



U.S. Department of Agriculture  
Food Safety and Inspection Service (FSIS)  
9 CFR Parts 301, 309, and 310 [Docket No. FSIS–2016–0017]  
RIN 0583–AD62  
Proposed Rule: Modernization of Swine Slaughter<sup>1</sup>

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The Institute for Agriculture and Trade Policy (IATP)<sup>2</sup> appreciates this opportunity to comment on the proposed rule. Some of the provisions in the proposed rule should not be controversial. For example, so long as FSIS provides training requirements for plant employees to sort out ante mortem swine prior to their inspection by FSIS veterinarians, and that plant management verifies to FSIS that these requirements are met, IATP does not oppose prudent delegation of this FSIS authority. In this comment, we remark on provisions of the rule that we judge to be controversial and in need of greater justification.

IATP has responded to earlier HACCP-based proposed rulemakings. A former IATP board member and former USDA official Rod Leonard advised federal meat inspectors in their successful lawsuit against FSIS in 2000 to prevent implementation of the HACCP-based Inspection Model Production (HIMP) applied to poultry slaughter plants.<sup>3</sup> The proposed rule summarizes modifications to HIMP that FSIS made to comply with the 2000 Court of Appeals ruling. In 2002, the Court deferred to the agency's authority to make HIMP compliant with the Federal Meat Inspection Act (FMIA) while delegating FSIS inspection authorities to plant management and employees, (Federal Register [FR] / Vol. 83, No. 22 / Thursday, February 1, 2018 / Proposed Rules, 4787).

In 2013, Mr. Leonard (now retired) wrote of the Foster Farms salmonella contamination of chicken consumed in eighteen states, and the severe reviews by the General Accountability Office (GAO) and the USDA's Office of the Inspector General (OIG) of FSIS HIMP Public Health Information System (PHIS) data quality, "Rather than grasp the Foster case as an opportunity to demonstrate the agency retains its historic commitment to protecting food safety and the public health, FSIS and USDA have chosen to obscure vital public information, welcome inaction and accept a mission as a servant of industry."<sup>4</sup>

In the following short comment, IATP urges the agency to evaluate and document comprehensively whether the implementation of its proposed rule to "modernize" swine slaughter, by delegating to industry the authority to determine production line speeds and delegating FSIS inspection authorities to slaughterhouse employees, will comply with FMIA objectives and requirements. To finalize the proposed rule, the agency must demonstrate, at a minimum, that PHIS data collection and analysis is comprehensive and verifiable by peer review. In 2015, the USDA's OIG stated:

FSIS did not implement sufficient internal controls to effectively monitor and evaluate the performance of PHIS, ensure that the system was accessible, that it was operating as

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designed, and that its information was both complete and accurate. FSIS' policy placed the responsibility on inspection personnel to ensure that data were accurate and complete. FSIS generally agreed with our recommendations, but expressed concerns with our findings.<sup>5</sup>

FSIS attempts to respond indirectly to the GAO and OIG criticisms of PHIS oversight, data collection and data analysis shortcomings in its "Hog HIMP Report." As summarized in the proposed rule, "The Hog HIMP Report found that establishments participating in HIMP performed as well as comparable large non-HIMP establishments and met the Agency's requirements for participating in the HIMP project." (FR, 4789) FSIS credits this "as well" performance to a greater number of offline FSIS verifications of plant Sanitary Operating Procedures and HIMP controls. "Based on these modeling results [a retrogression analysis of historical poultry HIMP slaughter performance data], FSIS thought it was reasonable to conclude that the redeployment of Agency resources to unscheduled offline activities was likely to contribute to improved food safety resulting from a lower prevalence of carcasses contaminated with Salmonella and Campylobacter, which in turn could lead to fewer human illnesses." (FR, 4789). The agency's Hog HIMP Report comparison of five hog slaughter HIMP and 21 non-HIMP slaughter plants was conducted based on PHIS reporting data and an earlier non-PHIS compatible reporting scheme over two distinct reporting periods.

Rather than depend on econometric extrapolations from incompatible data reporting systems and policy assumptions made about a greatly unequal number of hog HIMP slaughter plants with non-HIMP plants, IATP urges FSIS to make more direct comparisons of performance data based on the PHIS reporting of concern to the OIG and GAO. A more direct performance comparison, based on PHIS data reporting, would reduce the need for such speculations as this in the proposed rule. "Depending on how reallocation of inspection activities was implemented, it was likely that changes in off-line inspection could have resulted in a decrease in the numbers of positive microbial samples in FSIS-regulated young chicken and young turkey establishments," (FR, 4789). A major delegation of FSIS inspection authorities to plant management and employees must not be justified by policy assumptions and econometric modeling extrapolated from poultry HIMP inspecting establishments to the pilot swine HIMP establishments.

A direct HIMP vs. non-HIMP swine slaughterhouse comparison, based on compatible data sets and data categories, has been conducted by Food and Water Watch. It compared plant performance data, obtained through the Freedom of Information Act, for five pilot project New Swine Inspection System (NSIS) plants compared to five non-HIMP plants over a five-year period. The Food and Water Watch report showed a stunning NSIS performance failure in eight FSIS-mandated performance categories.<sup>6</sup> Based on the performance failure of the pilot NSIS plants, Food and Water Watch called for FSIS to withdraw the proposed rule, which, if finalized, would enable the expansion of the pilot project to all swine slaughtering facilities.<sup>7</sup> Unless and until FSIS is able to compare NSIS and non-NSIS plant performance using compatible data, the same data reporting period, and an equal number of plants evaluated, and show a marked superiority of NSIS plant performance, FSIS must not finalize the proposed rule.

Even though the NSIS is "a new optional inspection system for market hog slaughter establishments," (FR, 4780), the proposed rule provides an economic incentive for its adoption

that all but nullifies the “optional” character of the proposed rule’s adoption. Among other agency rationales for the proposed rule is to “remove unnecessary regulatory obstacles to innovation by revoking maximum line speeds and allowing establishments flexibility to reconfigure evisceration lines,” (FR, 4780). Nothing in the Federal Meat Inspection Act (FMIA) authorizes the Secretary to interpret the statute to revoke the maximum production line speed and authorize industry to determine line speeds. Nothing in the U.S. Code’s definition of the “Duties of [the] Secretary related to agricultural products”<sup>8</sup> authorizes the revocation of the maximum production line speed. In the proposed rule’s summary of its statutory authority, the agency invokes 21 USC 621, presumably, “said Secretary shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter, and all inspections and examinations made under this chapter, shall be such and made in such manner as described in the rules and regulations prescribed by said Secretary not inconsistent with provisions of this chapter.”

FSIS carries the burden of proof to show that the “efficient execution” of the public health requirements of the FMIA are not inconsistent with performance results of the proposed rule’s revocation of maximum line speeds and delegation to the plant managers of FSIS authority to determine the design of evisceration lines to meet performance requirements. If the expansion of the proposed NSIS increases regulatory violations, such as those reported by Food and Water Watch from the pilot NSIS plants, FSIS will have complied with industry’s desire for faster line speeds and greater hog processing capacity, while failing to comply with the letter and the spirit of the FMIA.

Another source of justification for the release of the proposed rule is the Market Hog Slaughter Risk Assessment,<sup>9</sup> (FR, 4785). The agency advises at the outset of the report, “Please note that an external peer review of this document has not yet been completed.” FSIS does not explain why it decided to release the proposed rule for comment in advance of a peer review of this legally and scientifically crucial risk assessment, contrary to good regulatory practice. Indeed, the agency failed to hold public meetings, at least with non-industry stakeholders, to discuss the design of the risk assessment, the parameters for evaluating risk assessment results, and the relevance of the risk assessment to the provisions of the proposed rule. If the peer review of the Market Hog Slaughter Risk Assessment shows it to be deficient, will FSIS hold a public meeting with all stakeholders to discuss the peer review report? Will the rulemaking process be suspended if peer review determines the risk assessment data and/or analysis to be inadequate, or deficient, and advises FSIS not to finalize the proposed rule unless and until a more adequate risk assessment is provided for another peer review?

If FSIS proceeds to finalize the rule in advance of the peer review, the decision to release the proposed rule for comment without a peer review will make the peer review process appear to be a pro forma feature of the agency’s pre-determined conclusion about the proposed rule. For example, the agency writes of the proposed rule’s risk assessment, “Projecting out illness reductions based on reduction in Salmonella prevalence in 35 plants results in wide uncertainty, but the [computer] model confidently estimates that the level of protection from Salmonella illnesses would be at least as good as the current system,” (FR, 4785). A risk assessment that forecasts a reduction in Salmonella contamination of pork products in 35 plants and of Salmonella cause foodborne illness concedes “wide uncertainty.”

Nevertheless, and without peer review or even a sample of the baseline assumptions, FSIS asserts, based a computer model—not actual performance of even the five NSIS pilot plants—that delegating FSIS inspection and line speed determination authority to plant managers and employees “would be at least as good as the current system.” This is a very underwhelming justification for abandoning FMIA-mandated inspection by trained federal inspectors in favor of delegating both inspection authority and inspector training to plant managers.

The agency appears to be retreating from not just comprehensive pathogen testing, but even regular pathogen testing, as it relies on computer modeling that extrapolates from very small and occasional sample testing, purportedly to save agency resources under Congressional budgetary pressure. According to the proposed rule, “FSIS is currently conducting exploratory sampling of raw pork products for pathogens of public health concern, as well as for indicator organisms (80 FR 12618) . . . The Agency may develop pathogen reduction performance standards for pork parts at a later date. In 2019, the Agency will use this data to determine whether standards or additional policies (e.g., training, guidance to industry, or instructions to field personnel) are needed to address Salmonella in pork products,” (FR, 4786).

FSIS should have pathogen reduction performance standards for pork parts published well in advance of the finalization of the proposed rule. Without such standards to use in the testing of samples, FSIS evaluation of NSIS performance will be reduced to verifying the assumptions of modeling analytics and to checking plant management HIMP paperwork and Sanitary Operating Procedures. Computer modeling of data cannot provide better forecasting of pathogen prevalence and foodborne illness than the accuracy and timeliness of the model’s inputted PHIS data, which the OIG and GAO have found to be deficient. Computer modeling, no matter how algorithmically complex, will not protect consumers if the pathogen reduction performance standards are lax and the data quality remains deficient, whether due to lack of plant management cooperation with the agency and/or FSIS management shortcomings.

IATP regrets that it is unable to answer most of the agency’s “Requests for comment” questions (FR, 4799-4800), as most of these very relevant questions are directed to establishment managements. Regarding the impact of the production line speed on injuries to workers (question 4), the agency must work with the Occupational Safety and Health Administration and the Centers for Disease Control and Prevention to enforce injury reporting and prevention requirements at slaughterhouses. The vast underreporting by plant management of the prevalence and severity of these injuries poses a threat to public health, as well as to worker health.<sup>10</sup> Delegating FSIS authority to plant management to set production line speed while allowing management to underreport injuries to the workers on whom the implementation of the proposed rule depends will result in failure to achieve the propose rule’s public health objectives.

Last, but not least, the proposed rule fails to address past OIG criticisms of FSIS enforcement shortcomings. In 2013, the OIG wrote to FSIS:

The Food Safety and Inspection Service’s (FSIS) enforcement policies do not deter swine slaughter plants from becoming repeat violators of the Federal Meat Inspection Act (FMIA). As a result, plants have repeatedly violated the same regulations with little or no consequence. We found that in 8 of the 30 plants we visited, inspectors did not always

examine the internal organs of carcasses in accordance with FSIS inspection requirements, or did not take enforcement actions against plants that violated food safety regulations. As a result, there is reduced assurance of FSIS inspectors effectively identifying pork that should not enter the food supply.<sup>11</sup>

The proposed rule responds extensively to identifying the costs to industry requirements, referring to Executive Orders 12866 and 13563, for implementing the proposed rule. There is no enforcement provision in the proposed rule designed to prevent repeat FMIA violators; nor is there an estimate of the enforcement budget nor the cost to public health from foodborne illness resulting from the consumption of contaminated pork products. The proposed rule must not be advanced without a detailed enforcement plan, probably located within the “V. Implementation” section of the proposed rule. The enforcement plan should include a budget estimate for enforcement activities and an estimate for the public health cost of pork product-related foodborne illness.

## Conclusion

IATP is aware that FSIS, like all federal agencies, is under intense industry, legislative and executive branch pressure to categorically preclude or reduce the number of regulations and enforcement actions and their costs to regulated entities.<sup>12</sup> Indeed, several pages of this rule summarize industry’s claims about the cost of implementing the proposed rule. However, since that legislation is far from enacted, and since an Executive Order to cut two regulations for every one promulgated is being challenged in court<sup>13</sup>, IATP strongly urges FSIS to deliberate on the proposed rule under current authorities, without anticipating the enactment of future changes to these statutes or to the rulemaking process.

Notwithstanding industry pressure to finalize this rule, in view of the lack of a peer-reviewed risk assessment, inferior NSIS pilot plant performance results compared to non-HIMP swine plant performance, and the lack of a response to OIG’s recommendations on FSIS enforcement shortcomings, FSIS must not finalize this proposed rule as written. If the agency finalizes and implements the proposed rule to achieve industry’s long-desired objective of revoking maximum line speeds, and the PHIS data comprehensiveness, timeliness and accuracy fail to demonstrate compliance with stringent FSIS pathogen reduction performance standards, the proposed rule likely will be in legal jeopardy.

IATP hopes that these comments will assist the agency as it finalizes the proposed rule. Thank you for your consideration of the comments.

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<sup>1</sup> <https://www.fsis.usda.gov/wps/wcm/connect/c17775a2-fd1f-4c11-b9d2-5992741b0e94/2016-0017.pdf?MOD=AJPERES>

<sup>2</sup> The Institute for Agriculture and Trade Policy (IATP) is a nonprofit, 501(c)(3) nongovernmental organization, headquartered in Minneapolis, Minnesota, with offices in Washington, D.C. and Berlin, Germany.

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<sup>3</sup> AFGE v. Glickman, 215 F.3d 7 (D.C.Cir.2000)

<sup>4</sup> Rod Leonard, “The USDA plan for deregulating and privatizing meat and poultry inspection: A short history,” Institute for Agriculture and Trade Policy, December 13, 2013.

<sup>5</sup> “Implementation of the Public Health Information System for Domestic Inspection,” U.S. Department of Agriculture Office of the Inspector General, Audit Report 24601-0001-23, August 2015, “What the OIG recommended,” <https://www.usda.gov/oig/webdocs/24601-0001-23.pdf>.

<sup>6</sup> “Translating the New Swine Inspection System,” Food and Water Watch, February 15, 2018. <https://www.foodandwaterwatch.org/insight/translating-new-swine-inspection-system>

<sup>7</sup> “New Documents Shows Privatized Hog Slaughter Inspection Scheme Rife with Food Safety Violations,” Food and Water Watch, February 21, 2018. <https://www.foodandwaterwatch.org/news/new-documents-show-privatized-hog-inspection-scheme-rife-food-safety-violations>

<sup>8</sup> 7 USC 1622.

<http://uscode.house.gov/view.xhtml?req=meat+inspection&f=treesort&fq=true&num=5&hl=true&edition=prelim&granuleId=USC-prelim-title7-section1622>

<sup>9</sup> “Assessment of the Potential Change in Human Risk of Salmonella Illnesses Associated with Modernizing Inspection of Market Hog Slaughter Establishments,” Food Safety Inspection Service. January 2018. <https://www.fsis.usda.gov/wps/wcm/connect/0c03ed4d-68bf-4bd9-80e0-b8f3aa6ff16e/ModernizationSwineSlaughterRiskAssessment.pdf?MOD=AJPERES>

<sup>10</sup> Grant Gerlock, “We Don’t Know How Many Workers Are Injured at Slaughterhouses. Here’s Why.” National Public Radio, May 25, 2016. <https://www.npr.org/sections/thesalt/2016/05/25/479509221/we-dont-know-how-many-workers-are-injured-at-slaughterhouses-heres-why>

<sup>11</sup> “Food Safety Inspection Service: Implementation and Enforcement Activities at Swine Slaughter Plants, U.S. Department of Agriculture Office of the Inspector General, Audit Report 24601-0001-41, May 2013, “What the OIG Found.” <https://www.usda.gov/oig/webdocs/24601-0001-41.pdf>

<sup>12</sup> E.g. Allison Cassidy and Myriam Alexander-Kerns, “The Powerful Corporations Pushing to Unravel Protections for Consumers, Public Health and the Environment,” Center for American Progress, May 9, 2017. <https://www.americanprogress.org/issues/green/news/2017/05/09/432053/powerful-corporations-pushing-unravel-protections-consumers-public-health-environment/>

<sup>13</sup> Evan Weinberger, “Groups Sue to Block Trump’s Regulatory 2 for 1 Order,” *Law360*, February 8, 2017. <https://www.law360.com/articles/889781/groups-sue-to-block-trump-s-2-for-1-regulatory-order>