

# FSIS Directive 5930.1 Revision 4

# Custom Exempt Review Process



# Purpose

- To provide instructions to Inspection
   Program Personnel (IPP) and Office of
   Program Evaluation Enforcement and
   Review (OPEER) personnel on how to
   review custom exempt facilities and
- To provide instructions on how to react to the findings from the review.



## Reason for Reissuance

- 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.



### Background

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.



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, sheep, swine, and other livestock. (Poultry slaughter is not included.) The HMSA applies at custom exempt facilities.



# FMIA & PPIA require that carcasses and products are:

- not adulterated or misbranded;
- handle livestock humanely;
- prepared under sanitary conditions;
- Keep certain records;
- properly marked & packaged; and
- stored separately from inspected products



Owner/operators who conduct custom exempt operations must comply with:

- Sanitation regulations 9 CFR 416.1 5 Except for 9 CFR 416.2 (g)(2) - (6)
- If an *official meat* establishment conducts custom exempt operations, then *all* the provisions of the sanitation regulations *416* apply to custom operations.



Poultry custom exempt operators cannot buy or sell any poultry products for use as human food. Thus, Federally inspected poultry establishment cannot conduct custom exempt poultry operations (21 USC 464 (c)(1)(B)).



# Roles of FSIS Personnel in Custom Reviews

Office of Field Operations (OFO), IIC, or designee will review custom exempt operations that occur at federally inspected meat establishments



# Roles of FSIS Personnel in Custom Reviews (Continued)

Agency personnel will review custom exempt operations at facilities in *designated states* that are not subject to routine inspection.

When the agencies of designated states conduct reviews of custom operation, FSIS monitors the cooperative agreements program in these designated states through audits and reviews



# Roles of FSIS Personnel in Custom Reviews (Continued)

FSIS expects Non-designated States to conduct reviews of custom exempt operation in their states in a manner that is equal to the Federal system.

FSIS monitors these states as part of its review of the overall State program.



# Conducting Reviews of Custom Facilities

In determining compliance, FSIS personnel From the 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



# Conducting Reviews of Custom Facilities (Continued)

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.

#### UNITED STATES DEPARTS FOOD SAFETY AND INSPE

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE	LTURE 1. CASE NUMBER SERVICE	
EXEMPT ESTABLISHMENT REVIEW REPORT (Meat & poultry operations) For instructions and Definitions: See Directive 6830.1.	2. EST. NUMBER (if applicable)	3. EST. ID (if applicable)
4a. EXEMPT EST. NAME	•	•
4b. EXEMPT EST. ADDRESS/P.O. BOX		
4c. CITY, STATE, ZIPCODE		
5a. ESTABLISHMENT IS OFFICIAL:  YES NO	Sb. IF OFFICIAL, NAME OF PHV (last, first	st) Sc. IF OFFICIAL, NAME OF IIC (last, first - If not PHV)
6. SPECIES:	•	•
Young Chickens Porcine	Ovine Caprine	Ducks Geese Guinea
Mature Chickens Calves	Turkeys Bovine	Ratites Other
<ol> <li>IDENTIFY EACH ITEM A THRU I AS BEING ACCEPTA IN ALL CASES USE YOUR PROFESSIONAL JUDGEM</li> </ol>		n of Deficiencies below).
CLASSIFICATION OF DEFICIENCIES:  Acceptable - when the custom exempt plant compile:  Unacceptable - when the custom exempt plant deviates		
human food or,	trid, or decomposed substance or is for any re	eason unsound, unhealthful, unwholesome, or otherwise unfit for confaminated with fith, or whereby it is rendered injurious to health.
A. HUMANE HANDLING OF LIVESTOCK:	Acceptable	Unacceptable
B. RECORDKEEPING AND DOCUMENTATION:	Acceptable	Unacceptable
C. SANITATION OPERATIONS:	Acceptable	Unacceptable
D. PEST CONTROL:	Acceptable	Unacceptable
E. INEDIBLE MATERIAL (Including SRM's):	Acceptable	Unacceptable
F. MARKING AND LABELING CONTROL:	Acceptable	Unacceptable
G. PATHOGEN CONTROL:	Acceptable	Unacceptable
H. WATER SUPPLY:	Acceptable	Unacceptable
I. SEWAGE AND WASTE DISPOSAL:	Acceptable	Unacceptable
(Check applicable box)     A. This facility is operating under an administrative consent agreement or other applicable legal order or requirement.		Yes No
<ul> <li>This Facility has been recommended to EED for removal of custom exempt privileges in the last year.</li> </ul>		Yes No
<ul> <li>The conditions observed at this facility during the current review make it likely that adulterated or misbranded product would occur.</li> </ul>		Yes No
D. Adulterated or misbranded product was observed	during this review.	Yes No
REVIEWER'S RECOMMENDED REVIEW INTERVAL IF     Yearly Semi-Annu		NO:
10. DESCRIPTION OF DEFICIENCY: Attach/	Save an MS Word document with	the full narrative to this PDF
11. NAME OF REVIEWER	12. DATE REVIEWED 13. COPY GIVE	N TO OWNER/OPERATOR 14. DATE GIVEN
FSIS FORM 5930-1 (02/06/2009)	PREVIOUS EDITIONS ARE O	B\$OLETE.





## 1. Humane Handling

FSIS personnel are to determine whether the facility is handling livestock in a humane manner by considering the following questions:

- Does the facility have water available to any livestock in holding pens?
- 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?



### 1. Humane Handling (Continued)

### FSIS personnel questions (Continued):

- 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?
- Does the facility slaughter animals in accordance with the ritual requirements of a religious faith?
- Did FSIS personnel observe any egregious situations (any act that is cruel to animals)?



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



(Continued)

- Does the facility maintain records that document the: number and kinds of custom livestock slaughtered and addresses of the owners of the livestock and products?
- Does the facility maintain records from the State or local health agency that show that the water and sewage systems are safe?



(Continued)

- 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?
- 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?



(continued)

- 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)?
- In federally inspected establishments that conduct custom exempt operations, does the establishment maintain Sanitation SOP records per 9 CFR 416.16 that reflect conditions during the custom operations?



# 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.



# 3. General Sanitation and Maintenance of Facilities, Dressing Rooms, Lavatories, and Toilets (Continued)

- 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?
- 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?



# 3. General Sanitation and Maintenance of Facilities, Dressing Rooms, Lavatories, and Toilets (Continued)

- 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?
- Does employees working in contact with product, food-contact surfaces, and product-packaging materials adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions?



### 4. Pest Control

- Does the facility maintain outside and all areas within the facility in a manner to prevent the harborage and breeding of pests?
- Is there any evidence of pest activity in the facility that might lead to product adulteration/contamination or create insanitary conditions?
- Does the facility use safe and effective pesticides?



### 5. Inedible Material Control

The facility must handle and maintain *control of inedible* material to prevent the diversion of inedible products (*including SRMs*) in the human food channels & adulteration of human food.



#### SRM are defined in 9 CFR 310.22(a) as the:

- Brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia from *cattle 30 months of age and older* and
- Distal ileum of the small intestine and the tonsils from all cattle



Cattle that are not ambulatory at the time of slaughter are condemned. 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.



- Are cattle ambulatory at the time they are delivered to slaughter?
- Does the facility handle and dispose of inedible products properly?
- Does the facility remove and dispose of SRM from cattle in a manner that prevents adulteration of product and the creation of insanitary conditions?
- How is the exempt operation handling and disposing of SRM material?



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



- Are cattle ambulatory at the time they are delivered to slaughter?
- Does the facility handle and dispose of inedible products properly?
- Does the facility remove and dispose of SRM from cattle in a manner that prevents adulteration of product and the creation of insanitary conditions?
- How is the exempt operation handling and disposing of SRM material?



# 6. Marking and Labeling

The facility must mark legibly as "NOT FOR SALE" all meat and poultry products or containers

- Part 303.1(a)(2)(iii) Plainly marked "Not For Sale"
- Part 381.10(a)(4) Owner's name and address
  Statement Exempted PL90-492



# 6. Marking and Labeling (Continued)

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



## 6. Marking and Labeling (Continued)

- Does the facility separate custom exempt products from inspected products?
- Are all custom exempt meat products marked "Not For Sale"?
- Are shipping containers for custom exempt poultry marked with the producer's name and address and the statement "Exempted -- P.L. 90-492"?
- Does the facility mark "Not for Sale"?



# 7. Pathogen Control

- Custom exempt facilities that cook product are to heat the product at a sufficient temperature & for a sufficient time to kill pathogens (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



## 7. Pathogen Control (Continued)

The facility must treat meat food products containing raw pork to destroy trichinae excluding fresh pork products as defined by 9 CFR 318.10



# 7. Pathogen Control (Continued)

- Dos the facility have controls in place to destroy trichinae in products that contain pork?
- Does the facility prevent adulteration of product by pathogens?
- For cooked product, does the facility cook product to a temperature that will kill pathogens?
- 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 in accordance with 42 USC Chapter 6A Section 300 g-1 40 CRF Part 141 and 9 CFR Part 416.2 (g)(1)

 Custom exempt operations conducted at noninspected facilities may not reuse water



### 8. Water Supply (Continued)

#### FSIS personnel are to consider the following:

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



### 9. Sewage and Waster 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 416.2(e) & (f)



### 9. Sewage and Waster Disposal (Continued)

#### FSIS personnel are to consider the following:

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



# Additional Requirements at Official Establishments

- Inspection program personnel are to verify that the establishment segregates animals intended for custom Exempt slaughter from animals designated for inspected slaughter.
- Once an establishment presents an animal for ante mortem inspection, the establishment can not change the status to "intended for custom exempt.



# Additional Requirements at Official Establishments (Continued)

When performing PBIS procedure 06B01, IPP are to verify that the establishment:

- Maintained separation of custom prepared product vs. inspected product throughout the process.
- Clearly mark all carcasses and parts from custom slaughter as "Not For Sale" (9 CFR 303.1(a)(2)(iii) and 316.16).
- Separate the "Not For Sale" carcasses from carcasses and parts slaughtered under inspection (9 CFR 303.1(a)(2)(ii))



# Additional Requirements at Official Establishments (Continued)

IPP performing the review are to verify that field slaughtered or farm-dressed carcasses or parts entering an official establishment for custom processing are:

- Delivered in a sanitary manner;
- Ready for cutting up or processing;
- Clearly marked "Not For Sale" upon entering any part of the facility; and
- Cattle are ambulatory at the time of slaughter, as provided in writing by the owner of the animal (309.3(e) and 303.1(f))



# Frequency of Reviews of Custom Exempt Operations

- 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
- The past performance of the operation will determine the frequency at which FSIS will conduct reviews



# Agency personnel responsibilities and actions IPP Responsibilities

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

- 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;
- Collect evidence, such as samples, photographs, statements, and facility records, to support any recommended action;



(Continued)

### IPP Responsibilities (Continued)

- Initiate official control action against product, as appropriate, when there is reason to believe that the product is adulterated or misbranded;
- Discuss the review findings with the owner or operator and inform the owner or operator of the conditions that need to be corrected;



(Continued)

### IPP Responsibilities (Continued)

- 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);
- 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
- Document evidence to support administrative enforcement actions in an Administrative Enforcement Report (AER)



### Agency personnel responsibilities and actions (Continued)

### District Manager or designees Responsibilities

- Coordinate the reviews and determine when a follow-up review;
- 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; or



### Agency personnel responsibilities and actions (Continued)

### District Manager or designees Responsibilities (Continued)

- Refer documentation showing repeated or serious noncompliance, such as an egregious situation with humane handling to OPEER, EED, with a recommendation for administrative or other enforcement action; and
- Refer potential criminal violations to OPEER, Compliance and Investigations Division (CID)



### Agency personnel responsibilities and actions (Continued)

### Compliance Investigator (CI) are to:

- Conduct reviews and accompany OFO reviewers, if requested.
- React as directed by the RD to the results of the OFO review; and
- Document Reports of Investigation (ROI) to support findings of violations of the FMIA, PPIA and related laws and regulation



(Continued)

### Regional Director (RD) or designees are to:

- Coordinate the reviews and determine when a follow-up review is necessary;
- Investigate alleged violations of the FMIA and PPIA that may require civil or criminal actions;
- Direct CI actions through supervisory investigators;
- Issue Notice of Warning (NOW) to custom exempt operator for minor violations (21 U.S.C. § 676);
- Refer ROI cases to OPEER, EED



(Continued)

#### Evaluation and Enforcement Division (EED) Responsibilities to:

- Review case evidence and recommendations to determine whether criminal, civil, or administrative action should be taken;
- Issue a "Show Cause" or "Present Your Views" letter to custom exempt operators before administrative action is taken;
- Issue a Notice of Ineligibility (NOI) to custom exempt operators that demonstrate their inability or unwillingness to implement and maintain compliance; and
- Refer criminal, civil, and administrative cases to the USDA Office of the General Counsel (OGC)



(Continued)

#### 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



### **Enforcement Actions**

- FSIS has the authority to take administrative, civil, or criminal action against the custom exempt operator if the Findings warrant action
- 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