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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: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending 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. These prescriptive regulations are no longer necessary and are inconsistent with the Hazard Analysis and Critical Control Point (HACCP) and sanitation regulations. Removal of these unnecessary provisions will provide establishments the flexibility to be innovative and operate in the most efficient, cost effective manner.

DATES: *Effective* [INSERT DATE 60 DAYS AFTER DATE OF 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, July 31, 2018 (83 FR 36797), FSIS proposed to eliminate the prescriptive regulatory requirements at 9 CFR 318.12 and 381.152 that govern the manufacture of uninspected, inedible products, such as pet food, and restrict the hours during which such products may be prepared in an official establishment. These prescriptive regulations were issued before FSIS published its regulations requiring HACCP, Sanitation Standard Operating Procedures (sanitation SOPs), and compliance with the Sanitation Performance Standards. Under 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 to prevent the movement of inedible products into commerce as human food.

FSIS is finalizing the proposed rule with one non-substantive technical correction. Specifically, FSIS is adding a reference to the revised regulations in 9 CFR 381.193, which govern the labeling of uninspected, inedible poultry products.

This citation was inadvertently left out of the proposal to revise the regulations at 9 CFR 381.152, but an analogous citation was proposed for meat regulations at 9 CFR 318.12(b).

Responses to Comments

FSIS received eight comments on the proposed rule submitted by a trade association representing the pet food industry, a trade organization representing the meat and poultry industry, five individuals, and a commenter purporting to be an airline. The meat and poultry trade organization and one individual supported the proposal. A summary of issues raised by other commenters follows:

Comment: The trade association representing the pet food industry urged FSIS to work with the U.S. Food and Drug Administration (FDA) to ensure that all establishments under FSIS regulatory oversight are aware that FDA regulations implementing the Food Safety Modernization Act (FSMA) require certain firms that produce animal food to perform a hazard analysis and establish and implement risk-based preventive controls (see 80 FR 56169).

Response: FSIS will continue to work with FDA regarding official FSIS establishments that may need to comply with FDA's good manufacturing practice and/or preventive controls for animal food regulations.

Comment: Two individuals opposed the rule, expressing concerns that it would result in there being no regulatory oversight of pet food production.

Response: Pet food products will continue to be regulated at both the Federal and State levels. At the Federal level, FDA regulates animal feed and companion animal food. The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that all animal foods, like human foods, be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled. Most states also have laws that require registration or licensing to sell animal food.

Comment: An individual asked for clarification on how the proposed change affects or applies to retail exempt facilities.

Response: This final rule removes requirements in 9 CFR 318.12 and 381.152, which only apply to official establishments producing meat and poultry products under Federal inspection. This final rule does not address the preparation or processing of animal food at retail firms, including those that operate under FSIS's retail exemption.

Comment: One comment from a former inspector expressed concerns that the proposal would lessen the ability of FSIS inspectors to ensure that inedible products are not put into commerce as human food.

Response: This rule does not affect the authority or ability of FSIS inspectors to verify that official establishments manufacturing inedible product are keeping it separate from meat and poultry products and not otherwise creating insanitary conditions through its manufacture. Nor does this rule affect the authority or ability of FSIS inspectors to take enforcement actions to prevent inedible product from entering commerce as human food.

Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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 Impact Analysis

As stated above, compliance with HACCP and sanitation regulations facilitates the production of safe, unadulterated

product by establishments and makes the prescriptive requirements in 9 CFR 318.12 and 381.152 unnecessary. Because these prescriptive requirements are no longer necessary to ensure the production of safe, unadulterated food, removing them will have no negative public health impact. In addition, this rule will not impose costs on the industry or the Agency.

Further, removing the unnecessary, prescriptive requirements should allow establishments additional flexibility to be innovative and to operate in the most efficient, cost effective manner. Similarly, the rule should also allow FSIS to use its resources more appropriately. However, FSIS cannot quantify these savings.

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 economic impact on a substantial number of small entities in the United States. 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 final rule is an E.O. 13771 deregulatory action.

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.

Paperwork Reduction Act

There are no paperwork or recordkeeping requirements associated with this proposed rule under the Paperwork Reduction Act of 1995 (44 USC 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 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.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: <http://www.fsis.usda.gov/federal-register>. FSIS will also announce and provide a link to it 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.

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Mail:

U.S. Department of Agriculture
Director, Office of Adjudication
1400 Independence Avenue, SW
Washington, DC 20250-9410

Fax: (202) 690-7442

E-mail: program.intake@usda.gov

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List of Subjects

9 CFR Part 318

Food additives, Food packaging, Laboratories, Meat inspection, Reporting and recordkeeping requirements, Signs and symbols.

9 CFR Part 381

Administrative practice and procedure, Animal diseases, Crime, Exports, Food grades and standards, Food labeling, Food packaging, Government employees, Grant programs-agriculture, Intergovernmental relations, Laboratories, Meat inspection, Nutrition, Polychlorinated biphenyls, Poultry and poultry products, Reporting and recordkeeping requirements, Seizures and

forfeitures, Signs and symbols, Technical Assistance,
Transportation.

For the reasons set forth in the preamble, FSIS amends 9
CFR parts 318 and 381 as follows:

**PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND
PREPARATION OF PRODUCTS**

1. The authority citation for part 318 continues to read as
follows:

Authority: 7 U.S.C. 138f, 450, 1901-1906; 21 U.S.C. 601
695; 7 CFR 2.18, 2.53.

2. Section 318.12 is revised to read as follows:

**§ 318.12 Manufacture of uninspected, inedible products at
official establishments.**

(a) Official establishments may manufacture pet food or
similar uninspected, inedible products in areas where edible
products also are produced, provided that the manufacture of
uninspected, inedible products does not:

(1) Adulterate edible products;

(2) Create insanitary conditions in the official
establishment whereby edible products may be adulterated; or

(3) Prevent or interfere with inspection or other program
tasks performed by FSIS personnel in the official establishment.

(b) Pet food and similar uninspected, inedible products
must be distinguished from edible products so as to avoid their

distribution as human food. Pet food or similar uninspected, inedible products must be labeled or otherwise identified in accordance with § 325.11(d) of this subchapter.

PART 381—POULTRY PRODUCTS INSPECTIONS REGULATIONS

3. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 451-470; 7 CFR 2.18, 2.53.

4. Section 381.152 is revised to read as follows:

§ 381.152 Manufacture of uninspected, inedible products at official establishments.

(a) Official establishments may manufacture pet food or similar uninspected, inedible products in areas where edible products also are produced, provided that the manufacture of uninspected, inedible products does not:

(1) Adulterate edible products;

(2) Create insanitary conditions in the official establishment whereby edible products may be adulterated; or

(3) Prevent or interfere with inspection or other program tasks performed by FSIS personnel in the official establishment.

(b) The immediate container of uninspected, inedible products manufactured in an official establishment shall be

conspicuously labeled so as to distinguish them from human food
in accordance with § 381.193 of this subchapter.

Done in Washington, DC.

Carmen M. Rottenberg,
Administrator.

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