to address whether its testing accurately measures *Salmonella* contamination in poultry and to make any necessary corrections to avoid false negatives.

V. Use data from USDA VetNet, the *Salmonella* Verification Testing Program, the CDC, and other sources, to improve trace back of pathogens and hold producers accountable.

Currently, the vast majority of foodborne illness—over 99.9%—is not traced back to a particular product. In fact, the data indicates that over 99.9% of foodborne illness cases are not linked to the causative food.²⁰ This low detection rate results in weaker incentives for companies to produce safe food. By testing for serotypes of pathogens throughout the food chain, however, FSIS can increase the probability of finding disease linkages. For example, Canadian researchers at McGill University found a linkage between human urinary tract infections and certain poultry products by such testing.²¹ Expanded and coordinated testing could support a farm to table pathogen database that facilitates more rapid trace back and more targeted food safety interventions. FSIS should use this review to examine the barriers to creating such a database, and to develop a plan for overcoming those barriers.

VI. Modify performance standards to make them up-to-date across the board, for all pathogens and all products, starting with *Salmonella* in ground beef.

Salmonella represents a major public health problem, killing more consumers than any other foodborne pathogen each year.²² *Salmonella* can cause aortitis, cholecystitis, colitis, endocarditis, epididymo-orchitis, meningitis, osteomyelitis, pancreatitis, septicemia, and splenic abscess. Long after news of an outbreak has faded, *Salmonella* can also cause long-term health problems such as reactive arthritis.²³ Yet as already indicated, and as illustrated in the figure below, CDC data show no change in the incidence of salmonellosis from 2006-2014.

²⁰ See Painter JA, Hoekstra RM, Ayers T, Tauxe RV, Braden CR, Angulo FJ, et al. Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998–2008. *Emerg Infect Dis* [Internet]. 2013 Mar [3/21/2016]. Available at: <http://dx.doi.org/10.3201/eid1903.111866> (noting that from 1998 to 2008, a total of 13,352 foodborne disease outbreaks were reported, and of these just “4,887 (37%), causing 128,269 (47%) illnesses, had an implicated food vehicle and a single etiology,” while “298 of those outbreaks were excluded because information about the vehicle was insufficient to categorize the ingredients.”). By comparison, CDC estimates that 47.8 million foodborne illnesses occur each year.

²¹ Racicot Bergeron C., Prussing C., Boerlin P., Daignault D., Dutil L., Reid-Smith R.J. (2012). Chicken as reservoir for extraintestinal pathogenic *Escherichia coli* in humans, Canada. *Emerg Infect Dis* 18(3), 415-421. <http://dx.doi.org/10.3201/eid1803.111099>

²² See Scallan E., Griffin P.M., Angulo F.J., Tauxe R.V., and Hoekstra R.M. (2011a). Foodborne illness acquired in the United States—unspecified agents. *Emerging Infectious Diseases*, 17(1), 16-22. Available at <http://dx.doi.org/10.3201/eid1701.P21101>; Scallan E., Hoekstra R.M., Angulo F.J., Tauxe R.V., Widdowson M.A., and Roy S.L. (2011b). Foodborne illness acquired in the United States—major pathogens. *Emerging Infectious Diseases*, 17(1), 7–15. Available at <http://dx.doi.org/10.3201/eid1701.P11101>

²³ Roberts, T., Kowalczyk, B., and Buck, P. (2011). The Long-Term Health Outcomes of Selected Foodborne Pathogens. Grove, City, Pennsylvania: Center for Foodborne Illness Research and Prevention. Available at http://www.foodborneillness.org/images/stories/cfi_pdfs/CFI_LTHO_PSP_report_Nov2009_050812.pdf.

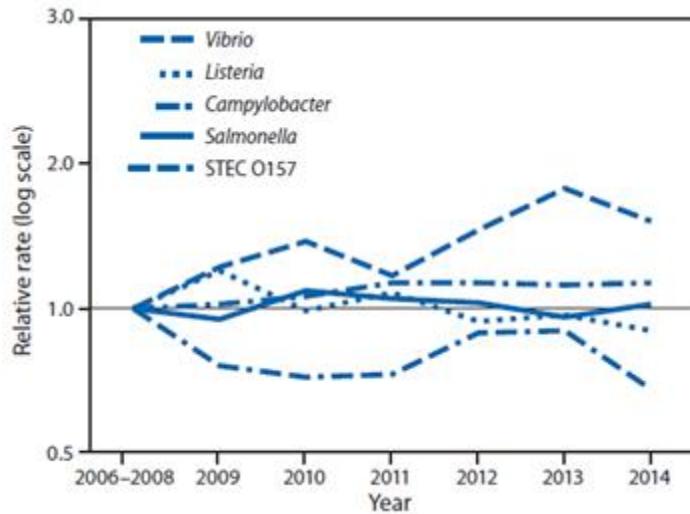


FIGURE 1. Relative rates of culture-confirmed infections with *Campylobacter*, STEC* O157, *Listeria*, *Salmonella*, and *Vibrio* compared with 2006–2008 rates, by year — Foodborne Diseases Active Surveillance Network, United States, 2006–2014†

Enforcing effective performance standards would help to reduce *Salmonella* infections. Ideally, Congress would pass legislation eliminating the restrictions imposed on FSIS by the Fifth Circuit’s opinion in *Supreme Beef v. USDA*.²⁴ However, under existing law, FSIS could do much more. The agency has ample authority to provide establishments with stronger incentives for meeting performance standards that better protect the public. In particular, ground beef, pork and poultry products are more likely to contain dangerous internal pathogens, because grinding mixes surface pathogens into the interior of the product, where common cooking practices may not result in a sufficiently high temperature to kill the pathogens. A similar phenomenon increases the risks associated with mechanically tenderized beef. Improving pathogen control in these products represents a logical starting point for FSIS. The agency can build on the lessons it learns from ground products to achieve continuous improvement in intact meat and poultry.

The HACCP rule establishes a goal of significant pathogen reduction in meat and poultry and continuing reduction in human illnesses. In particular, the Federal Register announcement for the final rule states:

“FSIS has concluded that HACCP-based process control, combined with appropriate food safety performance standards, is the most effective means available for controlling and reducing harmful bacteria on raw meat and poultry products. HACCP provides the framework for industry to set up science-based process controls that establishments can validate as effective for controlling and reducing harmful bacteria. Performance standards tell establishments what degree of effectiveness their HACCP plans will be expected to achieve and provide a necessary tool of accountability for achieving acceptable food safety

²⁴ 275 F.3d 432, 434 (5th Cir. 2001). According to the *Supreme Beef* decision, FSIS may not shut down a facility solely because testing reveals *Salmonella* contamination in its product. Rather, the agency must have some additional basis for determining that a facility is “insanitary” under the Federal Meat Inspection Act. 21 U.S.C. § 601(m)(4). Many commentators have challenged the reasoning of the *Supreme Beef* decision. See, e.g. Bill Marler. “Butz, Supreme Beef and FSIS’s *Salmonella* Policy – A Bit(e) of History” (Aug. 5, 2011) available at: <http://www.marlerblog.com/lawyer-oped/butz-supreme-beef-and-fsiss-salmonella-policy-a-bite-of-history/#.Vxo7NtQrKUK>

performance. Science-based process control, as embodied in HACCP, and appropriate performance standards are inextricably intertwined in the Agency’s regulatory strategy for improving food safety. Neither is sufficient by itself, but, when combined, they are the basis upon which FSIS expects significant reductions in the incidence and levels of harmful bacteria on raw meat and poultry products and, in turn, significant reductions in foodborne illness.”²⁵

Almost 20 years have passed since FSIS finalized the HACCP rule, yet significant reductions in *Salmonella* and resulting foodborne illness have not occurred. The lack of progress suggests that FSIS’s *Salmonella* performance standards for ground meat and poultry are not “appropriate” for food safety. FSIS should use this review to take steps toward stricter action, beginning with a new performance standard for ground beef product, which the agency had said it intended to develop and propose by September of 2015.²⁶

VII. Build a platform to allow food producers, processors and retailers to share data as public health partners in controlling antibiotic resistant bacteria in meat and poultry products.

The primary cause of antibiotic resistant (ABR) foodborne pathogens is the use of antibiotics in food animals.²⁷ Antibiotic resistance increasingly occurs in *Salmonella* and *Campylobacter*, the two foodborne pathogens causing the greatest number of confirmed foodborne illnesses in the U.S. each year.²⁸ ABR pathogens cause illnesses with greater severity, including increased risk of hospitalization, bloodstream infection, and treatment failure.²⁹ The CDC, the European Union, and the World Health Organization have all recognized that ABR zoonotic bacteria pose a substantial threat to public health.³⁰

To understand how animal antibiotic use affects public health, and to respond effectively, public health authorities must build an effective animal antibiotic surveillance system.³¹ Data on which animals receive treatment; the actual usage of animal antibiotic drugs, and the incidence of antibiotic resistant pathogens in farming communities, are critical to assessing the role that animal

²⁵ 61 *Fed. Reg.* 38805-38855, at 38811 (July 25, 1996) (emphasis added).

²⁶ 79 *Fed. Reg.* 32436-32440, at 32437 (June 5, 2014) (“FSIS intends to use the results from its verification sampling program to estimate *Salmonella* prevalence in raw ground beef and beef manufacturing trimmings and to develop a new *Salmonella* performance standard for ground beef product. FSIS will announce any new standard in the Federal Register and request comment on it before implementing it. *FSIS intends to develop and propose the new standard next fiscal year.*”). (Emphasis added).

²⁷ CDC. Public health impact of antibiotic use in food-producing animals. Updated March 29, 2016. Accessed 04/20/16 at: <http://www.cdc.gov/narms/animals.html>

²⁸ Huang JY, Henao OL, Griffin PM, et al. Infection with Pathogens Transmitted Commonly Through Food and the Effect of Increasing Use of Culture-Independent Diagnostic Tests on Surveillance — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2012–2015. *MMWR* 65(14);368–371. Accessed 4/16/16 at: <http://www.cdc.gov/mmwr/volumes/65/wr/mm6514a2.htm>.

²⁹ Kawakami V, L. Bottichio, K. Angelo et al. Notes from the Field: Outbreak of Multidrug-Resistant *Salmonella* Infections Linked to Pork — Washington, 2015. *MMWR Weekly Report*, 65(14);379–381. Accessed 4/16/16 at: <http://www.cdc.gov/mmwr/volumes/65/wr/mm6514a4.htm>

³⁰ Ventola CL. The Antibiotic Resistance Crisis: Part 1: Causes and Threats. *Pharmacy and Therapeutics*. 2015;40(4):277-283. Accessed 4/20/16 at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4378521/>

³¹ Landers TF, Cohen, B, Wittum, TE et al. (2012) A Review of Antibiotic Use in Food Animals: Perspective, Policy and Potential. *Public Health Rep.* Jan-Feb; 127(1):4-22. Accessed 4/16/16 at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3234384/>

antibiotics contribute to the growing ABR threat. The Institute of Medicine has recommended establishing an independent risk analysis and data management center for food-related research.³² We support that recommendation, however, in the meantime, FSIS should work with the U.S. Food and Drug Administration, CDC, and the other components of USDA to improve the data available for on-farm antibiotic use and the development of resistance.

Currently, FDA monitors animal antibiotic sales under the Animal Drug User Fee Act (ADUFA).³³ FSIS is charged with regulating the safety of meat and poultry products, but has no on-farm oversight, in contrast to several other USDA and FDA agencies that have some limited on-farm capabilities.³⁴ Recently, the House Appropriations Committee approved a bill for FY 2017 agriculture appropriations that would allocate \$9.9M³⁵ to USDA's Animal and Plant Health Inspection Service to collect additional data to inform policy related to the appropriate antibiotic use in agriculture and clinical medicine,³⁶ and the Department of Health and Human Services announced a funding opportunity³⁷ to enhance monitoring of antibiotic usage and management practices regarding food-producing animals. Despite this renewed interest in monitoring on-farm antibiotic use, a recent USDA Office of Inspector General report on the Department's response to antibiotic resistance identified budget constraints, staff retention and gaps in communication and strategic planning as factors hindering the development of a strong USDA surveillance program on animal antibiotic use. The Department should use this review to address these concerns.

VIII. FSIS should not use regulatory review to justify eliminating rules or requirements in the absence of strong evidence that such changes will significantly improve public health.

1. Regulatory review should not support expanding programs to “modernize” inspection by replacing USDA inspectors with company employees.

We oppose using this review to eliminate or weaken current rules or requirements that would not markedly improve public health. As indicated above, the New Poultry Inspection System (NPIS) illustrates the hazards of that approach. NPIS presumes that company employees can perform USDA inspectors' same slaughter line duties without diminishing the safety or

³² Institute of Medicine (2010) Enhancing the Safety of the Food Supply, Report Brief. *National Academy of Sciences*. Accessed 4/14/16 at: <http://www.nationalacademies.org/hmd/~media/Files/Report%20Files/2010/Enhancing-Food-Safety-The-Role-of-the-Food-and-Drug-Administration/Enhancing%20Food%20Safety%202010%20Report%20Brief.ashx>

³³ FDA. Questions and Answers: Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals. Question 2. Updated 10/02/14. Accessed 04/15/14 at: <http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm236149.htm>

³⁴ USDA's Animal and Plant Health Inspection Service (APHIS) can inspect animal farms to investigate animal diseases, while FDA conducts animal on-farm inspections in collaborations with the states through: 1) the Pasteurized Milk Ordinance that specifies Grade A milk standards and requires antibiotic residue testing to the National Milk Drug Residue Data Base (NMDRDB), and 2) the Prevention of Salmonella Enteritidis in Shell Eggs During Production, Transportation, and Storage Act (74 FR 33030), which requires on-farm visits of egg-laying facilities.

³⁵ About 10% of APHIS' 2017 budget, as listed in the House Appropriations Bill.

³⁶ U.S. House of Representative. 114th Congress, Second Session. AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2017. REPORT, p.27. Accessed 04/20/16 at: <http://appropriations.house.gov/uploadedfiles/hrpt-114-hr-fy2017-agriculture.pdf>

³⁷ HHS Center for Veterinary Medicine. Antimicrobial Use & Resistance Data Collection (U01); RFA-FD-16-046. Accessed 04/20/16 at: <http://grants.nih.gov/grants/guide/rfa-files/RFA-FD-16-046.html>

wholesomeness of the poultry produced. The data, however, suggests otherwise. Prior to the new rule, the agency had been conducting a pilot project using the inspection model in some 25 poultry slaughter plants since 1998. FSIS compared the *Salmonella* rates in the pilot plants with those in comparably sized plants that received conventional inspection, and in the most recent years leading up to the rule change, the agency's evaluations indicated that the poultry slaughtered in the pilot plants had higher *Salmonella* rates.³⁸ Nevertheless, the department dismissed these differences as insignificant, and ignored the corollary that the pilot project would fail to generate any marked improvement in food safety.

When the department finalized the NPIS rule, it claimed that increased testing requirements on plants shifting to the new system would yield safer poultry. Yet FSIS officials have indicated that the agency is not comparing testing data from the NPIS plants with data from similar plants under alternative inspection regimes.³⁹ FSIS should hasten to follow through on its promise to verify the theoretical claims it made in support of the final NPIS rule, and give the public access to sufficient information to evaluate those claims.

Until FSIS can provide such information, the agency should not seek to expand similar inspection models to other species under its jurisdiction. Last year, Deputy Under Secretary for Food Safety/Acting FSIS Administrator Alfred Almanza stated his intention to propose a rule to expand HIMP in hog slaughter from the current five pilot plants to all hog slaughter plants.⁴⁰ As with chicken, no evidence indicates that the hog HIMP pilot renders safer and more wholesome pork. To the contrary, a May 2013 audit report from the USDA Office of Inspector General questioned FSIS oversight of the program and pointed out that some of the hog HIMP pilot plants had some of the highest numbers of non-compliance reports filed against them by USDA inspectors. An FSIS November 2014 evaluation of the pilot confirms that hog HIMP has not led to any substantiated improvements in food safety, and a bipartisan letter signed by 60 members of Congress outlines the shortcomings of any effort to move forward with a proposed rule expanding hog HIMP.⁴¹ For reasons similar to those cited in that letter, we urge the agency to forego any attempt to expand HIMP as part of a regulatory reform package.

2. Regulatory reform should not support eliminating port-of-entry inspections.

As part of the Beyond the Border Action Plan, an outgrowth of the U.S.-Canada Regulatory Cooperation Council, FSIS worked with the Canadian Food Inspection Agency (CFIA) to develop a proposed "pre-clearance" pilot project.⁴² The pilot would have allowed certain Canadian meat processors to ship their products to the U.S. without the benefit of port-of-entry inspection. The Safe Food Coalition has opposed and will continue to oppose adopting this pilot program until

³⁸ See FSIS. "Evaluation of HACCP Inspection Models Project (HIMP)" (Aug. 2011) at p. 26, Table 3-12 (indicating that a comparison group of establishments under traditional inspection had lower *Salmonella* rates for the most recent two years analyzed) available at: http://www.fsis.usda.gov/shared/PDF/Evaluation_HACCP_HIMP.pdf

³⁸ 79 Fed. Reg. 49574 (August 21, 2014).

³⁹ Safe Food Coalition / FSIS Stakeholders Meeting (February 25, 2016).

⁴⁰ See House Committee on Agriculture Hearing Transcript, Serial No. 114-26, p. 168 (Sept. 15, 2015) available at: <https://www.gpo.gov/fdsys/pkg/CHRG-114hhrg96269/pdf/CHRG-114hhrg96269.pdf>

⁴¹ Letter from 60 members of Congress to Secretary of Agriculture Tom Vilsack (Jan. 19, 2016) available at <http://delauero.house.gov/images/pdf/1.19.16HogHIMPLetter.pdf>.

⁴² See CFIA. "Update: Beyond the Border (BtB) Pre-clearance Initiative Pilot Project on Import Re-inspection Activities for Fresh Meat" available at: <http://www.inspection.gc.ca/food/meat-and-poultry-products/program-changes/update-beyond-the-border/eng/1348789386214/1348789475806>. BETTER CITATION FOR THIS?

Canadian authorities take action to resolve important deficiencies in the Canadian meat inspection system. For example, Canada must conduct comparable testing for *Listeria monocytogenes* (*Lm*) at establishments producing ready-to-eat products, including environmental testing for *Lm* in food plants, consistent with U.S. requirements.

The Coalition also opposes the pilot because Canada has eliminated important food safety controls. In particular, Canada has implemented a form of HIMP in some of its beef slaughter plants, while in the U.S. there has not even been a pilot to test that inspection model for bovines. In fact, during the deliberations on the Beyond the Border pilot between FSIS and the CFIA in 2012, Canada experienced the largest meat recall in its history. Eighteen Canadian consumers were made ill from meat that was contaminated with *E. coli* O157:H7. USDA inspection personnel fingered the source of the contamination as the XL Foods plant in Alberta, which was operating under a HIMP-style inspection model. Nearly 4 million pounds of beef products from that plant were eventually recalled, including 2.5 million that had been exported to the U.S. The recall effectively stymied the Beyond the Border pilot, and with good reason. The incident underscores the need to maintain a robust import inspection system for Canadian meat imports. This holds particularly true as Canada continues to pursue dramatic cuts to the Canadian Food Inspection Agency's budget.⁴³

3. Regulatory review should not support delaying needed rules from taking effect.

We commend FSIS for the steps it has taken to protect consumers. During the past year, FSIS has issued new performance standards for *Salmonella* and *Campylobacter* in ground poultry and poultry parts, a final rule to require detailed recordkeeping from retail establishments that grind and sell raw beef products, and a final rule to require labeling of mechanically tenderized beef products. FSIS supported these actions with substantial evidence. For example, in its federal register notice announcing the final rule on labeling for mechanically tenderized beef products, the agency included detailed estimates of illnesses avoided and related economic benefits that will accrue from the new requirements.⁴⁴ This regulatory review process should not delay the roll out of these important food safety protections.

Nor should the process lead the agency to eliminate or weaken the new mandatory inspection program for fish of the order *Siluriformes* ("catfish") and catfish products.⁴⁵ Nearly eight years have passed since Congress directed the agency to develop the catfish inspection program. FSIS has held numerous public meetings in the U.S.,⁴⁶ as well as technical meetings abroad to explain U.S. import requirements to achieve equivalency status under the inspection regime.⁴⁷ Opposition from Vietnam or other importers should not deter FSIS from following through on the

⁴³ See, e.g., "Ottawa needs to beef up food safety: Editorial" (March 2, 2016) available at:

<http://www.thestar.com/opinion/editorials/2016/03/02/ottawa-needs-to-beef-up-food-safety-editorial.html>

⁴⁴ 80 Fed. Reg. 28153, at 28154 – Table 1 (May 18, 2015).

⁴⁵ 80 Fed. Reg. 75589 (Dec. 2, 2015).

⁴⁶ See, e.g. <http://www.fsis.usda.gov/wps/wcm/connect/084b5294-bcb6-4e33-b2f6-49afae3dbedc/Siluriformes-Educational-Meeting-Slides-012716.pdf?MOD=AJPERES>; <http://www.fsis.usda.gov/wps/wcm/connect/08882606-90dd-4934-9436-a0099cacd27e/Siluriformes-Meeting-030316.pdf?MOD=AJPERES>

⁴⁷ See "Asian Catfish Producers Line Up to Qualify to Ship to U.S.," Agri-Pulse, March 9, 2016, pp. 10-11.

implementation of this new inspection regime.⁴⁸ The program will improve the current regulatory regime and afford a safer domestic, and imported, supply of catfish.⁴⁹

IX. Conclusion

The Safe Food Coalition appreciates the opportunity to submit these comments and looks forward to continuing our work with FSIS and the Department's other agencies to protect consumers from foodborne illness.

Sincerely,

Center for Foodborne Illness Research & Prevention

Center for Science in the Public Interest

Consumer Federation of America

Consumers Union

Food & Water Watch

STOP Foodborne Illness

⁴⁸ *See, e.g.*, World Trade Organization, Committee on Sanitary and Phytosanitary Measures. "Comments of Viet Nam on the New Regulation of the United States on Mandatory Inspection of Catfish and Catfish Products," March 18, 2016. *See also* Nixon, Ron. "U.S. Catfish Program Could Stymie Pacific Trade Pact, 10 Nations Say," *New York Times*, June 27, 2014; Office of the U.S. Trade Representative. "U.S.-VN Letter Exchange on Catfish," February 4, 2016 *available at*: <https://ustr.gov/sites/default/files/TPP-Final-Text-US-VN-Letter-Exchange-on-Catfish.pdf>

⁴⁹ *See, e.g.* Tuoi Tre News. "Overuse of antibiotics in food causes scare in Vietnam" (Apr. 20, 2016) *available at*: <http://tuoitrenews.vn/society/34371/over-use-of-antibiotics-in-food-sparks-concerns>