TEXAS DEPARTMENT OF STATE HEALTH SERVICES MEAT SAFETY ASSURANCE AUSTIN, TEXAS

MSA DIRECTIVE

8160.1 Rev. 1

08/19/2022

CUSTOM EXEMPT REVIEW PROCESS

I. PURPOSE

- A. This directive provides instructions to Meat Safety Assurance (MSA) Inspection Program Personnel (IPP) on how to conduct reviews of custom exempt facilities that are not located at official establishments.
- B. This directive provides instructions to MSA 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 MSA Circuit Managers and the MSA Central Office or designees are to apply when determining actions based on custom exempt review findings, documentation, and referral.

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 IPP, CMs and the CO

II. CANCELLATION

MSA Directive 8160.1, Custom Exempt Review Process, 9/28/2020

III. BACKGROUND

A. The Texas Meat and Poultry Inspection Act (TMPIA), §433.006, identifies the custom slaughtering and preparation activities that are exempt from State 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 State inspection.

- B. The TMPIA , §433.006 (b), also provides that the adulteration and misbranding provisions apply to articles that are exempted from inspection.
- C. The Texas MSA Program (Program) has the authority to adopt rules necessary for the efficient execution of the TMPIA, per §433.008. The Program has promulgated rules within the Texas Administrative Code (TAC). Within TAC §221.11 the Department has adopted by reference federal regulations from the Code of Federal Regulations (CFR).
- D. In order to maintain sanitary conditions and prevent the production of adulterated product, MSA has promulgated rules for custom exempt operations in 25 TAC 221.14. Under these regulations, operators who conduct custom exempt livestock operations must prepare meat food products under sanitary conditions. The sanitation regulations in 9 CFR 416 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.
- E. Custom exempt livestock meat food products cannot contain Specified Risk Materials (SRMs), per 9 CFR 310.22(a)(2)(b), because such materials adulterate products. Non-ambulatory disabled cattle delivered by the owner are not eligible for custom slaughter or processing.
- F. Inedible materials, including SRMs, resulting from custom exempt slaughter or processing must be disposed of in accordance with 25 TAC 221.14(a)(10).
- G. 25 TAC 221.14(a)(7) requires 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. 25 TAC 221.14(c)(4)(A) requires the shipping containers of custom exempt poultry products to bear the owner's name and address and the statement "Exempted P.L. 90-492."

Custom exempt livestock slaughter operators must comply with 25 TAC 221.14(a)(4), regarding the humane treatment of animals.

- H. Custom exempt livestock operators must keep records as will fully and correctly disclose all transactions involved in their custom exempt business and all applicable recordkeeping requirements per 25 TAC 221.14(a)(2).
- I. The amenable livestock species that are subject to MSA custom exempt regulations are cattle, bison, sheep, swine, goats, horses, mules, other equines,

poultry, domestic rabbits, exotic animals, or domesticated game birds, per TMPIA 433.008(11).

IV. CONDUCTING REVIEWS OF CUSTOM EXEMPT FACILITIES TO DETERMINE COMPLIANCE

- A. 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, 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 MSA 59-4.
- B. IPP are to conduct periodic reviews of custom exempt slaughtering and processing operations, at official establishments or other facilities, generally at a frequency of once-per-quarter.
- C. IPP are to prioritize their reviews of custom exempt slaughtering and processing operations at in- commerce locations in accordance with the instructions in MSA 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 State establishments sometime during the calendar year when they receive the annual PHIS Custom Exempt task.
- E. When determining whether to conduct additional reviews (i.e., more than quarterly) of a custom exempt slaughtering and processing operation, either an in-commerce location or one at a State establishment, 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, based on findings of noncompliance during custom exempt reviews;

- 5. Issuance of enforcement letters, for violations of statutory or regulatory requirements (e.g., sale of custom exempt product, misbranding, or noncompliance with recordkeeping requirements);
- 6. Another legal order, settlement agreement, or binding requirement, such as an administrative consent decree, civil consent decree, or criminal plea agreement; and
- 7. Other relevant compliance information.
- 8. Availability of IPP to conduct custom exempt reviews.
- F. The MSA CO and CM will 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 LOC, LOW, or NOIE, or because of an applicable administrative consent agreement or other legal order, agreement, or requirement.
- G. During the routine quarterly review, 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 documenting their findings on the MSA 59-4.

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

- a. MSA 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. Poultry that die otherwise than by slaughter are considered adulterated. 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)). IPP are to consider the following questions about the recommended 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 scalder?
 - vii. Do facility personnel and equipment handle poultry in a manner that minimizes broken legs and wings?

2. Review of Recordkeeping and Documentation

- a. MSA 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 Act and the records that are required by the applicable 9 CFR regulatory requirements. IPP are to consider the following recordkeeping questions:
 - 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, telephone number

and addresses of the owners of the livestock and product?

- ii. Are the required records kept for poultry operations?
- iii. For custom exempt livestock facilities, are the required records maintained from the state or local health agency documenting water potability and that the sewage systems are adequate?
- 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 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?
- vi. Are records kept onsite for two years, beginning on January 1 of the previous year plus the current year to date?
- b. MSA recommends that custom exempt livestock operators keep voluntary records to demonstrate they are meeting the adulteration provisions TAC 221.14(a)(8)(C) with respect to SRMs. 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?

3. Review of Sanitary Operations

a. MSA personnel are to determine whether the custom exempt facility is maintained in a sanitary condition as required to prevent adulteration of product. 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. MSA personnel are to determine if the maintenance of the facilities used to slaughter and process custom exempt product prevents the adulteration of product. 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. MSA personnel are to determine if the facility's dressing rooms, lavatories and toilets are maintained in a sanitary condition. 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. MSA personnel are to determine if the grounds about the custom exempt facility prevent conditions that could lead to insanitary conditions or adulteration of product. 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. MSA 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. 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. Are cattle which became non-ambulatory after delivery for slaughter disposed of as inedible material?
 - iii. Does the operator handle and dispose of inedible products properly?
 - iv. Does the operator remove and dispose of SRM from cattle in a manner that prevents adulteration of product and the creation of insanitary conditions?

6. Review of Marking and Labeling Control:

- a. MSA personnel are to determine if the custom exempt operator appropriately marks and labels to prevent misbranding. 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"?

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. MSA personnel are to determine if the custom exempt operator prevents the adulteration of products by controlling microbial pathogens. 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. MSA personnel are to determine if the custom exempt facility has a potable supply of running water to prevent the adulteration of food products. 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?
 - 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. MSA personnel are to determine if the custom exempt facility properly removes sewage and waste materials to prevent the adulteration of food products. 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?

V. 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 <u>9 CFR part</u> 416?

2. Are the inspected products kept separate and apart from custom prepared products, 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 livestock for MSA inspection, they are subject to all regulatory requirements for inspection including but not limited to; ante- and post-mortem inspections, humane slaughter, sanitary dressing, SSOPs, HACCP, and zero tolerance.

- 3. Are carcasses and parts from custom livestock slaughter clearly marked with "Not for Sale" and include the owner's name or a code that allows for identification of the owner.
- 4. Are the shipping containers of custom exempt poultry marked "Exempted P.L. 90-492"?
- 5. Are facilities and equipment used for the preparation of any state inspected products cleaned and sanitized after custom operations have been completed, and do employees change outer garments as necessary before the operator prepares state inspected products?
- 6. Does the operator maintain the required records, including Sanitation SOP records required by <u>9 CFR 416.16</u>?
- B. IPP are not to issue a Noncompliance Record during custom exempt reviews at granted establishments, including if sanitation SOP recordkeeping noncompliance is observed. If noncompliance exists, mark this category on the MSA 59-4 as unacceptable, and document the findings on the form.

VI. IPP RESPONSIBILITIES AND ACTIONS

A. IPPS are to:

- 1. Prepare for the quarterly custom review by following the instructions found in MSA Directive 8010.1.
- 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 on form MSA 59-4
- 4. Inform the custom exempt operator of both the acceptable and unacceptable review findings, provide the custom exempt operator a copy of MSA 59-4 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. Report serious (egregious situation) or repeated noncompliance with humane handling or slaughter requirements to the CO through the supervisory channels as necessary as described in MSA Directive 6900.2, Humane Handling and Slaughter of Livestock.
- 7. Follow the instruction in MSA Directive 8010.1, Chapter VI, II, Other Irregularities, if they observe apparent violations or other irregularities involving non-amenable products or facility conditions not subject to MSA jurisdiction during the review.
- 8. Initiate official product control action, as appropriate, when there is reason to believe that the products are adulterated or misbranded. Refer to MSA Directive 8410.1, *Detention and Seizure*, for the procedures that MSA program personnel are to follow when detaining meat or poultry products.

B. MSA Central Office or designees are to:

- 1. Direct IPP actions through supervisory channels to review custom exempt establishments, as necessary.
- 2. Coordinate with Enforcement on significant findings of noncompliance, issuance of LOC, LOW, or NOIE, 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 or other action, by following instructions in MSA Directive 8010.5. The CO 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. 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 case documentation to Enforcement when documentation shows:
 - a. Repeated or serious noncompliance with custom exempt requirements or other violations of the TMPIA;
 - 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. MSA personnel are not to conduct investigation into criminal matters.

VII. QUESTIONS

Refer questions through supervisory channels.

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