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

FSIS DIRECTIVE

5930.1
Revision 3

4/26/07

CUSTOM EXEMPT REVIEW PROCESS

I. PURPOSE

This directive describes the policies and procedures for the review of custom livestock or poultry slaughtering and processing operations that are exempt from inspection requirements under the Acts, and the actions that FSIS may take when custom exempt facilities and operators do not maintain compliance with the applicable statutory and regulatory requirements. This directive also updates methodologies for determining whether establishments are meeting performance standards for sanitation as set out in the Sanitation Performance Standards regulations; reflects organizational changes in FSIS; and reflects policies regarding Bovine Spongiform Encephalopathy (BSE) and Specified Risk Materials (SRMs).

II. CANCELLATION

FSIS Directive 5930.1, Revision 2, dated 2/5/92

III. REASON FOR REISSUANCE

FSIS is reissuing this directive in its entirety to update the custom exempt review process.

IV. REFERENCES

21 U.S.C. 10, 12, 464, 623, 642, 1044, 42 U.S.C. Chapter 6A Section 300 g-1
9 CFR Parts 303.1, 310.22, 316.6, 381.10, 381.13, 381.14, and
416.1-5
FSIS Directives 5420.3, 5720.2, Revision 3, and 8410.1, Revision 2

DISTRIBUTION: Inspection Offices; T/A Inspectors;
Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC; Import Offices

OPI: OPPED

V. BACKGROUND

The Federal Meat Inspection Act and the Poultry Products Inspection Act exempt the preparation of livestock products and the processing of poultry products from mandatory inspection when the owner of the livestock slaughters it for his own use, or for use by members of his household or nonpaying guests. Custom slaughter or processing may also be conducted when the animal is slaughtered or processed by someone other than the owner for the personal use of the owner of the animal. The FMIA and PPIA require that those who custom slaughter or process meat and poultry ensure that carcasses and products are:

1. not adulterated or misbranded;

2. prepared under sanitary conditions;

3. properly marked and packaged; and

4. stored separately from other products.

Owner/operators who conduct custom exempt operations must comply with the meat and poultry regulations for exempt operations (9 CFR 303.1, 381.10, 381.13, and 381.14) and some of the sanitation regulations (9 CFR 416.1 through 416.5, except for 9 CFR 416.2(g)(2) through (6)). If an official meat establishment conducts custom exempt operations, all the provisions of the sanitation regulations (9 CFR Part 416) apply to the custom operations. Federally-inspected poultry establishments are prohibited under the PPIA (21 U.S.C. 464(c)(1)(B)) from conducting custom exempt poultry operations. In addition, poultry custom exempt operators cannot buy or sell any poultry products for use as human food.

NOTE: There are no custom exemptions provided for shell eggs or egg products in the Egg Products Inspection Act (EPIA) (21 U.S.C. 1044).

VI. RESPONSIBILITIES OF FSIS PERSONNEL IN REVIEWS OF CUSTOM EXEMPT OPERATIONS

A. Office of Field Operations' (OFO) program employees (Inspector-in-Charge (IIC) or designee) will review custom exempt operations that occur at federally-inspected meat establishments.

B. Agency personnel will review custom exempt operations at facilities in designated states that are not subject to routine inspection. Agencies of designated States may conduct reviews of custom exempt operations in those States under the terms of cooperative agreements with FSIS. FSIS monitors the cooperative agreements program through audits and reviews.

C. States that are not designated (i.e., that maintain their own meat or poultry inspection programs) are expected to conduct reviews of custom exempt operations in their State in a manner that is equal to the Federal system. FSIS monitors custom exempt review programs in these states as part of its review of the overall State program.

VII. CONDUCTING REVIEWS OF CUSTOM FACILITIES

FSIS employees conducting reviews at custom exempt facilities to determine compliance with sanitation or other statutory and regulatory requirements for exemption should observe each of the activities listed in this section and complete FSIS Form 5930-1, "Exempt Establishment Review Report," which is available in Outlook at: Public Folders/All Public Folders/Agency Issuance/Forms/FSIS Forms 5,000 Series.

NOTE: Commingling of fat trimmings and meat trimmings from custom exempt animals to facilitate rendering or sausage production is allowed when the owners involved accept the commingling. The proportionate distribution of product from the commingled trimmings must also be acceptable to the owners of the animals.

NOTE: Inspected product can be commingled with custom exempt trimmings to facilitate rendering or sausage production. All of the resulting commingled processed product must have the mark of inspection removed and must be clearly marked "Not for Sale."

Included in the discussion that follows is a series of questions that reviewers are to consider in making their determinations on acceptability. These questions are meant to focus the reviewers on significant matters. They are not intended as a checklist.

A. **Recordkeeping and Documentation.** FSIS employees should assess whether the facility is maintaining records to show that it is operating in a manner that is eligible for custom exemption; the chemicals used in the operation are safe in a food processing environment; SRMs are removed when required; and the water and sewage systems are approved by the appropriate authority (FMIA, PPIA, 9 CFR 303.1(b)(3), 310.22, 320, and 381.175).

1. Does the facility maintain records that document the number and kinds of custom livestock slaughtered, the quantities and types of custom product prepared, and the names and addresses of the owners of the livestock and products?

2. Does the facility maintain records from the State or local health agency that show that the water and sewage systems are safe?

3. Does the facility maintain records that demonstrate that the chemicals used in the facility are safe for the food processing environment?

4. Does the facility maintain records that document that cattle were ambulatory at the time of slaughter, and that the SRMs were properly disposed of?

5. In federally inspected establishments that conduct custom exempt operations, does the establishment maintain Sanitation Standard Operating Procedure (SSOP) records per 9 CFR 416.16 that reflect conditions during the custom operations.?

NOTE: If during the review of a custom exempt operation Agency personnel observe inhumane handling of livestock, they should immediately inform plant management. FSIS personnel will document their observations in a letter (original to the plant and copies to the plant file). If the facility is also a Federal establishment, the inspection personnel are to notify the District Office/Regional Manager (RM). The District Office/Regional Manager is to notify the appropriate State authority of the inhumane handling.

B. General Sanitation, Maintenance of Facilities, and Dressing Rooms, Lavatories, and Toilets

General Sanitation

FSIS employees should assess whether the facility is maintaining sanitary conditions that comply with 9 CFR 303.1(a)(2)(i), 381.10(e)(3)(i), 416.3, and 416.4.

1. Does the facility clean and sanitize all food contact surfaces, equipment, and utensils as frequently as necessary to prevent insanitary conditions and the adulteration of product?

2. Does the facility clean and sanitize nonfood contact surfaces, equipment, and utensils as necessary to prevent insanitary conditions and the adulteration of product?

3. Are all cleaning compounds, sanitizing agents, processing aids, and other chemicals used by the facility safe and effective under the conditions of use?

4. Does the facility protect product from adulteration during processing, handling, storage, loading and unloading, and transportation?

Maintenance of Facilities

FSIS employees should assess the maintenance of the facility used to slaughter and process custom exempt product (9 CFR 303.1(a)(2)(i), 381.10(a)(3) & (4), and 416.2(b)). The facility must ensure the production of wholesome and unadulterated product.

1. Are the buildings, including their structures, rooms, and compartments, kept in good repair, and are they of sufficient size to allow for processing, handling, and storage of product?

2. Does the facility clean and sanitize the walls, floors, and ceilings as necessary?

3. Does the facility maintain the walls, floors, ceilings, doors, windows, and other outside openings in a manner that prevents the entrance of vermin, such as flies, rats, and mice?

4. Does the facility process, handle, and store edible products and inedible products to prevent product adulteration, cross-contamination, or the creation of insanitary conditions?

5. Does the facility properly denature or decharacterize inedible product?

6. Is there direct product contamination?

Dressing Rooms, Lavatories, and Toilets

FSIS employees should assess the facility's dressing rooms, toilet rooms, and urinals to ensure the cleanliness of all persons handling any product (9 CFR 303.1(a)(2)(i), 381.10(a)(3) & (4), and 416.2(h)(1) & (3)).

1. Does the facility maintain dressing rooms, toilet rooms, and urinals (sufficient in number, ample in size, and conveniently located) in a sanitary condition and in good repair?

2. Are the dressing rooms, toilet rooms, and urinals separate from the rooms and compartments in which products are processed, stored, or handled?

3. Are there lavatories with running hot and cold water, and are soap and towels placed in or near toilet and urinal rooms and other places in the facility as necessary?

4. Are refuse receptacles constructed and maintained in a sanitary manner?

C. **Pest Control.** FSIS employees should assess whether the facility is maintaining the grounds around the operation to prevent conditions that could lead to insanitary conditions or adulteration of product. Facility operators must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within the facility (9 CFR 303.1(a)(2)(i), 381.10(a)(3) & (4), and 416.2(a)). FSIS reviewers are to assess the operator's pest control program to determine whether it is capable of preventing product adulteration.

1. Does the facility maintain all outside areas of the facility in a manner to prevent harborage and breeding of pests?

2. Does the facility maintain all areas within the facility in a manner to prevent the harborage and breeding of pests?

3. Is there evidence of direct product contamination?

D. **Inedible Material Control.** The facility must handle and maintain inedible material to prevent the diversion of inedible animal products (including SRMs) into human food channels and the adulteration of human food (9 CFR 303.1(a)(2)(i), 303.1(b)(4), 381.10(a)(3) & (4), 416.2(b)(4), and 416.3(c)). SRMs are defined as the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle 30 months of age or older, and the distal ileum of all cattle (9 CFR

310.22). Tonsils from all cattle are also considered inedible and, therefore, are not to enter the food supply (9 CFR 310.22). Cattle that are not ambulatory at the time of slaughter are inedible.

1. Does the facility handle and store inedible products, including SRMs, in a manner that prevents product adulteration and the creation of insanitary conditions?

2. If the facility processes beef, does it remove the SRMs and keep records documenting that the animal was less than 30 months of age at the time of slaughter?

3. Was the animal ambulatory at the time of slaughter, or are there records documenting that the livestock was ambulatory at the time of slaughter?

4. How is the exempt operation handling or disposing of SRM material?

E. Marking and Labeling Custom Exempt Products and Containers. The facility must mark legibly as "NOT FOR SALE" all meat and poultry products or containers (9 CFR 303.1(a)(2)(ii)&(iii) and 381.10(a)(4)).

1. Does the facility separate custom exempt meat and poultry products from other products?

2. Are all custom exempt meat products marked "NOT FOR SALE"?

3. Are shipping containers for custom exempt poultry marked with the producer's name and address and the statement "Exempted -- P.L. 90-492" if applicable?

NOTE: A custom exempt operator can process, as custom exempt, livestock carcasses that were slaughtered under inspection. However, the establishment cannot sell the processed meat because the product was not produced under FSIS inspection. The establishment is to remove the "INSPECTED AND PASSED" marks and mark the products "NOT FOR SALE" (21 U.S.C. 623).

F. Pathogen Control. Custom exempt facilities that cook product are to heat the product at a sufficient temperature and for a sufficient time to kill pathogens (9 CFR 303.1(b)(1) and 381.10(a)(3) & (4)). The custom exempt facility must sufficiently cool the product to prevent the growth of pathogens. The facility must treat meat food products containing raw pork to destroy trichinae (excluding fresh pork products as defined by 9 CFR 318.10 of the regulations). Poultry products containing pork as an ingredient are subject to the trichinae treatment requirements in 9 CFR 318.10 of the regulations for meat products consisting of mixtures of pork and other ingredients.

1. Are there controls in place to destroy trichinae in products that contain pork?

2. Is there evidence of a lack of control over the sanitary conditions in the facility such that the products being produced may be adulterated by pathogens?

G. **Water Supply.** The facility needs to have a supply of running water that complies with the National Primary Drinking Water Standards in accordance with 42 U.S.C. Chapter 6A Section 300g-1, 40 CFR 141, and 9 CFR 416.2(g)(1). Custom exempt operations conducted at non-inspected facilities may not reuse water. FSIS reviewers should seek answers to the following questions in making decisions on acceptability:

1. Does the facility provide sufficient quantities of water throughout the facility?

2. Does the facility have records documenting water potability in compliance with 9 CFR 416.2(g)(1)?

3. Is there sufficient water available at a sufficient temperature to ensure proper cleaning of equipment?

4. Is there adequate water pressure and is the water at a suitable temperature, in all areas where required, to ensure proper cleaning of equipment?

5. Are non-potable water pipes separate from potable water pipes? Does the facility properly identify them?

6. Does the facility reuse the water for any purpose?

H. **Sewage and Waste Disposal.** The facility must maintain sewage waste disposal systems that properly remove sewage and waste materials to prevent the adulteration of food products (9 CFR 303.1(a)(2)(i), 381.10(a)(3) & (4), and 416.2(e) & (f)).

1. Does the plumbing system properly transport sewage and disposable waste from the facility?

2. Does the plumbing system provide adequate floor drainage?

3. Does the facility have plumbing that prevents back-flow conditions and cross connections between piping systems that discharge wastewater or sewage, and piping systems that carry water for product manufacturing?

4. Does the plumbing prevent the backup of sewer gases?

5. Is the sewage disposed of into a sewage system separate from all other drainage lines or other means to prevent backup of sewage into areas where product is processed, handled, or stored?

6. If the sewage disposal system is a private system requiring approval by a State or local health authority, is the letter of approval available?

7. Is there evidence of direct product contamination?

VIII. ADDITIONAL REQUIREMENTS FOR CUSTOM EXEMPT OPERATIONS AT OFFICIAL ESTABLISHMENTS

In addition to the requirements in Section VII, which apply to all custom exempt operations, there are several requirements that only apply to custom operations that are conducted at official establishments.

A. Inspection program personnel are to verify that the establishment segregates animals intended for custom exempt slaughter from animals designated for inspected slaughter. If animals intended for the custom operation are commingled with animals designated for USDA-inspected slaughter, inspection program personnel are to consider the animals as "for inspection" and verify that the establishment handles them as such. Also, once an establishment presents an animal for ante-mortem inspection, the establishment cannot change the status to "intended for custom exempt."

NOTE: An establishment can perform custom exempt slaughter operations at the same time that USDA slaughter inspection is occurring as long as there is a complete physical separation of product and facilities. Inspection program personnel are to verify the separation of custom prepared and inspected product through the performance of PBIS procedure 06B01.

B. Inspection program personnel are to verify that the establishment clearly marks all carcasses and parts from custom slaughter as "NOT FOR SALE" and separates these carcasses from carcasses and parts slaughtered under inspection (see 9 CFR 316.16). When inspection program personnel observe an unmarked carcass, they are to retain the carcass and notify the IIC who will determine what other actions to take.

C. Inspection program personnel are to verify that when an establishment conducts custom exempt operations, such as cutting or boning, before the hours it operates under inspection, the establishment ensures that before its employees begin working during the hours of operation under inspection, they:

1. change outer garments;

2. clean and sanitize their hands; and

3. clean and sanitize the facilities and equipment as set out in the establishment's Sanitation Standard Operating Procedures.

D. Inspection program personnel are to verify that field-slaughtered or farm-dressed carcasses or parts entering an official establishment for custom processing are:

1. delivered in a sanitary manner;

2. ready for cutting up or processing;

3. clearly marked "NOT FOR SALE" upon entering any part of the facility; and

4. certified, in writing, as ambulatory at the time of slaughter by the owner of the animal (9 CFR 310.22).

E. Inspection program personnel are to verify that when an establishment packs custom exempt product with inspected product, it properly wraps, labels, and identifies all product, and that the shipping container of the custom exempt product does not have an official inspection legend.

IX. FREQUENCY OF REVIEWS OF CUSTOM EXEMPT OPERATIONS

FSIS program employees will conduct periodic reviews of custom slaughtering and processing operations to determine whether the operations that claim the custom exemption qualify for the exemption, and whether the facilities comply with all applicable regulations.

Custom exempt slaughtering and processing operations that operate in compliance with the statutory and regulatory requirements will typically receive no more than one scheduled verification review per year.

The past performance of the operation will determine the frequency at which FSIS will conduct reviews. Custom exempt operations that have a history of not operating at an acceptable level of performance and of not complying with all of the applicable statutory and regulatory requirements should receive follow-up verification reviews on a more frequent basis. District Offices and Regional Managers should schedule follow-up verification reviews based on consideration of the following factors:

1. nature of custom exempt operations and products produced under custom exemption;

2. compliance history;

3. observation of adulterated or misbranded product;

4. recordkeeping noncompliance;

5. sanitation noncompliance;

6. other relevant information, such as verified consumer complaints; and

7. availability of inspection program personnel.

NOTE: PBIS procedure 06B01 is not used to schedule and document the reviews of custom exempt operations as set out in this directive. Procedure 06B01 is used in inspected establishments to verify the proper separation of facilities and products in establishments where retail or custom activities are conducted.

NOTE: The frequency of reviews does not pertain to custom exempt plants operating under an administrative consent agreement or other applicable legal order or requirement (e.g., civil consent decree or plea agreement).

X. ENFORCEMENT ACTIONS

When FSIS reviews reveal that the custom exempt operations and facilities are out of compliance with applicable statutes or regulations, FSIS has the authority to take administrative, civil, or criminal action against the custom exempt operator to stop the exempt operations.

A. Agency employees that observe insanitary conditions, adulterated product, or misbranded product while reviewing custom exempt operations are to:

1. document the results of the review on FSIS Form 5930-1, fully describing any findings of noncompliance;

2. provide copies of FSIS Form 5930-1 to the owner/operator of the custom exempt facility and to the Regional Manager (OPEER reviewer) or the District Manager (DM) (OFO reviewer);

3. whenever possible, discuss the review findings with the owner/operator and inform the owner/operator of the conditions that need to be corrected;

4. conduct follow-up reviews as directed by the Regional/District Office; and

5. collect evidence, such as samples, photographs, statements, and facility records, to support any recommended action.

B. District Managers/ Regional Managers (or designees) are to:

1. determine when a follow-up review is necessary and direct the Agency employee to visit the custom exempt operation at that time;

2. upon notification that the custom exempt operator has failed to correct deficiencies in a satisfactory manner, issue a letter to the operator. The letter should state that the failure to take prompt and appropriate corrective action may result in a recommendation to pursue additional administrative or criminal sanctions; and

3. if noncompliance continues, refer documentation showing repeated or serious noncompliance with custom exempt requirements to the Office of Program Evaluation, Enforcement and Review (OPEER), Evaluation and Enforcement Division (EED), with a recommendation for administrative or other enforcement action.

NOTE: OFO employees document evidence to support administrative enforcement actions in an Administrative Enforcement Report (AER). Refer to FSIS Directive 5100.3 Revision 1, “Administrative Enforcement Reporting (AER) System” dated 3/7/06. The DM will forward the AER to the RM for the RM to forward to EED.

C. Regional Managers (or designees) will:

1. investigate alleged violations of the FMIA or PPIA involving the sale or distribution of products produced under custom exemption;

2. issue a “notice of warning” letter to the custom exempt operator when the violation is not serious enough to proceed with criminal proceedings. When the violation is serious enough, they will initiate administrative actions or forward an AER to OPEER, EED to pursue civil, injunctive, or criminal proceedings;

3. refer documentation showing repeated or serious noncompliance with custom exempt requirements or other violations of the FMIA or PPIA that warrant evaluation for criminal, civil, or administrative sanctions to the EED, OPEER, with a recommendation for action; and

4. ensure that the State programs are reviewing exempt operations in non-designated States to determine that each exempt operation meets the definitions and provisions contained in 21 U.S.C. 623 and 464 and accompanying regulations. These procedures are set out in FSIS Directive 5720.2, Revision 3, “State Cooperative Inspection Programs,” dated 11/16/04.

D. OPEER, EED Director (or designee) will:

1. review case evidence and recommendations to determine whether administrative action should be taken;

2. issue a “Show Cause” or “Present Your Views” letter to custom exempt operators before administrative action is taken;

3. issue a Notice of Ineligibility (NOI) to custom exempt operators that demonstrate their inability or unwillingness to implement and maintain compliance with applicable statutory and regulatory requirements and to ensure the production of unadulterated products. The NOI immediately terminates the eligibility of the owner/operator to operate under the custom exemption;

NOTE: An NOI can be issued without a “Show Cause” letter. In instances involving serious or egregious noncompliance, EED determines whether immediate administrative actions are appropriate.

4. refer criminal, civil, and administrative cases to the USDA Office of the General Counsel when the Agency wants to pursue such actions; and

5. when applicable, negotiate consent agreements with custom exempt operators.

Refer questions concerning the custom exempt review process to the Technical Service Center at 1-800-233-3935.

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