



**Billing Code 3410-DM-P**

**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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**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 Web site 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.

- 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; 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 preparation of inedible products in the same establishment.

FSIS is proposing to replace the prescriptive requirements in 9 CFR 318.12 and 381.152 with general standards governing the manufacture of uninspected, inedible products in official establishments. The proposed standards require that the manufacture of uninspected products in official establishments must not result in the adulteration of meat and poultry products, create insanitary conditions whereby meat and poultry products may be adulterated, or prevent or otherwise interfere with inspection or other program tasks performed by FSIS personnel. Establishments that manufacture pet food and other inedible products should be meeting these proposed standards already, through the implementation of their HACCP plans, Sanitation SOPs or other prerequisite programs.

**Executive Order 12866 and the Regulatory Flexibility Act**

This proposed rule has been designated as a "non-significant" regulatory action under section 3(f) of Executive Order (E.O.) 12866. Accordingly, the proposed rule has not been reviewed by the Office of Management and Budget under E.O.

12866.

### **Economic Impact Analysis**

As stated above, the HACCP and the sanitation regulations provide a framework or food safety system for establishments to produce safe, unadulterated product. Compliance with these requirements makes the prescriptive requirements in 9 CFR 318.12 and 381.151 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 manner. Similarly, the rule should also allow FSIS to use its resources more appropriately by relieving inspectors of unnecessary tasks.

### **Regulatory Flexibility Act (RFA)**

FSIS has examined the economic implications of the proposed rule as required by the RFA (5 U.S.C 601-612). If a rule has a significant economic impact on a substantial number of small entities, the RFA requires that regulatory options that would lessen the economic effect of the rule on small entities be analyzed. FSIS has determined that, should it become final, the proposed rule would not have a significant impact on a

substantial number of small entities.

**Executive Order 13771**

This proposed rule, if finalized as proposed, is expected to be a deregulatory action under E.O. 13771. Assessment of the costs and cost savings may be found in the preceding economic analysis.

**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 12988, Civil Justice Reform**

This proposed rule has been reviewed under Executive Order 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 Executive Order 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, the Food Safety and Inspection Service 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

E-mail: [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. The 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**

*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 is proposing to amend 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.

Done in Washington, DC.

Paul Kiecker,

Acting Administrator.

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