

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

6300.1
Rev. 2

DRAFT

MANUFACTURE OF ANIMAL FOOD OR UNINSPECTED ARTICLES AT OFFICIAL ESTABLISHMENTS

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) regarding their responsibilities in an official establishment that manufactures animal food or similar uninspected articles in the edible product department. FSIS is revising this directive because the Agency has issued a final rule removing the prescriptive regulatory requirements in 9 CFR 318.12 and 381.152 that govern the manufacture of uninspected products in edible product areas of official establishments and prohibit official establishments from manufacturing such products outside the hours of inspection. These amendments make the regulations at 9 CFR 318.12 and 381.152 consistent with the Hazard Analysis and Critical Control Point (HACCP) and sanitation regulations (9 CFR part 416 and 417).

KEY POINTS:

- Provides IPP information regarding establishments that produce pet food outside the hours of inspection.
- Provides IPP instructions for verifying an establishment's compliance with HACCP requirements when considering the manufacture of animal food or uninspected articles

II. CANCELLATION

FSIS Directive 6300.1, Manufacture of Animal Food or Uninspected Articles at Official Establishments, 3/20/15.

III. BACKGROUND

A. FSIS has published a final rule 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 (See [84 FR 40225](#)). The final rule is effective 10/15/19. Specifically, FSIS replaced the prescriptive requirements in 9 CFR 318.12 and 381.152, 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, with general sanitation standards. The new standards require that the manufacture of uninspected products in official establishments 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 or Sanitation Standard Operating Procedures (SOPs) or otherwise through compliance with the Sanitation Performance Standards.

B. The prescriptive regulations governing the manufacture of uninspected products were issued before FSIS published its regulations requiring HACCP, sanitation SOPs, and compliance with the Sanitation Performance Standards. At that time, meat and poultry establishments were not required to develop controls regarding the safe manufacture of uninspected, inedible products and thus FSIS allowed such manufacture only during hours of inspection.

C. Therefore, starting on 10/15/19, establishments can produce uninspected product outside the hours of inspection. Through compliance with the HACCP and sanitation regulations, establishments that produce uninspected products must prevent the commingling of inedible and edible products and the creation of insanitary conditions whereby meat and poultry products could be adulterated.

IV. IPP RESPONSIBILITIES IN ESTABLISHMENTS SUBJECT TO 9 CFR 318.12 and 381.152

A. IPP are to verify that establishments comply with [9 CFR 318.12\(a\)](#) or [381.152\(a\)](#) by using the PHIS Sanitation Performance Standards (SPS) Verification task and by following the instructions in [FSIS Directive 5000.1](#), *Verifying an Establishment's Food Safety System*, Chapter II, Part I and II.

B. IPP are to consider the following questions to determine whether inedible and uninspected products are being properly handled in the edible product department of the establishment:

1. Does the official establishment have adequate facilities to ensure that certain products are handled correctly under [9 CFR 310.16\(c\)](#), [314.10](#), [314.11](#), and other inedible products are prepared in a sanitary manner, i.e., facilities are adequate to ensure that only materials without pus, manure, diseased, septic, or toxic materials, or similar substances enter any edible product department?
2. Does the establishment have adequate facilities to maintain sanitary conditions if animal food is stored in the edible product department?
3. Is the animal food or uninspected product properly identified as required by [9 CFR 318.12\(b\)](#), [325.11\(d\)](#), [381.152\(b\)](#), or [381.193\(b\)](#)?

C. IPP are to document any noncompliance as set out in Chapter II of [FSIS Directive 5000.1](#).

D. IPP are to take a regulatory control action to stop the use of the equipment when the manufacturing of uninspected animal food:

1. Results in the creation of insanitary conditions;
2. Adulterates inspected product;
3. Interferes with the preparation of the inspected product; or
4. Interferes with inspection.

V. IPP RESPONSIBILITIES IN ESTABLISHMENTS NOT SUBJECT TO 9 CFR 318.12 AND 381.152

The regulatory requirements in [9 CFR 318.12](#) and [381.152](#) do not apply to the irradiation or high pressure processing (HPP) of animal food or similar uninspected articles not intended for human consumption provided that IPP verify that the establishment does the following:

1. Neither manufactures nor prepares animal food or other articles not intended for human food as discussed in 9 CFR [318.12](#) or [381.152](#). Under these regulations, “manufacturing” or “preparation” includes product formulation or physical handling of exposed raw materials;
2. Has procedures in its Sanitation SOP that address how it will ensure compliance with [9 CFR 416.12](#) when changing operation from uninspected articles processing to processing of inspected meat, poultry, or egg products. For example, the Sanitation SOP program has a written program to identify, control, and segregate the uninspected articles from inspected articles to include:
 - a. Distinguishing the animal food from articles of human food in accordance with 9 CFR [325.11\(d\)](#); or
 - b. Distinguishing the animal food from human food in accordance with 9 CFR [381.193\(b\)](#); and
3. Handles only sealed final-packaged inspected and uninspected articles that are not opened or exposed to the environment. This assumes leakers that occur during HPP are destroyed.

NOTE: When the requirements in [9 CFR 318.12\(b\)](#) and [381.193\(b\)](#) are met, the establishment may bring uninspected animal food and inedible product not intended for human consumption into the official establishment in accordance with [9 CFR 318.1\(a\)](#) and [381.145\(a\)](#).

VI. QUESTIONS

Refer questions regarding this directive to the Policy Development Staff through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 6300.1**.

Question Field: Enter your question with as much detail as possible.

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **Regulations/Agency Issuance** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: For additional information regarding how to submit a question in askFSIS, IPP are to refer to [FSIS Directive 5620.1](#), *Using askFSIS*.

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