

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

FSIS DIRECTIVE	8160.1	9/28/20
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CUSTOM EXEMPT REVIEW PROCESS

I. PURPOSE

A. This directive provides instructions to Office of Investigations, Enforcement and Audit (OIEA), Compliance and Investigations Division (CID), Compliance Investigators (CIs) on how to conduct reviews of custom exempt facilities that are not located at official establishments.

B. This directive provides instructions to Office of Field Operations (OFO), Inspection Program Personnel (IPP), on how to conduct reviews of custom exempt facilities that operate at official establishments.

C. This directive provides the methodologies that OIEA CID Regional Directors (RDs) or designees, OFO District Managers (DMs) or designees, and the OIEA Enforcement Operations Branch (EOB) are to apply when determining actions based on custom exempt review findings, documentation, and referral.

D. This directive has been moved from the 5000-series to the 8000-series due to increased emphasis on OIEA responsibilities for conducting reviews of custom exempt facilities at in-commerce locations.

E. This directive has also been generally updated to more clearly distinguish regulatory requirements from recommendations and to clarify procedures for recording custom exempt review results.

KEY POINTS:

- *Requirements applicable to custom exempt facilities and operations*
- *Frequencies of custom exempt reviews*
- *Methods for conducting and documenting reviews of custom exempt facilities and operations*
- *Roles and responsibilities of CIs, IPP, RDs and DMs*

II. CANCELLATION

FSIS Directive 5930.1, Rev. 4, *Custom Exempt Review Process*, 7/15/09

FSIS Form 5930-1, *Exempt Establishment Review Report*, 2/6/09

DISTRIBUTION: Electronic

OPI: OPPD

III. BACKGROUND

A. The Federal Meat Inspection Act ([FMIA](#)) (21 U.S.C. 623(a)) and the Poultry Products Inspection Act ([PPIA](#)) (21 U.S.C. 464(c)(1)(B)), identify the custom slaughtering and preparation activities that are exempt from Federal inspection. The slaughtering or preparation of an owner's animal exclusively for use in the household of such owner, by him and members of his household and his nonpaying guests and employees, is exempt from Federal inspection.

B. The FMIA (21 U.S.C. 623(d)) and the PPIA (21 U.S.C. 464(e)) provide that the adulteration and misbranding provisions apply to articles that are exempted from inspection. The regulations also state that adulteration provisions of the Acts apply to products exempt from inspection, including custom exempt product (9 CFR [303.1\(f\)](#) and [381.10\(a\)\(4\)](#)).

C. In order to maintain sanitary conditions and prevent the production of adulterated product, FSIS has promulgated regulations for custom exempt operations in 9 CFR [303.1](#) and [381.10\(a\)\(4\)](#). Under these regulations, operators who conduct custom exempt livestock operations must prepare meat food products under sanitary conditions in compliance with 9 CFR [303.1\(a\)\(2\)\(i\)](#). The sanitation regulations in 9 CFR [416.1](#) through [416.6](#), except for 9 CFR [416.2\(g\)\(2\)](#) through (6), apply to livestock facilities that conduct custom exempt operations because products not produced under the sanitary conditions required in these regulations would be considered adulterated. If custom exempt livestock operations are conducted at a location within a Federal establishment all of the provisions of 9 CFR [416](#) apply. Poultry custom exempt operations must slaughter and process under such sanitary standards, practices and procedures as will result in the preparation of poultry products that are sound, clean and fit for human food, per 9 CFR [381.10\(a\)\(4\)](#).

NOTE: The Sanitation Performance Standards in 9 CFR 416.1 through 416.6 are not incorporated by reference into the poultry custom exempt regulations. A facility may adopt these provisions to meet the sanitary standards cited in 9 CFR [381.10\(a\)\(4\)](#).

D. Custom exempt livestock meat food products cannot contain [Specified Risk Materials](#) (SRMs) because such materials adulterate products. Non-ambulatory disabled cattle delivered by the owner are not eligible for custom slaughter or processing. The Agency allows custom exempt operators to slaughter for human food cattle that become non-ambulatory disabled after they are delivered by the owner to the custom exempt slaughter facility if the operator does not observe any other condition that would render the animal unfit (i.e., adulterated) for human food. (See: [[DocketNo. FSIS-2008-0022](#)]).

E. Inedible materials, including SRMs, resulting from custom exempt slaughter or processing must be disposed of in accordance with 9 CFR [303.1\(b\)\(4\)](#), [325.11\(a\)](#), and [381.193\(a\)](#).

F. The FMIA (21 U.S.C. 623(a)) and 9 CFR [316.16](#) require custom exempt livestock meat food products to be plainly marked "Not for Sale" immediately after being prepared and to be kept so identified until delivered to the owner. The PPIA has no explicit labeling requirements for custom exempt poultry products; however, 9 CFR [381.10\(a\)\(4\)](#) requires the shipping containers of such poultry products to bear the owner's name and address and the statement "Exempted – P.L. 90-492."

G. Custom exempt livestock slaughter operators must comply with the Humane Methods of Slaughter Act ([HMSA](#)). Poultry slaughter is not included in the HMSA. Poultry custom exempt slaughter operators are required to slaughter poultry in accordance with [Good Commercial Practices \(70 FR 56624\)](#). Custom exempt poultry slaughter operators are required to slaughter in compliance with the PPIA (21 U.S.C. 458(a)(1)). If birds hung on the slaughter line die prior to slaughter due to mishandling or are killed in a manner that does not comply with the good commercial practices regulation ([9 CFR 381.65\(b\)](#)), the custom slaughter operation would not meet the requirements of the PPIA.

H. The FMIA (21 U.S.C. 642) requires custom exempt livestock operators to keep such records as will fully and correctly disclose all transactions involved in their custom exempt business and all applicable recordkeeping requirements in 9 CFR [303.1\(b\)\(3\)](#) and [320](#). The PPIA (21 U.S.C. 460(b)) requires custom exempt poultry operators to keep such records as are properly necessary for the effective enforcement of the PPIA and all applicable recordkeeping requirements in 9 CFR [381](#) Subpart Q.

I. For custom exempt livestock operations conducted at Federal establishments, the FMIA (21 U.S.C. 623(a)) requires that custom exempt livestock meat food products are separated at all times from inspected livestock meat food products at facilities that operate under both inspection and the custom exemption. Separation can be achieved through time or space. The PPIA (21 U.S.C. 464(c)(1)(B)) only exempts the custom exempt poultry operator from the inspection requirements if they do not engage in the business of buying or selling poultry products capable for use as human food. However, custom exempt poultry slaughter and processing can occur at a federally-inspected livestock establishment.

J. The amenable livestock species that are subject to FSIS custom exempt regulations are cattle, sheep, swine and goats, per 9 CFR [301](#). The amenable poultry species are domesticated chickens, turkeys, ducks, geese, guineas, ratites, or squabs per 9 CFR [381.1](#).

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). There are no custom exemptions for Siluriformes (catfish). Non-amenable species are not required to be inspected; therefore, the custom exemption provisions do not apply to them.

IV. STATE COOPERATIVE INSPECTION PROGRAMS CUSTOM EXEMPT REVIEWS

A. States that maintain their own “at least equal to” Meat and Poultry Inspection (MPI) programs conduct reviews of custom exempt operations in a manner that is at least equal to the Federal system. FSIS, OIEA, Federal State Audit Branch (FSAB), monitors the custom exempt review programs in these states as part of its review of the overall state programs. For more information on State reviews refer to [FSIS Directive 5720.2 State Cooperative Inspection Programs](#) and [FSIS Directive 5720.3 Methodology for Performing Scheduled and Targeted Reviews of State Meat and Poultry Inspection Programs](#).

B. States that do not maintain their own inspection programs may enter into special cooperative agreements with FSIS to conduct custom exempt reviews if beneficial to FSIS. The FSIS Administrator will approve such special cooperative agreements.

V. CONDUCTING REVIEWS OF CUSTOM EXEMPT FACILITIES TO DETERMINE COMPLIANCE

A. CIs and IPP are to conduct reviews at custom exempt slaughter and processing operations to determine if the operator complies with applicable statutory and regulatory requirements. During the review, CIs and IPP are to assess compliance in each of the nine categories listed below by considering the questions in each section. The information gathered is to be documented on FSIS Form 8160-1, *Exempt Facility Review Report*, which replaces FSIS Form 5930-1. This form can be found on the FSIS Intranet in the [8,000-series forms](#). Users need an e-authentication account to access this form. See [Section VII](#) (OIEA) and [Section VIII](#) (OFO) for additional documentation instructions. The FSAB is to provide the States with FSIS Form 8160-1.

B. OIEA CIs and OFO IPP are to conduct periodic reviews of custom exempt slaughtering and processing operations, at official establishments (IPP) or other facilities (CIs), generally at a frequency of once-per-year.

C. CIs are to prioritize their reviews of custom exempt slaughtering and processing operations at in-commerce locations in accordance with the instructions in [FSIS Directive 8010.1](#), *Methodology for Conducting In-Commerce Surveillance Activities*, Chapter II.

D. IPP are to perform reviews of custom exempt slaughtering and processing operations at Federal establishments sometime during the calendar year when they receive the annual Public Health Information System (PHIS) Custom Exempt task. IPP are to follow the instructions found in [FSIS Directive 13.000.1](#) *Scheduling In-Plant Inspection Tasks in The Public Health Information System (PHIS)*, Section XII, A, for documenting task results. IPP are to complete FSIS Form 8160-1 as instructed in Section V., A., above and Section VIII. below.

E. When determining whether to conduct additional reviews (i.e., more than yearly) of custom exempt slaughtering and processing operations at in-commerce locations and at Federal establishments, OIEA and OFO supervisory personnel are to consider the following factors:

1. Nature of custom exempt operations and products produced under custom exemption;
2. Custom exempt review findings, including compliance or noncompliance with sanitation, humane slaughter, recordkeeping, and other regulatory requirements;
3. Custom exempt review findings of adulterated or misbranded products;
4. Issuance of enforcement letters, such as a Letter of Warning (LOW), by OFO DM or OIEA RD, based on findings of noncompliance during custom exempt reviews;
5. Issuance of enforcement letters, such as a Notice of Warning (NOW), by OIEA RD or OIEA EOB, for violations of statutory or regulatory requirements (e.g., sale of custom exempt product, misbranding, or noncompliance with recordkeeping requirements);
6. Issuance of a Notice of Ineligibility (NOI), by OIEA, based on findings of serious or repeated noncompliance during custom exempt reviews;
7. An administrative consent agreement between FSIS and the custom exempt operator to resolve a NOI;
8. Another legal order, settlement agreement, or binding requirement, such as an administrative consent decree, civil consent decree, or criminal plea agreement;
9. Other relevant compliance information; and
10. Availability of CIs or IPP to conduct custom exempt reviews.

F. The OIEA EOB Branch Chief or designee, the OIEA RD or designee, and the OFO DM or designee are to coordinate the frequency and scope of reviews or follow-up reviews at custom exempt slaughtering and processing operations based on significant findings of noncompliance, issuance of LOW, NOW, or NOI, or because of an applicable administrative consent agreement or other legal order, agreement, or requirement.

G. During the routine annual review, CIs and IPP are to assess compliance with all the statutory and regulatory requirements in each of the nine categories listed below by considering the questions in each section and then selecting Yes, No, or N/A and including comments in the Comment box of FSIS Form 8160-1.

H. For questions regarding recommended practices, IPP and CIs are not to use FSIS Form 8160-1. Discussions and findings related to recommended practices are to be documented in the Findings tab of the PHIS Custom Exempt task (IPP) or in the Assurance Net (ANet) Surveillance Record (CIs).

1. Review of Livestock Humane Slaughter Requirements, Livestock Animal Welfare Practices and Poultry Good Commercial Practices

- a. The FMIA (21 U.S.C. 610(b)) prohibits slaughtering or handling livestock in connection with slaughter in any manner not in accordance with sections 1901 to 1906 of Title 7 (HMSA). FSIS personnel are to consider the following questions to determine if the operator is handling livestock in a humane manner:
 - i. Are all livestock rendered insensible to pain by a single blow or gunshot or an electrical, chemical, or other means that is rapid and effective, before being shackled, hoisted, thrown, cast, or cut?
 - ii. Are the methods of slaughtering and handling in accordance with the ritual requirements of the Jewish faith or any other 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?
 - iii. Are disabled animals dragged while still conscious?
- b. FSIS recommends that custom exempt livestock operators adopt the following additional, voluntary welfare practices. Although these practices are not strictly required, the Agency is interested in communicating these voluntary practices to the custom exempt operator if they are not already conducting them. CIs and IPP are to document this communication and the findings as described in paragraph H. CIs and IPP are to consider the following questions during their review about these voluntary livestock welfare practices:
 - i. Are animals provided water and feed in the pens?
 - ii. Is the facility maintained in good repair to prevent injury to animals?
 - iii. Are livestock driven with a minimum of excitement and discomfort?
 - iv. Are disabled animals separate from ambulatory animals?
- c. Poultry that die otherwise than by slaughter are considered adulterated per the PPIA (21 U.S.C. 453(g)(5)). Poultry products are more likely to be adulterated if they are killed in a manner inconsistent with [Good Commercial Practices](#) (9 CFR [381.65\(b\)](#)). CIs and IPP are to consider the following questions about the treatment of poultry at slaughter:
 - i. Are employees provided training in the handling of live poultry?
 - ii. Is feed and water withdrawal kept to the minimum level consistent with good processing practices?
 - iii. Is the facility appropriately designed and maintained for bird delivery to the facility?

- iv. Are holding areas equipped with an adequate number of fans to ensure proper ventilation for birds?
- v. Is stunning equipment (if applicable) and killing equipment constantly monitored to ensure proper functioning for humane processing?
- vi. Are poultry dead before entering the scalding?
- vii. Do facility personnel and equipment handle poultry in a manner that minimizes broken legs and wings?

2. Review of Recordkeeping and Documentation

- a. FSIS personnel are to determine if the operator keeps such records as will fully and correctly disclose all transactions involved in their business, as required by the Acts and the records that are required by the applicable 9 CFR regulatory requirements. See [Section III, H](#) above for the recordkeeping requirements. CIs and IPP are to consider the following recordkeeping questions:
 - i. Are the required records kept 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 product (9 CFR [303.1\(b\)\(3\)](#), 9 CFR [320](#))?
 - ii. Are the required records for poultry operations (9 CFR [381.175](#)) maintained?
 - iii. For custom exempt livestock facilities, are the required records maintained from the state or local health agency documenting water potability (9 CFR [416.2\(g\)\(1\)](#)) and that the sewage systems are adequate (9 CFR [416.2\(e\)](#), and [416.2\(f\)](#))?
 - iv. For custom exempt livestock facilities, are the required records that demonstrate that the chemicals used in the facility are safe for the food processing environment (9 CFR [416.4\(c\)](#)) maintained?
 - v. Are the required records maintained, including shipping papers if custom exempt products were transported at the owner's direction to another custom exempt facility for further processing (9 CFR [303.1\(b\)\(3\)](#), [320](#), and [381.175](#))?
 - vi. Are records kept onsite for two years after December 31 of the year in which the record was made (9 CFR [320.3](#) and [381.177](#))?
 - vii. Are records maintained that document the implementation and monitoring of the Sanitation Standard Operating Procedure (Sanitation SOP) (9 CFR [416.16](#)) if located at an official establishment? (OFO only)
- b. FSIS recommends that custom exempt livestock operators keep voluntary records to demonstrate they are meeting the adulteration provisions of the FMIA (21 U.S.C. 623(d)) with respect to SRMs. CIs and IPP are to consider the following questions:
 - i. Does the custom operator keep 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 farm-dressed or delivered to slaughter, and that SRMs were disposed of properly?

- ii. Does the custom operator keep 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?

3. Review of Sanitary Operations

- a. FSIS personnel are to determine whether the custom exempt facility is maintained in a sanitary condition as required to prevent adulteration of product. See [Section III, C](#) above for the requirements. CIs and IPP are to consider the following sanitation questions:
 - i. Are the food contact surfaces, equipment, and utensils cleaned and sanitized as frequently as necessary to prevent insanitary conditions and the adulteration of product?
 - ii. Are nonfood contact surfaces, equipment, and utensils cleaned and sanitized as necessary to prevent insanitary conditions and the adulteration of product?
 - iii. Are cleaning compounds, sanitizing agents, processing aids, and other chemicals used by the operator safe and effective under the conditions of use?
 - iv. Are products protected from adulteration during processing, handling, storage, loading and unloading, and transportation?
 - v. Are inedible containers conspicuously marked to prevent use for storing edible products?
 - vi. Is there evidence of direct product adulteration?
- b. FSIS personnel are to determine if the maintenance of the facilities used to slaughter and process custom exempt product prevents the adulteration of product. See [Section III, C](#) above for the requirements. CIs and IPP are to consider the following facility questions:
 - i. 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 products?
 - ii. Are the walls, floors, and ceilings maintained in sanitary condition?
 - iii. Do the walls, floors, ceilings, doors, windows, and other outside openings prevent the entrance of vermin and rodents, such as flies, rats, and mice?
 - iv. Does the operator 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?
 - v. Are inedible products properly denatured?

- vi. Do conditions exist that may lead to direct product contamination or adulteration?
- c. FSIS personnel are to determine if the facility's dressing rooms, lavatories and toilets are maintained in a sanitary condition. See [Section III, C](#) above for the requirements. CIs and IPP are to consider the following questions:
 - i. Are the dressing rooms, toilet rooms, and urinals (sufficient in number, ample in size and conveniently located) kept in a sanitary condition, in good repair and are separate from the rooms and compartments in which products are processed, stored, or handled?
 - ii. Do the lavatories have running hot and cold water, and have soap and towels placed in or near toilet and urinal rooms and other places as necessary?
 - iii. Are refuse receptacles constructed and maintained in a sanitary manner?

4. Review of Pest Control:

- a. FSIS personnel are to determine if the grounds about the custom exempt facility prevent conditions that could lead to insanitary conditions or adulteration of product. See [Section III, C](#) above for the requirements. CIs and IPP are to consider the following questions:
 - i. Are the outside areas of the facility maintained in a manner that will prevent harborage and breeding of pests?
 - ii. Are areas within the facility maintained in a manner to prevent the harborage and breeding of pests?
 - iii. Is there evidence of pest activity in the facility that might lead to product adulteration or contamination, or create insanitary conditions?
 - iv. Does the operator use pesticides safely?

5. Review of Inedible Material Control:

- a. FSIS personnel are to determine if the custom exempt operator handles inedible material, including SRMs, to prevent the creation of insanitary conditions and the diversion of inedible animal product into human food channels. See [Section III, E](#) above for the requirements. CIs and IPP are to consider the following questions:
 - i. Are cattle which were non-ambulatory at the time they were delivered for slaughter disposed of as inedible material?
 - ii. Does the operator handle and dispose of inedible products properly?
 - iii. Does the operator remove and dispose of SRM from cattle in a manner that prevents adulteration of product and the creation of insanitary conditions?
 - iv. If the facility is located in an official establishment and has Sanitation SOP procedures for the removal of SRMs, are those procedures being implemented during custom exempt operations per 9 CFR [416.13](#)? (OFO only)

6. Review of Marking and Labeling Control:

- a. FSIS personnel are to determine if the custom exempt operator appropriately marks and labels to prevent misbranding. See [Section III, F](#) above for the requirements. CIs and IPP are to consider the following questions:
 - i. Are custom exempt products kept separate from any products for sale by maintaining identity of the products as appropriate?
 - ii. Are custom exempt meat or meat food products promptly marked or labeled “Not for Sale”?
 - iii. Are field-dressed or farm-dressed carcasses or parts clearly marked “Not for Sale” upon entering the facility?
 - iv. Do shipping containers of custom exempt poultry bear the owner’s name and address and the statement “Exempted -- P.L. 90-492”?
 - v. Are livestock meat or meat food products marked “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](#))?

NOTE: 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](#).

7. Review of Pathogen Control:

- a. FSIS personnel are to determine if the custom exempt operator prevents the adulteration of products by controlling microbial pathogens, such as *Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes* and *Clostridium perfringens*. See [Section III, B](#) above for the requirements. CIs and IPP are to consider the following questions:
 - i. Is contamination prevented?
 - ii. Are ready-to-eat products cooked to a time and temperature that will kill pathogens?
 - iii. Are heated or cooked products cooled in a manner to prevent growth of pathogens?

8. Review of Water Supply

- a. FSIS personnel are to determine if the custom exempt facility has a potable supply of running water to prevent the adulteration of food products. See [Section III, C](#) above for the requirements. CIs and IPP are to consider the following questions:
 - i. Does the water supply at a custom exempt livestock facility comply with the National Primary Drinking Water regulations (40 CFR part 141)?
 - ii. Does the water supply used in processing custom exempt poultry result in the preparation of poultry products that are sound, clean and fit for human food (9 CFR

[381.10\(a\)\(4\)?](#)

- iii. Are sufficient quantities of water, at a suitable temperature and under adequate pressure, provided for cleaning equipment and for use throughout the facility?
- iv. Are non-potable water pipes separate from potable water pipes?
- v. Does the operator properly identify potable water pipes vs. non-potable water pipes?
- vi. Does the operator reuse water for any purpose?

9. Review of Sewage and Waste Disposal:

- a. FSIS personnel are to determine if the custom exempt facility properly removes sewage and waste materials to prevent the adulteration of food products (9 CFR [303.1\(a\)\(2\)\(i\)](#), [381.10\(a\)\(4\)](#), and, for custom exempt livestock facilities, [416.2\(e\) and \(f\)](#)). CIs and IPP are to consider the following questions:
 - i. Does the plumbing system properly transport sewage and disposable waste from the facility?
 - ii. Does the plumbing system provide adequate floor drainage?
 - iii. 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?
 - iv. Does the plumbing prevent the backup of sewage and sewer gases?
 - v. Is the sewage disposal system a private system which requires approval by a state or local health authority, and is a letter or certificate of approval available?
 - vi. Is there evidence of direct product contamination?

VI. REQUIREMENTS FOR CUSTOM EXEMPT OPERATIONS AT LOCATIONS WITH OFFICIAL ESTABLISHMENTS

A. In addition to the general requirements above that apply to all custom exempt operations, there are requirements that only apply to custom exempt operations conducted at locations with official livestock establishments. In addition to the IPP responsibilities in [Section VIII. A](#), below, IPP are to consider the following questions:

- 1. Do the custom operations comply with all of the provisions of part [416](#), including the [416.11-416.16](#) Sanitation SOP regulations?
- 2. Are the inspected products kept separate and apart from custom prepared products, per 9 CFR [303.1\(a\)\(2\)\(ii\)](#) and [305.2\(a\)](#), including that the establishment segregates live animals intended for custom exempt slaughter from animals designated for inspected slaughter?

NOTE: If an official livestock establishment chooses to present custom livestock for FSIS inspection, they are subject to all regulatory requirements for inspection as non-exempt livestock until ante- and post-

mortem inspections have been completed, including humane slaughter, sanitary dressing, SSOPs, HACCP, and zero tolerance.

3. Are carcasses and parts from custom livestock slaughter clearly marked “Not for Sale,” or are the shipping containers of custom exempt poultry marked “Exempted P.L. 90-492” (9 CFR [303.1\(a\)\(2\)\(iii\)](#), [316.16](#), [317.16](#) and [381.10\(a\)\(4\)](#))?
4. Are facilities and equipment used for the preparation of any federally-inspected products cleaned and sanitized after custom operations have been completed, and do employees change outer garments as necessary, before the operator prepares federally-inspected products?
5. Does the operator maintain the required records, including Sanitation SOP records required by 9 CFR [416.16](#)?
6. IPP are not to issue a [Noncompliance Record](#) during custom exempt reviews, including if Sanitation SOP recordkeeping noncompliance is observed. If noncompliance exists, mark this category on FSIS Form 8160-1 as unacceptable, and document the findings on the form.

VII. OIEA PERSONNEL RESPONSIBILITIES AND ACTIONS

A. OIEA CIs are to:

1. Prepare for the annual custom review by following the instructions found in [FSIS Directive 8010.1 Methodology for Conducting In-Commerce Surveillance Activities](#).
2. Perform reviews at in-commerce facilities conducting custom exempt slaughtering or processing operations in accordance with the methods in this directive;
3. Document the findings of the custom exempt review in ANet Surveillance module, Surveillance Record, Special Projects tab, by:
 - a. Answering the yes/no questions under the Custom Exempt Review section;
 - b. Providing comments in each of the associated comment boxes;
 - c. Providing any needed additional information regarding observations and findings in the ANet Surveillance Record;
 - d. Attaching the FSIS Form 8160-1 in the File Attachments tab; and
 - e. Completing and/or updating other ANet information by following the instructions in [FSIS Directive 8010.1](#).
4. Inform the custom exempt operator of both the acceptable and unacceptable review findings, provide the custom exempt operator a hard copy of FSIS Form 8160-1 and discuss, as necessary, other information (e.g., regulatory requirements, compliance findings, future reviews, issuance of correspondence).

5. Discuss findings from the custom exempt review with supervisory personnel and obtain further instructions, if any, including continued verification through future custom exempt reviews.
6. Initiate an investigation by following the instructions found in [FSIS Directive 8010.2](#), *Investigative Methodology* if apparent violations of the FMIA, PPIA, or related laws and regulations are observed. CIs are to collect evidence, such as samples, photographs, statements, and facility records, to support any recommended action. Follow the instructions found in [FSIS Directive 8010.3](#), *Procedures for Evidence Collection, Safeguarding and Disposal*, when collecting evidence. CIs are to prepare a Report of Investigation (ROI) by following the instructions in [FSIS Directive 8010.4](#), *Report of Investigation*. Violations that may require further action include, but are not limited to, the following:
 - a. The sale of custom exempt product;
 - b. The distribution of adulterated product;
 - c. Misbranding;
 - d. Recordkeeping; or
 - e. Inhumane slaughter or handling.
7. Follow the instruction in [FSIS Directive 8010.1](#), Chapter VI, II, Other Irregularities, if they observe apparent violations or other irregularities during the review. They are to inform the custom exempt operator and contact the appropriate Federal, State or local agencies to inform them of the apparent violation or irregularity, provide support to such authority, and document it on the FSIS Form 8160-1 in ANet.
8. Initiate official product control action, as appropriate, when there is reason to believe that the products are adulterated or misbranded. Refer to [FSIS Directive 8410.1](#), *Detention and Seizure*, for the procedures that FSIS program personnel are to follow when detaining meat or poultry products.
 - a. Inform the owner, owner's agent, or custodian that he or she may offer and make a voluntary disposition of the products before a detention action is taken.
 - b. Not take a detention action and not complete the detention form if the owner, owner's agent, or custodian makes an appropriate voluntary disposition of the products.
 - c. Complete FSIS Form 8080-4, *Voluntary Destruction of Human Food Notice*, or FSIS Form 8080-6, *Personal Use Notice*. These product disposition forms can be found on the FSIS Intranet in the [8,000-series forms](#) or under Product Control in ANet. Users need an e-authentication account to access these forms.
 - d. Detain the violative products, as set forth in [FSIS Directive 8410.1](#), Section VIII, if the owner, owner's agent, or custodian does not agree to an immediate disposition of the violative products, or does not complete the voluntary disposition in an appropriate manner. Complete FSIS Form 8080-1 *Notice of Detention*. This form can be found on the FSIS Intranet in the [8,000 series forms](#). Users need an e-authentication account to access this form.
 - i. For custom exempt products that are misbranded, maintain the detention until the custom exempt products are no longer misbranded. Complete FSIS Form 8400-1

Notice of Termination of Detention. This form can be found on the FSIS Intranet in in the [8,000 series forms](#). Users need an e-authentication account to access this form.

- ii. For custom exempt products that are adulterated, terminate the detention of products and complete FSIS Form 8400-1. Since custom exempt products are for the exclusive use of the owner in their household, and not for sale as an article of commerce, the products may be released to the owner for their personal use or voluntary destruction. Complete the appropriate product disposition form (FSIS Form 8080-4 or FSIS Form 8080-6.)

B. OIEA RD or designees are to:

1. Direct CIs' actions, as necessary, through supervisory investigators, to plan and conduct reviews of custom exempt slaughtering and processing operations at in-commerce locations and establishments, based on surveillance priorities in [FSIS Directive 8010.1](#).
2. Coordinate with EOB reviews based on significant findings of noncompliance, issuance of LOW, NOW, or NOI, or because of an applicable administrative consent agreement or other legal order, agreement, or requirement.
3. Evaluate findings from custom exempt reviews and determine action, if any, including continued verification through future custom exempt reviews, issuance of warning letters for noncompliance, referral to EOB, or other action, by following instructions in [FSIS Directive 8010.5](#), *Case Referral and Dispositions*.
4. Issue a LOW to the custom exempt operator for noncompliance findings with custom exempt requirements. The LOW should state that the failure to take prompt and appropriate corrective action may result in a recommendation to pursue additional administrative, civil, or criminal sanctions.
5. Review ROIs and other case documentation for violations of the FMIA or PPIA, as necessary, to determine the appropriate enforcement action or case referral. Take action for violations, including, but not limited to, surveillance, investigation, product control, issuance of NOW, referral to EOB, or referral to another agency, following the methods outlined in [FSIS 8,000-series directives](#).
6. Refer ROI cases to OIEA EOB, using methods in [FSIS Directive 8010.5](#), when documentation shows repeated or serious noncompliance with custom exempt requirements.

VIII. OFO RESPONSIBILITIES AND ACTIONS

A. IPP are to:

1. Prepare for the review by scheduling the annual PHIS Custom Exempt task on a day when the establishment will be conducting custom exempt slaughter or processing.
2. Perform reviews at custom exempt slaughtering or processing operations located at official establishments in accordance with the methods in this directive.
3. Document the findings of the review in PHIS, Custom Exempt task, by:

- a. Completing the task questionnaire under the Questionnaire tab from FSIS Form 8160-1;
 - b. Providing information regarding observations and findings in the Findings tab;
 - c. Attaching the 8160-1 in the Attachments tab; and
 - d. Completing and/or updating other PHIS information, as necessary.
4. Inform the custom exempt operator of both the acceptable and unacceptable review findings, provide the custom exempt operator a hard copy of FSIS Form 8160-1 and discuss, as necessary, other information (e.g., regulatory requirements, noncompliance findings, future reviews).
5. Discuss findings from custom exempt review with supervisory personnel (e.g., the Frontline Supervisor (FLS)) and obtain further instructions, if any, including continued verification through future custom exempt reviews.
6. Gather the appropriate information, such as additional records and observations, if IPP observe regulatory noncompliance. Noncompliance that may require further action, such as a LOW and referral to OIEA, includes, but is not limited to, the following:
 - a. The sale of custom exempt product;
 - b. The distribution of adulterated product;
 - c. Misbranding;
 - d. Recordkeeping noncompliance; or
 - e. Inhumane slaughter or handling.
7. Inform the custom exempt operator and FSIS supervisory personnel (e.g., the FLS) when IPP observe apparent noncompliance during the review that is subject to the laws and regulations of other Federal, State or local agencies. IPP are to document the apparent violation or other irregularity in the Findings tab of the Custom Exempt task.
8. Initiate official product control action, including retention of products as appropriate, when there is reason to believe that the exempt products are adulterated or misbranded. IPP are to seek guidance from their supervisor, as needed, on subsequent actions to release the products.
 - a. Inform the owner, owner's agent, or custodian that he or she may offer and make a voluntary disposition of the products before a retention action is taken.
 - b. Not take a retention action if the owner, owner's agent, or custodian makes an appropriate voluntary disposition of the products.
 - c. IPP complete FSIS Form 8080-4, *Voluntary Destruction of Human Food Notice*, or FSIS Form 8080-6, *Personal Use Notice*. These product disposition forms can be found on the FSIS Intranet in the [8,000-series forms](#). Users need an e-authentication account to access these forms.
 - d. Retain the exempt products if the owner, owner's agent, or custodian does not agree to an

immediate disposition of the violative products or does not complete the voluntary disposition in an appropriate manner.

- i. For custom exempt products that are misbranded, maintain the retention until the products are no longer misbranded. Record the findings in the findings tab of the Custom Exempt task.
- ii. For custom exempt products that are adulterated, terminate the retention of the products, and release them to the owner, the owner's agent, or the custodian for the owner's personal use or voluntary destruction. Since custom exempt products are for the exclusive use of the owner in their household, and not for sale as an article of commerce, the products may be released to the owner for their personal use or voluntary destruction. Complete the appropriate product disposition form (FSIS Form 8080-4 or FSIS Form 8080-6).

9. Conduct follow-up reviews as directed by the DM or designee (e.g., the FLS).

10. Report serious (egregious situation) or repeated noncompliance with humane handling or slaughter requirements to the District Veterinary Medical Specialist (DVMS) through the supervisory channels as necessary as described in [FSIS Directive 6900.2](#), *Humane Handling and Slaughter of Livestock*.

11. Refer to [FSIS Directive 5100.3](#), *Administrative Enforcement Reporting System*, for IPP roles and responsibilities for implementation and documentation of administrative enforcement actions taken by the DO, if any.

B. DMs or designees are to:

1. Direct IPP actions through supervisory channels to review custom exempt establishments, as necessary.
2. Coordinate with EOB reviews based on significant findings of noncompliance, issuance of LOW, NOW, or NOI, or because of an applicable administrative consent agreement or other legal order, agreement, or requirement.
3. Evaluate findings from custom exempt reviews and determine action, if any, including continued verification through future custom exempt reviews, issuance of warning letters for noncompliance, referral to EOB, or other action, by following instructions in [FSIS Directive 8010.5](#). The DM may contact the appropriate Federal, State, or local agencies to inform them of any apparent violations or irregularities under their jurisdiction and provide support to such authority, except as provided for in paragraph 5 below.
4. Issue a LOW to the custom exempt operator for noncompliance with custom exempt requirements per the instructions in [FSIS Directive 5100.3](#), Section VIII, B. The LOW should state that the failure to take prompt and appropriate corrective action may result in a recommendation to pursue additional administrative, civil, or criminal sanctions.

5. Refer Administrative Enforcement Report (AER) or other case documentation to OIEA CID or EOB in accordance with [FSIS Directive 8010.5](#), when documentation shows:
 - a. Repeated or serious noncompliance with custom exempt requirements or other violations of the FMIA or PPIA;
 - b. Repeated or serious noncompliance, such as an egregious situation with humane handling; and
 - c. Potential criminal violations, including distribution of adulterated meat, fraud, sale of uninspected meat, and slaughter of animals that were non-ambulatory at the time of delivery to the custom exempt facility. OFO personnel are not to conduct investigation into criminal matters.
6. Confirm the OFO District Case Specialist enters the custom exempt review and other case documentation into ANet in accordance with the instructions in [FSIS Directive 5100.3](#).

IX. OIEA EOB RESPONSIBILITIES AND ACTIONS

- A. The EOB Branch Chief or designee is to take one or more of the following actions, as appropriate:
 1. Review the ROI, AER, or other case documentation referred to EOB for criminal, civil, or administrative enforcement action and make a determination on the appropriate action (e.g., take or initiate administrative enforcement action to terminate custom exempt privileges; issue a NOW, a Letter of Information (LOI), or other enforcement correspondence; close case with no action; or take other action) by following instructions in [FSIS Directive 8010.5](#).
 2. Take administrative enforcement action, when necessary, to terminate custom exempt eligibility by issuing a “Notice of Ineligibility for Custom Exempt Status” (NOI) to custom exempt operators.
 3. Refer the ROI, AER, or other case documentation to Office of General Counsel for case follow-up (e.g., NOI response, hearing preparation, consent agreement negotiations).
 4. Issue “Show Cause” letters (SCL) to provide custom exempt operators the opportunity to present views and information regarding allegations prior to the initiation of administrative proceedings. EOB may determine, on a case by case basis, that SCLs are not necessary when in the public interest.

NOTE: Only EOB will issue SCLs.

5. Issue NOW, LOI, or other enforcement correspondence.
6. Close the case documentation with no action or recommend continued custom exempt reviews, surveillance, verification, or other regulatory activities.
7. Coordinate follow-up surveillance, investigation, or other activities, based on custom exempt findings, compliance history, NOI, settlement agreements, or otherwise as necessary, with the OIEA RD or OFO DM.

8. Take other action, as appropriate, following the methods in [FSIS Directive 8010.5](#).

X. QUESTIONS

Refer questions regarding this directive through your supervisor or submit your questions through [askFSIS](#). When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 8160.1**.
Question Field: Enter question with as much detail as possible.
Product Field: Select **General Inspection Policy** from the drop-down menu.
Category Field: Select **Federal Inspection-Exemptions** from the drop-down menu.
Policy Arena: Select "**Domestic**" from the drop-down menu.

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

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



Assistant Administrator
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