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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 316

[Docket No. FSIS 2018-0019]

RIN 0583-AD69

Elimination of the Requirement That Livestock Carcasses Be Marked "U.S. Inspected and Passed" at the Time of Inspection within a Slaughter Establishment for Carcasses to be Further Processed within the Same Establishment

AGENCY: Food Safety and Inspection Service (FSIS), USDA.

ACTION: Final rule.

SUMMARY: FSIS is amending the Federal meat inspection regulations to eliminate the requirement that livestock carcasses be marked with the official inspection legend at the time of inspection in a slaughter establishment, if the carcasses are to be further processed in the same establishment.

DATES: Effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

In the past, slaughter establishments often would ship carcasses to other establishments for further processing into primal, subprimal, and other meat cuts and products. Today however, most establishments that slaughter swine, cattle, sheep, or goats also fabricate the carcasses into various primal and subprimal parts, as well as other meat products. More specifically, after a carcass has passed inspection, the slaughter establishment typically moves it, under control, to another department in the same establishment for further processing. The establishment then typically ships the resulting meat food products, rather than marked carcasses, in fully labeled containers either for further processing at other establishments or into commerce.

FSIS regulations at § 316.9(a) have required that all livestock carcasses be marked with the inspection legend when they are inspected and passed on the slaughter floor, even if they are to be further processed within the same establishment. Numerous slaughter establishments have requested and been granted waivers (§ 303.1(h)) from this requirement, as they further process the carcasses elsewhere in the same establishment, after which the resulting products are marked with the inspection legend. FSIS experience with establishments

operating under these waivers has shown that they have no difficulty ensuring that only inspected, passed and properly marked parts enter into commerce and also ensuring, when applicable, that only inspected, passed and marked carcasses are shipped into commerce.

Accordingly, on July 31, 2018, FSIS proposed that establishments no longer be required to mark carcasses with the inspection legend on the slaughter floor, if the carcasses are to be further processed in the same establishment (83 FR 36794). The proposal did not change the regulations that require that all primals, subprimals, parts and other meat food products be properly labeled and bear the mark of inspection before entering commerce (§316.9(b)). Under the proposed rule, FSIS inspection personnel would verify whether the establishment is shipping marked carcasses or whether the establishment is further processing the carcasses in the establishment and marking the processed parts appropriately before the parts leave the establishment.

Final Rule

After consideration of all the comments, FSIS is finalizing the provisions of the July 31, 2018, proposed rule with one change. The final rule does not include the proposed requirement that establishments have procedures in their HACCP plans, Sanitation SOPs, or prerequisite programs to ensure that 1)

unmarked carcasses are further processed only in the slaughtering establishment; 2) unmarked carcasses that, for any reason, are not further processed in the slaughtering establishment do not leave the establishment unmarked; and 3) unmarked and retained carcasses or parts remain under FSIS control until the establishment makes any corrections that are necessary to render the carcass or part eligible to bear the mark of inspection.

Comments and Responses

FSIS received one comment from a trade association and five comments from individuals in response to this rule. One individual and the trade association generally supported the proposed changes. A summary of comments and FSIS responses follows.

Comment: A trade association representing members of the meat industry stated that the economic impact analysis assumes that all establishments that are currently marking carcasses will stop after the implementation of the final rule. According to the trade association, not all establishments will change their marking practices because some establishments ship whole carcasses, some package primals in bulk packaging (making the mark necessary to comply with regulation), and some will not want to incorporate controls for unmarked carcasses into their HACCP plans. The commenter also stated customer requirements,

production practices, and product mix can affect the marking of carcasses. The trade association argued that the proposed rule does not create a stronger incentive to discontinue carcass marking than the waiver process.

Response: The Agency agrees that it is likely that not all establishments will stop marking carcasses after implementation of the final rule. Establishments that ship whole carcasses will need to continue to mark carcasses. However, FSIS believes that the advantage to discontinuing the marking of carcasses is strong enough that most establishments will do this after implementation of the final rule, provided the establishment does not ship the carcass outside the establishment for further processing. In response to the comment, FSIS adjusted the expected post-rule percentage of carcasses that will not be marked from 100 percent to 90-95 percent in the final rule economic impact analyses. FSIS estimates that elimination of the requirement to mark carcasses will yield an annual cost-saving of \$0.82 million to \$0.93 million per year.

Comment: The same trade association comment stated that because the proposed rule would require establishments to incorporate unmarked carcass procedures into the HACCP system, sanitation SOPs, or other prerequisite programs, FSIS is just replacing one regulation with another, and that the proposed rule is not a deregulatory action as defined by E.O. 13771. The

comment stated that other, existing regulations require establishments to prevent uninspected or condemned carcasses from entering commerce and that inspected and passed carcasses and parts bear the mark before leaving the official establishment. Further, the comment argued that HACCP controls are specific to the establishment based on a thorough hazard analysis and that only if the movement of unmarked carcasses poses a significant food safety risk in the process should a control be put in place. The comment stated that the movement of unmarked carcasses likely would not pose a significant food safety risk at establishments.

Response: FSIS agrees that requirements concerning the movement and marking of carcasses already occur in other regulations: 9 CFR part 310, addresses the retaining of carcasses that may be unfit for human consumption; 9 CFR part 314, addresses condemned and inedible product; 9 CFR part 316, addresses marking of products and containers; and 9 CFR part 317, addresses labeling, marking devices, and containers. Together, these existing regulations adequately require that establishments control the movement of unmarked carcasses. Accordingly, in the final provisions in § 316.9(b), FSIS has removed the requirement that establishments incorporate unmarked carcass procedures into their HACCP plans, sanitation SOPs, or other prerequisite programs.

Comment: One individual questioned FSIS's regulatory authority to deviate from the exact language in the Federal Meat Inspection Act (FMIA) when changing the language in the regulations.

Response: The FMIA requires that carcasses and parts (21 U.S.C. 604) and meat food products (21 U.S.C. 606) found not to be adulterated be marked "Inspected and passed" by FSIS inspectors. The FMIA does not require that this marking be done at a specific time or in a specific location in the establishment, especially if carcasses are being processed into parts or into meat food products within the same establishment. The new regulations in 316.9(a) will ensure that the specific intent of the FMIA marking requirements continue to be met in the contemporary market, i.e., that carcasses, parts, and meat food products found not adulterated by USDA inspectors enter commerce only if marked "Inspected and Passed."

Comment: One individual opposed the changes and questioned the risk of a carcass leaving the facility unmarked under this rule. The individual also questioned FSIS's oversight for establishments under this new rule.

Response: The new language at § 316.9(a) states that "Each carcass that has been inspected and passed in an official establishment must be marked at the time of inspection with the official inspection legend containing the number of the official

establishment, if the carcass is to be shipped into commerce from the establishment without further processing." Therefore, all carcasses not further processed at the establishment must be marked with the official inspection legend before entering commerce. FSIS will continue to provide inspection at establishments to verify that establishments meet this requirement, as well as to ensure that all meat food products are properly marked and labeled before entering commerce.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders 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 benefits, distributive impacts, and equity). Executive Order (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 final rule has not been reviewed by the Office of Management and Budget (OMB) under E.O. 12866.

Economic Impact Analysis

FSIS is removing the requirement for carcasses slaughtered

in an establishment to bear the mark of inspection after being inspected and passed on the slaughter floor if the carcasses are to be further processed in the same establishment. Since this requirement is no longer necessary to prevent adulterated food product from entering commerce (see explanation in the Background section above), removing it will have no negative public health impact. Nor will it impose costs on the industry or the Agency.

Regarding benefits from the rulemaking, removing an unnecessary requirement will allow establishments the flexibility to innovate and to operate in the most efficient manner. In addition, it will also allow FSIS to utilize its resources more appropriately by relieving inspectors of unnecessary tasks. The expected benefits from this final rule will accrue from time and resource savings. Inspected and passed carcasses meant for further processing in the same establishment where the animals were slaughtered will not have to wait for the mark of inspection but can move directly to further processing. Thus, establishments that slaughter livestock and process livestock carcasses in the same facility will benefit from fewer delays in their operations and greater flexibility to conduct processing operations on inspected and passed carcasses.

FSIS received only one comment on the proposed rule's economic impact analysis. The comment, from the industry, argued that some establishments will continue to mark the carcasses after the implementation of the final rule. In response to this comment, FSIS adjusted the expected post-rule percentage of carcasses processed within the same establishment that will not be marked from 100 percent to 90-95 percent.

Agency data showed that there are approximately 797 meat slaughtering establishments, and approximately 676 of them (~85 percent) do both slaughtering and processing¹. FSIS estimates that in these 676 establishments, approximately 95 percent of the carcasses are further processed in the same establishment. Given that the annual production of meat by Federal inspected establishments is approximately 150 million heads,² roughly 120.9 million carcasses are subject to the requirements in §316.9 (150 million x 85 percent x 95 percent). Assuming that it takes establishment labor, on average, 3 seconds to mark each carcass, and that approximately half of the establishments already have waivers from the requirement, and that an additional 40-45 percent of the carcasses will not be marked after implementation of this final rule, approximately 40,310 to 45,349 additional

¹ Data source: Public Health Information System as of June 2017, provided by FSIS's Office of Data Integration and Food Protection (now the Office of Planning, Analysis and Risk Management).

² Livestock Slaughter 2016 Summary (April 2017). USDA, National Agricultural Statistics. <http://usda.mannlib.cornell.edu/usda/nass/LiveSlauSu//2010s/2017/LiveSlauSu-04-19-2017.pdf>, p.15, accessed 11/16/2018.

hours will be saved by this final rule. Most establishments use hired workers to do the marking. If we assume that the average hourly pay (salary plus benefits) is \$20³, then the time saved is equivalent to approximately \$0.81 to \$0.91 million annually.

In addition, such establishments will no longer need to replace the broken or worn out stamps previously used for marking carcasses on the slaughter floor. Typically, a stamp (usually made of bronze) costs \$225 and lasts 5 years⁴. The annualized cost of the stamp is \$55 (if the interest rate is 7 percent) or \$50 (if the interest rate is 3 percent). Assuming each establishment (that does not already have a waiver from the requirement to mark carcasses and is expected to stop marking because of the final rule) uses one stamp per year, the annual savings on these stamps will be between \$13,300 and \$16,700.

Additionally, establishments will no longer need to make written requests for waivers from the requirement to mark carcasses further processed within the same establishment and will no longer need to wait to have such requests approved. Further, because FSIS inspected and passed carcasses will no longer be required to bear the mark of inspection if they are sent for further processing in the same establishment, FSIS inspectors will no longer need to verify this mark, and will

³ Data source: Bureau of Labor Statistics (BLS) report of average wage of meat slaughterers and packers. <https://www.bls.gov/oes/current/oes513023.htm/>, accessed 06/2017.

⁴ Data from Ketchum Manufacturing Inc., a manufacturer of meat stamps, through telephone interview on 4/17/2017.

have more time to focus on activities that are more important in ensuring food safety, such as verifying that establishments meet HACCP regulations and collecting product samples. These savings are minimal and have not been quantified. There are no expected costs associated with this rule.

Regulatory Flexibility Act Assessment

The FSIS Administrator has made a determination that this final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). The final rule will not increase costs to the industry.

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 rule is an E.O. 13771 deregulatory action.

Paperwork Reduction Act

There are no new paperwork or recordkeeping requirements associated with this final rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

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.

Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under E.O. 12988, Civil Justice Reform. Under this 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) no administrative proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of E.O. 13175, "Consultation and Coordination with Indian Tribal Governments." E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O.

13175. If a Tribe requests consultation, FSIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

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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>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Constituent Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range

from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects in 9 CFR Part 316

Food labeling, Food packaging, Meat inspection.

For the reasons set forth in the preamble, FSIS is amending 9 CFR part 316 as follows:

PART 316 - MARKING PRODUCTS AND THEIR CONTAINERS

1. The authority citation for part 316 is revised to read as follows:

Authority: 21 U.S.C.601-695; 7 CFR 2.18, 2.55.

2. In § 316.9, revise paragraph (a), redesignate paragraphs (b) through (d) as paragraphs (c) through (e), respectively, and add a new paragraph (b) to read as follows:

§ 316.9 Products to be marked with official marks.

(a) Each carcass that has been inspected and passed in an official establishment must be marked at the time of inspection with the official inspection legend containing the number of the official establishment, if the carcass is to be shipped into commerce from the establishment without further processing.

(b) A passed and inspected carcass that is to be further processed in the slaughtering establishment need not be marked with the official inspection legend at the time of inspection.

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Done in Washington, DC.

Carmen M. Rottenberg
Administrator

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