



## POLICY & ACTION FROM CONSUMER REPORTS

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Food Safety and Inspection Service  
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**Comments of Consumers Union to the  
U.S. Department of Agriculture Food Safety and Inspection Service on the Proposed Rule  
on Modernization of Swine Slaughter Inspection  
Docket No. FSIS-2016-0017**

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### Summary

Consumers Union, the policy division of Consumer Reports,<sup>1</sup> welcomes the opportunity to comment on the U.S. Department of Agriculture's (USDA) Food Safety Inspection Service proposed rule on modernization of swine slaughter inspection, and urges that it be withdrawn, since available evidence suggests that it would not increase, and may well decrease, food safety.

The proposed rule would establish a new voluntary inspection system for market hog slaughter establishment, called the New Swine Slaughter Inspection System (NSIS). The NSIS represents an expansion of a pilot program—the hog Hazard Analysis and Critical Control Point (HACCP)-based Inspection Models Project (HIMP)—that the FSIS has carried out in five market hog slaughter plants since 1998—to any market hog slaughter establishment. The hog HIMP reduced the number of federal (or FSIS) inspectors and turning over some inspection tasks of live animals and carcasses to plant employees, and removing limits on line speeds. In 2013, the USDA Office of Inspector General (OIG) published an audit of the Swine HIMP pilot program which found that “In the 15 years since the program’s inception, FSIS did not critically assess

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<sup>1</sup> Consumer Reports is an independent, nonprofit organization that works side by side with consumers to create a fairer, safer, and healthier world. As the world's largest independent product-testing organization, Consumer Reports uses its more than 50 labs, auto test center, and survey research center to rate thousands of products and services annually. Founded in 1936, Consumer Reports has over 7 million subscribers to its magazine, website, and other publications.

whether the new inspection process had measurably improved food safety at each HIMP plant.”<sup>2</sup> A recent study—based on food safety performance data obtained from USDA via the Freedom of Information Act (FOIA)—of the five hog HIMP plants and five comparably-sized hog plants operating under traditional inspection between January 2012 through November 2016, found that the hog HIMP plants had “significant violation including fecal contamination, sanitation issues and failure to remove diseased carcasses from the food chain.”<sup>3</sup>

In addition, FSIS is proposing several changes to *all* plants that slaughter swine (market hogs, roaster pigs, sows, and feral hogs). FSIS would require all swine slaughter plants to develop, implement, and maintain in their HACCP systems written procedures to prevent the contamination of carcasses and parts by enteric pathogens that can cause foodborne illness, fecal material, ingesta, and milk throughout the entire slaughter and dressing operation. These procedures must include sampling and analysis for microbial organisms to monitor process control for enteric pathogens. FSIS also proposes to remove the current requirement that swine plants test for generic *Escherichia coli*, the codified *Salmonella* pathogen reduction performance standards, and allow companies to determine their microbial testing.

Given no evidence that the hog HIMP has improved food safety and some evidence that food safety may actually be lower in HIMP plants, and that the NSIS would also remove current requirement for testing for *E. coli* and *Salmonella*, we urge FSIS to withdraw this rule, and seek out evidence-based reforms that will improve food safety. FSIS should also require microbial testing for pathogens such as *Salmonella*, *Yersinia enterocolitica*, shiga-toxin producing *E. coli* (STEC), and *Staphylococcus aureus*, and set pathogen reduction standards for these pathogens in pork and pork products.

## Detailed comments

### *Contaminated pork causes significant foodborne illness*

Pork is associated with significant number of foodborne illnesses, hospitalizations and death. According to an analysis of foodborne outbreak data from 1998-2008 by the Centers for Disease Control and Prevention (CDC), pork may cause up to almost one and a half million cases of foodborne illness in the U.S. each year, leading to up to 7,000 hospitalizations and up to almost 200 deaths.<sup>4</sup> CDC estimates that *Salmonella*, the most important foodborne pathogen, causes some 1.2 million illnesses, 23,000 hospitalizations and 450 deaths each year.<sup>5</sup> CDC

<sup>2</sup> U.S. Department of Agriculture Office of Inspector General (USDA OIG). 2013. Food Safety and Inspection Service-Inspection and Enforcement at Swine Slaughter Plants, Audit Report 24601-0001-41. At: <https://www.usda.gov/oig/webdocs/24601-0001-41.pdf>

<sup>3</sup> Food and Water Watch (FWW). 2018. New documents show privatized hog inspection scheme rife with food safety violations. At: <https://www.foodandwaterwatch.org/news/new-documents-show-privatized-hog-inspection-scheme-rife-food-safety-violations>

<sup>4</sup> See Fig. 2 in Painter, JA, Hoekstra RM, Ayers T, Tauxe RV, Braden CR, Angulo F and PM Griffin. 2013. Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998-2008. *Emerging Infectious Diseases*, 19(3): 407-415. At: <https://wwwnc.cdc.gov/eid/article/19/3/pdfs/11-1866.pdf>

<sup>5</sup> Centers for Disease Control and Prevention (CDC). 2018a. Salmonella. At: <https://www.cdc.gov/salmonella/index.html>

estimates that, while the percentage of foodborne illness outbreaks attributed to pork did not increase between 1998 to 2008, the percentage of *Salmonella* outbreaks attributed to pork have more than doubled.<sup>6</sup> Based on foodborne illness outbreak data from 2009 to 2013, pork causes 9.3% of the *Salmonella* outbreaks each year.

Pathogens other than *Salmonella* also have also been linked to pork. Pork consumption has been linked to a 2016 outbreak of *Staphylococcus aureus* and outbreaks in 2011<sup>7</sup> and 2014<sup>8</sup> of *E. coli* O157:H7. CDC estimates that the pathogen *Yersinia enterocolitica*, almost exclusively associated with pork (particularly chitlins/chitterlings), causes 117,000 illnesses, 640 hospitalizations, and 35 deaths each year.<sup>9</sup>

The U.S. has not made adequate progress in reducing pathogen-associated foodborne illness. A 2016, CDC report concluded that the U.S. is not on track to reach its public health goals for reducing food illnesses caused by *Salmonella* and *Campylobacter*.<sup>10</sup> In addition, CDC data show that diagnosed *Yersinia* infections have increased almost three-fold between 2015 and 2017.<sup>11</sup> Given the lack of progress in reducing pathogen-associated foodborne illness, it is not surprising that pork products contain significant levels of pathogens. Consumer Reports tested 198 pork-chop and ground pork samples in 2012 found *Yersinia* in 69% of the samples, *Enterococcus* (which can be associated with urinary-tract infections) in 11%, *Staphylococcus aureus* in 7%, *Salmonella* in 4% and *Listeria monocytogenes* in 3%.<sup>12</sup> Based on these data, FSIS should clearly do more to protect the public from contaminated pork.

#### *NSIS would increase food safety risks*

The proposed NSIS differs significantly from traditional hog slaughter inspection. The NSIS represents an expansion of a pilot program—the hog Hazard Analysis and Critical Control Point (HACCP)-based Inspection Models Project (HIMP)—that the FSIS has carried out in five market hog slaughter plants since 1998—to any market hog slaughter establishment. The hog HIMP supposedly “allows innovation and flexibility” by reducing the number of federal (or FSIS) inspectors and turning over some inspection tasks of live animals and carcasses to plant

<sup>6</sup> Fig. 10 and Fig. 14 in Gould IA, Walsh KA, Vieria AR, Herman K, Williams IT, Hall AJ and D Cole. 2013. Surveillance of Foodborne Disease Outbreaks—United States, 1998-2008. *MMWR*, 62(2): June 28, 2013. At: <https://www.cdc.gov/mmwr/pdf/ss/ss6202.pdf>

<sup>7</sup> Trotz-William LA, Mercer NJ, Walters JM, Maki AM and RP Johnson. 2012. Pork implicated in a shiga-toxin producing *Escherichia coli* O157:H7 outbreak in Ontario, Canada. *Canadian Journal of Public Health*, 103(5): e322-e326. At: <http://journal.cpha.ca/index.php/cjph/article/view/3287/2695>

<sup>8</sup> Honish L, Punja N, Nunn S, Nelson D, Hislop N, Gosselin G, Stashko N and D Dittrich. 2017. *Escherichia coli* O157:H7 infections associated with contaminated pork products—Alberta, Canada, July-October 2014. *MMWR*, 65: 1477-148. At: <https://www.cdc.gov/mmwr/volumes/65/wr/mm6552a5.htm>

<sup>9</sup> CDC. 2018c. *Yersinia*. At: <https://www.cdc.gov/yersinia/>

<sup>10</sup> CDC. 2017. Healthy People 2020 Midcourse Review, Chapter 14 Food Safety. At: <https://www.cdc.gov/nchs/data/hpdata2020/HP2020MCR-C14-FS.pdf>

<sup>11</sup> Marder EP, Griffin PM, Cieslak PR, et al. 2018. Preliminary incidence and trends of infections with pathogens transmitted commonly through food—foodborne diseases active surveillance network, 10 U.S. sites, 2006-2017. *MMWR*, 67(11): 324-328. At: <https://www.cdc.gov/mmwr/volumes/67/wr/mm6711a3.htm>

<sup>12</sup> Consumer Reports. 2013. Pork chops and ground pork contaminated with bacteria. At: <https://www.consumerreports.org/cro/magazine/2013/01/what-s-in-that-pork/index.htm>

employees, and removing limits on line speeds. However the program has been seriously criticized by the OIG and GAO.

The hog HIMP pilot began in 1998 and involved five large market hog slaughter plants that volunteered to be part of the project.

Some 15 years later, in 2013, the USDA OIG audited FSIS' inspection and enforcement activities at hog slaughter plants to determine if they complied with food safety and humane handling laws. As part of the audit, FSIS looked at the five hog HIMP pilot plants. Although the goals of the hog HIMP "were to increase food safety and plant efficiency," the programs appears to have done the opposite. In terms of food safety, if a slaughter plant does not meet all regulatory food safety requirements, the plant will be issued a non-compliance record (NR). The OIG audit found that "3 of the 10 plants cited with the most NRs from FY 2008 to 2011 were HIMP plants. In fact, the swine plant with the most NRs during this timeframe was a HIMP plant—with nearly 50 percent more NRs than the plant with the next highest number."<sup>13</sup> The fact that 3 of the 10 hog plants with the most NRs are HIMP plants is surprising, given that there are 612 market hog slaughter plants. Thus, 60% (three of five) of the HIMP plants are in the top ten plants with the most NRs, while only 1.1% (7 of 607) of the non-HIMP plants are in the top ten. Clearly, HIMP plants are vastly overrepresented in the top 10 plants with the most NRs.. The OIG concluded as follows.

First, the OIG found that that were no measurable improvement in food safety and called on FSIS to "critically assess whether the new inspection process had measurably improved food safety at each HMP plant, a key goal of the program."<sup>14</sup> OIG called on FSIS to "evaluate HIMP plants' noncompliance histories and allow only those plants with a strong history of regulatory compliance to remain in the program."<sup>15</sup>

Second, at one of the five HIMP plants, there was no manual inspection of viscera for signs of disease or contamination, which is a key safety inspection that FSIS requires. As the OIG noted, "All other swine slaughter plants in the US manually inspect the viscera since some signs of disease and contamination can be detected only through manual inspection. Examples include tuberculosis nodules embedded within lymph nodes, parasites within the intestine, and inflamed or degenerated organs that are unusually sticky to the touch or excessively firm."<sup>16</sup>

The U.S. Government Accountability Office (GAO) issued a report in 2013 that questioned the ability of FSIS to make valid conclusions about whether the HIMP plants would ensure equivalent, if not better, level of food safety compared to non-HIMP plants.<sup>17</sup> More specifically, GAO noted some serious limitations on the ability to make comparisons between HIMP and non-HIMP plants. First, GAO noted that the chicken, swine and turkey HIMP pilot

<sup>13</sup> Pg. 17 in USDA OIG. 2013. *Op cit*.

<sup>14</sup> *Id*.

<sup>15</sup> Pg. 18 *Id*.

<sup>16</sup> *Id*.

<sup>17</sup> U.S. Government Accountability Office (GAO). 2013. Food Safety: More Disclosure and Data Needed to Clarify Impact of Changes to Poultry and Hog Inspections. GAO-13-775. At: <https://www.gao.gov/assets/660/657144.pdf>

programs did not analyze data for the majority of years of the pilot project in its evaluation. For the hog HIMP, FSIS only looked at data from, at most, 6 of the 15 years since the hog HIMP began in 1998. Second, the microbial sampling, FSIS did not collect samples from the same plants for each year, but used data collected as part of its microbial sampling program. Third, data from only five market hog plant cannot provide reasonable assurance that any conclusions would apply to the 607 hog plants in the US both because of the small sample size and because the five hog HIMP plants were self-selected and thus likely higher performing plants than others in the industry. GAO also cited stakeholder concerns that increased off-line inspections would not compensate for inadequate training of sorters, higher line speeds, and FSIS inspectors' reduced ability to see potential defects and to enforce standards such as zero tolerance for fecal contamination.<sup>18</sup> Finally, GAO concluded that “[w]ithout collecting and analyzing additional data, it will be difficult for USDA to draw conclusions about whether the pilot project for young hog plants is meeting its purpose.”<sup>19</sup>

*FSIS evaluation of hog HIMP and the risk assessment are severely flawed*

In response to the OIG audit, FSIS agreed to prepare a report that “will include an analysis of hog HIMP establishments’ performance compared to non-HIMP establishments as well as their performance with respect to performance standards established by an independent consulting firm contractor.”<sup>20</sup> To date, neither FSIS nor an independent contractor has established such performance standards for pork, or compared HIMP plants to non-HIMP plants.

FSIS published their evaluation of the HIMP for market hogs in November 2014 and concluded that the hog HIMP “are performing as well as comparable large non-HIMP market hog establishments and meeting FSIS expectations.”<sup>21</sup> However, the report does not support this weak conclusion. The FSIS evaluation assumes “that the number of inspection tasks performed per establishment is correlated with production of a safe product,”<sup>22</sup> but does not justify that assumption because it does not demonstrate the relationship of those inspection tasks to food safety performance. With respect to microbial testing, the report admits that the *Salmonella* performance standard testing did not reveal any statistically significant improvements in the five HIMP plants compared to the 21 non-HIMP comparison plants (they are all large market hog slaughter plants), in part due to small sample size. The deficiencies in the hog HIMP report were provided in a January 19, 2016 letter to then Secretary of Agriculture Vilsack signed by 64 members of Congress.<sup>23</sup>

A recent study<sup>24</sup> looking at food safety performance data (e.g., NRs) obtained from USDA via the Freedom of Information Act (FOIA) of the five hog HIMP plants and five

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<sup>18</sup> Pp. 19-21 in *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> Pg. 19 in USDA OIG. 2013. *Op cit.*

<sup>21</sup> USDA Food Safety Inspection Service (FSIS). 2014. Evaluation of HACCP Inspection Models Project (HIMP) for Market Hogs. Final Report. At: [https://www.fsis.usda.gov/shared/PDF/Evaluation\\_HACCP\\_HIMP.pdf](https://www.fsis.usda.gov/shared/PDF/Evaluation_HACCP_HIMP.pdf)

<sup>22</sup> Pg. 34 in *Id.*

<sup>23</sup> <https://delaware.house.gov/sites/delauro.house.gov/files/Hog-HIMP-Letter-1-19-16.pdf>

<sup>24</sup> FWW. 2018. *Op cit.*

comparably-sized hog plants operating between January 2012 through November 2016 under traditional inspection. The study found that the hog HIMP plants had “significant violation including fecal contamination, sanitation issues and failure to remove diseased carcasses from the food chain.” The hog HIMP plants received 84% of the NRs filed for problems with the food safety (HACCP) plans; 73% of the NRs filed for carcass contamination with feces, bile, hair or dirt; 65% of the reports filed for general carcass contamination; and 61% of the NRs filed for equipment sanitation. Thus, the hog HIMP plants have clearly not improved food safety and even may have decreased food safety.

FSIS published a risk assessment of the potential change in human risk of *Salmonella* associated with NSIS in January, 2018.<sup>25</sup> The results of the risk assessment were used to support the NSIS. However, the risk assessment has serious technical and procedural flaws. The risk assessment employed a stochastic simulation model using multi-variable logistic regressions to identify correlations between (1) the numbers of offline food-safety inspections procedures and (2) contamination of hog carcasses with *Salmonella*. The risk assessment found that increased numbers of offline food-safety procedures, particular unscheduled offline procedures, led to a statistically significant decrease in *Salmonella* contamination of hog carcasses. The correlations were used to predict the potential effect that devoting more resources to those offline procedures might have on human illness associated with consumption of pork products. As the proposed rule points out, the modelling predicts that, under a specific scenario of increased off-line inspection tasks, *Salmonella* illnesses due to consumption of pork products will decrease by 3.8% (or 2,533 fewer *Salmonella*-related illnesses) per year. Since “HIMP establishments have demonstrated the capacity for FSIS inspectors to conduct up to 50% more offline procedures than in non-HIMP establishments,” FSIS concludes that converting more plants to HIMP will lead to decreases in *Salmonella* rates.

On the surface, the results do not seem to make much sense, since if conducting more offline procedures at HIMP plants reduces *Salmonella* contamination, why are there no statistically significant reductions in *Salmonella* in the HIMP plants compared to the appropriate non-HIMP plants? Note that from 2006 through 2009 the *Salmonella* positive rate for market hogs was lower than those in non-HIMP plants but were higher in 2010.<sup>26</sup> Data from a baseline *Salmonella* study<sup>27</sup> from August 2010 through August 2011 found that the *Salmonella* contamination rate for carcasses in the HIMP plants was almost one-half the value of the rate in comparable non-HIMP plants—0.69% and 1.35%, respectively—but the difference was not statistically significant. However, since the HIMP plants have been running since 1998, FSIS has no real explanation of why the *Salmonella* positive rates for carcasses are sometimes higher in HIMP and sometimes lower.

Perhaps a more serious problem with the risk assessment is that it is based on the results of the *Salmonella* verification testing program, which FSIS discontinued in 2011 because the

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<sup>25</sup> USDA FSIS. 2018. Assessment of the Potential Change in Human Risk of *Salmonella* Illnesses Associated with Modernizing Inspection of Market Hog Slaughter Establishments. At: <https://www.fsis.usda.gov/wps/wcm/connect/0c03ed4d-68bf-4bd9-80e0-b8f3aa6ff16e/ModernizationSwineSlaughterRiskAssessment.pdf?MOD=AJPERES>

<sup>26</sup> Table 3-17 in USDA FSIS. 2014. *Op cit*.

<sup>27</sup> Table 3-18 *Id*.

contamination rates were so low—averaging less than 2%—and, thus, “was not an effective use for verifying process control.” Those results, along with the corresponding data on inspection tasks from 2010 and 2011 are out-of-date.

There are more up-to-date data that could be used for this risk assessment. Though FSIS stopped *Salmonella* carcass testing for market hogs in 2011, beginning in 2015, they started sampling not carcasses, but various raw pork parts, particularly intact cuts, non-intact cuts (which have been blade-tenderized) and comminuted pork parts (ground pork, sausage, patties, advanced meat recovery, etc.).<sup>28</sup> In the most recent pork parts testing study, from June 2017 through March 2018, FSIS tested 1,076 samples of intact pork cuts, 1,002 non-intact cuts, and 1,374 comminuted pork products, and the percent positive for *Salmonella* were 10.1% (109 positive), 7.0% (70 positive) and 21.4% (294 positive), respectively.<sup>29</sup> In contrast, as pointed out in the proposed rule, the *Salmonella* risk assessment model “estimates that the prevalence of *Salmonella* detected in carcasses will decline on average from an initial prevalence of 0.9407% to a final prevalence of 0.9066% if the 35 establishments identified adopt the new inspection system.”<sup>30</sup> Thus, *Salmonella* levels on pork products are far higher, from 7.4 fold to 22.7 fold higher, compared to estimated levels on carcasses from the risk assessment. In addition, FSIS has stated that it will be developing new performance standards for *Salmonella* for pork parts. However, FSIS has not shown any data or analysis that indicates that the NSIS would improve food safety by reducing *Salmonella* contamination in pork parts. Although FSIS may maintain that NSIS is for large slaughter plants and that most processing is done at other plants where the higher contamination rates are due to cross contamination, a 2005 survey of the meat industry by found that “[m]ore than 80 percent of meat plants also perform processing activities.”<sup>31</sup> Since the large majority of slaughter plants also process meat, the contamination rate of the products should be very relevant to the assessment of their “process control.”

The fact that the risk assessment was based only on testing market hog carcasses for *Salmonella*, which FSIS had discontinued due to low *Salmonella* contamination rates not including far higher contamination rates in pork parts is very troubling. We urge FSIS to redo the risk analysis model using data from the *Salmonella* parts testing when that testing has been finalized.

There is also a procedural flaw with the risk assessment. Since 2004, the Office of Management and Budget (OMB) has required that “important scientific information be peer reviewed by qualified specialists before it is disseminated by the federal government.” The peer review process must be “transparent by making available to the public the written charge to the peer reviewers, the peer reviewers’ names, the peer reviewers’ report(s), and the agency’s

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<sup>28</sup> USDA FSIS. 2017. Raw Pork Products Exploratory Sampling Program. At: <https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/special-sampling-projects/raw-pork-sampling>

<sup>29</sup> <https://www.fsis.usda.gov/wps/wcm/connect/68f5f6f2-9863-41a5-a5c4-25cc6470c09f/Sampling-Project-Results-Data.pdf?MOD=AJPERES>

<sup>30</sup> Pg. 4811 in 83 FR 2

<sup>31</sup> Pg. 5-2 in Cates SC, Viator CL, Karns SA and PH Siegel. 2005. Survey of Meat and Poultry Slaughter and Processing Plants. At: [https://www.fsis.usda.gov/shared/PDF/SRM\\_Survey\\_Slaughter\\_&\\_Processing\\_Plants.pdf](https://www.fsis.usda.gov/shared/PDF/SRM_Survey_Slaughter_&_Processing_Plants.pdf)

response to the peer reviewers' report(s)."<sup>32</sup> The FSIS risk assessment is clearly the type of document that should undergo peer review, since OMB states that "in the context of risk assessments, it is valuable to have the choice of input data and the specification of the model reviewed by peers before the agency invests time and resources in implementing the model and interpreting the results." More specifically, if the risk assessment "is a critical component of rule-making, it is important to obtain peer review before the agency announces its regulatory options" because "[if] a review occurs too late, it is unlikely to contribute to the course of the rulemaking." Early peer review "may provide net benefit by reducing the prospect of challenges to a regulation that later may trigger time consuming and resource-draining litigation."<sup>33</sup> Although the risk assessment began in early 2018, it will not be completed until after the comment period on the NSIS is over. Clearly, FSIS has not fulfilled OMB's requirements for timeliness and transparency of the peer review process.

Given the procedural and technical flaws in the *Salmonella* risk assessment FSIS should withdraw it and remedy the flaws before proceeding with rulemaking. In addition, FSIS should develop performance standards that are designed to reduce microbial contamination

*Procedures to address enteric pathogens, fecal material, ingesta, and milk contamination as hazards likely to occur.*

The NSIS also has three mandatory provisions for all swine slaughter plants that are designed to reduce microbial contamination of pork and pork products: providing written plans on how to prevent microbial contamination of carcasses throughout the entire slaughter and dressing operations, develop microbial sampling plans to demonstrate process control (e.g. that pathogens levels are significantly reduced between pre-slaughter and post-slaughter, and develop environmental microbial sampling).

FSIS is proposing to require that all swine slaughter plants, as part of the food safety (HACCP) system, develop, implement and maintain written procedures to ensure that no visible fecal material, ingesta or milk is present by the point of post-slaughter inspection. The present system, where microbial testing occurs at the end of the process, e.g. after the animal has been slaughtered and chilled, encourages industry to focus primarily on taking action on post-slaughter interventions, while the new system encourages them to focus on prevention throughout the slaughter process so as to contain microbial contamination as close to the origin as possible, so that cross contamination of carcasses does not occur. The plants will be required to keep daily written records to document the implementation and monitoring of their process control procedures. Requiring plants to keep daily records as part of their HACCP plan, will allow both the plants and FSIS to identify specific points in the production process where a lack of process control results in microbial contamination or insanitary conditions. We agree with FSIS that plants should be required to develop such written plans and incorporate them into their HACCP plans.

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<sup>32</sup> Pg. 2,3 in Office of Management and Budget (OMB). 2004. MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES: Issuance of OMB's "Final Information Quality Bulletin for Peer Review. At: <https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2005/m05-03.pdf>

<sup>33</sup> Pp 14, 15 in *Id.*



Under the NSIS, plants would have to develop microbial sampling plans to demonstrate process control. The proposed rule would require plants to do microbial sampling at two points—after the animal has been killed and the hide removed, but before the animal has been eviscerated (e.g. when the internal organs are removed from the carcass), and after the animal has been dressed, e.g. put into the chiller. This is a marked improvement over present microbial testing, which is just done at the post-chill stage. By sampling the same carcass at the pre-evisceration and post-chill, it is much easier to see if your process control system is working, as you would expect the level of microbial contamination to dramatically decrease between these two points. When the microbial sampling is only done at the end of the process, it is very hard to know how contaminated the animal before it was eviscerated. We commend FSIS for requiring sampling at two points in the slaughter process.

FSIS also proposes to prescribe a minimum frequency with which plants would be required to collect two samples, one at pre-evisceration and one at post-chill. Under the proposed rule, except for very small and very low volume plants, plants would be required to collect samples at a frequency of one per 1,000 carcasses (same as for the old generic *E. coli* sampling), such that the same carcass would be tested at both the pre-evisceration and post-chill stage. This would give good evidence of how well the process control system works. We agree with this proposed sampling frequency.

At the present time, plants must monitor their process control by sampling generic *E. coli* (as indicator organism). Since *E. coli* is found in the gut, its presence on the carcass is evidence of fecal contamination. Presently, high volume establishments are required to take one sample per 1,000 carcasses. There is also a requirement to test for a pathogen, usually *Salmonella*. So, presently all plants must test for both an indicator organism (e.g., *E. coli*) and a pathogen at a specific frequency. The proposed NSIS would waive the *E. coli* testing requirements and also cancel the *Salmonella* verification sampling. The NSIS would allow the company to decide what to test—an indicator organism (such as *E. coli*, *Enterococcus*, or aerobic plate counts) or a pathogen of their choosing, e.g. *Salmonella*, *Yersinia enterocolitica*, *Staphylococcus aureus*, etc.), but they would not be required to test for both an indicator organism and a pathogen.

In addition, FSIS is proposing to allow plants to substitute alternative locations to pre-evisceration and post-chill, as long as the alternative sampling locations provide improvement in monitoring process control than at pre-evisceration and post-chill. In addition, FSIS is proposing to allow plants to substitute alternative sampling frequencies as well.

We strongly disagree with letting the company make the decision on what to test for, where to test, and how frequently to test, as this could open the door to abuse and potentially unsafe food. Under the proposed NSIS, a company could decide to test for an indicator organism and not test for any pathogen. We think this is unacceptable. We urge FSIS to require testing of one indicator organism and at least one, or more, pathogens. For the indicator organism, the companies should choose one that is as widespread as possible, thus making it easier to see evidence of how effective the process control, e.g., a reduction in bacteria level between pre-evisceration and post-chill, is.

We also do not believe that a company should be allowed to determine where the sampling should be done. We agree with FSIS that sampling should be at the pre-evisceration and post-chill stage. We also think that FSIS should require that the sampling frequency be no fewer than one in 1,000 and that each carcass sampled should be tested twice—at pre-evisceration and post-chilling.

The proposed rule does not mandate that plants meet specific performance standards for microbial testing. The rule has already cancelled the performance standard for *Salmonella* in carcasses of market hogs. We think that FSIS should require performance standards. Experience with performance standards in the poultry industry shows that having set goals (contamination frequencies) for pathogens such as *Salmonella* and *Campylobacter*, and making public the names of companies that are not meeting those goals works to reduce the levels of the various pathogens in poultry. This has been confirmed since levels of *Salmonella* in young chickens have declined significantly over the past 15 years. Thus, we urge FSIS to consider setting performance standards for various pathogens. FSIS should start by setting performance standards for *Salmonella* in pork parts. FSIS should also consider setting standards for both carcasses and parts for other pathogens found in hogs as well, such as *Yersinia enterocolitica*, shiga-toxin producing *E. coli* (STEC), and *Staphylococcus aureus*. In addition, the results of in-plant microbial testing data should be shared with FSIS.

#### *Allowing company employees to perform some of the ante-mortem inspection could create food safety risks*

Another problematic part of the NSIS is that it would allow untrained company employees to perform some of the pre-slaughter inspection activities now done by FSIS inspectors. FSIS inspectors are very highly trained to detect when an animal is sick with a potentially dangerous reportable disease or a foreign animal disease such as foot and mouth disease (FMD) or classic swine fever, which could have huge economic consequences. In addition, there are a number of diseases—such as swine vesicular disease, porcine enterovirus infection, or vesivirus infection—that cannot be distinguished from FMD just based on clinical signs. It takes a trained veterinarian to be able to detect the difference. While FSIS veterinarians have significant scientific training, the NSIS does not require plant employees who perform the pre-slaughter inspection task to have equivalent training. These company employees could condemn an animal and dispose of it without presenting it to an FSIS Veterinarian for disposal. Given the potential economic consequences of FMD, the possibility of that such an animal might be disposed of by a company employee who misdiagnoses the FMD as porcine enterovirus infection or vesivirus infection and does not present the condemned animal to an FSIS Veterinarian is dangerous.

#### *Environmental sampling*

FSIS is proposing to require that all official swine slaughter plants develop, implement, and maintain in their HACCP system written procedures to prevent contamination of the pre-operations environment by enteric pathogens. These procedures must include sampling and analysis of food contact surfaces in the pre-operational environment at a frequency adequate to monitor the plant's ability to maintain sanitary conditions in the preoperational environment. We

strongly support this proposed environmental sampling requirement. FSIS is proposing this environmental sampling because in 2015, 152 people became ill after eating a product produced at a plant where FSIS found evidence of insanitary condition, including tables and knives in the preoperational environment that were contaminated with *Salmonella*.

We also think that all the microbial testing data that the plants do should all be shared with FSIS.

Thank you for your consideration of our comments.

Sincerely,



Michael Hansen, Ph.D., Senior Scientist

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