

**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, USDA.**ACTION:** Proposed rule.

**SUMMARY:** FSIS is proposing to amend 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:** Comments must be received on or before October 1, 2018.

**ADDRESSES:** FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail, including CD-ROMs:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250–3700.

- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

- *Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2018–0005. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

*Docket:* For access to background documents or comments received, call (202) 720–5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

**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, or sheep also fabricate the carcasses into various primal and subprimal parts, as well as other meat products. 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.

The Federal Meat Inspection Act (FMIA) requires the inspection of all livestock carcasses and parts of livestock carcasses prepared in slaughter establishments as articles of commerce capable of use as human food (21 U.S.C. 604). In this same provision, the FMIA requires that such carcasses and parts of carcasses found to be not adulterated be stamped as “inspected and passed” before they enter commerce. The FMIA also gives FSIS broad authority to promulgate rules and regulations necessary to carry out its provisions (21 U.S.C. 621).

The regulations at 9 CFR 316.9 set forth more prescriptive, and partially outdated, requirements for the marking of inspected carcasses. Specifically, the regulation at 9 CFR 316.9(a) requires each carcass at an official establishment to be marked at the time of inspection with the official inspection legend. This requirement is intended to prevent uninspected carcasses from being shipped in commerce from slaughter establishments or elsewhere. However, given contemporary practices at slaughter establishments, marking the carcass on the slaughter floor is often unnecessary, as the carcass will be moved elsewhere in the same establishment for further processing.

**Requests To Move Carcasses and Parts of Carcasses To Processing Without Marking the Carcass**

Numerous slaughter establishments have requested waivers from the

requirement in 9 CFR 316.9(a), *i.e.*, that the carcasses they further process in-house not be required to be marked at the time of inspection. The information presented with these requests has described the steps that establishments would take to ensure that uninspected, unmarked, or adulterated product does not enter commerce. These steps typically include: (1) Ensuring that all carcasses inspected and passed by USDA, but not marked on the slaughter floor, are stored and processed in the establishment; (2) ensuring that all products shipped from the establishment bear the mark of inspection or are shipped in fully labeled containers that bear the mark of inspection; and (3) ensuring that FSIS still maintains control over any carcasses that do not pass inspection.

FSIS has granted many of these waivers, per the regulations at 9 CFR 303.1, thereby allowing inspected and passed carcasses to move, without the mark of inspection, from the slaughter floor to processing departments in the same establishment. At one point, because of the high number of waivers granted, FSIS issued an administrative notice to inspectors (FSIS Notice 17–16) with instructions for verification activities at establishments that had received a waiver from these requirements. FSIS has allowed this notice to expire, in anticipation of this rulemaking. Further, based on discussions with FSIS District Offices, while a significant number of establishments are currently operating under such waivers, there are no reports of unmarked carcasses being shipped into commerce.

FSIS has carefully considered the available information on allowing establishments to move carcasses and parts of carcasses to processing without marking the carcass with the inspection legend. From its experience with establishments to which it has provided waivers, the Agency has concluded that controls that establishments have put in place and Agency procedures to address inspection of unmarked carcasses have been successful in preventing unmarked carcasses from leaving the establishment for processing in an outside facility. FSIS is thus proposing that establishments not be required to mark carcasses with the inspection legend when the carcasses leave the slaughter floor to be further processed within the same establishment. However, all primals, subprimals, parts and other meat food products will have to be properly labeled and bear the mark of inspection before entering commerce.

Under the proposed rule, FSIS inspection personnel will continue to

verify that the establishment has in place in its Hazard Analysis and Critical Control Point (HACCP) plan, Sanitation Standard Operating Procedures (SOPs), or other prerequisite programs, controls to ensure that unmarked carcasses are further processed in the establishment and that carcasses that are not further processed in the establishment do not leave the establishment unmarked. Additionally, should this rule become final, inspectors would verify through records review or direct observation that the establishment's procedures ensure that: (1) The establishment properly identifies and handles carcasses or parts eligible for the mark of inspection through edible channels, so that only edible, inspected and passed product proceeds to fabrication; (2) the establishment can account for the number of carcasses it slaughters and moves through its establishment and that it correctly identifies the species slaughtered on the final label; (3) retained carcasses or parts remain under FSIS control until the establishment makes corrections that render the carcass or part eligible to bear the mark of inspection (e.g., carcasses retained for residue sample or pending pathology disposition are held in FSIS controlled retained cages in the cooler); and (4) whole carcasses transported to another establishment bear the mark of inspection.

#### **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 proposed 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 (OMB) under E.O. 12866.

#### **Economic Impact Analysis**

FSIS is proposing to remove 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.

In regard to benefits from the rulemaking, removing an unnecessary requirement will allow establishments the flexibility to be innovative 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 proposed rule would accrue from time and resource savings. Inspected and passed carcasses meant for further processing would not have to wait for the mark of inspection but could move directly to further processing. Thus, establishments that slaughter livestock and process livestock carcasses in the same facility would benefit from fewer delays in their operations and greater flexibility to conduct processing operations on inspected and passed carcasses.

Agency data show that there are approximately 797 meat slaughtering establishments, and approximately 676 of them (~85 percent) do both slaughtering and processing.<sup>1</sup> FSIS estimates that approximately 644 of these 676 establishments (~95 percent) further process the carcasses they slaughter. Given that the annual production of meat by Federal inspected establishments is approximately 150 million heads,<sup>2</sup> roughly 120.9 million carcasses are subject to the requirements in 9 CFR 316.9 (150 million  $\times$  85 percent  $\times$  95 percent). Assuming that it takes establishment labor, on average, 3 seconds to stamp each carcass, and that approximately half of the establishments already have waivers from the requirement, approximately 50,417 additional hours would be saved. Most establishments use hired workers to do the stamping. If we assume the average hourly pay (salary plus benefits) is \$20,<sup>3</sup> then the time saved is equivalent to approximately \$1.01 million annually.

In addition, such establishments would 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 years.<sup>4</sup> 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) uses one stamp per year, the annual savings on these stamps would be between \$16,700 and \$18,600.

Additionally, establishments would no longer need to make written requests for waivers from the requirement to stamp carcasses further processed within the same establishment and would no longer need to wait to have such requests approved. Further, because FSIS inspectors would no longer need to ensure that inspected and passed carcasses bear the mark of inspection before they are sent for further processing, FSIS inspectors would have greater flexibility to focus on activities that are more important in ensuring food safety, such as verifying that establishments meet HACCP regulations and collecting product samples. However, the time needed for submitting a written waiver request and waiting for approval is minimal, and the saving of that time would be offset by the increase in time needed for establishments to amend their HACCP plans, Sanitation SOPs, or prerequisite programs to add controls for the movement of these unmarked carcasses under this proposed rule. Similarly, the time saved for FSIS inspectors to ensure that inspected carcasses bear the mark of inspection would be offset by the increase in time to verify that establishments meet HACCP regulations.

There are no expected costs associated with this proposed rule. Establishments already operating under a waiver will have procedures in their HACCP plans, Sanitation SOPs, or prerequisite programs that ensure that carcasses that are not further processed in the establishment do not leave the establishment unmarked. Other establishments will need to revise these procedures. However, FSIS expects that any costs associated with revising the procedures would be offset by increased flexibility allowed to those establishments as discussed in the foregoing section.

#### **Regulatory Flexibility Act Assessment**

The FSIS Administrator has made a preliminary determination that this

<sup>1</sup> Data source: Public Health Inspection System as of June 2017, provided by FSIS's Office of Data Integration and Food Protection.

<sup>2</sup> Livestock Slaughter 2016 Summary (April 2017). USDA, National Agricultural Statistics. <http://usda.mannlib.cornell.edu/usda/current/LiveSlauSu/LiveSlauSu-04-19-2017.pdf>, p.15. accessed 06/01/2017.

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

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

proposed 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 proposed 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 proposed rule would yield cost savings. Therefore, if finalized as proposed, this rule is expected to be an E.O. 13771 deregulatory action.

#### Paperwork Reduction Act

There are no paperwork or recordkeeping requirements associated with this proposed 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 proposed 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.

#### USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

#### How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at [http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain\\_combined\\_6\\_8\\_12.pdf](http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf), or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email: *Mail:* U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410; *Fax:* (202) 690–7442; *Email:* [program.intake@usda.gov](mailto:program.intake@usda.gov).

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

#### 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. Constituent updates are 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 email 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 proposing to amend 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, provided the establishment develops and implements, as part of a HACCP plan, Sanitation SOPs, or other prerequisite program, procedures 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 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.

\* \* \* \* \*

Done in Washington, DC.

**Paul Kiecker,**

*Acting Administrator.*

[FR Doc. 2018-16345 Filed 7-30-18; 8:45 am]

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## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

#### 9 CFR Parts 318 and 381

[Docket No. FSIS 2016-0032]

RIN 0583-AD66

#### Preparation of Uninspected Products Outside of the Hours of Inspectional Supervision

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** FSIS is proposing to amend the Federal meat and poultry products inspection regulations to eliminate prescriptive requirements governing the manufacture of uninspected products, such as pet food, in edible product areas of official establishments and to allow official establishments to manufacture such products outside the hours of inspection.

**DATES:** To receive full consideration, comments should be received by August 30, 2018.

**ADDRESSES:** FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail, including CD-ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

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*Docket:* For access to background documents or comments received, call (202) 720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

**FOR FURTHER INFORMATION CONTACT:**

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

**SUPPLEMENTARY INFORMATION:**

**Background**

FSIS regulations at 9 CFR 318.12 and 381.152 govern the manufacture of pet food and other uninspected, inedible products in official meat and poultry establishments. These regulations set forth prescriptive requirements intended to prevent the creation of insanitary conditions in official establishments, the commingling of inedible and edible meat and poultry products, and the movement of inedible meat and poultry products into commerce as human food. They also require that pet food and other inedible products be manufactured in official establishments *only* when an FSIS inspector is on premises.

These prescriptive requirements for the production of pet food and other inedible products (*e.g.*, inedible rendered fats, lungs, lung lobes, and experimental products) are incompatible with the Hazard Analysis and Critical Control Point (HACCP) regulations at 9 CFR part 417 and the related sanitation regulations at 9 CFR part 416. Under the HACCP regulations, establishments are responsible for developing and implementing HACCP plans incorporating the controls determined by the establishment to be necessary and appropriate to produce safe, unadulterated products. Specifically under HACCP, official establishments must determine the food safety hazards reasonably likely to occur in the production process; institute controls necessary to prevent those hazards from occurring or keeping them within acceptable limits; monitor the performance of controls and verify the HACCP system is working as intended; and maintain required HACCP records. HACCP is a flexible system that appropriately places the responsibility for food safety on establishments and enables them to tailor their control systems to the needs of specific processes and operating conditions.

Similarly, the Sanitation Performance Standards (SPS) and requirements for Sanitation Standard Operating Procedures (SOPs) at 9 CFR part 416 set forth sanitation objectives to be

achieved, while allowing establishments to develop and employ innovative and effective sanitation procedures customized to the nature of their operations. Under the Sanitation SOP regulations, FSIS requires that all inspected establishments develop and implement written Sanitation SOPs to prevent direct contamination or adulteration of product before and during operations. An establishment's Sanitation SOP typically covers the scheduled, daily pre-operational and operational cleaning and sanitation of equipment and surfaces that may contact product directly. Under the SPS regulations, establishments must address all of the other aspects of establishment sanitation that can affect food safety, *e.g.*, pest control, adequate ventilation, lighting, and plumbing systems.

Under the HACCP and sanitation requirements, an establishment that produces both edible and inedible meat and poultry products must develop and implement the controls and procedures necessary to prevent the adulteration of edible products by insanitary conditions and product commingling, as well as the movement of inedible products into commerce as human food. FSIS inspectors verify the implementation and effectiveness of these controls through inspection, records review and, as necessary, product sampling. Thus, FSIS inspectors do not need to be present in an official establishment when it manufactures inedible products in order to verify that edible products are not adulterated as a result.

**Proposed Changes**

FSIS is proposing to eliminate the prescriptive regulatory requirements at 9 CFR 318.12 and 381.152 governing the manufacture of uninspected, inedible products, such as pet food, and restricting the hours during which such products may be prepared in an official establishment. Specifically, these regulations set forth specific requirements regarding the sanitary handling of inedible products and their separation from edible products, as well as the placement, movement and cleaning of equipment in areas where inedible product is manufactured. They also require that the manufacture of uninspected, inedible products be conducted only during those hours in which the establishment operates under inspectional supervision. These regulations were issued before FSIS published its HACCP and Sanitation SOP regulations, when prescriptive regulatory requirements were deemed necessary to prevent the adulteration of meat and poultry products by the