

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

FSIS NOTICE	58-09	8/26/09
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**MANUFACTURE OF ANIMAL FOOD OR UNINSPECTED ARTICLES
AT OFFICIAL ESTABLISHMENTS**

I. PURPOSE

This notice provides instructions to inspection program personnel (IPP) on the Agency's policy, and their responsibilities, in an official establishment that manufactures animal food or similar uninspected articles in the edible product department. FSIS is issuing this notice to provide clarification because of concerns raised by an askFSIS question and answer regarding animal food. Specifically, this notice addresses when inedible products may enter the edible product department for the manufacture of animal food or uninspected articles.

II. BACKGROUND

9 CFR 318.12 and 381.152 outline the regulatory requirements for manufacturing animal food or similar articles in an official establishment. These regulations permit the preparation of animal food or other uninspected articles (uninspected meat or meat food products) in the edible and inedible departments of official establishments. Additionally, animal food manufacturing is subject to the Federal Food, Drug, and Cosmetic Act requirements.

III. REGULATORY REQUIREMENTS

A. Under 9 CFR 318.12(a), animal food and other uninspected products may be manufactured in the same department as edible product, provided:

1. there is sufficient space and adequate equipment allotted to the production of the uninspected articles not intended for human food, so that such production in no way interferes with the handling and preparation of edible product, and such articles in no way commingle with, contaminate, or adulterate inspected product intended for human consumption;

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2. where necessary to avoid adulteration of inspected product, separate equipment is used for production of the uninspected articles not intended for human food; and

3. the preparation of the uninspected articles is subject to the same sanitary conditions that apply to operations in the edible product departments to avoid the creation of insanitary conditions in the edible product departments.

B. Under 9 CFR 381.152(a), official establishments that produce poultry products may manufacture animal food in the edible product department from inspected and passed product, provided:

1. the inedible product is prepared so as not to be contaminated with feces or other digestive tract content, and it does not contain entrails, feathers, or septic or toxic materials (9 CFR 381.152(b), 38.195, and 381.193);

2. the establishment has adequate space and equipment to ensure that the preparation of animal food does not interfere with the handling and preparation of edible product;

3. the manufacture of animal food is subject to the same sanitary conditions as the preparation of edible product (9 CFR 416); and

4. the establishment uses separate equipment for the production of animal food, or in some other way ensures that the equipment does not contaminate inspected product.

IV. IPP RESPONSIBILITIES

A. IPP are to verify that establishments comply with 9 CFR 318.12 or 381.152 by using the Performance Based Inspection System (PBIS) Inspection System Procedure 06D01 *Facilities and Equipment* and by following the instructions in FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*, Chapter I, Parts V., XI.,XII.

<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5000.1Rev3.pdf>

B. IPP are to use 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 so that the carcasses or parts saved under 9 CFR 314.11 and other inedible products are prepared in a sanitary manner without pus, manure, septic, toxic materials, or similar substances before entering any edible product department?

2. Is the manufacturing of uninspected products, such as animal food, in the edible product departments limited to the establishment's approved hours of operation?

3. Does the establishment have adequate facilities to maintain sanitary conditions if animal food is stored in the edible product department?

4. Is the animal food or uninspected product properly identified as required by 9 CFR 318.12(c), 325.11(d), 381.193(b), or 9 CFR 381.152(c)?

NOTE: The brain and spinal cord from cattle 30 months of age and older are to be removed from any article used for preparation of animal food as required by the Food and Drug Administration's regulations (21 CFR 589.2001).

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=8f6d4f71330c3337921d820e1854476e&rgn=div5&view=text&node=21:6.0.1.1.26&idno=21>

C. IPP are to document any non-compliances as set out in Chapter IV of FSIS Directive 5000.1.

D. When the manufacture of the uninspected animal food interferes with the preparation of, poses a food safety hazard to, or results in adulteration of the inspected product, or when it could interfere with inspection, IPP are to take a control action to stop the use of the equipment. In this situation, the establishment is to provide separate equipment for the uninspected articles in accordance with 9 CFR 318.12(a).

V. DATA ANALYSIS

The Office of Data Integration and Food Protection, Data Analysis and Integration Group (DAIG) will analyze PBIS data monthly for 06D01 non-compliances to identify establishments that manufacture animal food or similar uninspected articles in the edible product department and have a high rate of noncompliance with 9 CFR 318.12 and 381.152. That analysis will also evaluate trends in noncompliance with 9 CFR 318.12 and 381.152. The DAIG will report the findings of those analyses to the Office of Policy and Program Development and the Office of Field Operations.

Refer questions regarding this notice to the Policy Development Division through askFSIS at <http://askfsis.custhelp.com> or by telephone at 1-800-233-3935.



Assistant Administrator
Office of Policy and Program Development