

MEMORANDUM

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Re: FSIS Issues Guidance on Retailer and Restaurant Exemptions from Inspection Under the Federal Meat Inspection Act

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) recently released a guidance document to help companies determine whether their operations are exempt from the inspection requirements of the Federal Meat Inspection Act (FMIA). ^{1/} This guidance marks FSIS's first significant attempt to articulate policy addressing the applicability of its retailer and restaurant exemptions to newer food distribution models, such as online retailers and home delivered meal services. In particular, the guidance confirms that online-only grocery stores and home delivery meal kit services are eligible for the retailer exemption from FSIS inspection.

This memorandum focuses on new aspects of FSIS's guidance that apply to operations such as online grocery stores, online markets, meal kit delivery services, and restaurants, although the guidance addresses other exemptions including custom slaughter operations. ^{2/} Any company operating under an exemption to FSIS inspection should review the entire guidance carefully, as there are a number of helpful references, including decision-making and summary charts and a list of relevant definitions.

Notably, the guidance is focused on the inspection exemptions for meat and meat products under the FMIA. FSIS has an existing compliance guidance addressing the poultry and poultry product inspection exemptions, which was last updated in 2006 and does not address newer retail

^{1/} FSIS Guideline for Determining Whether a Livestock Slaughter or Processing Firm is Exempt from the Inspection Requirements of the Federal Meat Inspection Act, *available at* <https://www.fsis.usda.gov/wps/wcm/connect/16a88254-adc5-48fb-b24c-3ea0b133c939/Compliance-Guideline-Livestock-Exemptions.pdf?MOD=AJPERES>.

^{2/} This memorandum does not provide an exhaustive summary of the regulatory requirements of the various exemptions.

models. ^{3/} The relevant retail and restaurant exemptions in FSIS's regulations for both meat and poultry, however, are generally the same, and it is unclear whether FSIS intends to similarly update its guidance for poultry exemptions. ^{4/}

General Regulatory Framework for Retail Store and Restaurant Exemptions

The FMIA exempts from FSIS inspection requirements retail stores and restaurants that further prepare meat and meat food products for sale to consumers. Specifically, FSIS's regulation states:

"The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to operations of the 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." ^{5/}

Operations Performed at Retail Stores and Restaurants

To qualify for either the retail store or the restaurant exemption, the operation must only perform the types of operations "traditionally and usually conducted" at retail stores and restaurants, which FSIS elaborates on its regulations,^{6/} and must satisfy other requirements intended to differentiate between retailer and restaurants and meat processors.

New FSIS Guidance on Retail Store Exemption

The compliance guidance addresses the criteria for each of the various exemptions from FSIS inspection. Companies engaged in online grocery sales, meal kit delivery, and similar businesses may be especially interested in the following clarifications of FSIS policy.

Sale at the Location Where Meat is Prepared

FSIS created its retail store exemption decades ago, when retail stores were generally brick-and-mortar stores that consumers visited in person, such as a butcher counter, to purchase meats in that physical location. FSIS recognizes in the guidance that today's retail venues vary greatly in format and that consumers can purchase meat without entering an actual store, such as through online sales. FSIS clarifies in the guidance that a retail store's sales can consist solely of orders placed by a consumer remotely (e.g., online or phone orders) and shipped from the retail store without the consumer actually ever having to visit the physical location and still be considered a sale to a consumer at the location where the meat products are prepared for purposes of the retail store exemption. This position clarifies that online-only grocery retailers may operate under the retailer exemption.

^{3/} Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of the Poultry Products Inspection Act, *available at* https://www.fsis.usda.gov/wps/wcm/connect/0c410cbe-9f0c-4981-86a3-a0e3e3229959/Poultry_Slaughter_Exemption_0406.pdf?MOD=AJPERES.

^{4/} See 9 C.F.R. § 381.10(d) (poultry) and 9 C.F.R. § 303.1(d) (meat).

^{5/} 9 C.F.R. § 303.1(d).

^{6/} 9 C.F.R. § 303.1(d)(2).

FSIS also confirms that exempt meat food products may be produced at a central retail store location for sales to consumers at that central location, as well as for unlimited distribution and subsequent sale to consumers at satellite retail outlets owned by the same company.

Sales Only to Consumers and Limitations on Quantity Sold

To qualify for the retail store exemption, FSIS regulations specify that the store's sales to "other-than-household" consumers, i.e., hotels, restaurants, and similar institutions (HRI), may not exceed 25% of the store's total sales, and at least 75% of the total sales must be to individual household consumers (known as the 75/25 rule). In addition, there is an annual dollar amount limitation on the amount of products that may be sold to other-than-household consumers (updated annually to adjust for inflation). FSIS clarifies several points about how these figures are to be calculated:

- Sales of pass-through (box-in, box-out, unopened) meat products that were federally inspected do not apply toward the total sales limitations, as these limitations only apply to products prepared under the retail exemption.
- The 75/25 rule should be calculated on a store-by-store basis, not on a company-wide basis. This could in theory result in some stores being eligible for the exemption while others are not, depending on the customer profile of each individual store.
- The guidance also indicates that "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."

Online Markets

FSIS affirms in its guidance that the FMIA does not prohibit a person, firm or corporation from performing online marketing services (e.g., advertising/marketing, hosting the platform on which the products are marketed to consumers, transporting or distributing the product, or collecting the money for the sale of the products to consumers) for a company operating under the retail store inspection exemption. FSIS's policy is that the online market may serve as an agent for the exempt retail store operator and would be expected to provide documentary proof of the agency relationship. FSIS expects the online market to register with FSIS as a meat food handler, and the exempt retail store is required to maintain ownership of the products and sell the product to the consumer (even if the third party collects the payment).

Home Delivered Meals and Meal Kits

The guidance discusses the applicability of the retail store exemption to home delivered meal services, which deliver prepared meals or meal kits for in-home preparation to consumers. FSIS states that companies that sell either ready-to-eat (RTE) or uncooked meals to consumers are a retail store, and must meet the retail store exemption criteria in order to operate without inspection.

Food Hubs

According to FSIS, 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, in order to strengthen their ability to satisfy wholesale, retail, and institutional demand. Therefore, FSIS views the food hub as acting as a middleman to connect local/regional producers to

consumers and allowing these producers to access larger volume markets, similar to the role of many online markets. FSIS states that food hubs may advertise, broker, and deliver retail exempt meat food products for an 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. FSIS expects the food hub to register with FSIS as a meat food handler. If the food hub prepares meat food products, it must do so under inspection, or under one of the inspection exemptions.

Considerations for Meat Sold in Local and Regional Markets

FSIS's guidance also speaks to the growing practice of sales of "local" foods, such as through direct-to-consumer sales at farmer markets or Community Supported Agriculture, or through intermediate markets, such as food hubs, which then market foods to consumers directly. A farmers market booth can be considered an additional retail outlet of a retail store, where a product is sold to individual household consumers in normal retail quantities. FSIS explains that if meat is slaughtered and processed under federal or state inspection, then local meat may be sold to household consumers through farmers markets and to other-than-household consumers, subject to the limitations for retail stores.

FSIS reinforces that only federally-inspected meat may be sold in interstate commerce, and that state-inspected meat may only be sold intrastate. If local meat products are slaughtered under Federal or State inspection and then subjected to further processing (of the type typically performed at retail stores) by a local seller, the local seller must either be subject to inspection or meet the retail store exemption criteria. FSIS also recommends that farmers and businesses operating through local markets follow voluntary food safety practices to reduce the risk of foodborne illness, including developing a food safety plan, training employees in proper food safety management, and documenting all farm practices.

Restaurant Exemption

FSIS also exempts from inspection requirements establishments that it considers restaurants. ^{7/} In the guidance, FSIS expands on two particular aspects of the restaurant exemptions: caterers, and restaurant central kitchens. While FSIS's guidance largely discusses the codified regulatory requirements for the caterer and restaurant central kitchens exemptions, FSIS does provide a few clarifications on these exemptions:

- **Caterer Exemption.** FSIS emphasizes in the guidance that selling products to consumers other than individual household consumers (i.e., HRI) would disqualify the caterer from the caterer exemption.
- **Restaurant Central Kitchen Exemption.**
 - FSIS states that foods from restaurant central kitchens that are refrigerated prior to delivery should be held in accordance with good manufacturing practices (GMPs) and kept at 40°F or below.
 - FSIS also confirms in the guidance that distribution to franchise locations is permissible under the restaurant exemption provided that the franchises are owned or operated by the same person, firm, or corporation that operates the restaurant central kitchen.

^{7/} 9 C.F.R. § 303.1(d)(2)(iv).

New FSIS Guidance on When Product is “In Commerce”

FSIS’s exemption regulations frequently focus on product that is “in commerce,” although that term is not formally defined in regulation. In the guidance, FSIS defines “in commerce” product 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). Further, 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 consumers. FSIS clarifies that the similar terms “of commerce” and “for commerce” mean “an article of human food being offered for commercial gain.” FSIS states in the guidance that these definitions are intended to apply to the analysis of retail exempt operations. FSIS is silent as to whether it intends to also apply these definitions to the numerous other instances in which FSIS regulations refer to products being “in commerce.”

Adulteration and Misbranding

FSIS reminds that the retail exemption is an exemption from FSIS inspection, not an exemption from the FMIA entirely. Establishments operating under the retail exemption are still subject to the general requirements under the FMIA that foods not be adulterated or misbranded, and FSIS expects retail-exempt operators to take steps to ensure their products remain safe. FSIS is particularly attentive to potential temperature abuse issues during transport. For example, FSIS recommends consulting USDA’s report on Identifying Food Safety Risk Factors and Educational Strategies for Consumers Purchasing Seafood and Meat Products Online to make safety determinations regarding mail order sales. 8/

The guidance also reaffirms that exempt establishments remain subject to the recordkeeping requirements of the FMIA. In particular, FSIS’s Office of Investigation, Enforcement and Audit (OIEA) may request access to records to verify whether a firm meets the relevant exemption requirements.

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FSIS’s guidance is noteworthy for addressing for the first time in a detailed written policy how certain newer types of food distribution operations may fit within the exemptions from the inspection requirements in the FMIA. FSIS’s guidance confirms that many newer food distribution models, such as online retailers, home meal delivery services, food hubs, and farmers markets can fit within the retail store exemption provided certain criteria are met. In addition to the exemptions discussed above, the guidance addresses other specialized exemptions such as the personal use and custom slaughter exemptions. Further, FSIS also offers guidance to companies who provide “farm to school” meat products. Any company operating under one of the FMIA inspection exemptions should review FSIS’s new guidance as it provides new insights into how the agency views newer methods of food distribution.

Please do not hesitate to contact us if you have any questions on this or any other matter.

8/ This report is available at <https://portal.nifa.usda.gov/web/crisprojectpages/0226297-identifying-food-safety-risk-factors-and-educational-strategies-for-consumers-purchasing-seafood-and-meat-products-online.html>.