

How to Become USDA (United States Department of Agriculture) FSIS (Food Safety Inspection Service) Inspected

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Introduction

SELLING MEAT PRODUCTS involves complying with regulations. Consequently, it is important to know more about the process. Let's take a quick look first at its legal origins.

Although several federal, state, and local agencies regulate food safety, the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) oversee the entire process. The origins of their authority trace back to 1906, when President Theodore Roosevelt signed two pieces of legislation, the Pure Food and Drug Act and the Federal Meat Inspection Act. The Pure Food and Drug Act banned the trafficking of adulterated or misbranded foods, drugs, and liquors. The USDA's Bureau of Chemistry initially enforced it, but reorganized later into what we know today as the Food and Drug Administration. The Federal Meat Inspection Act (FMIA) made illegal the sale of adulterated and misbranded meat and meat products. The USDA's Bureau of Animal Industry enforced it. The Poultry Products Inspection Act (1957) added poultry, followed by eggs in 1970 (Egg Products Inspection Act). Like the FDA, the USDA Bureau of Animal Industry endured several reorganizations, until 1981, when it became the Food Safety and Inspection Service (FSIS). Its stated mission is to ensure "that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged" (USDA 2015).

The regulations are so comprehensive that even if you don't slaughter livestock, if your product contains meat or meat ingredients you likely must comply with FMIA regulations. Indeed, only products with "relatively small proportions" of meat or meat products are exempt See USDA 2005 for definitions (review the entry titled "Amenability"). So check to make sure that your facility isn't classified as dual jurisdiction and thus subject to FDA and FSIS requirements.

FMIA-FSIS Inspection

The FSIS and FDA regulate and ensure the safety of food in different ways. This bulletin focuses only on those of the FSIS (hence, meat, poultry, and egg products). As required by the FMIA, the FSIS inspects meat products that are sold in the commercial market during the slaughter and processing stages. To verify the humane handling of animals and to ensure products are safe to eat, they conduct antemortem and postmortem inspections of the carcass and organs. In addition, they certify that meat products are packaged and labeled properly. Lastly, FSIS personnel inspect the processing facility to ensure its conditions comply with the Hazard Analysis Critical Control Point (HACCP) food-safety plan required by the FSIS and to confirm that the facility has adequate sanitary conditions maintained in accordance with Sanitation Standard Operating Procedures (SSOPs) developed by the producer in accordance with the regulation.

Exemptions

The FSIS offers a few exemptions to on-site inspections. The following list defines a few of the basic ones. For more detailed information, see USDA 2015 and USDA FSIS 2018.

- Personal use exemption. Slaughtering or processing livestock for a person's own use is a process that does not require inspection. Note that the exemption does not apply if the meat is sold to someone else.
- Custom exemption. Similar to the personal use exemption, in that a facility that slaughters/ processes meat for personal use qualifies. However, the processing of some meat products for sale qualify as well, but only if they are sold to the owner of the livestock; they cannot be sold commercially. Additionally, although FSIS-inspection personnel need not be present at a custom-exempt facility, the facility must still comply with sanitation and recordkeeping requirements to ensure that the meat product is not adulterated or misbranded.
- Retail/Restaurant exemption. The processing
 of a meat product at a retail or restaurant-style
 facility for normal consumer or household use
 qualifies for this exemption (for example, a deli).

Benefits

The benefit to having your facility inspected by the FSIS include the following:

- Improves marketing: FSIS certification allows you to sell your products to other processors, retailers, and other, larger distribution networks.
 In addition, you can export your product. Being inspected greatly increases your ability to widen your customer and distribution base.
- Increases food safety: Complying with the FSIS food-safety plan helps you to avoid compromising others' health with your products and within your processing facility.

Other Necessary Actions

Once you have ruled out any exemptions, it is almost time to apply for inspection. But your operation needs to begin carrying out the following programs:

- Sanitary design requirements. A facility needs to be cleanable (conduct a risk assessment to determine if your facility is acceptably hygienic). A facility must meet requirements in eight categories to ensure that their products are safely processed (unadulterated nor crosscontaminated). For more information about the standards, see Office of the Federal Register 2015.
- Develop an HACCP plan (see USDA FSIS 2020 in the HACCP Helpful Links section herein). An HACCP plan must be developed by someone who has been trained in the five preliminary steps and seven principles of HACCP (Figure 1). HACCP is a systematic approach to food safety. It is a logical, simple, and effective system that guarantees the safe production of food products. The plan intends to prevent food-safety incidents from developing by identifying programs, policies, and procedures to implement when you recognize that a biological, chemical, or physical hazard exists within your process and/ or ingredients. Many resources are available to help you develop an HACCP plan. See the HACCP Helpful Links section for more information; Figures 2 and 3 provide a sample flow diagram and CCP summary for one meat product.
- Write and document your SSOPs. These are procedures that describe how to clean a facility

and its equipment. The directive needs to be detailed enough to enable an inexperienced person to do a passable job of cleaning a piece of equipment. Several resources to help you script one are available (see SSOPs Helpful Links), but a few initial tips include the following: mention details like the correct chemical to use and its concentration, the proper tools to use, the order of operations, as well as covering any other helpful hints or safety concerns. Although you will be writing it, avoid inserting lengthy paragraphs; pictures are effective supplements too. In addition, write the SSOPs in a language understood by the staff completing the tasks (for example, English or Spanish).

• Apply for label approval (USDA FSIS 2011). While HACCP and SSOPs help to prevent adulteration, proper (approved) labeling creates more accurate labels, thus reducing the opportunity for misbranding. Indeed, proper labels ensure that you are using the correct information and making trustworthy claims (note that because many claims rest on legal definitions, be careful to verify that they meet the legal requirements). A proper label includes a product's name, its facility's number and contact information, product ingredients and nutritional information, and proper handling and storage information. See Labeling Helpful Links for numerous guidelines and examples of labeling requirements.



Figure 1. Steps to develop an HACCP plan.

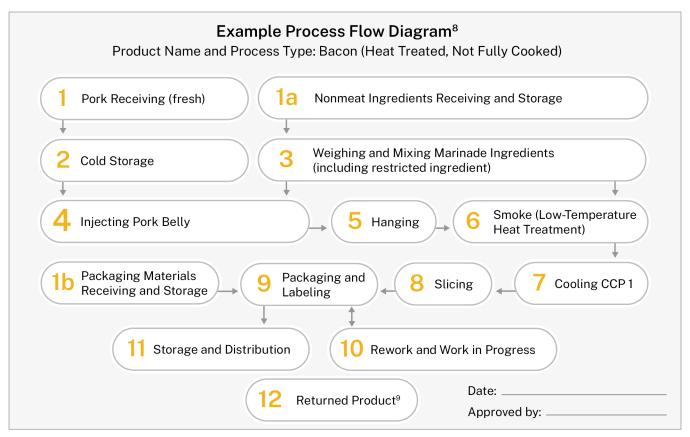


Figure 2. Example of a flow diagram for an HACCP plan for heat-treated and not fully cooked bacon. For contents of footnotes 8 and 9, see USDA FSIS 2021. Adapted from <u>USDA FSIS 2021</u> (click on Full Guideline hyperlink). CCP, Critical Control Point.

Critical Control Point (CCP)		CCP 1 Cooling
Significant Hazard(s)		B: Clostridium perfringen, C. botulinum, and Staphylococcus aureus
Critical Limits for Each Control Measure		Cooling: from 120°F to 80°F in five hours and 80°F to 45°F in ten hours (fifteen hours total of cooling time). See Taormina and Bartholomew 2005 for more information.
Monitoring Procedures	What	Measure the product temperature and the time taken to determine the number of hours the product is held in the 120°F–80°F and 80°F–45°F temperature zones.
	How	Measure the product temperature in the center of the largest piece in the batch and that is held in the cooler's warmest spot. Record the times between critical temperatures at regular intervals.
	Frequency	Each batch
	Who	Designee
Corrective Action		If a deviation from the critical limit occurs, the supervisor will 1. Hold all product produced from the last acceptable check until appropriate dispensation is taken (no product injurious to health enters commerce); 2. Determine and eliminate the deviation cause; 3. Bring the CCP under control; and 4. Take measures to prevent a recurrence. See 9 CFR 417.3 for more information.
Verification		Supervisor weekly observes a designee perform chill temperature checks. Supervisor calibrates thermometers weekly for product and cooler use per the manufacturer's instructions. Manager performs a weekly records review.
Records		Five logs: temperature smoke/cool; thermometer calibration; direct observation; records review and corrective actions.

Figure 3. Example of a CCP summary for an HACCP plan for heat-treated and not fully cooked bacon. Adapted from Taormina and Bartholomew 2005.

Although you can begin working on the inspection application before establishing these programs, a front-line supervisor needs to evaluate them before approving a grant. So it is better to put them in place before filling out the FSIS Form 5200-2, *Application for Federal Inspection* (USDA 2023). After completing it, locate your district's Office of Field Operations (USDA FSIS n.d.) and send it to them.

After its submission, a grant curator works with you and the area front-line supervisor to gather the remaining required documentation and to review your programs and facility to make sure they meet the requirements. While discussing your processing schedule with the front-line supervisor, both will work with you to set up an inspection schedule. There is no charge for the inspector; however, the process may incur holiday and overtime costs. After your facility has passed inspection, it is in compliance and issued an FSIS Inspected Establishment Identification Number.

Maintaining Your Grant of Inspection

Rapport with the inspector is vital before, during, and after earning the grant of inspection. Indeed, compliance is an ongoing process. Your operation must continue to follow the programs you put in place (HACCP, SSOPs, labeling, sanitation, infrastructure suitability, etc.); it must maintain regulatory requirements, like those involving water-source suitability, etc. Thus, allow an inspector to do their job. Let them reevaluate your facility and pull samples for testing to verify the safety of the meat products, according to the schedule determined with the front-line supervisor. It is a very important business relationship; beware if you don't maintain it amiably.

Fact Summary

- If you process meat or meat products, you must comply with the FMIA.
- The USDA FSIS inspects your facility to verify that it meets the regulatory requirements.
- Develop and maintain SSOPs, an HACCP plan, and approved labels to ensure your meat products are not adulterated or misbranded.
- Many resources are available to help you develop the necessary programs: local Extension

personnel, the FSIS front-line supervisor, local Manufacturing Extension Partnership client personnel, the contacts listed with the USDA's Small Plant Help Desk, and others you can find online. See all the Helpful Links listed at the end of this bulletin to get you started.

Further Reading

Office of the Federal Register. 2015. "Code of Federal Regulations. Title 9 Animals and Animal Products. Chapter III, Subchapter E, Section 416.2." Washington, DC: Government Publishing Office. https://www.govinfo.gov/content/pkg/CFR-2015-title9-vol2/xml/CFR-2015-title9-vol2-sec416-2.xml.

Taormina, P. J., and G. W. Bartholomew. 2005. "Validation of Bacon Processing: Conditions to Verify Control of Clostridum perfringens and Staphylococcus aureus." *Journal of Food Protection* 68(9): 1831–39.

United States Department of Agriculture (USDA). 2005. Food Standards and Labeling Policy Book. 188 p. https://www.fsis.usda.gov/sites/default/files/import/Labeling-Policy-Book.pdf.

USDA. 2015. Summary of Federal Inspection Requirements for Meat Products. https://www.fsis.usda.gov/sites/default/files/media-file/2021-02/Fed-Food-Inspect-Requirements.pdf.

USDA. 2023. *Application for Federal Inspection*. FSIS Form 5200-2. 8 p. https://www.fsis.usda.gov/sites/default/files/2020-08/Form_5200-2.pdf.

USDA Food Safety and Inspection Service (FSIS). n.d. "Office of Field Operations (OFO)." https://www.fsis.usda.gov/contactus/fsis-offices/office-field-operations-ofo.

USDA FSIS. 2011. "Application for Approval of Labels, Marking or Device." FSIS Form 7234-1. https://www.fsis.usda.gov/sites/default/files/2020-08/FSIS_7234-1_Approval of Labels.pdf.

USDA FSIS. 2018. "FSIS Guideline for Determining Whether a Livestock Slaughter or Processing Firm is Exempt from Inspection Requirements of the Federal Meat Inspection Act." 31 p. https://www.fsis.usda.gov/sites/default/files/import/Compliance-Guideline-Livestock-Exemptions.pdf.

USDA FSIS. 2021. "HACCP Model for Bacon (Heat-Treated, Not Fully Cooked)." Guideline ID FSIS-GD-2021-0002. https://www.fsis.usda.gov/guidelines/2021-0002.

Helpful Links

General

USDA FSIS. "Small & Very Small Plant Guidance." https://www.fsis.usda.gov/inspection/compliance-guidance/small-very-small-plant-guidance.

HACCP Helpful Links

USDA FSIS. n.d. "Applying for a Grant of Inspection." https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/GOI_HACCP.pdf.

USDA FSIS. n.d. "Small & Very Small Plant Guidance." Open "HACCP Models" to open list postings. https://www.fsis.usda.gov/inspection/compliance-guidance/small-very-small-plant-guidance.

USDA FSIS. 2018. "Meat and Poultry Hazards and Controls Guide." Guideline ID FSIS-ID-2018-0005. https://www.fsis.usda.gov/guidelines/2018-0005.

USDA FSIS. 2020. "Guidebook for the Preparation of HACCP Plans." Guideline ID FSIS-GD-2020-0008. https://www.fsis.usda.gov/guidelines/2020-0008.

University of Wisconsin Madison Extension/Center for Meat Process Validation. 2022. https://meathaccp.wisc.edu/index.html.

Labeling Helpful Links

USDA FSIS. n.d. "Claims Guidance." https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/claims-guidance.

USDA FSIS n.d. "Label Submission and Approval System (LSAS)" (home page). https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/label-submission-and-approval-system-lsas.

USDA FSIS. n.d. "Labeling Policies." https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/labeling-policies.

SSOPs Helpful Links

College of Food, Agricultural, and Environmental Sciences, The Ohio State University–Meat Science Extension. 2023. "SSOP Models." https://meatsci.osu.edu/node/116.

"Grant of Inspection—Establishment Sanitation. Part 416: Sanitation Performance Standards (SPS)." https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/GOI_Sanitation.pdf.

USDA FSIS. n.d. "Attachment 4: Sample [of] Sanitation Standard Operating Procedure (SSOP)." *Guidelines for Obtaining a Federal Grant of Inspection for Meat and Poultry Establishments*. https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/Grant_of_Inspection_Attachment4.pdf.

USDA FSIS. 2016. "Sanitation Performance Standards Compliance Guide." Guideline ID FSIS-GD-2016-0003. https://www.fsis.usda.gov/guidelines/2016-0003.

