

Food Safety and Inspection Service U.S. DEPARTMENT OF AGRICULTURE

> Overview: Production of Meat and Poultry Products Under FSIS Jurisdiction 2023

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Our Mission

The Food Safety and Inspection Service is the public health agency in the USDA that's responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled.



Federal Acts Governing FSIS





Federal Meat Inspection Act (FIMA), 1906

Agricultural Marketing Act (AMA), 1946

Poultry Products Inspection Act (PPIA), 1957

Egg Products Inspection Act (EPIA), 1970

Humane Methods of Livestock Slaughter Act, 1958





9,000 FSIS EMPLOYEES



7,800 FRONT LINE WORKFORCE



6,800 FEDERALLY REGULATED ESTABLISHMENTS

What Product is under FSIS Jurisdiction – Amenability:

Amenability

- All meat and poultry products capable of use as human food are <u>amenable</u> to the FMIA and PPIA <u>unless an exemption from the definition of a</u> <u>meat/poultry food product exists</u>.
- Not all products containing meat or poultry ingredients are amenable to the Acts and require Federal inspection.

Meat food product (9 CFR 301.2)

"<u>Any article capable of use as human food</u> which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, <u>except those exempted from definition as a meat food</u> <u>product by the Administrator</u> in specific cases or by the regulations in part 317 of this subchapter, upon a determination that they <u>contain</u> <u>meat or other portions of such carcasses only in a relatively small</u> <u>proportion</u> or <u>historically have not been considered by consumers as</u> <u>products of the meat food industry</u>," This term means <u>any product capable of use as human food</u> which is made in part from any poultry carcass or part thereof, <u>excepting those exempted from definition as a poultry</u> <u>product in § 381.15</u>.

Amenability

In general, any food product containing the following is <u>**not**</u> subject to the FMIA or PPIA (i.e., to FSIS inspection):

- 1) Products prepared for human consumption that contain meat or poultry ingredients in <u>relatively small proportions</u>,
- 2) It is not a product that <u>historically</u> has been <u>considered by</u> <u>consumers</u> as a product of either the meat or poultry industry.

Criterion 1: Relatively Small Proportion – Meat

- 3% or less raw meat
- Less than 2% cooked meat
- 30% or less fat, tallow, or meat extract alone or in combination

Criterion 1: Relatively Small Proportion – Poultry

- Less than 2% cooked poultry meat
- Less than 10 percent cooked poultry skins, giblets or fat, separately
- Less than 10 percent cooked poultry skins, giblets, fat and poultry meat (limited to less than 2 percent) in any combination

Criterion 2: Historic Consumer Perception

- USDA has determined the application of the "historical perception" criterion to food products containing meat or poultry <u>on a case-by-case basis.</u>
- Useful resources for amenability determination:
 - o The Food Standards and Labeling Policy Book
 - <u>9 CFR 317 and 381.15</u>
 - Submit a question to FSIS Labeling and Program Delivery Staff (LPDS) through <u>askFSIS</u>

FSIS Inspection

What Production Activities Require FSIS Inspection?

- Under the FMIA and PPIA, FSIS conducts inspection in all establishments where amenable species are *slaughtered or processed for sale as articles of commerce*, unless an *exemption* from inspection applies (<u>9 CFR 302.1</u> for meat & <u>9 CFR 381.6</u> for poultry)
 - <u>9 CFR 302.1</u> requires establishments that **PREPARE** product to be inspected, unless exempted: (a) **Inspection under the regulations in this subchapter is required at**: (1) Every establishment, except as provided in § 303.1 (a) and (b), or (c) of this subchapter, in which any livestock are **slaughtered** for transportation or sale as articles of commerce, or in which any products of, or derived from, carcasses of livestock are, wholly or in part, **PREPARED for transportation or sale as articles of commerce**, which are intended for use as human food;
 - <u>9 CFR 301.2</u> defines Prepared as "Slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed".

Grant of Inspection

- A business that has obtained an approved Federal Grant of Inspection for producing meat or poultry products is called an official establishment.
- A Federal Grant of Inspection will enable the establishment to sell its product in interstate commerce for resale.
- The establishment will operate under FSIS inspection and must meet FSIS regulations.
- The products will bear the mark of inspection.



How to Obtain a Grant of Inspection?

In order to obtain a Grant of Inspection from USDA-FSIS, the establishment needs to at least meet the following:

- 1. A suitable facility which meets sanitation performance standards (SPS) and other facility requirements (<u>9 CFR 416.1-416.5</u>, <u>307.1</u>, <u>381.36</u>, <u>533.3</u>)
- 2. A Sanitation Standard Operating Procedure (<u>9 CFR 416.12-16</u>).
- 3. A HACCP Plan. A new establishment must design a HACCP System as required by <u>9</u> <u>CFR part 417</u>
- 4. A written recall procedure (<u>9 CFR 418</u>)
- 5. Label approval FSIS Labeling Policies

Guidelines Available for FSIS Establishments

- 1. Sanitation Performance Standards Compliance Guide (9 CFR 416.1-416.5)
- 2. Mobile Slaughter Unit Guide
- 3. <u>A Sanitation Standard Operating Procedure Model (9 CFR 416.12-16)</u>.
- 4. <u>Guidebook for the Preparation of HACCP Plans</u> (9 CFR part 417)
- 5. FSIS HACCP Plan models
- 6. <u>FSIS Compliance Guideline: HACCP Systems Validation</u> (9 CFR part 417)
- 7. <u>Recall guidebook</u> and <u>Guideline for Industry Response to Customer Complaints</u> (9 CFR 418).
- 8. <u>FSIS Labeling Policies</u> webpage
- 9. <u>The Food Standards and Labeling Policy Book</u>
- 10. FSIS Guideline for Label Approval

How to Apply for a Grant of Inspection?

- General information on how to obtain a Grant of Inspection and an overview of the requirements is found on the <u>Apply for a Grant of Inspection</u>.
- Submit a completed
 FSIS Form 5200-2
 Application for
 Federal Inspection to
 your local FSIS District
 Office

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Exemptions

What are the Exemptions?

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

Livestock slaughtered for personal useLivestock 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

What are the Exemptions?

The PPIA, in <u>21 U.S.C. 464</u>, exempts from routine Federal inspection:

- Personal Use
- Custom Slaughter/Processing
- Poultry Producer Grower 1,000 Limit
- Poultry Producer/Grower 20,000 Limit
- Poultry Producer/Grower or Other Person (PGOP)
- Small Enterprise
- Retail Exemption (Store/Dealer/Restaurant)

What are the Exemptions?

- A common misconception
 - \circ An exempt operation is exempt from all requirements of the FMIA and PPIA.
- Exempt from what?
 - Exempt operations are exempt from continuous carcass-by-carcass (bird-by-bird) inspection and the <u>routine daily FSIS inspection</u> during the operation.
 - Facilities operating under an exemption are <u>not exempt</u> from the <u>adulteration and</u> <u>misbranding</u> requirements of the FMIA and PPIA, and may be subject to State or local regulatory requirements.
 - Business records required (<u>9 CFR 320.1</u> and <u>381.175</u>)
- FSIS Office of Investigation, Enforcement and Audit (OIEA) Compliance Investigators periodically verify whether the firm meets the relevant exemption requirements.

Restaurant Exemption - 9 CFR 303.1(d)(2)(iv)

- Ready-to-eat (RTE) meals prepared and sold directly to individual consumers for consumption
- Sales only to individual household consumers; no sales to HRI
- Only federally or state inspected and passed product (or product prepared at a retail store per <u>9 CFR 303.1(d)(2)(iii)</u>) is handled or used in the preparation of the product
- No sale in excess of normal retail quantity in <u>9 CFR 303.1(d)(2)(ii)</u>
- Applicable records to be maintained per <u>9 CFR 320.1</u>

Restaurant Exemption – Operations (9 CFR 303.1(d)(2)(i))

 Operations of types traditionally and usually conducted at retail stores and restaurants:

(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, <u>except slaughtering or the retort processing of canned products;</u>

(d)Breaking bulk shipments of products;

(e)Wrapping or rewrapping products.

Caterer Exemption - 9 CFR 303.1(d)(2)(iv)(b)

- Subset of the restaurant exemption subject to the restaurant requirements
 - The caterer, or their employees, delivers or serves the meals, or entrées, to the individual consumers.
 - 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 subject to the adulteration provisions of the FMIA per 9 CFR 303.1(f), 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.

Exemption Guidelines Available

- FSIS Guideline for Determining Whether a Livestock Slaughter or Processing Firm is Exempt from the Inspection Requirements of the Federal Meat Inspection Act
- <u>Guidance for Determining Whether a Poultry Slaughter or Processing</u>
 <u>Operation is Exempt from Inspection Requirements of the Poultry Products</u>
 <u>Inspection Act</u>

Voluntary Reimbursable Inspection Services:

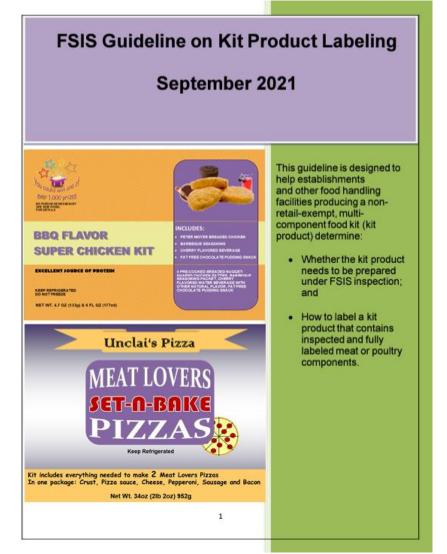
Types of Voluntary Reimbursable Inspection Services:

- Identification service (ID Service) (<u>9 CFR 350.3(a), 362.2(c)</u>, <u>592.300</u>, <u>317.12</u> and <u>381.140</u>)
- Food inspection service (<u>9 CFR 350.3(c)</u> and <u>362.2(a)</u>)
- Export certification service (<u>9 CFR 350.3(b), 362.2(b)</u>, and <u>592.20(d)</u>)
- Voluntary inspection of exotic animals (e.g., bison, elk, deer) for wholesomeness (<u>9 CFR part</u> <u>352</u>)
- Voluntary inspection of migratory waterfowl or game bird (<u>9 CFR part 362</u>)
- Voluntary inspection of rabbits (<u>9 CFR part 354</u>)

Assembling Kit Products that Contain a Meat or Poultry Component

The Agency has determined that the act of assembling a kit product that contains meat or poultry does not need to be done under FSIS inspection, if the following conditions are met:

- 1. The meat or poultry component is prepared and separately packaged under FSIS inspection and labeled with all required features;
- 2. The outer kit label identifies all of the individual components in the kit; and
- 3. The outer kit label clearly identifies the product as a single unit or "kit," such as "Chicken BBQ Dinner Kit" and "Beef Lasagna Meal."



Guidance for Shelf Stable Products:

HACCP Processing Categories for Shelf Stable Products

- Heat Treated-Shelf Stable
- Not Heat Treated-Shelf Stable
- Thermally Processed, Commercially Stable

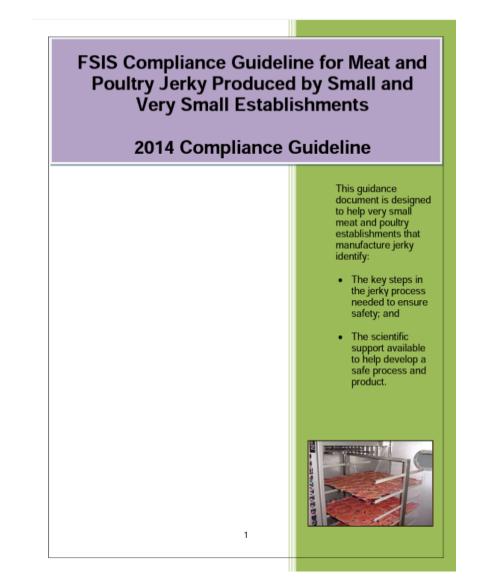






Heat Treated-Shelf Stable

- This HACCP processing category applies to establishments that further process by using a <u>heat treatment</u> processing step <u>to</u> <u>achieve food safety</u> in combination with curing, drying, or fermenting processing step to achieve food safety. The finished products are shelf stable and not required to be frozen or refrigerated for food safety purposes.
- <u>HACCP Model for Ready-to-Eat, Heat-</u> <u>Treated, Shelf-Stable (Beef Jerky)</u> (Jun 2021)



Post-lethality exposed Ready-to-Eat (RTE) products

Ready-to-Eat (RTE) product is 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 safe-handling instructions or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products. (<u>9 CFR 430.1</u>)

Post-lethality exposed product: Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Additional Guideline for Post-lethality exposed RTE products in 9 CFR 430:

 Controlling Listeria Monocytogenes in Postlethality Exposed Ready-to-Eat Meat and **Poultry Products** - This guidance guideline provides specific recommendations that official establishments producing postlethality exposed ready-to-eat (RTE) meat and poultry product may follow to meet the requirements of 9 CFR part 430, the Listeria Rule. It also provides information on sanitation, testing for Listeria monocytogenes (Lm), and prevention of cross contamination of post-lethality exposed, RTE meat and poultry products.



Additional Guideline for Cooking and Cooling Meat and Poultry Products:

- <u>FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) -</u> This guideline provides information on the Agency regulatory requirements associated with safe production of ready-to-eat (RTE) products with respect to the destruction of *Salmonella* and other pathogens.
- <u>FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B)</u> -This guidance document assists official establishments that produce heat-treated (both fully and partially heat-treated) ready-to-eat (RTE) and not-ready-to-eat (NRTE) meat and poultry products to stabilize their products (by cooling or hotholding).

Not Heat Treated-Shelf Stable

 This HACCP processing category applies to establishments that further process by <u>curing, drying, or fermenting</u> processing step as the means by which product achieves food safety. Establishments in this HACCP processing category may apply <u>a low-level heat treatment</u> as long as the heat treatment is not used as means to achieve food safety. The finished products produced under this HACCP processing category are shelf stable.

Not Heat Treated-Shelf Stable

- As there is an increasing interest in producing artisanal/niche shelf-stable RTE fermented, saltcured, or dried products that rely on multiple hurdles (i.e., salt, nitrite, reduced pH, reduced water activity; <u>rather than heat</u>) for lethality
- <u>This guideline</u> provides information on the Agency regulatory requirements associated with safe production of ready-to-eat (RTE) shelf-stable, fermented, salt-cured, and dried products that rely on multi-hurdle approaches to achieve lethality and shelf-stability.

FSIS Ready-to-Eat Fermented, Salt-**Cured, and Dried Products Guideline** May 5, 2023 Document ID: FSIS-GD-2023-0002 This guideline provides information on the Agency regulatory uirements associated with safe production of ready-to-eat (RTE) If-stable, fermented, salt-cured, and dried products that rely on multi-hurdle approaches to achieve ethality and shelf-stability. It applies to small and very small meat and poultry official establishments although large establishments can also benefit rom the information. It relates to 9 CFR part 417

Thermally Processed, Commercially Sterile Products

- Thermally Processed-Commercially Sterile (TPCS): This HACCP processing category applies to establishments that use a thermal processing step in a retort or aseptic processing system. TPCS products are hermetically sealed in cans or flexible containers such as pouches, or semi-rigid, as in lunch bowls.
- Canned product: A meat or poultry food product with a water activity above <u>0.85</u> which receives a <u>thermal process</u> either before or after being packed in a <u>hermetically sealed container</u>. (<u>9 CFR 431.1</u>)

Thermally Processed, Commercially Sterile Products:

- Official establishments that produce TPCS meat and poultry products must meet the requirements in <u>9 CFR 431</u> which requires the establishment must have a <u>process schedule</u> for each canned meat or poultry product to be packed by the establishment <u>(9 CFR 431.3(a))</u> and process schedules must be developed or determined by a <u>processing authority (9 CFR 431.3(b)(1))</u>
- The HACCP regulations in <u>9 CFR</u> <u>417.2(b)(3)</u> exempt establishments from having to address food safety hazards associated with microbiological contamination if the product is produced <u>in accordance with the requirements of 9</u> <u>CFR part 431</u>.

§ 431.1	Definitions.
§ 431.2	Containers and closures.
§ 431.3	Thermal processing.
§ 431.4	Critical factors and the application of the process schedule.
§ 431.5	Operations in the thermal processing area.
§ 431.6	Equipment and procedures for heat processing systems.
§ 431.7	Processing and production records.
§ 431.8	Record review and maintenance.
§ 431.9	Deviations in processing.
§ 431.10	Finished product inspection.
§ 431.11	Personnel and training.
§ 431.12	Recall procedure.

Additional FSIS Guidelines - HACCP models

- <u>Guidebook for the Preparation of HACCP Plans</u> (Oct 2020)
- <u>Sanitation Standard Operating Procedures</u> (Oct 2020)
- <u>HACCP Model for Ready-to-Eat, Heat-Treated, Shelf-Stable (Beef Jerky)</u> (Jun 2021)
- <u>HACCP Model for Thermally Processed, Commercially Sterile product</u> (Aug 2021)
- <u>HACCP Model for Fully Cooked Not Shelf Stable Roast Beef</u> (April 2022)
- More HACCP models on <u>FSIS website</u>

askFSIS - Resource for Policy Related Question

- askFSIS answers questions about meat, poultry, and egg products inspection, FSIS policies and related topics from inspection personnel, industry and other stakeholders.
- askFSIS: <u>https://www.fsis.usda.gov/contact-us/askfsis</u>
- Or call us: 1-800-233-3935

askFSIS

Please note: Any information you provide on this form is voluntary. Please do not include any confidential information such as social security numbers or birth dates in your comments. Please review our <u>Privacy Policy</u> for more information.

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Email *:	Enter a valid email address
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Subject *:	
Details/Question *:	



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