OKLAHOMA DEPARTMENT OF AGRICULTURE,
FOOD, AND FORESTRY
MEAT AND POULTRY INSPECTION SERVICE
OKLAHOMA CITY, OK

MPI NOTICE	902	8/24/2011

CUSTOM EXEMPT REVIEW AND OVERSIGHT PROCESS

I. PURPOSE

This notice describes the policies and procedures for the review and oversight of custom livestock or poultry slaughtering and processing operations that are exempt from inspection requirements under the Acts, and the actions that ODAFF MPI may take when custom exempt facilities and operators do not maintain compliance with the applicable statutory and regulatory requirements. This notice also updates methodologies for determining whether establishments are meeting performance standards for sanitation as set out in the Sanitation Performance Standards regulations; and reflects policies regarding Bovine Spongiform Encephalopathy (BSE) and Specified Risk Materials (SRMs). In addition, it provides updated instructions concerning non-ambulatory disabled cattle and humane handling and slaughter requirements. It also cancels OK MPI Notice 10-07 and contains updated references that reflect the revised MPI Notice numbering system.

II. CANCELLATION

OK MPI Notice 10-07

III. REFERENCES

2 O.S. § 2-4(A)(8); § 2-18; § 6-195; § 6-202; § 6-265; § 6-280.5; and § 6-290.5
OAC 35:37-3-5; 35:37-3-Part 3; 35:37-5-2(b); 35:37-5-4; and 35:37 Subchapter 7
9 CFR Parts 303.1; 309; 310.22; 313; 316.6; 381.10; 381.13; 381.14; and 416.1-5
FSIS Directives 5420.3; 5720.2, Revision 3; 5930.1, Revision 4; 6900.1; and 6900.2, Revision 2
Federal Register (74 FR 11463) "Requirements for the Disposition of Cattle that Become Non-Ambulatory Disabled Following Ante-Mortem Inspection" – Final Rule, March 18, 2009

IV. BACKGROUND

The Oklahoma Meat Inspection Act, the Poultry Products Inspection Act, the Rabbit and Rabbit Products Inspection Act; and the Exotic Livestock and Exotic Livestock Inspection Act exempt the preparation of livestock products and the processing of poultry products from mandatory inspection when the owner of the livestock slaughters it for his own use, or for use by members of his household or nonpaying guests.

Custom slaughter or processing may also be conducted when the animal is slaughtered or processed by someone other than the owner for the personal use of the owner of the animal. The Acts require that those who custom slaughter or process meat and poultry ensure that carcasses and products are:

1. not adulterated or misbranded;
2. prepared under sanitary conditions;
3. properly marked and packaged; and
4. stored separately from other products.

Owners/operators who conduct custom exempt operations must comply with the meat and poultry regulations for exempt operations (OAC 35:37-3-5; 35:37-3-Part 3: 35:37-5-2(b); 35:37-5-4; and 35:37 Subchapter 7; 9 CFR 303.1, 381.10, 381.13, and 381.14) and some of the sanitation regulations (9 CFR 416.1 through 416.5, except for 9 CFR 416.2(g)(2) through (6)). If an inspected meat establishment conducts custom exempt operations, all the provisions of the sanitation regulations (9 CFR Part 416) apply to the custom operations. Oklahoma-inspected poultry establishments are prohibited under the PPIA (2 O.S. § 6-265(A)(4)) from conducting custom exempt poultry operations. In addition, poultry custom exempt operators cannot buy or sell any poultry products for use as human food.

V. RESPONSIBILITIES OF ODAFF MPI PERSONNEL IN THE REVIEW AND OVERSIGHT OF CUSTOM EXEMPT OPERATIONS

A. ODAFF MPI program supervisory employees will review custom exempt operations that occur at state licensed custom-exempt only meat establishments.

B. In-plant inspection personnel will oversee custom exempt operations that occur at state-inspected meat establishments.

VI. CONDUCTING REVIEWS OF CUSTOM FACILITIES

ODAFF MPI supervisory employees conducting reviews at custom exempt facilities to determine compliance with sanitation or other statutory and regulatory requirements for exempt operations should observe each of the activities listed in this section and complete Form 5000-9-OK – Establishment Review Checklist.

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

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

Sale."

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

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

NOTE: When conducting reviews of custom exempt facilities, focus on the facilities and not on the product. All noncompliances should be fully documented (who, what, when, where, why).

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

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

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

4. Does the facility maintain records that document 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?

5. 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: ODAFF encourages the operators to keep these records to support that they are meeting the adulteration provisions of the Oklahoma Meat Inspection Act.

6. 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.

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

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

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

General Sanitation

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

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

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

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

NOTE: The establishment has the responsibility to ensure that: meat and poultry products are not contaminated through the misuse of proprietary substances and nonfood compounds; all proprietary substances and nonfood compounds are safe for their intended use and used, handled, and stored to prevent the creation of insanitary conditions; and documentation substantiating safe use of a chemical in a food-processing environment is available for review per 9 CFR 416.4(c).

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

Maintenance of Facilities

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

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

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

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

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

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

6. Is there direct product contamination?

Dressing Rooms, Lavatories, and Toilets

ODAFF MPI employees should assess the facility's dressing rooms, toilet rooms, and urinals to ensure the cleanliness of all persons handling any product (9 CFR

303.1(a)(2)(i), 381.10(a)(3) & (4), and 416.2(h)(1) & (3)).

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

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

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

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

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

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

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

3. Is there evidence of direct product contamination?

NOTE: The pest management program is not required to be written. When conducting an assessment of a plant's pest management program, ODAFF MPI personnel should follow the instructions from FSRE Training for 9 CFR 416.2(a).

D. Inedible Material Control. The facility must handle and maintain inedible material to prevent the diversion of inedible animal products (including SRMs) into human food channels and the adulteration of human food (9 CFR 303.1(a)(2)(i), 303.1(b)(4), 381.10(a)(3) & (4), 416.2(b)(4), and 416.3(c)). SRMs are defined as the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle 30 months of age or older, and the distal ileum of all cattle (9 CFR 310.22). Tonsils from all cattle are also considered inedible and, therefore, are not to enter the food supply (9 CFR 310.22). Cattle that are not ambulatory at the time they are delivered to 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. ODAFF MPI personnel are to consider the following:

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

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

2. If the facility processes beef, does it remove the SRMs and keep records documenting that the animal was less than 30 months of age at the time of slaughter, or if not does it handle all cattle as if they were more than 30 months of age?

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

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

NOTE: If one custom-exempt facility needs to transport carcasses with SRMs (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.

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

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

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

3. Does the facility mark "Not for Sale" in a manner which ensues 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.

4. 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: A custom exempt operator can process, as custom exempt, livestock carcasses that were slaughtered under inspection. However, the establishment cannot sell the processed meat because the product was not produced under ODAFF MPI inspection. The establishment is to remove the "INSPECTED AND PASSED" marks and mark the products "NOT FOR SALE" (2 O.S. § 6-195).

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

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

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

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

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

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

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

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

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

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

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

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

2. Does the plumbing system provide adequate floor drainage?

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

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

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

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

7. Is there evidence of direct product contamination?

NOTE: All custom facilities should have a copy of the letter of approval for their sewage system available for review by OK MPI personnel.

NOTE: When conducting reviews of custom facilities in Oklahoma, it is important to remember that in addition to meeting the requirements found in the Sanitation Performance Standards (9 CFR 416.1 – 6) the facility must also meet all the requirements of the CONSTRUCTION STANDARDS FOR MEAT PACKING PLANTS (OAC 35:37-7-1 through 35:37-7-99)

I. Humane Handling and Slaughter. As provided in the Oklahoma Meat Inspection Act custom-exempt plants must handle and slaughter all cattle, bison, sheep, swine, goats, horses, mules and other equines humanely (2 O.S. § 6-183(B)). It is expected that all applicable requirements found in 9 CFR Part 313 will be met in custom-exempt operations. ODAFF-MPI 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:

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

2. 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?

3. 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?

4. 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 does the facility implement humane handling procedures in connection with such slaughtering?

5. Did ODAFF-MPI personnel observe any egregious situations (any act that is cruel to animals or a condition that is ignored and leads to the harm of animals) or repeated noncompliance with inhumane slaughter?

NOTE: If during the review of a custom exempt operation Agency personnel observe inhumane handling of livestock, they should immediately inform plant management. ODAFF personnel will document their observations on Form 5000-9-OK. Any egregious situation will be immediately reported to the ODAFF Director of Meat Inspection.

VII. ADDITIONAL REQUIREMENTS FOR CUSTOM EXEMPT OPERATIONS AT INSPECTED ESTABLISHMENTS

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

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

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

C. 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.

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

1. change outer garments;

2. clean and sanitize their hands; and

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

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

1. delivered in a sanitary manner;

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

3. in the case of bovines, it is certified, in writing, that the animal was ambulatory at the time of slaughter by the owner of the animal (9 CFR 309.2(b) and 309.3).

NOTE: Any custom facility that receives any field-slaughtered or farm-dressed carcasses or parts must meet all the requirements of the Field-Slaughtered or Farm-Dressed Carcasses or Parts Policy, which was described in OK MPI Notice 301, and a completed Owner Certification for Establishment to Receive and Custom Process

Animals Slaughtered Off Premises must accompany the carcass before it can be received into a custom processing facility.

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

G. Inspection program personnel are to verify that when an inspected establishment conducts custom exempt operations, all sanitation, adulteration and misbranding requirements have been met. These requirements are to be verified by inspection program personnel using the appropriate ISP codes for SSOPs (01B01, 01B02, 01C01, 01C02), Sanitation Performance Standards (06D01), and custom exempt operations (06B01).

VIII. FREQUENCY OF REVIEWS OF CUSTOM EXEMPT OPERATIONS

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

Custom exempt slaughtering and processing operations that operate in compliance with the statutory and regulatory requirements will be reviewed at least quarterly.

IX. ENFORCEMENT ACTIONS

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

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

1. document the results of the review on Form 5000-9-OK, fully describing any findings of noncompliance;

2. provide copies of FSIS Form 5000-9-OK to the owner/operator of the custom exempt facility and to the Circuit Supervisor (MI Supervisor reviewer) or State Director (Circuit Supervisor reviewer);

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

4. conduct follow-up reviews as directed by the Oklahoma City Office; and

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

B. State Director (or designee) is to:

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

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

3. if noncompliance continues, refer documentation showing repeated or serious noncompliance with custom exempt requirements to the Office of General Counsel, with a recommendation for administrative or other enforcement action.

Refer questions concerning the custom exempt review and oversight process through supervisory channels.

Stan Stromberg
State Director

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