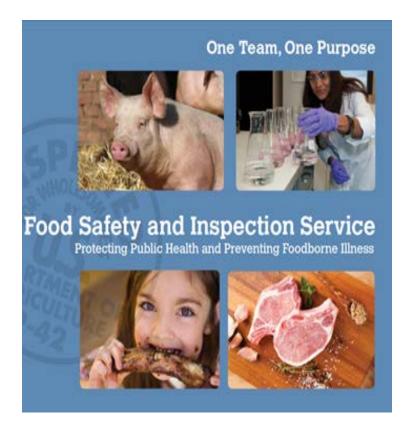
FSIS Guideline for Determining Whether a Livestock Slaughter or Processing Firm is Exempt from the Inspection Requirements of the Federal Meat Inspection Act

May 24, 2018



This guideline is designed to help firms that slaughter livestock or process meat and meat products determine whether they are exempt from required Federal inspection under the Federal Meat Inspection Act.

USDA-FSIS

What is the purpose of this guideline?

Many businesses are interested in slaughtering livestock or producing meat or meat food products but are not sure if they are required to operate under Federal inspection. This guideline explains each of the exemptions from inspection, when they apply, and which Food Safety and Inspection Service (FSIS) regulatory requirements must still be met.

Who is this guideline designed for?

This guideline is designed for any person or business seeking more information about the exemptions from the requirements for inspection by FSIS, or emerging business model operators that handle meat or meat food products that are exempt from

inspection requirements. FSIS currently requires inspection, unless exempted, for meat or meat food products from cattle, sheep, swine and goats.

This guideline will be especially useful for producers and businesses that are exempt from inspection by regulation:

- small and very small slaughter or processing establishments wishing to provide custom exempt services (see page 4) to owners of livestock;
- retail stores making sales directly to consumers at a single location or at satellite stores owned or operated by the retail store;

FSIS currently requires inspection, unless exempted, for meat or meat food products from cattle, sheep, swine, and goats.

- restaurants selling or serving ready-to-eat (RTE) meals to individual consumers;
- caterers delivering or serving RTE meals to individual consumers;
- restaurant central kitchens sending RTE meals to their satellite restaurant locations or vending machines;
- businesses that are a combination of a retail store and a restaurant;
- internet advertisers, marketers, and brokers of meat or meat food products to consumers:
- firms using common couriers to transport meat or meat food products to consumers; and
- farmers wishing to engage in direct purchase agreements with school food service authorities for livestock slaughtered and prepared under State or Federal inspection.

This guideline reflects FSIS's policies and procedures and can be used now. However, FSIS is requesting comments on this guideline and may make changes to it based on comments.

How can I comment on this guideline?

FSIS seeks comments on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content,

readability, applicability, and accessibility. The comment period will be 60 days and the document will be updated in response to the comments.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal Online submission at regulations.gov: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to http://www.regulations.gov and follow the online instructions at that site for submitting comments.

Mail, including - CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name - FSIS, and document title: FSIS Guideline for Determining Whether a Livestock Slaughter or Processing Operation is Exempt from the Inspection Requirements of the Federal Meat Inspection Act 2017. Comments received will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

What if I still have questions after I read this guideline?

If the desired information cannot be found within the Guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the <u>askFSIS</u> database or submit questions through <u>askFSIS</u>. Documenting these questions helps FSIS improve and refine present and future versions of the Guideline and associated issuances.

When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Guideline for Livestock Exemptions**Question Field: Enter question with as much detail as possible.

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **Agency Issuances** from the drop-down menu. Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press Continue.

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Introduction

Under the Federal Meat Inspection Act (FMIA), FSIS conducts inspection in all establishments where cattle, goats, sheep and swine are slaughtered or processed for sale as articles of commerce, unless an exemption from inspection applies. See page 23 for more about what is meant by "commerce." The USDA's Food Safety and Inspection Service (FSIS) is the public health agency responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. FSIS does this by verifying compliance with its regulations, found in 9 Code of Federal Regulations (CFR) 300-599. Daily inspection is provided by FSIS or by States that operate their own meat and poultry inspection (MPI) programs that are "at least equal to" FSIS's inspection program.

The FMIA exempts some slaughter and processing activities and operations from its inspection requirement. Those exemptions are found in <u>21 U.S.C. 623 and 661</u>, and FSIS issued regulations on those exemptions (<u>9 CFR 303.1</u>). Facilities operating under an exemption are not exempt from the adulteration and misbranding requirements of the FMIA and may be subject to State or local regulatory requirements.

Note: Exemption guidance for poultry products can be found in <u>Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of the Poultry Products Inspection Act.</u>

What requirements apply to persons, firms or corporations wishing to conduct business under the livestock inspection exemptions?

Although exempt from the daily inspection requirements, these exempt facilities remain subject to the access and examination provisions of the FMIA (21 U.S.C. 642). Therefore, business records, per <u>9</u> <u>CFR 320.1</u>, must be maintained and access to places of business and opportunity for examinations of facilities, inventory, and records must be provided to authorized FSIS personnel.

As is noted above, meat products exempt from inspection are not exempt from the adulteration or misbranding provisions of the FMIA. The adulteration and misbranding provisions of the FMIA can be found in 21 U.S.C. 601.

- A meat food product is adulterated if it
 - was prepared, packed or held under insanitary conditions;
 - is for any reason unsound, unhealthful, unwholesome or unfit for human food;
 - o consists in whole or part of any filthy, putrid, or decomposed substance;
 - o may have been rendered injurious to health; or
 - bears or contains any poisonous or deleterious substance which may render it injurious to health (i.e. undeclared allergen, chemical residue).
- A meat food product is economically adulterated when any valuable constituent, in whole or in part, has been omitted or removed, or in which a less valuable substance has been substituted.
- A meat food product is misbranded if its label is false or misleading, or if it does not contain the required labeling features.

Who determines whether an operation qualifies for an exemption?

There is no registration requirement with FSIS or approval process from FSIS to operate under an exemption. The person operating the business makes the initial determination and decides which, if any, exemption applies. However, FSIS Office of Investigation, Enforcement and Audit (OIEA) Compliance Investigators periodically verify whether the firm meets the relevant exemption requirements in <u>9 CFR 303.1</u>.

For assistance in understanding the regulations applicable to exempt operations, please contact the FSIS Policy Development Staff at 1-800-233-3935 or submit your questions through askFSIS.

The person operating the business determines if he or she is qualified for an exemption.

FSIS OIEA Compliance Investigators may verify that the establishment meets the exemption requirements in 9 CFR 303.1.

What are the exemptions from USDA FSIS inspection?

The FMIA, in <u>21 U.S.C. 623(a)</u>, exempts from routine Federal inspection:

- Livestock slaughtered for personal use
- Livestock custom slaughtered or prepared

The FMIA, in <u>21 U.S.C. 661(c)(2)</u>, exempts from routine Federal inspection, operations of types traditionally and usually conducted at:

- Retail stores
- Restaurants
- Restaurant central kitchen facilities
- Caterers

Criteria and Notes for Each Exemption

A. PERSONAL USE

Mandatory inspection for the slaughter and processing of privately owned livestock is not required, provided the criteria below are met (21 U.S.C. 623; <u>9 CFR 303.1(a)(1)</u>):

- (a) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to:
- (1) The slaughtering by any individual of livestock of their own raising, and the preparation by them and transportation in commerce of the carcasses, parts thereof, meat and meat food

products of such livestock exclusively for use by them and the members of their household and their nonpaying guests and employees.

Personal Use Criteria:

- 1. The resulting product from the animal slaughtered and processed under this exemption is exclusively for the private use by the:
 - a. owner raising the livestock,
 - b. members of their household,
 - c. household nonpaying guests, or
 - d. household employees.
- 2. The slaughter and processing of the livestock is performed by the owner of the livestock.
- 3. No livestock are slaughtered which are unfit for human consumption. <u>Specified risk materials</u> (SRMs)are inedible and prohibited for use as human food.
- 4. The carcass and parts are not prepared, packed, or held under insanitary conditions.

Personal Use Notes:

- 1. All of the criteria above must be met, otherwise, the livestock is not eligible to be slaughtered and processed under this exemption, and inspection is required.
- 2. There is no limit on the number of livestock that an owner may slaughter and process for their personal use.
- 3. A person may purchase livestock from a farm or ranch and then slaughter it onsite using the farm or ranch facilities or equipment.
 - a. If a person purchases livestock, and uses the onsite facilities without assistance from the seller, then the activity remains personal use.
 - b. If the seller participates in the slaughter or processing activity, then the facility owner is subject to the custom exempt criteria described below.
- 4. Personal use products, although uninspected, may move across State lines.
- 5. The owners of the livestock may or may not reside at the same physical location as the animal.
- 6. The exempt meat food products may not be sold or donated.

B. CUSTOM SLAUGHTER AND CUSTOM PROCESSING

A custom exempt operator slaughters livestock belonging to someone else and processes the carcasses and parts, for the exclusive use, in the household of that owner, by the owner, members of the owner's household, non-paying-guests, and employees. The custom exempt operator may also engage in the business of buying or selling other meat and meat food products, derived from State or Federal inspected sources.

A custom exempt operator may slaughter, or process custom exempt product, or do both. The owner of the livestock may opt to have his or her livestock slaughtered under the custom exemption by one

custom exempt operator, and then choose to have a second custom exempt operator do the processing. The owner of the livestock may also slaughter the animal and then have the carcass further processed at a custom exempt processing facility.

The applicable regulatory requirements are found in <u>9 CFR 303.1(a)(2):</u>

- (a) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to:
- (2) The custom slaughter by any person of cattle, sheep, swine, or goats delivered by the owner thereof for such slaughter, and the preparation by such slaughterer and transportation in

commerce of the carcasses, parts thereof, meat and meat food products of such livestock, exclusively for use, in the household of such owner, by the owner and members of their household and their nonpaying guests and employees; nor to the custom preparation by any person of carcasses, parts thereof, meat or meat food products derived from the slaughter by any individual of cattle, sheep, swine, or goats of their own raising or from game animals, delivered by the owner thereof for such custom preparation, and transportation in commerce of such custom prepared articles, exclusively for use in the household of such owner, by the owner and members of their household and their nonpaying guests and employees.

Custom exempt
operations must
result in meat and
meat food products
that are fit for human
consumption.

Custom Slaughter and Custom Processing Criteria:

- The resulting product from the animal slaughtered and processed under this exemption is exclusively for the private use of the:
 - a. owner of the livestock:
 - b. members of his the owner's household;
 - c. nonpaying guests; or
 - d. household employees.
- 2. Records of the names and addresses of the owner of the livestock and products must be kept by the custom exempt operator. The recordkeeping requirements of <u>9 CFR 320.1</u> apply to custom exempt operations.
- 3. No livestock are slaughtered which result in food unfit for human consumption.
 - a. For reference, in official establishments non-ambulatory disabled cattle are considered unfit for human food and must be condemned, including those that become nonambulatory after passing ante-mortem inspection (9 CFR 309.3). However, custom operators may slaughter for human food cattle that become non-ambulatory disabled after they are delivered to the custom slaughter facility if the operator of the facility does not observe any other condition that would render the animal unfit for human food (74 FR 11463, 11464).
 - b. Field-dressed livestock (cattle, sheep, swine, goats) may be brought in for custom exempt processing. The custom exempt operator may ask the owner of any fielddressed cattle to provide a written statement that the animal was ambulatory at the time of slaughter. This statement helps to support that the beef products are safe, wholesome and unadulterated.

- c. The facility must handle and maintain inedible material to prevent the diversion of inedible animal products (including SRMs) into human food channels, resulting in the adulteration of human food (9 CFR 303.1(a)(2)(i), 303.1(b)(4), 381.10(a)) (4), 416.2(b)(4), and 416.3(c)).
- d. The regulation 9 CFR 303.1(b)(1) states that "exempted custom prepared products ... shall not be adulterated as defined in paragraph 1(m) of the Federal Meat Inspection Act." Therefore, custom exempt product cannot contain SRMs, including the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle 30 months of age and older. The distal ileum of the small intestine and tonsils from all cattle are SRMs, considered inedible and, therefore, are not to enter the food supply (9 CFR 310.22). See FSIS Using Dentition to Age Cattle for more information.
- 4. Livestock must be slaughtered and handled in compliance with the <u>Humane Methods of</u> Livestock Slaughter Act.
- 5. The facility must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.
 - a. The regulatory requirements of 9 CFR 416.1 to 416.6, except for 416.2(g)(2)-(6), apply to all custom exempt facilities.
 - b. The additional regulatory requirements, including recordkeeping, of 9 CFR 416.12 to 416.16, apply to custom exempt operations that are conducted in an official establishment, 9 CFR 303.1(a)(2)(i).
- 6. The custom exempt product cannot be sold or donated as it is exclusively for the use by the owner in their household. Articles which are capable for use as human food, if not delivered to the owner, must be denatured or otherwise identified in accordance with <u>9 CFR 325.13</u>, so as to be made distinguishable from human food, per <u>9 CFR 303.1(b)(4)</u>.
- 7. The carcasses and parts prepared on a custom exempt basis shall be marked as "Not for Sale," or if placed in immediate containers labeled with "Not for Sale," until delivered to the owner, per 9 CFR 316.16.
- 8. In a facility that hosts both an official establishment and an unofficial custom exempt operation, the custom exempt prepared livestock products must be kept separate and apart, per <u>9 CFR 303.1(a)(2)(ii)</u>, from any products that are for sale. Separation can be achieved by <u>time or space</u>. For example, the same cooler can be used to store both custom exempt products and inspected products. The custom exempt products are stored on separate rails or shelves and marked "Not for Sale," which makes them separate and distinct from the inspected product.

Custom Slaughter and Custom Processing Notes:

- There is no registration requirement with FSIS or approval process from FSIS to operate under the custom exemption. FSIS recommends that operations that are exempt from FSIS inspection are appropriately permitted through the State and local (county, city) authorities. Check with those authorities for their applicable licensing requirements. FSIS will verify compliance with the FMIA statutory requirements, and 9 CFR regulatory requirements, annually.
- 2. There is no limit to the amount of livestock that an owner may slaughter and process for their personal use under the custom exemption.

- 3. If any of the eight criteria above are not met, the custom exempt operator may be ineligible for the exemption.
- 4. If the custom operations are conducted in a facility that also has an official USDA inspected operation, an owner's animal may be slaughtered under USDA inspection if so desired by the owner. After the animal passes both ante-mortem and post-mortem inspections, it can be returned to the owner, unless condemned. The animal should be kept separate throughout the process in order to be returned to the owner.
- 5. Selling livestock to a customer does not disqualify a business from the custom exemption. A custom exempt operator may sell livestock to a person(s) prior to slaughter and then custom slaughter the animal for the new owner. The custom exempt operator would be required, upon request, to provide records, per <u>9 CFR 320.1(a)</u>, that fully disclose the transfer of ownership prior to slaughter or processing of the livestock.
- 6. The operator of a custom exempt facility may also slaughter and process their own livestock for their exclusive consumption, or members of their household, nonpaying guests or employees, under the personal use exemption.
- 7. Selling livestock to a customer and then allowing that owner to use onsite facilities for the slaughter of the livestock still constitutes personal use slaughter. However, once the seller assists in the slaughter or processing, then the facility becomes a custom exempt facility, subject to <u>9 CFR 303.1(a)(b)</u>.
- 8. A custom exempt operation may use a mobile slaughter and processing unit.
- 9. The equipment used for custom exempt slaughter and processing must be thoroughly cleaned and sanitized prior to their use for preparing any inspected products, per <u>9 CFR 416.12(a)</u>, to prevent direct contamination or adulteration of product(s).
- 10. The risk of infection from Trichinae is increased in swine that have access to rodents and wildlife, such as pasture-raised, free-range and feral swine. All forms of fresh pork, including fresh unsmoked sausage, are customarily well cooked in the home by the consumer, and therefore the treatment of such products for the destruction of trichinae is not needed. However, in order to produce a safe, wholesome and unadulterated product, pork products that might be eaten rare or without thorough cooking because of the appearance of the finished product, may require treatment for the destruction of trichinae.
- 11. FSIS recommends, but does not require, that custom exempt operators keep production records of cooking and cooling of meat food products to support that they produce safe, wholesome, unadulterated products as required by the FMIA.
- 12. Any canned product from custom exempt livestock must be prepared in accordance with <u>9</u> <u>CFR 318 Subpart G Canning and Canned Products</u>, including written processing schedules.
- 13. Although the items listed below are not specifically required by the HMSA, FSIS recommends the custom exempt operators:
 - a. provide water and feed for animals in pens,

- b. maintain facilities in good repair to prevent injury to animals,
- c. drive the livestock with a minimum of excitement and discomfort,
- d. separate disabled animals from ambulatory animals,
- e. not drag disabled animals while still conscious, and
- f. handle animals in accordance with applicable state and local laws.
- 14. If an owner of the livestock wishes to transport custom exempt product from one custom exempt facility to another for further processing, they may do so. (The product must be marked "Not for Sale" during transportation, per 9 CFR 303.1(a)(2)(iii).)
- 15. Commingling of fat trimmings and meat trimmings from custom exempt animals to facilitate rendering or sausage production is allowed with each owner's written consent. All of the resulting commingled product must be clearly marked "Not for Sale." See <u>FSIS Directive</u> 5930.1, <u>Custom Exempt Review Process</u>, page 9, for more information.
- 16. There may be more than one owner of the live animal. Sharing a live animal is acceptable provided proof of ownership of the live animal is available, upon request to the custom exempt operator, for Agency review.
- 17. The custom exempt operator must maintain records showing the identity of the individual owners' names prior to slaughter. In the case of more than one owner of the livestock, a list of the individual owners' names is required prior to slaughter, per 9 CFR 303.1(b)(3).
- 18. Carcasses and other products of custom slaughter are not eligible to be sold. Therefore, sale or purchase of the live animal using the services of a custom exempt operator would be based on live weight, price-per-head, or other quantity pertaining to the live animal. The custom exempt operator can only charge the owner a service fee for the livestock slaughtered or prepared on a custom basis, not for the meat food product itself which is derived from the custom slaughter or processing because the custom exempt operator does not own the live animal nor the resultant product.
- 19. The custom exempt operator can arrange the purchase of a live animal for a customer, conduct the subsequent slaughter and processing, and arrange the delivery of the "Not for Sale" product to the owner because the FMIA does not preclude the custom exempt operator from acting as an agent on behalf of the livestock owner. The custom operator would be required, per 9 CFR 303.1(b)(3), to provide the name and address of the owner prior to custom slaughter.

A retail store's sales could consist solely of orders placed by the consumer via fax, phone, or online, and shipped from the retail store.

C. RETAIL STORES

The FMIA and meat inspection regulations provide a retail store exemption for businesses that further prepare meat and meat food products for sale to consumers. Traditionally, a retail store in the 1970s, when the 9 CFR 303.1(d) regulations were implemented, consisted of a physical brick-and-mortar store. It typically included a butcher counter, where consumers could buy steaks, chops, roasts, ground meats, or meat food products that were cooked, cured, or smoked.

With the rise of catalog sales and use of the internet, today's retail venues may differ greatly from that traditional retail store. Consumers can now easily order meat food products, further prepared without FSIS inspection, under the retail store exemption, without leaving their homes.

The applicable regulatory requirements are found in 9 CFR 303.1(d)(1):

- (d)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments.
- (2) For purposes of paragraph (d)(1) of this section:
 - (i) Operations of types traditionally and usually conducted at retail stores and restaurants are the following:
 - (a) Cutting up, slicing, and trimming carcasses, halves, quarters, or wholesale cuts into retail cuts such as steaks, chops, and roasts, and freezing such cuts;
 - (b) Grinding and freezing products made from meat;
 - (c) Curing, cooking, smoking, rendering or refining of livestock fat, or other preparation of products, except slaughtering or the retort processing of canned products;
 - (d) Breaking bulk shipments of products;
 - (e) Wrapping or rewrapping products.

Retail Store Criteria:

- 1. The retail exempt operation must have sales to consumers at the location where the meat food products are prepared under the exemption, as defined in 303.1(d)(1).
 - a. Traditionally, this means a walk-in brick-and-mortar facility where a consumer can purchase meat from a retail display case.
 - b. However, a retail store's sales can consist solely of orders placed by the consumer via fax, phone, or online, and shipped from the retail store, without actually having customers walk into the store.
- 2. In order to maintain eligibility for the retail store exemption sales can only be to consumers. There are two types of consumers:
 - a. individual household consumers, and
 - b. "other-than-household" consumers, more commonly known as hotels, restaurants and similar institutions (HRI) as determined by the Administrator in specific cases, as defined by 303.1(d)(2)(vi).
- 3. Neither slaughtering of livestock, nor retort processing (canning) of meat food products, can occur under the retail store exemption. Those activities require either Federal or State inspection in states that operate their own Meat and Poultry Inspection (MPI) programs (referred to as non-designated States).

- 4. A retail store can prepare multi-ingredient meat food products for sale to other-than-household consumers, within the limitations defined in 303.1(d)(2)(i)(c). Limitations on sales to other-than-household-consumers:
 - a. If a retail exempt store prepared the meat food product by curing, cooking or smoking, rendering or refining the product, it cannot sell that product to other-than-household consumers, as defined in 303.1(d)(2)(iii)(f).
 - b. A retail store could slice or grind meat that was cured, cooked or smoked under Federal or State inspection and sell that product to HRI accounts.
 - c. Sales to HRI accounts cannot exceed 25% of total sales to consumers of retailprepared meat. At least 75%, in terms of dollar value, of total sales of product represents sales of product to household consumers. This is known as the 75/25 Rule.
 - d. Sales to HRI accounts cannot exceed the <u>calendar year dollar limitation</u> set by the Administrator.
- 5. For all sales, whether to individual household consumers or to HRI, no sale is made in excess of normal retail quantities, as defined in <u>9 CFR 303.1(d)(2)(ii)</u>.

Any quantity or product purchased by a consumer from a particular retail supplier shall be deemed to be a normal retail quantity if the quantity so purchased does not in the aggregate exceed one-half carcass. The following amounts of product will be accepted as representing one-half carcass of the species identified:

	One-half carcass pounds
Cattle	300
Calves	37.5
Sheep	27.5
Swine	100
Goats	25

- 6. Only federally inspected source materials can be used in the preparation of meat food products made for sales to consumers destined for interstate commerce. In states that operate their own MPI programs, State inspected source materials can be used in the preparation of meat food products that are limited to intrastate sales.
- 7. Records, such as bills of sale to consumers or cash register receipts, and raw ground beef production records (if applicable) are maintained as required by <u>9 CFR 320.1</u>. FSIS OIEA Investigators are to have access to examine such records to verify compliance. The misbranding provisions of the FMIA apply to meat food products that are prepared under exemption from inspection requirements. Labeling of retail exempt meat food products is enforced by FSIS investigators, and by State or local authorities. State and local authorities use the FDA Food Code as guidance for labeling. Absent the following label features, per <u>9 CFR 301.2</u>, *Misbranded*, a retail meat food product would be misbranded, if in a package or container, unless it bears a label showing:
 - a. the name and place of business of the manufacturer, packer, or distributor;

- b. an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count:
- c. any word, statement, or other information (such as Safe Handling Instructions for meat products that are not RTE) required by or under authority of the Act;
- d. the common or usual name of the food, if any there be;
- e. the common or usual name of each ingredient if the product is fabricated from two or more ingredients;
- f. a handling statement such as "Keep Refrigerated" or "Keep Frozen" if product requires special handling to maintain its wholesomeness;
- g. nutrition labeling as specified in 9 CFR 317, Subpart B Nutrition Labeling, unless an exemption in <u>9 CFR 317.400</u> applies.

Retail Store Notes:

- 1. FSIS recommends that operations that are exempt from inspection are appropriately permitted through the State, local (county, city), and tribal authorities. Check with those authorities for their applicable licensing requirements and applicable foodservice ordinances.
- 2. Typically, after permitting, the exempt operation will be subject to periodic inspections by the local authorities. Those inspections often compare the operations to the <u>Food and Drug</u> Administration's Food Code.
- 3. To ensure the product does not become unwholesome or adulterated during mail order deliveries to consumers by a retail exempt operation, or its contracted couriers, the retailer and courier must safeguard against adulteration due to temperature abuse during transportation, per FMIA 21 U.S.C. 610(d), until the consumer takes possession of such product. <u>USDA's Identifying Food Safety Risk Factors And Educational Strategies For Consumers Purchasing Seafood And Meat Products Online</u> can be a valuable resource to retailers for making food safety determinations regarding mail order sales. Retailers and couriers need to be aware of the FDA's <u>Sanitary Transportation of Human and Animal Food</u> requirements for shippers, loader and couriers.
- 4. The FMIA does not prohibit retail exempt store operators from using third-party businesses, such as a food hub, to:
 - a. advertise,
 - b. market,
 - c. store product in commerce at an independent warehouse or food hub, prior to delivery to the consumer,
 - d. deliver, and
 - e. collect the money for the sale of their exempt products to consumers, but the retailer must sell the exempt meat or meat food product to the consumer in order to be exempt. The retailer cannot sell the product to the third-party business for re-sale to the consumer.
- 5. The FMIA does not prohibit a person, firm or corporation from preparing exempt meat food products at a central retail store location, for sale to consumers at that central location, and for unlimited distribution and subsequent sale to consumers at their satellite retail outlets, owned

- or operated by them, such as their additional retail stores, kiosks, farmers market booths, or mobile food pantries.
- 6. FSIS recognizes that consumers may purchase raw meat or RTE meat products from a retail store via phone, fax, or online orders, and have that purchase delivered. Retailers that sell meat food products must maintain records, such as bills of sale, in accordance with <u>9 CFR</u> 320, that disclose that sales were made to consumers at such location.
- 7. The total sales of product (303.1(d)(2)(iii)), and the annual dollar limitations for sales to other-than-household consumers, apply to individual retail stores, rather than cumulative retail stores operating under a corporate structure.
- 8. The sales of pass-through (box-in, box-out, not opened) meat food products that were federally inspected do not apply to the total sales of product found in 9 CFR 303.1(d)(2)(iii)(b). Those total sales limitations apply only to products prepared under the retail exemption. There is no limit on the sales of federal or state inspected products that are not further prepared at the retail establishment.
- A retail store can donate meat food products that they prepared, or are selling, to non-profit organizations, but that product must have been from federally or <u>state inspected</u> source materials.
- 10. Meat food product prepared under the retail exemption will NOT bear the USDA marks of inspection on the label as it was prepared <u>without</u> inspection.
- 11. Labels applied at retail are not required to have FSIS sketch approval. A retailer may carry forward any special claims found on inspected source materials. A retailer cannot apply any new claim to the product prepared under the retail store exemption. It would be false and misleading (misbranding) to apply a claim which was not found on the source material. FSIS labeling guidance can be found in <u>A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products</u>.

D. RESTAURANTS

A restaurant is a business where meals, which may include meat food products, may be purchased. While a traditional restaurant experience may involve dining in, other restaurant business models include drive-thru windows, delivery, or carry-out options.

The applicable regulatory requirements are found in <u>9 CFR 303.1(d)(2)(iv)</u>.

Restaurant Criteria:

- 1. RTE meat food products are prepared for sale or service in meals or as entrees directly to individual consumers at such establishments.
- 2. Only federally or <u>state inspected</u> and passed product, or product prepared at a retail store exempted by 303.1(d)(2)(iii), is handled or used in the preparation of any product.

- 3. No sale of product is made in excess of a normal retail quantity as defined in 303.1(d)(2)(ii). See page 10.
- 4. The preparation of product is limited to traditional and usual operations as defined in 303.1(d)(2)(i). See page 8.
- 5. Records are maintained as required by <u>9 CFR 320.1</u>.

Restaurant Notes:

- 1. The restaurant serves the individual consumers directly at the physical location where the RTE meat is prepared for immediate consumption.
- 2. Sales made by the restaurant are not subject to the 75/25 rule, nor the <u>calendar year dollar limitation</u> for retail stores, as restaurants do not sell exempt product to other-than-household consumers (HRI: hotels, restaurants and similar institutions).
- 3. The restaurant is subject to the State and local (county, city), and tribal inspection laws. Check with those authorities for their applicable licensing requirements and applicable foodservice ordinances.
- 4. The restaurant is subject to the adulteration provisions of the FMIA per <u>9 CFR 303.1(f)</u>, therefore, the RTE meals must not be prepared, packed or held under insanitary conditions.

E. CATERERS

A caterer is a person who delivers or serves product in meals to individual consumers.

Caterer Criteria:

- 1. The definition of a restaurant includes a caterer, per <u>9 CFR 303.1(d)(2)(iv)(b)</u>. Product is prepared only for sale or service in meals or as entrees to individual consumers.
- 2. Only federally or <u>state inspected</u> and passed product, or such product prepared at a retail store exempted by 303.1(d)(1), is handled or used in the preparation of any product. Meals prepared from State-inspected source material are eligible solely for sale within such State.
- 3. No sale of product is made in excess of a normal retail quantity as defined in 303.1(d)(2)(ii) of this section.
- 4. The preparation of product is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.
- 5. Records are maintained as required by the <u>FMIA 21 U.S.C. 642</u> and <u>9 CFR 320.1</u>, which include records that fully and correctly disclose all transactions involved in their business.

Caterer Notes:

- 1. The caterer is a subset of the restaurant exemption. Caterers must meet the terms of the restaurant exemption, delineated above in 1-5, in order to be eligible for the exemption from Federal inspection.
- 2. The caterer, or their employees delivers or serves the meals, or entrées, to the individual consumers, per <u>9 CFR 303.1(d)(2)(iv)(b).</u>

- 3. In order to maintain eligibility for the catering exemption sales can only be to individual consumers. Products not sold to consumers disqualify the caterer from the exemption and the caterer must apply for a grant of inspection. Records which fully and correctly disclose the sale of the catered product to the consumer are required per 9 CFR 320.1(b)(1).
- 4. The caterer is subject to in-commerce surveillance reviews by FSIS OIEA investigators, including access and examination of facilities, inventory, and records, per FMIA 21 U.S.C. 642. The caterer is also subject to State and local licensing requirements and periodic inspection by local authorities to ensure proper sanitation and food handling.
- 5. The caterer is subject to the adulteration provisions of the FMIA per <u>9 CFR 303.1(f)</u>, therefore, the catered RTE meals must not be prepared, packed or held under insanitary conditions. The caterer, or their employees, should consider storage, holding, and reheating conditions in order to ensure delivery to consumers of a safe, unadulterated meal. Inadequate storage, holding, or reheating temperatures could lead to dangerous levels of pathogens in the foods.

F. RESTAURANT CENTRAL KITCHENS

The increase in large restaurant chains and fast food operations has contributed to a trend in the centralization of meat preparation systems. By centralizing preparation of products, a restaurant business can improve its efficiency. A restaurant central kitchen (RCK) exemption is provided, in 9 CFR 303.1(d)(2)(iv))(c), for a central kitchen that prepares RTE meat products for sale to consumers at their satellite restaurants.

Restaurant Central Kitchen Criteria:

- 1. The product is RTE upon departure from the RCK (i.e., no further preparation such as cooking is needed, except that it may be reheated prior to serving).
- 2. The transportation is direct between the RCK and satellite restaurant or vending machine location with no intervening transfer or storage. Only federally inspected source materials can be used in the preparation of meat food products destined for interstate sales. Meals prepared from State-inspected source material are eligible solely for sale within such State.
- 3. The product is to be served, without intervening sale, in meals or as entrées only to customers at satellite restaurants, or through vending machines, owned or operated by the same individual, firm, or corporation owning or operating the restaurant central kitchen.
- 4. The facilities are maintained in a sanitary manner.
- 5. Records are maintained as required by 9 CFR 320.1.

Restaurant Central Kitchen Notes:

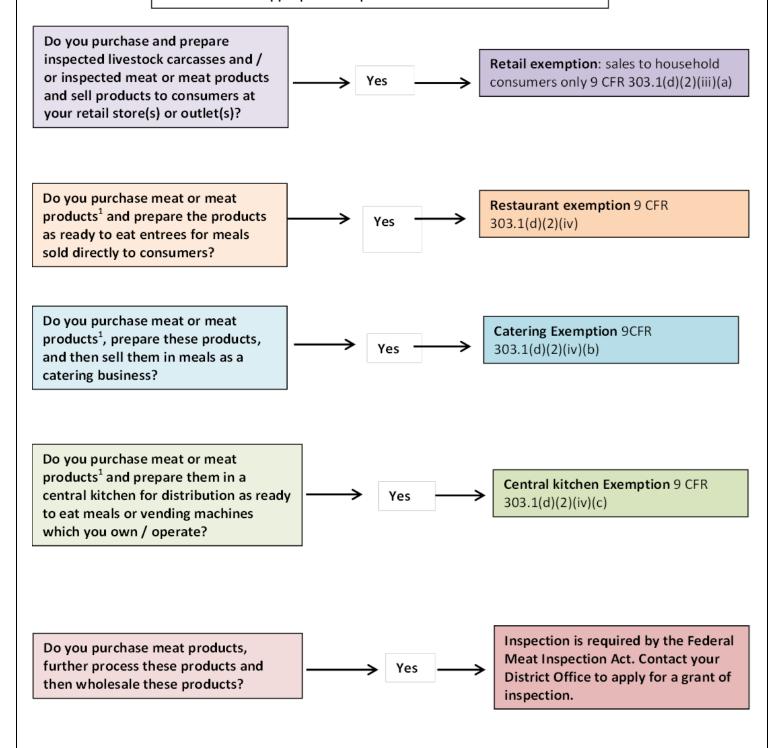
- 1. The RCK may or may not serve consumers at the RCK location.
- 2. The RCK is subject to the State and local (county, city) inspection laws. Check with those authorities for their applicable licensing requirements and applicable foodservice ordinances.
- 3. All RCKs are subject to periodic inspection by local governments and by FSIS to ensure proper sanitation and food handling.

- 4. To lessen the likelihood of product mishandling and potential adulteration, the RTE product must be sent directly to the satellite restaurant by satellite restaurant or RCK employees. Distribution to franchise restaurants is acceptable if the franchises are owned or operated by the same person, firm or corporation that owns or operates the RCK.
- 5. If refrigerated prior to delivery, good manufacturing practices should be used that ensure the RTE meals are kept at 40°F or below.
- 6. RCKs operated by a city, county, or State also qualify for the exemption, provided meals are served at facilities controlled by the city, county, or State.

How do I determine if I am eligible for one of these exemptions?

Custom slaughter exemption Personal Use Exemption 9 CFR 303.1(a)(1) 9 CFR 303.1(a)(2) Custom Processing exemption Inspection is required by the Federal Meat Inspection Act. Contact exemption from the Federal Meat Inspection Act, ask yourself the question in the bold type and then In order to determine whether your livestock slaughter or meat processing operation qualifies for an your District Office to apply for a grant of inspection 9 CFR 303.1(a)(2) Inspection is required by the Federal District Office to apply for a grant of Meat Inspection Act. Contact your **Custom Processing Exemption** ŝ follow the appropriate Yes or No response arrow. inspection. Are the products from the livestock you products to the owner for his / her personal slaughter returned to the owner of the meat food products delivered by the owner of the livestock and return those processed Do you custom process carcasses or cuts or livestock for his / her personal use? ŝ > ջ

In order to determine whether your retail, restaurant, central kitchen or catering operation qualifies for an exemption from the Federal Meat Inspection Act, ask yourself the question in the bold type and then follow the appropriate response arrow.



¹ Must start with inspected and passed product or raw product prepared at a retail exempt store

Considerations for Meat Sold in Local and Regional Markets

Growing consumer demand for local food is creating new challenges and opportunities for producers. Farmers and ranchers selling into local and regional food systems have unique needs from navigating seeds, breeds, and production systems to adopting on-farm risk management and food safety activities. USDA supports and invests in local and regional food systems from coast to coast, in every state, as part of the department's commitment to revitalizing rural America. USDA strengthens local and regional food systems by coordinating relevant activities across its 17 agencies and by investing in projects that recruit and train farmers and ranchers, expand economic opportunities for small businesses, and increase access to healthy foods. Consumers across the country can find locally produced food at their neighborhood grocery stores, restaurants, and farmers markets. Learn more about USDA's tools and programs to help farmers, ranchers, processors, and distributors produce food for local and regional markets at USDA Agricultural Marketing Service, Local and Regional Food Sector.

The information below provides guidance for meat production in a variety of local market business models.

Local Marketing and Direct-to-Consumer sales

Consumers and businesses are increasingly interested in direct, regional, and local markets that minimize the distance that food products travel from production to consumption. Local and regional sales can be either direct-to-consumer – for example, through farmers markets or Community Supported Agriculture – or sold through so-called "intermediated markets" such as food hubs, which then market to consumers.

Local and regional marketing can add value to a food product by maintaining farm identity in marketing, building relationships and loyalty between consumers and producers, targeting specialty or niche markets, and making production practices and ingredients more transparent. USDA does not officially define local or regional, so the exact meaning of the terms currently used in commerce may vary depending on the goals of the producer, buyer, or organization promoting local market connections.

Local and Regional Marketing and Direct-to-Consumer Sales Notes:

- When selling locally-produced meat direct to consumers, keep in mind that only livestock slaughtered and processed under Federal inspection can be sold across state lines (interstate). Meat from livestock slaughtered and processed under <u>State inspection</u> is limited to commerce within the state (intrastate).
- If slaughtered and processed under Federal or <u>State inspection</u>, local meat can be sold direct to household consumers through farmers markets and to other-than-household consumers, within limitations described above in Retail Store Criteria, page 8.
- If local meat products are slaughtered under Federal or <u>State inspection</u> and are then further prepared (i.e. operations of types traditionally and usually conducted at retail stores: see <u>9</u> <u>CFR 303.1(d)(2))</u>, by a local seller, the local seller must be inspected unless it is eligible for the retail store exemption (see page 8). Retail stores that are exempt from Federal inspection, however, are subject to State and local (city, county) inspection laws.

For all local and regional food markets, FSIS recommends:

- Farmers and businesses follow voluntary food safety practices to ensure a standard of care for their products and to reassure buyers regarding the steps taken to reduce risks of foodborne illness.
- Farmers and businesses reduce the risk of dangerous bacteria or toxins in farm products by following established food safety guidance, including the following:
 - o develop a food safety plan,
 - o train employees in proper food safety management, and
 - document all farm practices.

Emerging Local and Regional Food Business Models

What are some of the emerging business models?

Business models, including those described below, are emerging as a result of the growing demand for locally and regionally produced food.

Farmers Markets

A farmers market is an open retail market that features fruits, vegetables, meats, eggs, and other commodities sold directly from producer to consumers. Typically, each producer brings their own booth, tables, or stands, and consumers purchases products directly from the farmers. This facilitates personal connections and creates mutual benefits for local producers, consumers, and communities. USDA's Agricultural Marketing Service (AMS) defines a farmers market as markets that feature two or more farm vendors selling agricultural products directly to customers at a common, recurrent physical location.

Farmers Markets Notes:

- Livestock meat food products, like beef jerky, must have been prepared from federally or <u>state inspected</u> source material. If the meat food product sold at the farmers market is moved in interstate commerce, then the source material used to prepare the meat food product must be federally inspected.
- 2. FSIS OIEA Compliance Investigators may do reviews of booths selling meat food products, in accordance with <u>FSIS Directive 8010.1</u>.
- 3. Typically, the booths are appropriately permitted by the local (county, city) authorities and regulated by the local food establishment requirements.
- 4. Onsite preparation of meat food products at farmers markets may be regulated by State and local laws, or the farmers market's own food safety rules.
- 5. A farmers market booth can be an additional retail outlet of a retail store, where product is sold to individual household consumers in normal retail quantities.
- 6. Perishable meat should be properly refrigerated at the market and be kept in closed coolers with adequate amounts of ice to maintain cool temperatures. See FSIS Refrigeration and FoodSafety guidance for more information.

- 7. Raw meat should be handled appropriately so that the juices, which may contain harmful bacteria, do not come in contact with other foods or food contact surfaces.
- 8. RTE meat products should not be handled with bare hands, or by ill food handlers.
- 9. Packaged meat food products must not be misbranded. Be sure the label contains:
 - a. The common name of the meat food product.
 - b. A list of ingredients if there are more than two ingredients, in descending order of predominance.
 - c. Net quantity specifications (weight, volume).
 - d. Name and address of the business that prepared the meat food product.
 - e. No marks of USDA inspection, or <u>state inspection</u>, unless the meat food product was actually prepared under inspection and is still intact as prepared and packaged by the federally or state inspected establishment.
 - h. Safe-handling instructions if the product is raw.
 - i. A handling statement such as "Keep Refrigerated" or "Keep Frozen" if product requires special handling to maintain its wholesomeness.
 - f. nutrition labeling as specified in 9 CFR 317, Subpart B Nutrition Labeling, unless an exemption in <u>9 CFR 317.400</u> applies.
- 10. Check with your State and local (county, city) authorities about using a private kitchen in a person's living quarters for preparing meat food products sold at farmers markets.

Food Hubs

A food hub is a business or organization that actively manages the aggregation, distribution, and marketing of source-identified food products – primarily from local and regional producers – to strengthen their ability to satisfy wholesale, retail, and institutional demand. They provide a bridge from food producer to consumer by creating a business that actively works to distribute and market locally and regionally sourced food products. By providing small producers with access to larger volume markets, food hubs can support producers while also helping buyers meet the growing consumer demand for local food.

Food Hub Notes:

- Food hubs can advertise, broker, and deliver retail exempt meat food products for the exempt operator, but the exempt operator must maintain ownership of the product and make the sale to the consumer in order to be exempt from inspection. The records maintained by the retailer must fully and correctly disclose the sale of the meat food product from the retailer to the consumer.
- 2. The food hub may market:
 - federally inspected product in intact packages from the federally inspected establishment, which is eligible to move in interstate commerce,
 - State inspected product in intact packages from the state inspected establishment, which is eligible to move only in intrastate commerce,

- Retail exempt product prepared under the retail store exemption, which is owned by the retailer. The retail exempt operator must own and sell the retail exempt product to the consumer. Bills of sale, which fully and correctly disclose the sale of the exempt product by the retail exempt operator to the consumer, must be maintained.
 - Retail exempt product prepared from Federally inspected source materials product may move in interstate commerce.
 - Retail exempt product prepared from state inspected source material, in those <u>States that operate their own meat and poultry inspection (MPI) programs</u>, are restricted to intrastate commerce only.
- 3. The food hub must maintain records, per <u>9 CFR 320.1</u>, such as invoices, bills of lading, and receiving and shipping papers for any meat food product that is shipped, received, transported or otherwise handled. All such records are subject to examination by USDA Investigators.
- 4. The food hub must register with the USDA as a meat food handler (transporting in commerce) with FSIS Form 5020-1, Registration of Meat and Poultry Handlers.
- 5. Generally speaking, food hubs <u>do not</u> prepare meat food products. If a food hub prepares (see: <u>9 CFR 301.2</u> definition for *prepared*) meat food products, then it must do so under inspection, or under one of the exemptions described above.

Farm to School

Within local and regional markets, schools offer a compelling opportunity to connect young people to local food and agriculture. Farm to school initiatives include efforts to bring locally or regionally produced foods into school cafeterias; hands-on learning activities such as school gardening, farm visits, and culinary classes; and the integration of food-related education into the regular, standards-based classroom curriculum. Locally sourced food (which creates economic opportunities for local food producers) can span the school meal tray and include everything from fresh fruit and vegetable servings to the wheat in the pizza crust, beans in the chili, rice in the stir fry, turkey in the sandwiches, and cheese in the quesadillas. Farm to school includes all types of producers and food businesses, including farmers, ranchers, and fishermen, as well as food processors, manufacturers, and distributors.

Farm to School Notes:

FSIS requirements:

- 1. All meat products that are to be served in a school lunch program must be, at a minimum, slaughtered in a federally or state inspected facility.
- 2. Meat and meat food products may be further prepared under the exemptions described above only if sold to consumers. Consumers are defined in <u>9 CFR 303.1(d)(2)(vi)</u>. Schools are an other-than-household consumer as an institution similar to a hotel.
- 3. Animals that are slaughtered or processed under a custom exemption, or under the personal use exemption, are not allowed to be used in school lunch programs. That meat is to be used exclusively by the owner of the animal in their household.

Additionally, FSIS recommends that farmers and schools involved in farm to school or school garden programs follow accepted food safety practices and have a food safety plan in place to reduce the risk of foodborne illnesses. More guidance for schools interested in procuring local meat, poultry,

game, and eggs for child nutrition programs is available here: http://www.fns.usda.gov/procuring-local-meat-poultry-game-and-eggs-child-nutrition-programs.

Online Markets

Online markets are much like food hubs in that they bridge the gap from food producer to consumer, but instead of having a physical market, all transactions are performed through the Internet. This gives consumers the convenience of placing orders online with established producers who sell fresh, local goods. Often, an online market will feature products from many different producers.

In some cases, the online marketplace does not take ownership of the product, but simply provides services such as:

- advertising/marketing,
- hosting the platform on which the products are marketed to consumers,
- transporting or distributing the product,
- collecting the money for the sale of the products to consumers.

The FMIA does not prohibit a person, firm or corporation from performing these online marketing services for a retail exempt operator. The FSIS policy is, therefore, that an online market (or a food hub) is not precluded from acting as an agent of the retailer. The online market and the retail exempt operator would be expected to provide documentary proof of their agency relationship. Both the retail exempt operator and the online market would be required to keep records and to fully and correctly disclose all transactions involved in their business, per <u>9 CFR 320.1</u>, including bills of sale from the retail exempt operator to the consumer for the meat food product produced under exemption and sold to the consumer.

Online Market Notes:

- 1. Retail exempt meat food products offered on an online market must be owned by the retailer, not by the online market.
- 2. In order to be exempt, the retail store must sell the product to the consumer.
- 3. The online market must register with the USDA as a meat food handler (broker or transporter) with FSIS Form 5020-1.

Home Delivered Meals

Home delivered meals programs deliver prepared meals or meal kits for in-home preparation to consumers. Many new companies are following this idea and creating businesses that design and deliver fresh, healthy meals to consumer's doorsteps. These companies may market their products as a way to lose weight or conveniently follow a healthier lifestyle by including fresh, locally sourced products in their meals.

Home Delivered Meals Notes:

- 1. Since they sell either RTE or uncooked meals to consumers, they are a retail store. As such, see the retail store exemption criteria and notes above starting on page 8.
- 2. The Home Delivered Meals business is subject to the state and local (county, city) inspection laws. Check with those authorities for their applicable licensing requirements and applicable food establishment ordinances.

How does FSIS verify that facilities exempt from inspection meet applicable requirements?

States with "equal to" meat inspection programs, or FSIS's Office of Field Operations (OFO) District Office, or FSIS OIEA designated personnel typically review custom exempt operations.

At retail stores, warehouses, and other in-commerce establishments, OIEA Compliance Investigators conduct onsite reviews to verify compliance with the FMIA and FSIS's regulations. The investigators, or any duly authorized representative of the Secretary, also have access to your place of business at all reasonable times and have the opportunity to examine your facility, inventory, and records.

Although your business may not be subject to the daily inspection requirements by the FSIS, FSIS still has statutory authority, per FMIA 21 U.S.C. 672, to detain (to officially prevent the meat food product from leaving a place) your exempt product should it be found to be adulterated or misbranded.

At facilities that house both an official establishment and a retail exempt establishment, the OFO inspectors will verify that sanitary conditions are maintained for the federally inspected establishment. The State and local government, or the FSIS OIEA Compliance Investigators, will verify the exempt operations meets sanitation and recordkeeping requirements. If your facility houses both an official establishment and an exempt establishment, be aware you will have to maintain separation between the official (inspected) and unofficial (exempt) establishments per 9 CFR 305.2(a), and, as always, maintain sanitary conditions for both operations. If OFO inspectors have concerns about the exempt facility, they will not inspect that operation, but they will turn over their concerns to the OIEA Compliance Investigators.

What other government entity will have an active role in my exempt business

While FSIS maintains jurisdiction over amenable meat food products that are "in-commerce," the Department of Health and Human Service Food and Drug Administration (FDA) regulates all food service establishments and food processing establishments that are not under FSIS jurisdiction. FDA regulates food products not under FSIS inspection such as rabbit, buffalo, venison (if none of these are under FSIS voluntary inspection), fish (except of the order Siluriformes), seafood, and food ingredients introduced into or offered for sale in interstate commerce. The FDA's regulations are in Title 21 of the CFR.

The FDA also provides a uniform <u>Food Code</u> that many States and local authorities have adopted to safeguard public health and ensure that food is unadulterated and honestly presented when offered to consumers.

To carry out certain provisions of the Bioterrorism Act, FDA established regulations requiring that food facilities <u>register with FDA</u>. Be aware of any impact the FDA's rules under the <u>Food Safety and Modernization Act</u> has on your exempt business or related business.

Generally, the FDA does not inspect retail food service establishments. The retail food establishments are regulated by State and local (county, city) governments, although FDA retains jurisdiction over these retail operations. More than 3,000 State, local, and tribal agencies have primary responsibility to regulate the retail food and foodservice industries in the United States. They are responsible for the inspection and oversight of over 1 million food establishments – restaurants

and grocery stores, as well as vending machines, cafeterias, and other outlets in health-care facilities, schools, and correctional facilities. Most custom exempt operations are under State or local regulation as well.

You can use the <u>Directory of State and Local Officials</u> to obtain more information from State and local regulatory officials involved with food and food defense.

The slaughter of other animals for food is regulated by the Food and Drug Administration (FDA). However, FSIS provides voluntary inspection on a fee-for-service basis for certain species, including bison, buffalo, deer, rabbits, migratory water fowl, and game birds (see <u>9 CFR 352</u>, <u>354</u>, and <u>362</u>). Some States do consider these species to be inspected under State inspection.

What is meant by "in commerce" with regards to exempted meat food products?

For the purpose of this regulation, the Agency defines "in commerce" as product that is out of the producing establishment's direct control and is in distribution (e.g., in another Federal establishment, in a warehouse, distribution center, retail facility, restaurant, or other institution). Domestic product is considered in commerce if it has been shipped from a firm without Agency or firm controls or restrictions and is free to be moved to any consignee or to consumers.

The term "of commerce" (<u>9 CFR 302.1(a)(1)</u>, or "for commerce" (<u>9 CFR 320.1(a)(1)</u>) means an article of human food being offered for commercial gain.

Custom exempt meat food products may be transported "in commerce" from the location where the animal was slaughtered or processed to the owner of the animal from which the meat was derived. The custom exempt meat food products must not bear the mark of inspection, since they were not prepared under USDA inspection, and must be marked Not for Sale.

Meat food products prepared under the retail store or restaurant exemptions from federally inspected meat sources may move in interstate commerce. Therefore, products sold to consumers in other states (including products shipped to consumers in other states) must be derived from USDA inspected source materials. Retail-exempt meat food products prepared from state inspected product can be sold solely within such State.

Additional Guidance

- Sanitation Guidance for Beef Grinders
- Best Practices Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens
- <u>FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small</u> and Very Small Establishments
- Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of the Poultry Products Inspection Act
- Sanitation Performance Standards Compliance Guide
- USDA National Agricultural Library, Food Safety Information Center
- MOBILE SLAUGHTER UNIT COMPLIANCE GUIDE
- USDA's Farm to School Program
- Local Meat in Schools Fact Sheet
- <u>USDA FNS Procuring Local Meat, Poultry, Game, and Eggs for Child</u> Nutrition Programs
- FDA Food Safety Modernization Act
- Sanitary Transportation of Human and Animal Food
- Requirements for the Disposition of Cattle that Become Non-Ambulatory
 Disabled Following Ante-Mortem Inspection
- <u>FSIS Compliance Guideline for the Prevention and Control of Trichinella and</u>
 Other Parasitic Hazards in Pork and Products Containing Pork
- AFDO Retail Meat and Poultry Processing Guidelines
- Using Dentition to Age Cattle

Attachment 1: A Summary Table of Exemptions and Limitations

Criteria	Personal Use Exemptio n	Custom Slaughter Exemption	Custom Processing Exemption	Retail Store Exemption	Restaurant Exemption	Restaurant Central Kitchen Exemption	Catering Exemption
Do I need to own the animal?	Yes	Yes, client must own the livestock	Yes, client must own the livestock	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Required to start with Inspected and Passed product?	No	No	No	Yes	Yes, or certain products prepared at a retail exempt store	Yes, or certain products prepared at a retail exempt store	Yes, or certain products prepared at a retail exempt store
Donate to nonprofit organization?	No	No	No	Yes	Yes	Yes	Yes
Retort Processing (canning) allowed?	Yes	Not Applicable	Yes	No	No	No	No
				Yes - Individual 			
Sales allowed in normal retail quantities?	Cannot be sold or donated	Cannot be sold or donated	Cannot be sold or donated	Yes, sales to HRI cannot exceed 25% of total sales. Sales to HRI cannot exceed yearly dollar limitations	Yes, cannot be made in excess of normal retail quantity	Yes, cannot be made in excess of normal retail quantity	Yes, cannot be made in excess of normal retail quantities
							Yes

Attachment 2: Definitions

1 THE FOLLOWING REGULATORY AND COMMON STANDARD DICTIONARY DEFINITIONS WILL BE USEFUL IN UNDERSTANDING THE EXEMPTIONS.

Regulatory definitions (found in <u>9 CFR 300-599</u>):

Exotic animal. Any reindeer, elk, deer, antelope, water buffalo, yak or bison

Firm. Any partnership, association, or other unincorporated business organization.

Further processing. Smoking, cooking, canning, curing, refining, or rendering in an official establishment of product previously prepared in official establishments.

"Inspected and passed" or "U.S. Inspected and Passed" or "U.S. Inspected and Passed by Department of Agriculture" (or any authorized abbreviation thereof). This term means that the product so identified has been inspected and passed under the regulations in this subchapter, and at the time it was inspected, passed, and identified, it was found to be not adulterated.

Label. A display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

Livestock. Cattle, sheep, swine, or goat.

Meat. (1) The part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing. As applied to products of equines, this term has a comparable meaning.

- (i) Meat does not include the muscle found in the lips, snout, or ears.
- (ii) Meat may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).

Misbranded. This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

- (1) If its labeling is false or misleading in any particular;
- (2) If it is offered for sale under the name of another food;
- (3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated;
- (4) If its container is so made, formed, or filled as to be misleading;
- (5) If in a package or other container unless it bears a label showing:
 - (i) The name and place of business of the manufacturer, packer, or distributor; and
 - (ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in part 317 of this subchapter with respect to the quantity of contents;

- (6) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
- (7) If it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the regulations in part 319 of this subchapter unless:
 - (i) It conforms to such definition and standard, and
 - (ii) Its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;
- (8) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by the regulations in part 319 of this subchapter, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;
- (9) If it is not subject to the provisions of paragraph (vv)(7)(ii) of this section unless its label bears:
 - (i) The common or usual name of the food, if any there be, and
 - (ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except as otherwise provided in part 317 of this subchapter;
- (10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is required by the regulations in part 317 of this subchapter.
- (11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided by the regulations in part 317 of this subchapter; or
- (12) If it fails to bear, directly thereon or on its containers, when required by the regulations in part 316 or 317 of this subchapter, the inspection legend and, unrestricted by any of the foregoing, such other information as the Administrator may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

Official establishment. Any slaughtering, cutting, boning, meat canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations in this subchapter.

Official inspection legend. Any symbol prescribed by the regulations in this subchapter showing that an article was inspected and passed in accordance with the Act.

Official mark. The official inspection legend or any other symbol prescribed by the regulations in this subchapter to identify the status of any article or animal under the Act.

Person. Any individual, firm, or corporation.

Prepared. Slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(I) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

Restaurant. A food establishment where product is prepared for sale or service as RTE meals to individual consumers at such establishments.

Retort. A pressure vessel designed for thermal processing of product packed in hermetically sealed containers.

Voluntary inspection service. An inspection and certification service for wholesomeness relating to the slaughter and processing of exotic animals and the processing of exotic animal products.

Regulatory definitions (found in FDA Food Code 2017)

CFR. Code of Federal Regulations

Comminuted. Reduced in size by methods including chopping, flaking, grinding, or mincing.

Consumer. A person who is a member of the public, takes possession of FOOD, is not functioning in the capacity of an operator of a FOOD ESTABLISHMENT or FOOD PROCESSING PLANT, and does not offer the FOOD for resale.

Employee. The PERMIT HOLDER, PERSON IN CHARGE, FOOD EMPLOYEE, PERSON having supervisory or management duties, PERSON on the payroll, family member, volunteer, PERSON performing work under contractual agreement, or other PERSON working in a FOOD ESTABLISHMENT.

FDA. The U.S. Food and Drug Administration.

Food employee. An individual working with unPACKAGED FOOD, FOOD EQUIPMENT or UTENSILS, or FOOD-CONTACT SURFACES.

Food Establishment.

- (1) "Food establishment" means an operation that:
- (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides FOOD for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides FOOD directly to a CONSUMER or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or FOOD bank; and
- (b) relinquishes possession of FOOD to a CONSUMER directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.
- (2) "Food establishment" includes: (a) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the REGULATORY AUTHORITY; and

- (b) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the PREMISES; and regardless of whether there is a charge for the FOOD.
- (3) "Food establishment" does not include: (a) An establishment that offers only prePACKAGED FOODS that are not TIME/TEMPERATURE CONTROL FOR SAFETY FOODS;
- (b) A produce stand that only offers whole, uncut fresh fruits and vegetables;
- (c) A FOOD PROCESSING PLANT; including those that are located on the PREMISES of a FOOD ESTABLISHMENT
- (d) A kitchen in a private home if only FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by LAW and if the CONSUMER is informed by a clearly visible placard at the sales or service location that the FOOD is prepared in a kitchen that is not subject to regulation and inspection by the REGULATORY AUTHORITY;
- (e) An area where FOOD that is prepared as specified in Subparagraph (3)(d) of this definition is sold or offered for human consumption;
- (f) A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers FOOD to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the CONSUMER is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the FOOD is prepared in a kitchen that is not regulated and inspected by the REGULATORY AUTHORITY; or
- (g) A private home that receives catered or home-delivered FOOD.

Game Animal.

- (1) "Game animal" means an animal, the products of which are FOOD, that is not classified as livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR 301.2 Definitions, or as Poultry.
- (2) "Game animal" includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes.
- (3) "Game animal" does not include RATITES.

HACCP plan. Means a written document that delineates the formal procedures for following the HAZARD Analysis and CRITICAL CONTROL POINT principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

Law. Means applicable local, state, and federal statutes, regulations, and ordinances.

Permit. Means the document issued by the REGULATORY AUTHORITY that authorizes a PERSON to operate a FOOD ESTABLISHMENT.

Premises. Means:

- (1) The PHYSICAL FACILITY, its contents, and the contiguous land or property under the control of the PERMIT HOLDER; or
- (2) The PHYSICAL FACILITY, its contents, and the land or property not described in Subparagraph (1) of this definition if its facilities and contents are under the control of the PERMIT HOLDER and may impact FOOD ESTABLISHMENT personnel, facilities, or operations, and a FOOD ESTABLISHMENT is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

Regulatory authority. Means the local, state, or federal enforcement body or authorized representative having jurisdiction over the FOOD ESTABLISHMENT.

Vending machine. Means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of FOOD in bulk or in packages without the necessity of replenishing the device between each vending operation.

Terms with no regulatory definition

(If neither 9 Code of Federal Regulations (CFR), nor 21 CFR, nor the Statute defines a term, then the usage found in any **Standard American English dictionary** applies.)

Broker: a person who helps other people to reach agreements, to make deals, or to buy and sell property (such as stocks or houses)

1.1.1.1 Community Supported Agriculture (CSA): a system in which a farm operation is supported by shareholders within the community who share both the benefits and risks of food production. Courier. a person who transports a meat food product to the consumer

Mail order: a meat food product that is sent by mail to the consumer who bought it

Operate: control the functioning of (a machine, process, or system).



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