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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 310

[Docket No. FSIS-2018-0005]

RIN 0583-AD68

Eliminating Unnecessary Requirements for Hog Carcass Cleaning

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations by removing the provision requiring the cleaning of hog carcasses before any incision is made preceding evisceration. Other regulations require carcass cleaning, the maintenance of sanitary conditions, and the prevention of hazards reasonably likely to occur in the slaughter process. Removal of this unnecessary provision will enable official establishments to adopt more efficient, effective procedures under other regulations to ensure that carcasses and parts are free of contamination.

DATES: Effective date: [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development, FSIS; Telephone: (202)-205-0495.

SUPPLEMENTARY INFORMATION:

Background

On May 16, 2018, FSIS proposed (83 FR 22604) to amend the Federal meat inspection regulations by removing from the post-mortem inspection regulations requirements for the cleaning of hog carcasses before incision for inspection or evisceration (9 CFR 310.11). FSIS noted that regulations on sanitation and standard operating procedures (9 CFR parts 304, 416), hazard analysis and critical control point (HACCP) systems (9 CFR part 417), and another post-mortem inspection regulation (9 CFR 310.18) require sanitary conditions for the handling of carcasses. The regulation at 9 CFR 310.18, in particular, addresses the prevention and removal of contamination from carcasses (before or after incision), organs, and other parts. The regulation requires the removal of any contamination remaining or occurring post-incision or post-evisceration.

After reviewing comments on the proposed rule, FSIS is finalizing it without changes.

Responses to Comments

FSIS received nine comment letters on the proposed rule from industry and consumer-advocacy groups, as well as from individuals. The issues raised in the comments and the Agency responses are summarized below.

Pre-incision Cleaning, APA Compliance, and Public Health

Benefits

Comment: A group advocating humane treatment of livestock stated that other current regulations do not obviate the need for 9 CFR 310.11. According to the comment, this is the only regulation that addresses pre-incision cleaning, which is integral to preventing contamination of pig carcasses. Similarly, the comment stated that studies show that pre-incision cleaning is necessary to ensure food safety, and FSIS provides no evidence to the contrary. Pig carcasses are relatively smooth compared to beef and potentially more susceptible to external contamination. For this reason, pre-evisceration cleaning is even more necessary and more effective in removing bacteria from pig carcasses. Eliminating this requirement, therefore, does not have a scientific basis, would endanger food safety, and is arbitrary and capricious.

Response: The regulations at 9 CFR 310.10, which remain, require the washing and cleaning of hide-on or skin-on livestock carcasses before incision for removal of any parts or for evisceration. Additionally, establishments commonly scald, dehair, and singe hog carcasses after bleed-out, before inspection. And, as explained elsewhere in this document, the removal of other trim defects on hog carcasses, such as hair, scurf, nails, and hooves, which 9 CFR 310.11 addressed, is still

required under 310.18 and can be completed in a different manner and at different points in the slaughter process. This can be done without creating insanitary conditions and before the product enters commerce. Under this final rule, an establishment will have to handle its carcasses and parts in a sanitary manner to prevent their contamination with hair, dirt, or foreign matter. The establishment will have to carry out all carcass dressing and further processing activities in a manner consistent with its Sanitation SOPs, other prerequisite programs, and its HACCP plan.

Comment: Comments from consumer advocacy groups, an animal welfare organization, and individuals argued that the proposal would yield no public health benefits, just efficiency, and that industry efficiency is not a goal of the Federal Meat Inspection Act (FMIA; 21 U.S.C. 601 et seq.). The animal welfare group went farther and argued that the proposed rule is arbitrary and capricious under the Administrative Procedure Act (APA, 5 U.S.C. Subchapter II) because, in constructing and making the proposal, the Agency relied on factors Congress did not intend it to consider, failed to consider an important aspect of the problem, and offered an implausible explanation running counter to evidence and not based on differences in expertise or viewpoints. According to the animal welfare group, the Agency proposed the rule to ensure the efficiency of establishment

operations, but ensuring this efficiency is not a responsibility of FSIS. Therefore, according to the comment, the Agency relied on factors Congress did not intend it to consider, making the proposed regulation arbitrary and capricious. One consumer advocacy argued that the cost-benefit analysis was flawed because it did not address potential public health implications of removing 9 CFR 310.11.

Response: Congress, through the FMIA, requires the Agency and its inspection program to address and prevent the distribution in commerce of meat and meat food products that are adulterated (21 U.S.C. 602). Congress empowered the Agency to promulgate regulations for the efficient execution of the Federal Meat Inspection Act (21 U.S.C. 621). The elimination of unnecessary regulations creates efficiencies for both FSIS inspection and industry.

Specifically, since FSIS made final its HACCP regulations in 1996, appropriately shifting the full responsibility for producing safe meat and poultry products to the regulated industry, the Agency has revised many of its prescriptive food safety regulations to give industry more flexibility to customize processes under HACCP. This flexibility often results in greater efficiencies for regulated establishments, but also allows them to fully employ HACCP to better ensure the production of safe meat and poultry products. The proposal to

remove the requirements for hog carcass cleaning before incision for evisceration is part of these continuing efforts and was promulgated in accordance with the APA procedures.

Removing a regulation that other requirements for sanitation and the prevention of adulteration have made redundant, will make the enforcement of the Act more efficient. This change will not negatively affect public health because, as explained above, establishments are still required to remove contamination from carcasses and to produce products that are safe, wholesome, and not adulterated.

New Swine Inspection System

Comment: A consumer advocacy organization, an animal welfare organization, and an individual stated that the proposal assumes the implementation of the new swine inspection system.

Response: The scurf proposal cites the future implementation of the new swine inspection system as more support for eliminating § 310.11, "if finalized" (83 FR 22605).

Industry Non-compliance, Need for the Regulation

Comment: One consumer advocacy group stated that FSIS inspection program personnel (IPP) are still issuing noncompliance records (NRs) for 9 CFR 310.11 violations; hence, the regulation is not redundant.

Response: In the proposal, the Agency explained that the requirement in 9 CFR 310.11 is not needed because compliance

with other regulations and accompanying procedures achieve its objective, i.e., clean hog carcasses and parts. Further, that this prescriptive regulation is cited in NRs does not show that it is in fact needed to ensure the production of safe food.

Regulatory Waivers

Comment: Comments from consumer advocacy groups stated that the Agency seems to be basing the proposal on the five regulatory waivers granted to a major processor. The commenters were concerned that FSIS was relying on a small sample to justify removing 9 CFR 310.11.

Response: Information from establishments that operated under waivers from this specific regulation shows that they operated without jeopardizing food safety and supports the removal of the specific requirement.

Relation of HACCP to the Proposal

Comment: Comments from consumer advocacy groups stated that HACCP plans are doubtful substitutes for the requirements of 9 CFR 310.11.

Response: Based on FSIS and establishment testing data, HACCP has proven to be an effective system for reducing or eliminating food safety hazards, and establishments may elect to clean hog carcasses before incision as a part of a HACCP system. Establishments also may elect to clean hog carcasses through a

Sanitation SOP or other prerequisite program. And, notably, establishments must continue to comply with the regulations at 9 CFR 310.18, which require that livestock carcasses be cleaned of contamination to the satisfaction of FSIS.

Administration Support for the Proposal

Comment: One consumer advocacy organization stated that the proposed rule is without adequate support in the Trump Administration. According to the commenter, at a June 27, 2018, House Oversight and Government Reform Committee hearing on the proposed Government reorganization, a Member asked an OMB official about the Agency's proposed repeal of the hog carcass cleaning regulation and how this deregulation would protect consumers or whether it was proposed at the behest of slaughterhouse operators. The OMB official said she was unfamiliar with the proposed rule.

Response: This rulemaking has been listed in the Unified Agenda of Regulatory and Deregulatory Actions, reviewed and published by OMB, since Fall 2017.

Need for Microbiological Performance Standards

Comment: One consumer advocacy organization remarked that, according to the 1995 HACCP notice of proposed rulemaking, "Science-based process control ... and appropriate performance standards are inextricably intertwined in the Agency's

regulatory strategy for improving food safety" (60 FR 6774, 6786; Feb. 3, 1995). The commenter also stated that the 1996 HACCP final rule established *Salmonella* performance standards for pork carcasses, but in 2011 FSIS stopped testing to ensure compliance with the standard, reasoning that violation rates were too low to justify the effort. The commenter questioned the wisdom of the Agency's decision, noting that the performance standards of the 1990's were intended to be a first step toward broader reliance on pathogen-specific performance standards. The commenter recommended that FSIS update the performance standards for whole carcasses, develop alternative standards for pork parts, or implement other performance standards to reduce *Salmonella* in pork products.

Response: The Government Accountability Office (GAO), in a recent review of FSIS efforts to control pathogens in meat and poultry products¹, recommended that the Agency set timeframes for determining what pathogen standards or additional policies might be needed to address pathogens in beef carcasses, ground beef, port cuts, and ground pork. As indicated in the GAO's review report, FSIS concurred with the recommendation and is continuing

¹U.S. Govt. Accountability Office, GAO-18-272, Food Safety: USDA Should Take Further Action to Reduce Pathogens in Meat and Poultry Products (March 2018). <https://www.gao.gov/assets/700/690709.pdf> (Accessed Oct. 22, 2018).

its sampling and testing raw pork cuts and pork comminuted products for *Salmonella* under its exploratory study.

As FSIS stated in its response to GAO, in 2019, the Agency will use the data from the exploratory study 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. If the Agency decides to institute new standards, it will collect and evaluate data to determine whether establishments meet the standards.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated as a "non-significant" regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Economic Analysis

FSIS is adopting the preliminary regulatory impact analysis (PRIA) published in the proposed rule as the final regulatory impact analysis (FRIA) in this final rule, without change.

Expected Cost Savings and Benefits Associated with the Final Rule

This final rule is expected to reduce swine slaughter labor costs by approximately \$11.81 million annually. These savings are due to industry's practice of dedicating labor pre-incision, solely to comply with 9 CFR 310.11. Under the final rule, this labor will no longer be needed because the work can be accomplished by existing labor located post-incision. FSIS's labor cost savings estimate assumes that the labor affected by the final rule is equivalent to that in the Bureau of Labor Statistics' (BLS's) slaughtering and meat-packing occupational category, for which the industry annual wage is \$27,140². The Agency sought, but did not receive, comment on this assumption. Applying a benefits-and-overhead factor of 2 brings this occupation's total annual labor costs per position to \$54,280 (\$27,140 x 2).

²BLS Occupational Employment Statistics (OES) May 2016 National Industry-Specific Occupational Employment and Wage Estimates for North American Industrial Classification (NAICS) code 311600 (Animal Slaughtering and Processing) <https://www.bls.gov/oes/current/naics4_311600.htm> Last Modified 3/31/2017 Accessed on 1/19/2018

The number of positions affected at each establishment depends on the establishment's size, slaughter volume, number of lines and shifts it operates, and days of operation. Large³ swine establishments are thought to dedicate from one to three full-time positions per line and per shift to comply with 9 CFR 310.11; while small⁴ high-volume⁵ establishments dedicate between one and two positions for the same purpose. Small low-volume and very small⁶ establishments are thought to dedicate between one quarter-time and one full-time position to comply with this regulation. The Agency sought, but did not receive, comment on these labor-demand estimates.

According to data from the Agency's electronic Public Health Information System (PHIS), 479 very small establishments, 54 small low-volume establishments, 51 small high-volume establishments, and 23⁷ large swine establishments will be affected by this rule. This analysis takes into consideration the fact that some large and small high-volume establishments operate multiple lines and multiple shifts. This analysis assumes that all other establishments operate one line and one

³ A large establishment has 500 or more employees.

⁴ A small establishment has between 10 and 499 employees.

⁵ 9 CFR 310.25(a)(2)(v) defines very low volume swine slaughter establishments as slaughtering 20,000 head annually or fewer. For the purposes of this analysis, FSIS has labeled swine establishments that annually slaughter more than 20,000 head per year as high-volume establishments.

⁶ A very small establishment has less than 10 employees or less than \$2.5 million in annual sales.

⁷ While there are 28 large swine establishments, five are operating under waivers from 9 CFR 310.11 and are not expected to experience a decrease in their demand for labor resulting from implementation of this final rule.

shift per day. Data from PHIS also show that, on average, large establishments annually operate 266 days, small high-volume establishments 239 days, small low-volume establishments 95 days, and very small establishments 67 days. The final rule is expected to lead to a reduction in industry positions at these establishments; see table 1. Table 2 provides the estimated labor cost savings from the final rule, given the expected labor costs, number of positions, and days of operation. The annual cost savings range from \$5.27 million to \$19.03 million, with a mid-point of \$11.81 million.

Table 1: Estimated Industry Labor Reductions from Removing 9 CFR 310.11

Size of Est	No. Of Establishments*	Number of Positions **		
		Low	Medium	High
Large	23	37	74	111
Small High Volume	51	26	77	102
Small Low Volume	54	14	27	54
Very Small	479	120	240	479
Combined	607	196	417	746

*Public Health Information System (PHIS)

** Note, the totals may not equal the sum due to rounding.

Table 2: Labor Wage Cost (Savings) from Removing 9 CFR 310.11, 2016

Size of Est	No. Of Establishments*	Total Annual Labor Costs (Savings)** (M\$)***		
		Low	Medium	High
Large	23	(\$2.06)	(\$4.11)	(\$6.17)
Small High Volume	51	(\$1.27)	(\$3.82)	(\$5.09)
Small Low Volume	54	(\$.27)	(\$.54)	(\$1.07)
Very Small	479	(\$1.68)	(\$3.35)	(\$6.7)
Combined	607	(\$5.27)	(\$11.81)	(\$19.03)
Annualized Costs (Savings), Over 10 Years (M\$)				
Assuming a 3% Discount Rate		(\$5.27)	(\$11.81)	(\$19.03)
Assuming a 7% Discount Rate		(\$5.27)	(\$11.81)	(\$19.03)

*Public Health Information System (PHIS)

** Note, the totals may not equal the sum due to rounding.

*** Wage estimates were sourced from BLS OES May 2016 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 311600

<https://www.bls.gov/oes/current/naics4_311600.htm#51-0000> Last Modified 3/31/2017. Accessed on 11/26/2018.

Expected Costs Associated with this Action

The final rule has no expected costs associated with it.

Regulatory Flexibility Act Assessment:

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-602), this final rule will not have a significant impact on a substantial number of small entities in the United States. The expected labor cost reductions associated with the final rule are not likely to be large enough to significantly impact an entity. Further, the final rule does not have any cost increases.

Executive Order 13771

Consistent with E.O. 13771 (82 FR 9339, February 3, 2017), FSIS has estimated that this final rule will yield cost savings. Therefore, this final rule is an E.O. 13771 deregulatory action.

Paperwork Reduction Act

No new paperwork requirements are associated with this final rule.

Executive Order 12988

This final rule has been reviewed under E.O. 12988, Civil Justice Reform. Upon the effective date of this final rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) No retroactive effect will be given to this rule; and (3) Administrative proceedings will not be required before parties may file suit in court challenging this rule.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

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List of Subjects in 9 CFR Part 310

Animal diseases, Meat inspection.

For the reasons set out in the preamble, FSIS is amending 9 CFR part 310 as follows:

PART 310 - POST-MORTEM INSPECTION

1. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

§310.11 [Removed and reserved]

2. Section 310.11 is removed and reserved.

Done, at Washington, DC.

Carmen M. Rottenberg,

Administrator.

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