**VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS**
**FOOD SAFETY CONSUMER PROTECTION DIVISION**
**Meat Inspection Service**
**MONTPELIER, VT**
**Anson Tebbetts, Secretary**

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| | **MIS DIRECTIVE**<br>Adopted from FSIS Directive 8160.1 Rev. 1 | 8160.1 Rev. 1 | 10/1/2022 |

## CUSTOM EXEMPT REVIEW PROCESS

### I. PURPOSE

A. This directive provides instructions to Food Safety Specialists on how to conduct reviews of custom exempt facilities that operate at official establishments or are located at in-commerce locations.

B. This directive provides the methodologies that supervisors 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*

### II. CANCELLATION

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

### III. BACKGROUND

A. Per 6 V.S.A 6 V.S.A. § 3305(8), …"The federal meat inspection regulations and federal poultry inspection regulations of the U.S. Department of Agriculture, Title 9, Code of Federal Regulations, Chapter 3, 9 CFR §§ 300.1 et seq., together with any amendments, supplements, or revisions thereto, are adopted as part of this chapter."
The Federal Meat Inspection Act (FMIA) (21 U.S.C. 623(a)), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 464(c)(1)(B)), and 6 V.S.A. Chapter 204, identify the custom slaughtering and

preparation activities that are exempt from Federal and 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 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 or State 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) and 6 V.S.A. § 3312.

**NOTE:** The Sanitation Performance Standards in 9 CFR 416.1 through 416.6 are not incorporated by reference into the poultry custom exempt regulations 6 V.S.A. § 3312(a), (b) and (c). A facility may adopt these provisions to meet the sanitary standards cited in 9 CFR 381.10(a)(4). The Sanitation Performance Standards in 9 CFR 416.1 through 416.6 are however, incorporated by reference into the poultry custom exempt regulations 6 V.S.A. § 3312 (d).

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: [Docket No. 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. 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." 6 V.S.A. § 3312(e) requires all poultry sold from the farm, at a farmers' market, or to a food restaurant pursuant to the exemption in subsection (b), (c), or (d) shall be labeled with specific requirements.

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 State and 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 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.

## 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*.

## V. CONDUCTING REVIEWS OF CUSTOM EXEMPT FACILITIES TO DETERMINE COMPLIANCE

A. FSS 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, FSS 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 VT Form 8160-1, *Exempt Facility Review Report*, which replaces VT Form 5930-1. This form can be found on the Sharepoint Forms Folder.

B. FSS are to conduct periodic reviews of custom exempt slaughtering and processing operations, at official establishments or other facilities, periodically, generally at least once-per-year.

C. IPP are to perform reviews of custom exempt slaughtering and processing operations at official 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.

D. 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 official establishments, 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), based on findings of noncompliance during custom exempt reviews;

5. Issuance of enforcement letters, such as a Notice of Warning (NOW), for violations of statutory or regulatory requirements (e.g., sale of custom exempt product, misbranding, or noncompliance with recordkeeping requirements);

6. Suspension of License, based on findings of serious or repeated noncompliance during custom exempt reviews;

7. An administrative consent agreement between VAAFM and the custom exempt operator to resolve a NOV;

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 FSS to conduct custom exempt reviews.

E. The Chief 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 NOV, or because of an applicable administrative consent agreement or other legal order, agreement, or requirement.

F. During the routine annual review, FSS 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 VT Form 8160-1.

H. For questions regarding recommended practices in official establishments, FSS are to

document in the Findings tab of the PHIS Custom Exempt task. In in commerce custom establishments, VT Form 8160-1 can be used.

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. It is recommended 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)). FSS 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 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. FSS 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. FSS 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. It is recommended 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. FSS 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. FSS 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. FSS 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. FSS 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. FSS 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. FSS 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. FSS 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. FSS 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. FSS 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. FSS 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. FSS are to determine if the custom exempt operator appropriately marks and labels to prevent misbranding. See Section III, F above for the requirements. FSS 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. FSS 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. FSS 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. FSS 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. FSS 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. FSS 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)). FSS 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 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 VT Form 8160-1 as unacceptable, and document the findings on the form.

## VII. RESPONSIBILITIES AND ACTIONS AT CUSTOM EXEMPT

A. FSS are to:

1. Inform the custom exempt operator of both the acceptable and unacceptable review findings, provide the custom exempt operator a hard copy of VT Form 8160-1 and discuss, as necessary, other information (e.g., regulatory requirements, compliance findings, future reviews, issuance of correspondence).

2. Discuss findings from the custom exempt review with supervisory personnel and obtain further instructions, if any, including continued verification through future custom exempt reviews.

3. Supervisor should refer any apparent violations to the Chief and the Meat Safety Consumer Enforcement Specialist (MSCES).

B. MSCES or FSSIIICI are to:

4. Initiate an investigation by following the instructions found in VT Directive 8010.2, *Investigative Methodology* if apparent violations of the FMIA, PPIA, V.S.A., 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 VT 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 VT 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.

5. Follow the instruction in VT 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 VT Form 8160-1.

6. Initiate official product control action, as appropriate, when there is reason to believe that the products are adulterated or misbranded. Refer to VT Directive 8410.1, *Detention and Seizure*, for the procedures that 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 MI- C&E- 23E, *Voluntary Destruction of Human Food Notice*, or VAA-MI-C&E-29E, *Personal Use Notice*. These product disposition forms can be found on the MI Sharepoint Site in the Compliance forms folder.

d. Detain the violative products, as set forth in VT 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 MI-C&E-8E *Notice of Detention.* This form can be found on the MI Sharepoint site, in the Compliance Form folder.

    i. For custom exempt products that are misbranded, maintain the detention until the custom exempt products are no longer misbranded. Complete MI-C&E-25E *Notice of Termination of Detention.* This form can be found on the MI Sharepoint site, in the Compliance Form folder.

    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. Meat Program Supervisor and Chief are to:

1. Direct FSS' actions, as necessary, to plan and conduct reviews of custom exempt slaughtering and processing operations at in-commerce locations and establishments, based on surveillance priorities in VT Directive 8010.1.

2. Coordinate 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 the MSCES, or other action.

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 or V.S.A., 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 another agency.

6. Refer ROI cases to the AAG, when documentation shows repeated or serious noncompliance with custom exempt requirements.

## VIII. RESPONSIBILITIES AND ACTIONS AT OFFICIAL ESTABLISHMENTS

A. FSS 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 (*this is currently not yet available in PHIS*);

    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 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 FSS observe regulatory noncompliance. Noncompliance that may require further action, such as a LOW and referral, 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 VAAFM supervisory personnel when FSS observe apparent noncompliance during the review that is subject to the laws and regulations of other Federal, State or local agencies. FSS 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. FSS are to seek guidance from their supervisor, as needed, on subsequent actions to release the products.

1. 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.

2. Not take a retention action if the owner, owner's agent, or custodian makes an appropriate voluntary disposition of the products.

3. Complete MI- C&E- 23E, *Voluntary Destruction of Human Food Notice*, or VAA-MI-C&E-29E, *Personal Use Notice*. These product disposition forms can be found on the MI Sharepoint Site in the Compliance forms folder.

4. 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 (MI- C&E- 23E or VAA-MI-C&E-29E).

9. Conduct follow-up reviews as directed by the Meat Program Supervisor or the Chief (e.g., the FLS).

10. Report serious (egregious situation) or repeated noncompliance with humane handling or slaughter requirements to the Veterinarian through the Chief as necessary as described in VT Directive 6900.2, *Humane Handling and Slaughter of Livestock*.

B. Meat Program Supervisor or Chief is to:

1. Direct FSS actions through supervisory channels to review custom exempt establishments, as necessary.

2. Coordinate with the AAG 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, or other action.

4. Issue a LOW to the custom exempt operator for noncompliance with custom exempt requirements per the instructions in VT 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 case documentation to AAG 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. VAAFM personnel are not to conduct investigation into criminal matters.

## IX. DIVISION RESPONSIBILITIES AND ACTIONS

A. The Chief, Deputy Director and Director is to take one or more of the following actions in consultation with the AAG, as appropriate:

1. Review the ROI or other case documentation referred 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).

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. Per the policy of the Agency, custom exempt operators are given the opportunity to present views and information regarding allegations during the pre-hearing conference or formal hearing process, if an NOV is issued.

4. Issue NOW, LOI, or other enforcement correspondence.

5. Close the case documentation with no action or recommend continued custom exempt reviews, surveillance, verification, or other regulatory activities.

6. Coordinate follow-up surveillance, investigation, or other activities, based on custom exempt findings, compliance history, NOI, settlement agreements, or otherwise as necessary.

7. Take other action, as appropriate, following the methods in VT Directive 8010.5.

## X. QUESTIONS

Refer questions regarding this directive through your supervisor