

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

FSIS DIRECTIVE

5930.1
Revision 4

7/15/09

CUSTOM EXEMPT REVIEW PROCESS

I. PURPOSE

This directive provides instructions for Food Safety and Inspection Service (FSIS) Inspection Program Personnel (IPP) and Office of Program Evaluation Enforcement and Review (OPEER) personnel to use when conducting reviews of custom exempt facilities to determine their compliance with the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), and applicable regulations. It also provides instructions to personnel on how to react to the findings from the review.

Key Points Covered:

- *Humane slaughter is now part of the custom exempt review process*
- *Handling and disposition of inedible materials including Specified Risk Materials (SRM)*
- *How to review Sanitation Standard Operating Procedure (Sanitation SOP) records at custom exempt facilities that are also Federal establishments*
- *The use of a new review form, FSIS Form 5930-1*
- *Information regarding Non-ambulatory Disabled Rule*

II. CANCELLATION

FSIS Directive 5930.1, Rev. 3, Custom Exempt Review Process, dated 4/26/2007

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to:

- Address FSIS policy on humane slaughter at custom exempt facilities;

- Issue a new version of FSIS Form 5930-1;
- Answer questions received by Office of Policy and Program Development (OPPD) and OPEER; and
- Explain the conditions under which custom exempt products can be transported between custom exempt facilities.

IV. REFERENCES

21 U.S.C. 10, 12, 610(b), 464, 623, 642, 1044, 42 U.S.C. Chapter 6A Section 300 g-1
 9 CFR parts 303.1, 309.3, 310.22, 313, 316.6, 320.1, 381.10, 381.13, 381.14, and
 416.1-5
 FSIS Directives 5420.3, 5720.2, and 8410.1

V. BACKGROUND

A. The FMIA and the PPIA exempt the preparation of livestock and poultry products from mandatory inspection when they are for the owner's own use, for use by members of the owner's household and nonpaying guests, or for persons employed by the owner.

B. 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.

C. Under 21 U.S.C. 610(b), slaughterers of livestock must comply with the Humane Methods of Slaughter Act (HMSA). The HMSA applies to the slaughter of cattle, calves, horses, mules, sheep, swine, and other livestock. (Poultry slaughter is not included.) The HMSA applies at custom exempt facilities.

D. Custom exempt product cannot be sold or donated.

E. The adulteration and misbranding provisions of the FMIA and PPIA apply to articles that are exempted from inspection requirements.

F. The FMIA and PPIA require that custom exempt operations:

1. Not adulterate or misbrand products;
2. Handle livestock humanely (FMIA);
3. Prepare products under sanitary conditions;
4. Keep certain records;
5. Properly mark, label, and package product; and

6. Keep exempt products separate from inspected products.

G. Owners and 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)). However, under 9 CFR 303.1(a)(2), if an official meat establishment at specified times conducts custom exempt operations, even though those operations are exempt from inspection, the establishment must, while conducting the custom exempt operations, comply with all of the provisions of the sanitation regulations (9 CFR part 416).

H. 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. ROLES OF FSIS PERSONNEL IN REVIEWS OF CUSTOM EXEMPT OPERATIONS

A. The Inspector-in-Charge (IIC) is to review custom exempt operations that occur at federally inspected 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 – meaning that they 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 EXEMPT FACILITIES TO DETERMINE COMPLIANCE

A. In determining compliance, FSIS personnel from the Office of Field Operations (OFO) or OPEER are to gather information by conducting reviews at custom exempt facilities (either in official establishments or a separate facility) to determine their acceptability under the sanitation, adulteration, mislabeling, and other statutory and regulatory requirements.

B. In determining overall acceptability, FSIS personnel are to consider the questions below in this section. They are to observe and review the records for each of the nine activities listed in item 7 in FSIS Form 5930-1, describe their findings in a MS Word document, and attach it to the review report.

NOTE: FSIS Form 5930-1, "Exempt Establishment Review Report," is available in Outlook at: *Public Folders/All Public Folders/Agency Issuance/Forms/FSIS Forms 5,000 Series*.

1. Humane Handling:

The HMSA requires that livestock be humanely handled in connection with slaughter, (21 U.S.C. 610(b)). FSIS personnel are to determine whether the facility is handling livestock in a humane manner by considering the following questions about any relevant activity that they observed:

- a. Does the facility have water available to any livestock in holding pens?
- b. Does the facility handle livestock humanely, moving animals calmly, and without excessive prodding? Are pens and alleys in good repair? Does the facility handle any disabled livestock humanely?
- c. Does the facility appropriately and effectively administer stunning methods that produce unconsciousness in any animal slaughtered before the animal is shackled, hoisted, thrown, cast, or cut?
- d. Does the facility slaughter animals in accordance with the ritual requirements of a religious faith that prescribes a method of slaughter whereby the animal suffers loss of consciousness by anemia of the brain, caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument and handling in connection with such slaughtering?
- e. Did FSIS personnel observe any egregious situations (any act that is cruel to animals or a condition that is ignored and lead to the harm of animals) or repeated noncompliance with inhumane slaughter?

2. Recordkeeping and Documentation:

FSIS personnel are to assess whether the facility maintains records that demonstrate that it is operating in compliance with the FMIA, PPIA, and the applicable regulatory requirements (9 CFR 303.1(b)(3), 309.3, 310.22, 320, and 381.175). For example, does the facility have records that demonstrate that the chemicals it uses in its operation are safe in a food processing environment; that inedible materials, including SRMs, are removed when required; and that the water and sewage systems are approved by the appropriate authority. FSIS personnel are to consider the following:

a. 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 (9 CFR 303.1(b)(3), 9 CFR 320)?

b. Does the facility maintain records for poultry operations (9 CFR 381.175), as applicable?

c. Does the facility maintain records from the state or local health agency documenting water potability (9 CFR 416.2(g)(1)) and the sewage systems are adequate (9 CFR 416.2(e), and 416.2(f))?

d. Does the facility maintain records that demonstrate that the chemicals used in the facility are safe for the food processing environment (9 CFR 416.4(c))?

e. Does the facility maintain records that document the ages of slaughtered cattle (less than 30 months or 30 months of age and older), that cattle were ambulatory at the time they were delivered to slaughter, and that SRMs were disposed of properly?

f. Does the facility maintain records that document the custom operator did not observe any condition that would render the cattle unfit for human food, or if they became non-ambulatory disabled after they were delivered to the facility?

NOTE: The Agency encourages the operators to keep these records to support that they are meeting the adulteration provisions of the FMIA and PPIA.

g. Does the facility maintain records demonstrating that the product is or was being transported at the product owner's direction, or if the custom exempt facility is transporting product to another custom exempt facility for further processing (9 CFR 303.1(b)(3) and part 320)?

NOTE: If an owner wishes to move custom exempt product from one custom exempt facility to another for further processing, the owner must demonstrate that it maintains control over the product, either by having direct physical control or by giving written direction to the custom facility owner or operator to move the product.

h. Does the facility keep records for two years after December 31 of the year in which the record was made (9 CFR 320.3 and 381.177)?

i. Does the custom exempt operation conducted in a federally inspected establishment maintain records to document the implementation and monitoring of the Sanitation SOP (9 CFR 416.16)?

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

Custom exempt operations must comply with the sanitation performance standard (SPS) regulations (9 CFR 416.1 through 416.5, except for 9 CFR 416.2(g)(2) through (6)). All the requirements in 9 CFR part 416 apply to custom exempt operations conducted in an official meat establishment.

General Sanitation

FSIS personnel are to assess whether the facility is maintaining sanitary conditions (9 CFR 303.1(a)(2)(i), 381.10(e)(3)(i), 416.3, and 416.4). FSIS personnel are to consider the following:

- a. 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?
- b. Does the facility clean and sanitize nonfood contact surfaces, equipment, and utensils as necessary to prevent insanitary conditions and the adulteration of product?
- c. Are all cleaning compounds, sanitizing agents, processing aids, and other chemicals used by the facility safe and effective under the conditions of use?
- d. Does the facility protect product from adulteration during processing, handling, storage, loading and unloading, and transportation?
- e. Are all inedible containers conspicuously marked to prevent use for storing edible products?
- f. Does the sanitary condition of the facility prevent product adulteration?
- g. Is there evidence of direct product adulteration?

Maintenance of Facilities

FSIS personnel are to assess the maintenance of the facilities used to slaughter and process custom exempt products, (9 CFR 303.1(a)(2)(i), 381.10(a)(3) & (4), and 416.2(b)), and verify that the facility's management is ensuring the production of wholesome and unadulterated product. FSIS personnel are to consider the following:

- a. Are the buildings, including structures, rooms, and compartments kept in good repair, and are they of sufficient size to allow for processing, handling, and storage of product?
- b. Does the facility maintain their walls, floors, and ceilings in good sanitary conditions?

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

d. Does the facility process, handle, and store edible products and inedible products in a manner that will prevent product adulteration, cross-contamination, or the creation of insanitary conditions?

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

f. Could any facility maintenance conditions lead to direct product contamination or adulteration?

Dressing Rooms, Lavatories, and Toilets

FSIS personnel are to assess the facility's dressing rooms, toilet rooms, and urinals to ensure that they promote 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)). FSIS personnel are to consider the following:

a. 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?

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

c. 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?

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

4. Pest Control:

FSIS personnel are to 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 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 personnel are to consider the following:

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

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

c. Is there any evidence of pest activity in the facility that might lead to product adulteration/contamination or create insanitary conditions?

d. Does the facility use safe and effective pesticides?

5. Inedible Material Control:

The facility must handle and maintain inedible material to prevent the diversion of inedible animal products (including SRM) into human food channels, resulting in the adulteration of human food (9 CFR 303.1(a)(2)(i), 303.1(b)(4), 381.10(a) (4), 416.2(b)(4), and 416.3(c)).

The regulation 9 CFR 303.1(b)(1) states that “exempted custom prepared products ... shall not be adulterated as defined in paragraph 1(m) of the Federal Meat Inspection Act.” Therefore, custom exempt product cannot contain SRM. SRM are defined as the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle 30 months of age and older. The distal ileum of the small intestine and tonsils from all cattle are SRM, considered inedible and, therefore, are not to enter the food supply (9 CFR 310.22).

Cattle that are not ambulatory at the time they are delivered to slaughter are condemned (9 CFR 309.3(e) and 303.1(f)). However, custom operators are permitted to slaughter for human food cattle that become non-ambulatory disabled after they are delivered to a custom operation if the custom operator does not observe any other condition that would render the animal unfit for human food. FSIS personnel are to consider the following:

a. Are cattle ambulatory at the time they are delivered to slaughter?

b. Does the facility handle and dispose of inedible products properly?

c. Does the facility remove and dispose of SRM from cattle in a manner that prevents adulteration of product and the creation of insanitary conditions?

d. How is the exempt operation handling and disposing of SRM material?

NOTE: If one custom-exempt facility needs to transport carcasses with SRM (vertebral column) for removal and further processing to another custom exempt facility, it may do so if the owner directs in writing that this movement occurs. Each custom exempt facility should have a copy of the owner’s written communication as evidence of the owner’s continuing control.

6. Marking and Labeling Custom Exempt Products and Containers:

The meat products must be marked legibly as “Not for Sale” to meet the requirements of (9 CFR 303.1(a)(2)(ii)&(iii), 316.16). The poultry products must meet

the requirements of 9 CFR 381.10(a)(3) and (4). 9 CFR 381.10(a)(3) refers to labeling of the shipping containers with the **producer's** name and address and the P.L. 90-492. 9 CFR 381.10(a)(4) refers to labeling of the shipping containers with the **owner's** name and address and the P.L. 90-492. FSIS personnel are to consider the following:

- a. Does the facility separate custom exempt products from inspected products?
- b. Are all custom exempt meat products marked "Not For Sale"?
- c. Are shipping containers for custom exempt poultry marked with the producer's name and address and the statement "Exempted -- P.L. 90-492"?
- d. Does the facility mark "Not for Sale" in a manner which ensures that it remains applied in letters at least 3/8" high (9 CFR 316.16 and 317.16)? The wording may be on a tag or card securely attached to the meat, the immediate container, or paper wrapping the meat. If the wording is inked directly onto the meat it must meet the requirements of 9 CFR 316.5.
- e. Does the custom processing facility remove the mark of inspection and mark the products "Not For Sale" when they process inspected product under the custom exemption for an individual owner?

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 as indicated on records. All of the resulting commingled processed product must have the mark of inspection removed and must be clearly marked "Not for Sale."

7. 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 to prevent adulteration of products (9 CFR 303.1(b)(1) and 381.10(a)(3) & (4)). The custom exempt facility must properly cool the product to prevent the growth of pathogens. The facility must treat meat food products containing raw pork or pork as ingredient to destroy trichinae (excluding fresh pork products that are customarily well cooked in the home or elsewhere as defined by 9 CFR 318.10(a)). FSIS personnel are to consider the following:

- a. Does the facility have controls in place to destroy trichinae in products that contain pork?
- b. Does the facility prevent adulteration of product by pathogens?
- c. For cooked product, does the facility cook product to a temperature that will kill pathogens?

d. Does the facility cool heat-treated product in a manner to prevent growth of pathogens?

8. Water Supply:

The facility needs to have a supply of running water that complies with the National Primary Drinking Water Standards (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 cannot reuse water. FSIS personnel are to consider the following:

- a. Does the facility provide sufficient quantities of water throughout the facility?
- b. Is there sufficient water available at a sufficient temperature to ensure proper cleaning of equipment?
- c. Is there adequate water pressure, and is the water at a suitable temperature in all areas where required, to ensure proper cleaning of equipment?
- d. Are non-potable water pipes separate from potable water pipes?
- e. Does the facility properly identify potable water pipes vs. non-potable water pipes?
- f. Does the facility reuse the water for any purpose?

9. 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)). FSIS personnel are to consider the following:

- a. Does the plumbing system properly transport sewage and disposable waste from the facility?
- b. Does the plumbing system provide adequate floor drainage?
- c. 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?
- d. Does the plumbing prevent the backup of sewer gases?

e. 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?

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

g. Is there evidence of direct product contamination?

VIII. ADDITIONAL REQUIREMENTS FOR CUSTOM EXEMPT OPERATIONS AT OFFICIAL ESTABLISHMENTS

A. In addition to the general requirements above that apply to all custom exempt operations, there are several requirements that **only** apply to custom exempt operations conducted at official establishments.

B. IPP performing the review are to verify that the establishment segregates animals intended for custom exempt slaughter from animals designated for inspected slaughter.

NOTE: Once an establishment offers an animal for ante-mortem inspection, the establishment cannot change the animal status to “intended for custom exemption.”

C. An official establishment can maintain a custom exempt operation if there is a complete physical separation of product and processes by time and space.

D. When performing PBIS procedure 06B01, used in inspected establishments to verify the proper separation of facilities and products in establishments where custom or retail activities are conducted, IPP are to verify that the establishment:

1. Maintained separation of custom prepared product vs. inspected product throughout the process.

2. Clearly mark all carcasses and parts from custom slaughter as “Not For Sale” (9 CFR 303.1(a)(2)(iii) and 316.16).

3. Separate the “Not For Sale” carcasses from carcasses and parts slaughtered under inspection (9 CFR 303.1(a)(2)(ii)).

4. Upon observing an unmarked carcass, retain the carcass and notify the IIC or Frontline Supervisor (FLS) to help them determine what other actions to take when necessary.

5. Document an unmarked custom exempt slaughtered carcass on a Noncompliance Record (NR) under ISP code 06B01, citing 9 CFR 303.1(a)(2)(iii) and 316.16.

6. Document an unmarked inspected carcass on an NR under ISP code 04B04 citing 9 CFR 316.9, unless the establishment is following 9 CFR 316.8 or 325.5 for unmarked inspected products.

E. IPP performing the review 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, that they:

1. Change outer garments;

2. Clean and sanitize their hands; and

3. Clean and sanitize the facilities and equipment as set out described in the establishment's Sanitation SOPs.

F. IPP performing the review 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. Cattle are ambulatory at the time of slaughter, as provided in writing by the owner of the animal (9 CFR 309.3(e) and 303.1(f)).

IX. FREQUENCY OF REVIEWS OF CUSTOM EXEMPT OPERATIONS

A. IPP or Compliance Investigators (CIs) are to conduct periodic reviews of custom slaughtering and processing operations when directed by the District Office (DO) or Regional Manager (RM) to determine whether the operations meet the requirements of the exemption, and whether the facilities comply with all applicable regulations.

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

C. 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. The DO or RM are to schedule follow-up reviews based on consideration of the following factors:

1. Nature of custom exempt operations and products produced under custom exemption;
2. Compliance history with humane slaughter, sanitation, and recordkeeping;
3. Observation of adulterated or misbranded product;
4. Other relevant information, such as verified consumer complaints; and
5. Availability of IPP or CIs.

D. Procedure 06B01 is used in inspected establishments to verify the proper separation of facilities and products in establishments where custom or retail activities are conducted. Do not use PBIS procedure 06B01 to schedule and document the reviews of custom exempt operations in official establishments.

E. OPEER, Evaluation and Enforcement Division (EED) will coordinate the frequency of reviews at custom exempt facilities operating under an administrative consent agreement or other applicable legal order or requirement, such as a civil consent decree or plea agreement.

X. AGENCY PERSONNEL RESPONSIBILITIES AND ACTIONS

A. IPP Responsibilities

1. Public Health Veterinarians (PHVs), Enforcement, Investigations, and Analysis Officers (EIAO), CSI, or FLS are to conduct the reviews of custom exempt facilities. The DO will coordinate the reviews.

2. Based on the information gathered, PHV, EIAO, CSI, and FLS are to determine compliance by performing the following tasks:

- a. Document the results of the review on FSIS Form 5930-1 in items 7 and 8, and fully describe any findings of noncompliance in an attached MS Word document;
- b. Collect evidence, such as samples, photographs, statements, and facility records, to support any recommended action;
- c. Initiate official control action against product, as appropriate, when there is reason to believe that the product is adulterated or misbranded;

NOTE: Refer to FSIS Directive 8410.1, *Detention and Seizure*, for the procedures that FSIS program personnel are to follow when detaining, or preparing a recommendation to seize, meat or poultry found in commerce when there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the FMIA or PPIA. <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8410.1Rev5.pdf>

d. Discuss the review findings with the owner or operator and inform the owner or operator of the conditions that need to be corrected;

e. Provide copies of FSIS Form 5930-1 to the owner or operator of the custom exempt facility, immediate supervisor, and to the DM (OFO reviewer);

f. Conduct follow-up reviews as directed by the District;

g. Report serious (egregious situation) or repeated noncompliance with inhuman handling requirements to the District Veterinary Medical Specialist (DVMS) through the supervisory channels as necessary; and

h. Document evidence to support administrative enforcement actions in an Administrative Enforcement Report (AER). Refer to FSIS Directive 5100.3 Administrative Enforcement Reporting System.

<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5100.3Rev1.pdf>

B. DM Responsibilities

1. DM or designees are to:

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

b. Determine the appropriate next step upon notification of a noncompliance with custom exempt requirements, such as follow up review, issuance of a “Letter of Warning” (LOW), or referral to OPEER EED. The LOW should state that the failure to take prompt and appropriate corrective action may result in a recommendation to pursue additional administrative or criminal sanctions; or

c. Refer documentation showing repeated or serious noncompliance, such as an egregious situation with humane handling, with custom exempt requirements through the supervisory channels to OPEER, EED, with a recommendation for administrative or other enforcement action; and

d. Refer potential criminal violations to OPEER, Compliance and Investigations Division (CID), including distribution of adulterated meat, fraud, sale of uninspected meat, slaughter of animals that were non-ambulatory at the time of delivery to the custom exempt facility.

C. CI Responsibilities

1. CIs are to:

- a. Conduct reviews and accompany OFO reviewers, if requested. The DO and Regional Director (RD) will coordinate this need;
- b. React as directed by the RD to the results of the OFO review; and
- c. Document Reports of Investigation (ROI) to support findings of violations of the FMIA, PPIA and related laws and regulation. Refer to FSIS Directive 8010.4, Report of Investigation <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8010.4Rev2.pdf>

D. RD Responsibilities

1. RD or designees are to:

- a. Coordinate the reviews and determine when a follow-up review is necessary and direct the Agency FSIS employee to visit the custom exempt establishment;
- b. Investigate alleged violations of the FMIA and PPIA that may require civil or criminal actions, such as:
 - i. Sale of custom product;
 - ii. Distribution of adulterated product;
 - iii. Misbranding; and
 - iv. Inhumane handling.
- c. Direct CI actions through supervisory investigators;
- d. Issue Notice of Warning (NOW) to custom exempt operator for minor violations (21 U.S.C. § 676);
- e. Refer ROI cases to OPEER, EED when documentation shows repeated or serious noncompliance with custom exempt requirement or other violations of the FMIA or PPIA to pursue civil, administrative, or criminal proceedings; and
- f. Follow methods outlined in FSIS Directive 8010.2 *Investigative Methodology*.
<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8010.2Rev2.pdf>

E. EED Responsibilities

1. EED Director or designee is to:

- a. Review case evidence and recommendations to determine whether criminal, civil, or administrative action should be taken;

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

c. 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.

d. Refer criminal, civil, and administrative cases to the USDA Office of the General Counsel (OGC) when the Agency wants to pursue such actions; and

e. When applicable, negotiate consent agreements with custom exempt operators.

F. Federal State Audit Branch (FSAB) Responsibilities:

FSAB is to audit the state programs to verify that the State Cooperative Meat and Poultry Inspection 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. Refer to FSIS Directive 5720.2, *State Cooperative Inspection Programs*
<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5720-2Rev3.pdf>

XI. ENFORCEMENT ACTIONS

A. FSIS has the authority to take administrative, civil, or criminal action against the custom exempt operator if the findings warrant action.

1. The DO can:

a. Take administrative sanctions such as, issue a LOW for minor violations;
and

b. Refer administrative, civil or criminal cases to OPEER for legal proceedings.

2. OPEER can:

a. Initiate civil actions such as:

- i. Injunctions
 - ii. Consent decrees
 - iii. Seizures
 - iv. Civil suits, and
 - v. Other settlement agreements.

- b. Initiate administrative actions such as:
 - i. Termination of exempt privileges
 - ii. Consent decisions, and
 - iii. Other settlement agreements.

- c. Initiate criminal actions such as:
 - i. NOW letters, and
 - ii. Initiation of consideration for criminal prosecution.

B. FSIS Directive 8010.5, *Case Referral and Disposition* describes the procedures and methodologies that are to be followed by FSIS, OPEER, CID, and EED for determining actions on reports for criminal, civil, and administrative enforcement actions.

<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8010.5Rev2.pdf>

Refer questions regarding this directive 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