



Consumer Federation of America

September 15, 2017

The Honorable George “Sonny” Perdue III
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250

Re: Identifying Regulatory Reform Initiatives (ID: USDA-2017-0002-0001)

Dear Secretary Perdue:

Consumer Federation of America submits this letter in response to the U.S. Department of Agriculture’s request for “ideas on regulations, guidance documents, or any other policy documents that are in need of reform.” This notice, and Executive Order 13777 more generally, proceeds from the premise that excessive federal government regulation inhibits job creation, imposes arbitrary constraints, and makes Americans poorer. This premise undoubtedly holds true in some cases. For decades, academic researchers have described the phenomenon of “capture,” in which “regulation becomes ‘a method of subsidizing private interests at the expense of a public good.’”¹ At the same time, inadequate regulation in defense of the public good can be bad for business, stymying job creation and destroying wealth. This is easy to see in the case of food safety, where an outbreak caused by one unchecked bad actor can cripple an industry for years, generating millions or even billions of dollars in losses.²

These comments focus on the role of USDA’s Food Safety Inspection Service, or FSIS, and reforms that would help it advanced its stated mission: “Protecting the public’s health by ensuring the safety of meat, poultry, and processed egg products.” This mission is vital to Americans’ economic well-being, and to the economic vitality of the food industry. Foodborne illness is a serious national public health problem and increasingly a serious trade issue. There is a steady stream of highly publicized foodborne illness outbreaks and large recalls of contaminated foods ranging from ground turkey to chicken breasts to cucumbers, frozen strawberries, and papaya. Public opinion research shows that over the past four years Americans have lost confidence that the food they eat and feed their children is safe. Concern about the safety of imported food, especially from China, is a potential threat to international food trade. Already under this Administration, FSIS has fueled these concerns by proposing a rule that would authorize poultry imports from China. In a similar vein, USDA has

¹ See Dion Casey, “Agency Capture: The USDA’s Struggle to Pass Food Safety Regulations,” 7 *Kan. J.L. & Pub. Policy* 142, 156 (Spring 1998) citing John Shepard Wiley Jr., *A Capture Theory of Antitrust Federalism*, 99 *Harv. L. Rev.* 713, 722 (1986) (internal citations omitted).

² See, e.g., Associated Press. “Peanut industry: Recall price tag \$1 billion” (March 11, 2009) available at: http://www.nbcnews.com/id/29634279/ns/business-going_green/t/peanut-industry-recall-price-tag-billion/#.V7M-ZJgrKUK; Huifang Zhang, Thomas L. Marsh, Jill J. McCluskey. “A Generalized Event Analysis of the 2006 E. coli Outbreak in Spinach and Lettuce” available at: http://www.impact.wsu.edu/MarshFiles/E.coli_paper_V1.pdf.

announced that the U.S. Codex Office will be removed from FSIS and placed in a newly created Trade and Foreign Agricultural Affairs office. These actions suggest an intent to subordinate food safety to trade interests.

To help navigate the inevitable conflicts that arise between food safety and trade liberalization goals, FSIS needs strong leadership. That is why this Administration must act quickly to appoint qualified public health expert to serve as Under Secretary for Food Safety. Congress created the Office of Under Secretary for Food Safety in 1994 to address recurring charges of conflicts of interest between the U.S. Department of Agriculture's marketing and promotion activities and its public health regulatory functions. The Under Secretary is the federal government's highest ranking food safety official, yet the position has remained vacant since Dr. Elisabeth Hagen resigned in 2013. The new Under Secretary should have a strong commitment to protecting public health, the expertise necessary to guide the policies and programs carried out by FSIS, and a record of working effectively to find new ways to reduce foodborne illness.

Several reforms to FSIS would create jobs and improve Americans' well-being, including significant financial benefits in the form of avoided medical costs, fewer sick days, and other savings. Currently, FSIS regulates meat and poultry, catfish, and processed egg products, under an antiquated legal framework. While passage of the Food Safety Modernization Act gave the U.S. Food and Drug Administration new authority to regulate food producers under its jurisdiction, FSIS has limited authority to issue recalls, enforce pathogen reduction standards, or address the root causes of foodborne illness, which often originate prior to animals coming through the slaughterhouse door. In some cases, USDA has exacerbated these problems with an exceedingly narrow interpretation of FSIS' authority. For food safety advocates, this reluctance to take action partly reflects the inherent conflict of interest at USDA between marketing foods and assuring their safety. For that reason, we have supported Representative DeLauro's and Senator Durbin's Safe Food Act, which would reorganize FSIS', FDA's, and other agencies' food safety functions into an independent single food safety agency. We have also supported proposals, such as in Senator Gillibrand's Safe Meat and Poultry Act, to modernize meat and poultry inspection by basing inspection intensity on product risk.

In addition to supporting these legislative reforms, many regulatory reforms would improve FSIS' capacity to ensure food safety. Specifically, FSIS should modify its interpretation of "adulterant" to include antibiotic resistant strains of Salmonella; modify and potentially eliminate the New Poultry Inspection System and analogous program for hogs on the basis of a quantitative food safety data analysis; modify rules on chicken processors' use of antimicrobial sprays and pathogen testing protocols to ensure that test results are accurate; increase incentives to control pathogens before they enter through the slaughterhouse door; update the Safe Handling Instructions label for raw meat and poultry and enforce existing labeling requirements; update out-of-date performance standards for various pathogens and products; and harness market forces to improve food safety by publishing establishment specific data that enables more discerning buyers to avoid underperforming firms. These reforms are detailed further below:

1. Define "adulterant" to include antibiotic resistant strains of Salmonella when found in meat and poultry.

The Federal Meat Inspection Act and the Poultry Products Inspection Act give FSIS the authority to shut down a plant operating under "insanitary conditions" if its products test positive for

an “adulterant.” FSIS has authority to decide what pathogens qualify as adulterants. Most recently, in 2011, the agency declared six serotypes of shiga-toxin producing *E. coli* (STECs) to be adulterants. FSIS treats *Salmonella*, however, as an indicator organism that is allowed to be present in up to 15 percent of some raw product samples. Poultry plants are not required to include *Salmonella* as a “hazard likely to occur,” in their hazard analysis and critical control point (HACCP) plans, and many processors do not work with growers or otherwise attempt to control *Salmonella* contamination in poultry before it enters the slaughterhouse door. The prevailing attitude is that *Salmonella* is unavoidable.³

Not all *Salmonella* poses an equal danger, however. Salmonellosis is the leading foodborne illness killer today in large part thanks to antibiotic-resistant strains of the pathogen that have become more prevalent in recent years. Even low levels of antibiotic-resistant strains of *Salmonella Heidelberg*, *Salmonella Hadar*, *Salmonella Newport*, and *Salmonella Typhimurium*, among others, can cause illness. FSIS should issue an interpretive rule that, similar to the 2011 STEC rule, classifies as adulterants antibiotic resistant strains of *Salmonella* linked to human illness.

Currently, the agency treats antibiotic-resistant *Salmonella* as if it were an adulterant on a case-by-case basis, reacting after an outbreak has occurred and prolonging the time that contaminated products sit on the shelves. This is largely in response to a 2001 decision by the Fifth Circuit Court of Appeals, *Supreme Beef v. USDA*, which ruled that *Salmonella* is not an “adulterant *per se*.” Since that decision, technologies such as whole genome sequencing have greatly improved the ability to distinguish the more dangerous, virulent, antibiotic resistant strains of *Salmonella* from other, comparatively benign strains. These technologies allow producers and inspectors to quickly identify *Salmonella*-contaminated products that are “injurious to public health” in the same manner as STEC-contaminated products.

2. Undertake a review of the New Poultry Inspection System and the pilot HACCP-based Inspection Models Project (HIMP) for hog slaughter and eliminate these programs if quantitative data cannot demonstrate that they improve food safety.

FSIS issued its final rule on the New Poultry Inspection System (NPIS) in August 2014 and at least 59 establishments are now operating under NPIS. The system transfers inspection responsibilities to plant employees, and redirects a reduced number of FSIS inspectors to focus less on carcass-by-carcass inspections and more on “off-line” food safety tasks such as microbial testing, records review, and plant and equipment sanitation. FSIS should collect and compare data from traditionally inspected establishments with those operating under NPIS to verify whether NPIS actually improves food safety.

We recognize the need to modernize FSIS inspection. However, no evidence currently available indicates that NPIS improves food safety. In 2012, when FSIS first proposed NPIS, the agency analyzed data from 20 young chicken slaughter establishments participating in the poultry

³ Some major companies, such as Walmart, are demonstrating just how underperforming FSIS *Salmonella* controls have become, with supplier requirements that necessitate on-farm interventions to drastically reduce the incidence of *Salmonella* contamination in chicken. See Coral Beach. “Wal-Mart’s chicken safety program shows significant results” *Food Safety News* (Aug.12, 2016), <http://www.foodsafetynews.com/2016/08/130453/#.WbwxssiGOUk> (“Before the new supplier requirements went into effect, 17 percent of the chicken parts provided to Wal-Mart were positive for *Salmonella*. By January this year that number was cut to 5 percent. By June this year only 2 percent of chicken parts from U.S. suppliers were testing positive for *Salmonella* . . .”).

HIMP pilot program, which the rule sought to expand. That data did not demonstrate that the pilot program reduced pathogen contamination better than, or even equivalent to, the traditional inspection regime. Agency modeling, however, supported the conclusion that NPIS “would likely result in” reduced contamination.

With NPIS fully implemented in at least 59 establishments, FSIS should verify whether this “likely result” has come to pass. Inexplicably, the agency reports that it is currently only looking at data at the “establishment level” to verify that each facility, whatever the inspection system, meets the minimum performance standards. At the same time, it has sought to move ahead with similar reforms for hog slaughter, based on pilot projects with similarly problematic food safety records. An ‘apples-to-apples’ comparison of pathogen contamination rates in NPIS and HIMP versus traditionally inspected plants is long overdue.

3. Reform FSIS rules on the use of antimicrobial processing aids to ensure the validity of pathogen testing and protect workers’ health.

When USDA established its Salmonella testing procedures in 1998, companies applied chemical interventions like chlorine earlier in the slaughter process. Processed carcasses would proceed to solutions in chillers at the end of the line, which would wash off and dilute the chlorine, or other anti-microbial agents that had been applied. Today, processors apply antimicrobial agents later in the process, including post-chill intervention sprays. Increased use of sanitizer sprays has created an occupational safety hazard at many establishments, and appears to have caused the death of at least one FSIS inspector at an upstate New York chicken processing facility.

In addition to hurting workers, increased sanitizer use has raised food safety concerns. In May 2016, the Agricultural Research Service published findings that the use of these sanitizer sprays tends to create false negatives in testing for Salmonella. FSIS responded by adopting a new testing solution, which appears to help neutralize the sanitizers’ effects, and has caused an uptick in positive test results for whole carcasses. However, more data is needed to support the new testing solution’s capacity to eliminate the false negative problem in Salmonella testing. Under no circumstances should the agency pass a new rule that relieves poultry plants of meeting Salmonella performance standards to account for more accurate testing, as some industry lobbyists have suggested.

4. Increase incentives to control pathogens before they enter through the slaughterhouse door.

Under the National Residue Program, FSIS tests for unlawful residues of antibiotics, pesticides and heavy metals in meat, and the agency traces back violations to the farm or feedlot. Livestock operations that deliver contaminated livestock for slaughter may end up on the “residue repeat violator” list posted on the FSIS website. This list helps processors and other livestock buyers to avoid sources of contamination, and provides an important incentive for compliance.

A similar program should exist for microbial adulteration of meat. Unlike chemical residues, pathogens grow and spread and so the risk of cross-contamination within the slaughterhouse is higher. Knowing that a contaminated sample came from a certain animal does not necessarily implicate the farm that delivered the animal to the slaughterhouse. With whole genome sequencing technology, however, FSIS or the establishments themselves can compare samples taken on-farm with those collected in the slaughterhouse to identify the origin of pathogens. FSIS does not have statutory authority to go on-farm, but through the Food Safety Assessment process—particularly when it is

triggered by noncompliance or a disease outbreak—the agency could provide incentives for plants to collect samples from their suppliers and conduct traceback investigations.

5. Update the Safe Handling Instructions label for raw meat and poultry and enforce existing labeling requirements.

By law, safe handling instructions must appear on the label of raw meat and poultry products. FSIS has not updated the rules for this labeling since 1994. Over the past two decades, research on consumer behavior and pathogen survival has demonstrated the need for clearer cooking instructions on labels. For example, labels should feature internal cooking temperatures rather than an ambiguous directive to “cook thoroughly.” FSIS also needs to ensure that retailers are complying with new rules for labels on meat and poultry products “injected with solutions,” and for labels on “mechanically tenderized beef” products. The latter rule, for example, requires that “product names . . . include the descriptive designation ‘mechanically tenderized,’ ‘blade tenderized,’ or ‘needle tenderized,’” yet some major retailers are ignoring this requirement. As a result, many consumers are not aware of the need to more thoroughly cook these comparatively high-risk products.

6. Develop more robust performance standards for Salmonella and Campylobacter.

Currently, FSIS Salmonella performance standards are based on the percentage of samples that test positive for Salmonella. For example, the performance standard for chicken parts is 15.4 percent. An establishment provides 52 samples over the course of a year (one a week), and no more than eight of those samples may test positive for Salmonella. If only seven samples test positive, the establishment is in compliance, even if the positive samples carry an extremely high pathogen load. Recent research, however, indicates that high pathogen loads correlate closely with salmonellosis risk. In other words, when comparing two plants, the one with fewer samples that test positive for Salmonella could nevertheless pose a higher risk to public health, if the Salmonella contamination that is detected is more severe.

Historically, testing to estimate the number of Salmonella pathogens on a positive sample was prohibitively expensive. However, enumerative testing technology has advanced considerably in recent years and some foreign jurisdictions, such as New Zealand, are using so-called semi-quantitative performance standards, in addition to prevalence-based standards. Under these standards, a plant has to meet a standard for the overall prevalence of Salmonella positive samples, and an additional standard for the number of samples that harbor a number of Salmonella colony-forming units (CFU) that exceed some defined threshold. FSIS will have to resolve many outstanding questions before establishing a similar semi-quantitative performance standard, including how will it define the CFU threshold for the standard, and how it will relate that standard to the current prevalence-based performance standards. An empirically justified standard, however, could potentially better focus inspection resources to improve public health.

7. Make publicly available establishment specific data as quickly and as comprehensively as possible, in a manner that makes the data actionable for wholesale buyers and individual consumers alike.

A more transparent food system is a safer food system. A recent USDA Economic Research Service (ERS) study confirms this as it relates to the availability of establishment

specific data on poultry processors. The ERS study reports that public disclosure of food safety performance correlated with reductions in *Salmonella* contamination in poultry. The ERS study focuses on the time period immediately after FSIS adopted its metric for poultry plant performance (Category 1, 2 or 3) under the *Salmonella* Initiative Program (SIP), which was then followed by a practice of posting plant compliance ratings on the agency website, and then a suspension of that practice, which continues today. The ERS researchers found that posting establishment specific data corresponded with substantial (4.5 percent) declines in the share of samples of broilers testing positive for *Salmonella*.⁴

FSIS has announced a plan for resuming publication of the poultry data,⁵ and some other establishment specific data, e.g. *Salmonella* and *Listeria* sampling data for egg products, is available online now.⁶ However, compared to the initial poultry data, with its category ratings that made clear which plants were above and below average, this data seems less likely to influence purchasing decisions. The prolonged rollout of the data release plan, which pegs the release of the dataset for turkey carcass sampling at July of 2018, is also concerning. FSIS should consider accelerating its dissemination of this data, and exploring how buyers and consumers can use it to create appropriate incentives for regulated establishments.

Thank you for considering these comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'Thomas Gremillion', with a stylized flourish at the end.

Thomas Gremillion
Director, Food Policy Institute
Consumer Federation of America

⁴ ERS Study. Public Disclosure of Tests for Salmonella: The Effects on Food Safety Performance in Chicken Slaughter Establishments, <https://www.ers.usda.gov/publications/pub-details/?pubid=83660>

⁵ FSIS Establishment Specific Data Release Strategic Plan (July 2016), <https://www.fsis.usda.gov/wps/wcm/connect/0803f8a0-a3cc-4945-87b6-f992acdca9b/Establishment-Specific-Data-Plan-Final.pdf?MOD=AJPERES>

⁶ FSIS. “Establishment-Specific Datasets: Laboratory Sampling Data” <https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/data/datasets-laboratory-sampling>