

Applying for USDA FSIS Inspection

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Purpose

The United States Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) developed this guidance to provide businesses interested in applying for FSIS inspection with information regarding the application process and statutory requirements. FSIS encourages those interested in applying for a grant of inspection to reach out to the Agency as described below in the [Applying for a Grant of Inspection](#) section. A business with a conditional or approved FSIS grant of inspection for meat, poultry, or egg products is referred to as an official establishment.

Determining need for FSIS inspection

Amenable Products: Products Required to be FSIS Inspected

Federal laws, which FSIS calls Acts, provide FSIS with legal authority over certain kinds of products intended for human consumption. Products required to have routine FSIS inspection services unless otherwise exempt (as explained in the next section below) include:

- **Meat and meat products** derived from carcasses and parts of cattle, swine, sheep, goats, or fish of the order Siluriformes (e.g., catfish and catfish-like species like basa and swai)¹, under the Federal Meat Inspection Act ([FMIA](#));
- **Poultry and poultry products** derived from domesticated chickens, turkeys, ducks, geese, guineas, ratites, or squabs under the Poultry Products Inspection Act ([PPIA](#)); and
- **Egg products** that are dried, frozen, or liquid are amenable to FSIS inspection under the Egg Products Inspection Act ([EPIA](#)). Shell eggs and cooked eggs are not FSIS-inspected products unless the establishment is cooking egg products in place of pasteurization.

Reinspection is required for **imported products** when first presented for entry into the United States for sale or distribution, and these facilities are official import inspection establishments.

If the products are not amenable (not under FSIS jurisdiction), they are likely under the jurisdiction of the [Food and Drug Administration](#) (FDA) and subject to the FDA's requirements and any applicable state or local laws. Shell eggs and cooked eggs are two examples of FDA products.

FDA regulates the production of pet food. Products produced and packaged for pet food, or as pet food, are considered by FSIS to be inedible. FSIS requires denaturing or

¹ Siluriformes is an order of bony fish that includes all catfish. The name catfish refers to the long barbels, or feelers, which are present about the mouth of the fish and resemble cat whiskers. All catfish have at least one pair of barbels on the upper jaw, with many possessing spines in front of the dorsal and pectoral fins. Catfish comprise nearly 2,900 species placed in about 35 families. Most species inhabit fresh water, but a few species are marine (salt-water).

other means to distinguish inedible from human food. FSIS does not inspect or certify pet food or ingredients handled by a business that are intended for and identified as pet food (e.g., a business cuts raw beef rounds that will be shipped elsewhere to be dried into pet treats). The cutting of meat for pet food (inedible) is not a FSIS inspected activity. However, the Acts require such uninspected inedible articles to be clearly distinguished from human food by denaturing or other means prior to leaving a FSIS establishment premises.

Exemptions: Products Exempt from Routine USDA FSIS Inspection

Under the FMIA, PPIA, and EPIA, FSIS conducts routine inspection in all establishments where the species of livestock or poultry specified in the laws are slaughtered or processed, or where egg products are processed for sale as articles of commerce, unless an exemption from inspection applies. FSIS also conducts inspection at all Siluriformes fish processing establishments. Exemptions from FSIS inspection exist under the FMIA, PPIA, and EPIA. Amenable exempted products are under the jurisdiction of FSIS and are subject to the adulteration and misbranding provisions of the FMIA, PPIA, and EPIA.

- The [FSIS Guideline for Determining Whether a Livestock Slaughter or Processing Firm is Exempt from the Inspection Requirements of the Federal Meat Inspection Act](#) contains information about exemptions from the inspection requirements for livestock slaughter and processing.
- The [Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of the Poultry Products Inspection Act](#) contains information about exemptions from the inspection requirements for poultry slaughter and processing.
- The EPIA provides for two limited exemptions from inspection requirements as found in [9 CFR 590.100](#).
 1. A poultry producer processing and selling eggs of their own flock's production. Sales are to be directly to household consumers, exclusively for use by the consumer and members of the household and its nonpaying guests and employees.
 2. Use of eggs containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs for processing in non-official plants such as bakeries, restaurants, and other food processors. The processing is of certain categories of food products which contain eggs or egg products as an ingredient, as well as the sale and possession of such products. These products are under FDA jurisdiction.

Other resources are available for businesses trying to determine if they are required to be under FSIS inspection. These include trade organizations, state departments of agriculture, academic institutions, local health departments, state health departments, and local community development offices. Since these resources vary by jurisdiction,

FSIS recommends that businesses reach out to the appropriate jurisdictional authority for more information.

The Association of Food and Drug Officials maintains a [Directory of State and Local Officials](#) that can be useful for finding contact information at the state and local levels. Some of these resources will be needed for licensure or other requirements if the business is not required to be under daily FSIS inspection.

Some business models will instead operate under an exemption from routine inspection or under a different jurisdiction (e.g., State inspection available in certain states, limiting product distribution to within that state¹), depending on the exact situation. FSIS still has legal authority over amenable products even when the business is meeting all exemption requirements or being produced under equivalent State inspection. As an example, the FSIS Office of Investigation, Enforcement and Audit Compliance Investigation Division will periodically verify compliance with the applicable requirements of an exempt operation, such as a retail butcher shop or a custom exempt slaughter or processing business at a location separate from an official establishment. Meat and poultry handlers that do not prepare, process, or package meat or poultry are not required to obtain a Federal grant of inspection but are required to register with FSIS as a Meat and Poultry Handler using [FSIS Form 5020-1](#), *Registration of Meat and Poultry Handlers*.

A business that does not prepare or process amenable products for human consumption is not eligible for a grant of inspection; however, there are some voluntary reimbursable inspection services available through FSIS. These voluntary reimbursable services include:

- Identification services (not available at the same location as an official establishment) to maintain federally inspected identity, applying the mark of inspection when breaking bulk and repackaging;
- Export certification services;
- Exotic animal slaughter and processing services (reindeer, elk, deer, antelope, water buffalo, bison, buffalo, or yak);
- Rabbit slaughter and processing services;
- Food inspection services for the processing of certain food articles that contain meat or poultry but do not require mandatory Federal inspection under the FMIA or PPIA;
- Migratory water fowl or game bird slaughter and processing services; and

¹ More information about State inspection can be found on the [State Inspection Programs](#) webpage.

- Specific verification activities for egg products inspection.

Businesses interested in voluntary reimbursable services are to submit [FSIS Form 5200-6](#), *Application/Approval for Voluntary Reimbursable Inspection Service*, to the appropriate FSIS Office of Field Operations (OFO) [District Office](#).

Requirements for Applying for FSIS Inspection

There are several resources available to help potential operators of small and very small establishments, even before they apply for a federal grant of inspection. Before a new establishment will be approved for a conditional grant of inspection (GOI)², the facility, written food safety programs, and labels must meet certain requirements. New establishments are responsible for compliance with any other applicable Federal, state, and local codes and licensing requirements.

Mark of Inspection

Businesses seeking FSIS inspection need to obtain a federal grant of inspection. The establishment will operate under mandatory FSIS inspection and must meet regulatory requirements. The products that are inspected and passed by FSIS will bear the marks of inspection (see Figures 1 for examples of marks of inspection for FSIS inspected products).

Figure 1. Examples of USDA mark of inspections

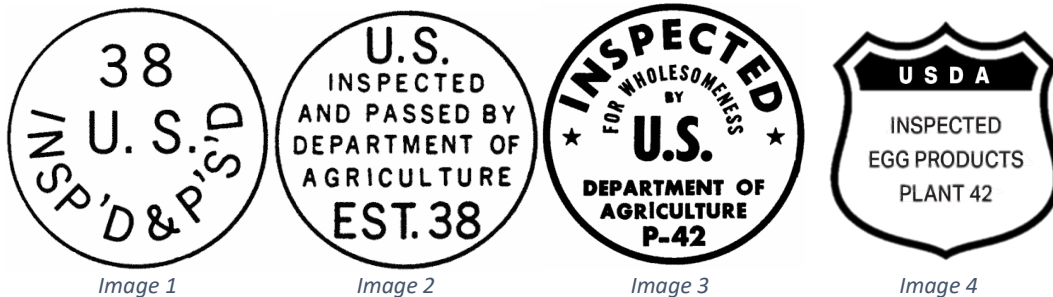


Image 1: Example of the mark of inspection for meat carcasses. 9 CFR 312.2(a).

Image 2: Example of the mark of inspection for meat products. 9 CFR 312.2(b)(1).

Image 3: Example of the mark of inspection for poultry products. 9 CFR 381.96.

Image 4: Example of the mark of inspection for egg products. 9 CFR 590.413.

²A conditional grant of inspection (GOI) is issued when the District Manager (DM) decides that the establishment meets the requirements for inspection. During the 90 calendar days following the issuance of the conditional GOI, the DM is to decide whether the establishment meets the terms of the conditional GOI by drawing on information gathered and recorded in the Public Health Information System by inspection personnel. No sooner than 90 calendar days after issuing the conditional GOI, if the DM determines that the establishment has validated its HACCP system as required by [9 CFR 417.4](#) and has met all other applicable requirements, the DM is to sign and issue a final GOI.

Facility Requirements

FSIS regulations do not prescribe the type of material or equipment used in a federally inspected establishment but do require that the building and processing area be constructed in a manner to allow for FSIS inspection and to maintain sanitary conditions so meat or poultry products are not adulterated.

The requirements for establishments under FSIS inspection are included in [9 CFR 416.1-416.5](#). In addition, the 1997 Federal Register publication, [62 FR 45045-Sanitation Requirements for Official Meat and Poultry Establishments](#), and the [Sanitation Performance Standards Compliance Guide](#) from March 2016 provide recommendations on basic structure for new establishments.

Import establishments that inspect product under FSIS jurisdiction that is imported from other countries must meet specific requirements, such as the requirements in [9 CFR part 416](#), as well as those in [9 CFR 327.6](#) for meat, [9 CFR 381.199](#) for poultry, [9 CFR 557.4](#) for fish, and [9 CFR 590.925](#) for egg products. Official import inspection establishments must also meet certain requirements to receive specific products. For example, these establishments need to have an incubator if they will be receiving thermally processed-commercially sterile product, sufficient refrigerated space to hold entire shipments of refrigerated or frozen products, and a thaw tank and white trays if the establishment wants to be eligible to receive product from countries determined to have Foot-And-Mouth disease (FMD) or other USDA Animal and Plant Health Inspection Service (APHIS) designated program diseases. Official import establishments that are interested in becoming eligible to receive product from countries determined to have FMD or other APHIS designated program diseases must be approved by APHIS after receiving an FSIS grant of inspection for import inspection.

FSIS Office, Secure Storage, and Locker Room as Needed

The basic FSIS office requirements are described in [9 CFR 381.36\(a\)](#) for poultry and [9 CFR 307.1](#) for meat, [9 CFR 533.3](#) for Siluriformes fish and fish products, and [9 CFR 590.136](#) for egg products. There may be different needs and flexibility for requirements depending on location-specific factors. The local FSIS Frontline supervisor working with the business to approve the application for a grant of inspection will discuss specific needs at that location before the conditional grant of inspection is approved.

Hazard Analysis and Critical Control Point (HACCP) Systems

An establishment is to design and implement components of a HACCP system as required by [9 CFR part 417](#). The HACCP system includes the HACCP plan, the Sanitation Standard Operating Procedures (SOPs) plan, and other prerequisite programs. The [Guidebook for the Preparation of HACCP Plans](#) provides information on developing a HACCP plan. The Guidebook and Generic HACCP Models for various products are available on the [Small and Very Small Plant Guidance](#) webpage under the

green bar "HACCP Models." The HACCP Models include example production flow charts and hazard analyses. The [Meat and Poultry Hazards and Controls Guide](#) is a helpful reference. Each establishment will need at least one individual who is HACCP-trained in meat, poultry, or egg products processing to develop and maintain the HACCP plan. This can be someone who works for the establishment or a contractor. Additional resources include the [HACCP Guidance](#) webpage, which includes resources for validation of HACCP plans such as the [FSIS Compliance Guideline: HACCP Systems Validation](#), and the HACCP Models.

Prerequisite Programs

The [Guidebook for the Preparation of HACCP Plans](#) mentioned above also includes information on prerequisite programs. Prerequisite programs are written procedures that describe particular activities of an establishment/plant that can be used to support decisions made in the hazard analysis. Prerequisite programs do not control food safety hazards. Good Manufacturing Practices (GMPs) or Sanitation Standard Operating Procedures (SOPs) are examples of prerequisite programs. The Sanitation SOPs are required by [9 CFR 416.12-416.16](#), and the [Sanitation Standard Operating Procedure Model](#) includes information on developing Sanitation SOPs. Other prerequisite programs are procedures implemented as written on an ongoing basis in support of decisions made in the hazard analysis that food safety hazards are not reasonably likely to occur. Official import establishments must meet the requirements for Sanitation SOPs, but not the HACCP requirements in [9 CFR part 417](#).

Additional Requirements for the Slaughter HACCP Processing Category

- All livestock slaughter establishments must ensure facilities comply with the [Humane Methods of Slaughter Act](#) and the Humane Handling requirements in [9 CFR part 313](#).
- Beef slaughter establishments must be aware of Specified Risk Material (SRM) removal requirements in [9 CFR 310.22](#) and consider how Shiga toxin-producing *Escherichia coli* (STEC) will be addressed and prevented.
- All slaughter establishments are to consider sanitary dressing processes and procedures. Poultry and swine slaughter establishments are required to incorporate them into their HACCP System.
- All poultry slaughter establishments must comply with Poultry Good Commercial Practices in [9 CFR 381.65\(b\)](#).

Slaughter facility requirements vary by slaughter class, but in addition to the information in the above Facility requirements section:

- **Livestock slaughter facility requirements** are listed in [9 CFR 307.2](#) and [9 CFR part 310](#) and vary depending on carcass and viscera presentation methods;
- **New Swine Inspection System facility requirements** are listed in [9 CFR 309.19](#), [9 CFR 310.1](#), and [9 CFR 310.26](#); and

- **Poultry facility requirements** are listed in [9 CFR 381.36](#). The specific requirements vary by inspection system.

Additional Requirements for Post Lethality Exposed Ready-to-Eat (RTE) Products

Establishments producing post-lethality exposed RTE products must address *Listeria monocytogenes* (*Lm*) and comply with [9 CFR part 430](#). The design of RTE production areas must consider how the establishment will meet the requirements in [9 CFR part 430](#).

Recall plan

An official meat or poultry establishment is required by [9 CFR 418.3](#) to prepare and maintain written recall procedures. Information on how to develop recall procedures can be found in [Recall Plan Booklet -How to Develop a Meat and Poultry Product Recall Plan](#). Egg products establishments and official import inspection establishments are not required to develop a recall plan.

Labeling

All meat, poultry, and egg products must be labeled, and the labels must be truthful and not misleading. Before a grant of inspection is approved, an official establishment must obtain a label approval. Depending on the information desired on the label, labels can either be approved by generic approval or sketch approval. Generic approval means the label needs to meet all requirements but does not need to be submitted to, reviewed, and approved by the FSIS Labeling and Program Delivery Staff (LPDS). LPDS approval is also referred to as sketch approval. The FSIS [Labeling Policies](#) and the FSIS [Labeling and Label Approval](#) webpages provide information on labeling requirements and approval procedures.

FSIS Guidance

Establishments can search for guidance for specific products on the [FSIS Guidelines](#) webpage, which includes all FSIS guidelines for a variety of products and processes. Some guidelines have been translated into several languages, and translations for these are available online. Some commonly used guidelines for some specific products (not all inclusive of those available on the FSIS Guidelines webpage) are included in this guide:

- [Mobile Slaughter Unit Compliance Guide](#);
- [FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli \(STEC\) in Beef \(including Veal\) Slaughter Operations](#);
- [FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli \(STEC\) in Beef \(including Veal\) Processing Operations](#)

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- [Bovine Spongiform Encephalopathy \(BSE\) and Specified Risk Material \(SRM\) Guidance Materials and Resources](#);
- [FSIS Guideline: Modernization of Swine Slaughter Inspection - Developing Microbiological Sampling Programs in Swine Slaughter Establishments](#);
- [FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork and Products Containing Pork](#);
- [FSIS Guideline for Controlling *Campylobacter* in Raw Poultry](#);
- [FSIS Guideline for Controlling *Salmonella* in Raw Poultry](#);
- [FSIS Compliance Guideline: Modernization of Poultry Slaughter Inspection - Microbiological Sampling of Raw Poultry](#);
- [Controlling *Listeria Monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products](#);
- [Meat and Poultry Jerky Produced by Small and Very Small Establishments](#);
- [Ready-to-Eat Fermented, Salt-Cured, and Dried Products Guideline](#);
- [FSIS Cooking Guideline for Meat and Poultry Products \(Revised Appendix A\)](#);
- [FSIS Stabilization Guideline for Meat and Poultry Products \(Revised Appendix B\)](#);
- [FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products](#);
- [Compliance Guide for a Systematic Approach to the Humane Handling of Livestock](#)

Finding Resources for Small and Very Small Establishments

The FSIS [Small & Very Small Plant Guidance](#) webpage has helpful resources including the individual State Hazard Analysis and Critical Control Point (HACCP) Contacts and Coordinators found under the green bar “HACCP Directories & Resources” tab. State coordinators are also found on the [HACCP Validation](#) webpage, under the green bar “HACCP Coordinators.” Coordinators are affiliated with universities and are often extension specialists. Coordinators provide additional one-on-one advice and assistance to small and very small establishments related to HACCP and HACCP validation. The [Small & Very Small Plant Guidance](#) webpage has a green bar section titled “Education & Training” including one section titled “Online Tools and Documents” with the link to a brochure for [USDA Inspection in Shared Spaces, including Commercial Kitchens](#) along with other helpful resources.

FSIS Inspection Cost

There is no cost to apply for Federal inspection, and there is no cost for routine inspection services within the approved hours of operation. Approved hours of operation

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are up to 8 working hours in a shift and up to 40 working hours within a work week. There are costs when inspection service is requested outside of the approved hours of operation (i.e., overtime, weekends, and Federal holidays) or when services beyond the inspection activities described in the FMIA, PPIA, and EPIA are requested by a facility. This posted Knowledge Article provides the overtime rates for the current year: [askFSIS Public Q&A: FSIS Overtime, Holiday, Laboratory, and Export Application Services Rates](#). The establishment is to complete [FSIS Form 5200-15](#), Hours of Operations Request/Approval, and to work out the details of inspected days and hours with the FSIS District Office.

FSIS Verification

FSIS inspection program personnel (IPP) verify the safety and required labeling of meat, poultry and egg products. IPP conduct inspection activities to verify that the establishment maintains proper sanitation, follows their HACCP system procedures and complies with all regulatory requirements pertaining to their slaughter and processing operations. Verification activities serve to protect the public from foodborne hazards. The specific verification activities vary by process and product. Sampling and testing products under FSIS jurisdiction for microbiological hazards and chemical residues are key FSIS inspection verification activities. For more information see FSIS [Sampling Program](#) webpage.

Applying for a Grant of Inspection

Businesses interested in operating a federally inspected meat, poultry, or egg products establishment, that are in compliance with the applicable requirements for the products produced, may submit [FSIS Form 5200-2, Application for Federal Inspection](#). The application will be submitted to the Grant Curator at the [District Office](#) with jurisdiction over the area where the facility will operate. Questions about the status of the application may be submitted to the Grant Curator or the Frontline supervisor, while questions about any of the requirements discussed above can be submitted to [askFSIS](#) and the [Small Plant Help Desk](#).

Contacting FSIS

Businesses interested in applying for FSIS inspection can reach out to the District Office with jurisdiction over the location of the facility. District Office contact information can be found on the [Office of Field Operations \(OFO\)](#) webpage. Establishments can find answers to common questions in publicly posted askFSIS Public Questions and Answers (i.e., Knowledge Articles) by using the [USDA Have a Question?](#) search bar tool and using “askFSIS” along with the search terms.

Additionally, interested businesses can contact FSIS via the [askFSIS](#) and [Small Plant Help Desk](#) web platform, or by phone at 1-800-233-3935 or at 1-877-374-7435, to ask questions. Some examples include

Small Plant Help Desk

Phone: 1-800-233-3935 or

1-877-374-7435

Email: InfoSource@usda.gov

clarification of facility requirements, amenability determinations, and exemption requirements.