



United States Department of Agriculture

One Team, One Purpose



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Food Safety and Inspection Service:

Retail Recordkeeping for Establishments and Retail Stores That Grind Raw Beef Products

Food Safety and Inspection Service:

Agenda

- **Introduction**
- **Policy Overview of the Retail Recordkeeping Rule**
- **Enforcement of the Rule**
- **Questions and Answers**
- **Wrap Up and Adjournment**

Food Safety and Inspection Service: Policy Overview of the Retail Recordkeeping Rule



Food Safety and Inspection Service: Foodborne Illness Outbreaks

- Foodborne illnesses cost the US economy \$15.6 billion every year.
- The Centers for Disease Control estimates that each year roughly 1 in 6 Americans (or 48 million people) contract a foodborne illness. This includes 128,000 hospitalizations and 3,000 deaths.
- Contaminated meat and poultry are responsible for 22% of these illnesses and 29% of these deaths.
- Between 2007 and 2013, FSIS investigated 130 outbreaks of human illness. Of those, 31 (24 percent) were linked to beef ground at a retail venue.

Food Safety and Inspection Service: Why Ground Beef?

- Ground beef can be produced from materials from multiple suppliers, and multiple production lots.
- The grinding process can spread pathogens throughout each lot of ground beef, and between lots if grinding equipment and/or food contact surfaces are not properly cleaned.
- Additionally, ground beef is not always cooked sufficiently to destroy pathogens.

Food Safety and Inspection Service:

Previous Approaches to Retail Recordkeeping

2002: “*E. coli* O157:H7 Contamination of Beef Products” Federal Register Notice

- When collecting a ground beef sample for O157:H7 testing at retail, FSIS announced that it would also gather:
 - Names and establishment numbers of the establishments supplying the source materials for the lot of ground beef sampled
 - Supplier lot numbers and production dates
 - Any other information that would be useful to suppliers if they were later notified of an *E. coli* O157:H7 positive finding

Food Safety and Inspection Service:

Previous Approaches to Retail Recordkeeping

2009: FSIS provided guidance on its Web site

- Recommended that retail stores keep records of:
 - The lot/batch number of source materials used to prepare raw ground beef
 - Exact name/type of product produced

Food Safety and Inspection Service:

Why do we need this rule?

- It will improve FSIS' ability to accurately trace the source of foodborne illness outbreaks involving ground beef products and identify the source materials that need to be recalled.
- It will provide FSIS with proper documentation in efforts to trace ground beef products back to supplier(s).

Food Safety and Inspection Service: **Why do we need this rule?**

- Despite efforts by FSIS, industry associations, and other regulators to provide retailers and official establishments with guidance and examples of best practices, **the level of recordkeeping was still less than what was needed** for timely and accurate traceability investigations.

Food Safety and Inspection Service:

How to detect Foodborne Illness Outbreaks?

- The cleaning and sanitizing of equipment used to grind raw beef is important because it prevents the transfer of *E. coli* O157:H7 and other bacteria from one lot of product to another.
- When records are available and complete, FSIS is often able to identify specific production in an official establishment.

Status of retail grinding record	Number of investigations	Number resulting in recalled product
Available and complete	11	6
Not available	11	1
Available, but incomplete	6	1

Food Safety and Inspection Service:

Legal Basis for Recordkeeping

21 U.S.C. 642

- Official establishments and retail stores that grind raw beef products for sale in commerce must keep records that will fully and correctly disclose all transactions involved in their businesses that are subject to the FMIA.
- Records specifically required to be kept under 9 CFR 320.1(b) include, but are not limited to, bills of sale, invoices, bills of lading, and receiving and shipping papers.
- Businesses must also provide access to and permit inspection of these records by FSIS personnel (9 CFR 320.4).

Food Safety and Inspection Service: **FSIS Rulemaking**

- In 2009 and 2011, FSIS held two public meetings, in Washington, DC, to discuss the traceability issue, using ground beef as an example.
- On July 22, 2014, FSIS published a proposed rule, “Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products.”
- On December 14, 2015, FSIS published the final rule, “Records to be Kept by Official Establishment and Retail Stores That Grind Raw Beef Products.”

Food Safety and Inspection Service: Final Rule

The authority citation for 9 CFR part 320 continues to read as follows:

“Authority: 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, 2.53.”

Main recordkeeping provisions for grinding activities:

- (1) Mandatory recordkeeping
- (2) Location of records
- (3) Retention Period

Food Safety and Inspection Service:

Final Rule

Mandatory Recordkeeping

9 CFR 320.1(b) – Records to be kept.

Added (4)(i) In the case of raw ground beef products, official establishments and retail stores are required to keep records that fully disclose:

- (A) The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product;
- (B) All supplier lot numbers and production dates;
- (C) The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;
- (D) The date and time each lot of raw ground beef product is produced; and
- (E) The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.

Food Safety and Inspection Service: Final Rule

Mandatory Recordkeeping (cont.)

Table 3: Sample Grinding log with final rule requirements.

<p>NEW WAVE STORE</p> <p>123 Main Street</p> <p>Anytown, USA, Zip Code</p> <p>FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST</p> <p>Employee Name _____ Today's Date _____</p>					
Date and Time of Grind	Manufacturer Name of Source Material Used for Product Produced	Supplier Lot #s, Product Code and/or Pack Date of Source Material Used	Est. Number(s) of Est. providing source material	Date and Time Grinder and Related FCSs Cleaned and Sanitized	Comments
<p>_____</p> <p>Signature of Store Management Reviewer Date</p>					

Food Safety and Inspection Service: Final Rule

- 9 CFR 320.1(b)(4) continued:
- (ii) Official establishments and retail stores covered by this part that prepare ground beef products that are ground at an individual customer's request must keep records that comply with paragraph (b)(4)(i) of this section.
- (iii) For the purposes of this section of the regulations, a lot is the amount of ground raw beef produced during particular dates and times, following clean up and until the next clean up, during which the same source materials are used.

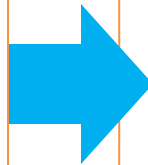
Food Safety and Inspection Service: Final Rule

Location of Records

9 CFR 320.2(a)

In general, establishments and retail stores must keep the records required by paragraph 320.1(b) “at the place where such business is conducted.”

But, if the business giving rise to the records occurs at multiple locations, the records may be kept at a “headquarters’ office.”



9 CFR 320.2(b) (added)

For beef grinding, the records must be kept at the location where the beef is ground.

This requirement will save investigators valuable time and will reduce the risk that records will be lost or misplaced.

Food Safety and Inspection Service: Final Rule

Location of Records (cont.)

9 CFR 320.2 Place of maintenance of records.

(a) **Except as provided in paragraph (b) of this section**, any person engaged in any business described in § 320.1 and required by this part to keep records must maintain such records at the place where such business is conducted, except that if such person conducts such business at multiple locations, he may maintain such records at his headquarters' office. When not in actual use, all such records must be kept in a safe place at the prescribed location in accordance with good commercial practices.

(b) Records required to kept under paragraph (b)(4) of § 320.1 must be kept at the location where the raw beef was ground.

Food Safety and Inspection Service:

Final Rule

Retention Period

9 CFR 320.3

- In general, records required by paragraph 320.1(b) must be retained for 2 years after December 31 of the year in which the transaction occurred, meaning a period of up to 3 years.
- FSIS shortened the retention period for beef grinding records to one year after the date of the recorded grinding activity.

Food Safety and Inspection Service:

Final Rule

Retention Period (cont.)

9 CFR 320.3 Record retention period.

(a) **Except as provided in paragraphs (b) and (c) of this section,** every record required to be maintained under this part must be retained for a period of 2 years after December 31 of the year in which the transaction to which the record relates has occurred and for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such records under this part.

(b) Records of canning as required in subpart G of this subchapter A, 9 CFR chapter III, must be retained as required in § 318.307(e); except that records required by § 318.302(b) and (c) must be retained as required by those sections.

(c) **Records required to be maintained under paragraph (b)(4) of § 320.1 must be retained for one year.**

Food Safety and Inspection Service:

Imports

- To be eligible to export raw beef product to the United States, **countries must maintain an equivalent inspection system for beef**; traceback and traceforward systems for beef products that allow the country to identify the source of contamination.
- This means grinding operations that export raw ground beef products to the U.S. will have to maintain a recordkeeping system equivalent to this final rule.

Food Safety and Inspection Service: **Frequently Asked Questions**

Which products are covered by the Final Rule?

- The Final Rule does not apply to specific products. It requires that official establishments and retail stores that grind raw beef keep records of their grinding activities.
- But, if the ground beef is cooked before being put into commerce, FSIS does not intend to enforce the recordkeeping requirements.
- The rule does not set new recordkeeping requirements for mechanically-tenderizing or needle-injecting raw beef.

Frequently Asked Questions

How is a ground beef lot defined in the final rule?

- 9 CFR 320.1(b)(4)(iii) defines a ground beef lot as the amount of ground raw beef produced during particular dates and times, following clean up and until the next clean up.
- As long as the date and time of cleaning is recorded, the lot will be clearly identifiable.
- Lots may include raw beef from multiple suppliers and/or source materials.

Food Safety and Inspection Service: **Frequently Asked Questions**

Which ingredients have to be recorded?

- Only raw beef that is ground must be recorded.
- For example, spices, casings, vegetables, or other types of meat or poultry in a product containing raw ground beef do not have to be recorded.
- Product labels do not have to contain any additional information under this rule.

Food Safety and Inspection Service: **Frequently Asked Questions**

Where can I find the production dates and supplier lot numbers?

- Production dates and supplier lot numbers should be evident on boxes of source materials.
- If this information is not apparent, FSIS recommends contacting the supplier for the information. If the information is not available at the time of grinding, FSIS recommends recording any other available source material information that may facilitate a swifter traceback, such as bar code numbers, invoice numbers, etc.

Food Safety and Inspection Service: Enforcement of the Retail Recordkeeping Rule

USDA
United States Department of Agriculture

One Team, One Purpose



Food Safety and Inspection Service
Protecting Public Health and Preventing Foodborne Illness



Food Safety and Inspection Service: Implementation

June 2016

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

The rule became effective on June 20, 2016. It will be enforced by FSIS investigators and inspection personnel beginning on October 1, 2016.

Food Safety and Inspection Service: Implementation

NEW WAVE STORE

123 Main Street

Anytown, USA, Zip Code

FRESH|GROUND BEEF PRODUCTION LOG/TRACKING LIST

Employee Name _____ Today's Date _____

Date and Time of Grind	Manufacturer Name of Source Material Used for Product Produced	Supplier Lot #s, Product Code and/or Pack Date of Source Material Used	Est. Number(s) of Est. providing source material	Date and Time Grinder and Related FCSs Cleaned and Sanitized	Comments

Signature of Store Management Reviewer

Date

Grinding Log Enforcement

How will the final rule be enforced?

- October 1, 2016 – March 31, 2017
 - OIEA Investigators will review grinding logs and educate retailers
- After April 1, 2017
 - OIEA will re-evaluate enforcement next steps (e.g. Letter of Information, Notice of Warning)

Food Safety and Inspection Service: Frequently Asked Questions

How will the final rule be enforced?

- In retail stores, FSIS' Office of Investigations, Enforcement and Audit (OIEA) Compliance Investigators will verify compliance by following the instructions found in FSIS Directive 8010.1, *Methodology for Conducting In-Commerce Surveillance Activities*.
- In FSIS establishments, FSIS' Office of Field Operations (OFO) Consumer Safety Inspectors will verify compliance.

Food Safety and Inspection Service: **Frequently Asked Questions**

Will failure to maintain records result in a recall?

- A recall is a firm's removal of distributed meat products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act.
- Recall will be initiated if there is reason to believe there is adulterated or misbranded product in commerce.

Food Safety and Inspection Service: Education Materials

Sanitation Guidance for Beef Grinders:

http://www.fsis.usda.gov/wps/wcm/connect/b002d979-1e1e-487e-ac0b-f91ebd301121/Sanitation_Guidance_Beef_Grinders.pdf?MOD=AJPERES.

Ground Beef and Food Safety:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/meat-preparation>.

Food Safety and Inspection Service:

Retail Recordkeeping for Establishments and Retail Stores That Grind Raw Beef Products

Questions and Answers

Food Safety and Inspection Service:
Wrap Up and Adjournment

**Retail Recordkeeping for Establishments and Retail Stores
That Grind Raw Beef Products**

Food Safety and Inspection Service: *askFSIS*

The screenshot displays the askFSIS website interface. At the top, the USDA logo and "United States Department of Agriculture Food Safety and Inspection Service" are visible, along with navigation links for "About FSIS", "District Offices", "Careers", "Contact Us", "Ask Karen", "askFSIS", and "En Español". Below this is a main navigation bar with "Home", "Topics", "Programs & Services", "Newsroom", and "Forms". A secondary navigation bar includes "Home", "Answers", "My Questions", and "Help". On the right side, there are links for "Site Map" and "Help", and a "Log In | Sign Up" button.

The central search area features two dropdown menus: "Limit by product" (set to "All") and "Limit by category" (set to "All"). Below these is a search input field with the placeholder text "Find the answer to your question" and a "Search" button. There are also "Sort by" and "Direction" dropdown menus, with "Sort by" set to "Default" and "Direction" set to "Ascending". A "Search Tips" link is located to the right of the search filters.

Below the search area is a section titled "Most Popular Answers" containing a list of links to frequently asked questions, such as "What is a Code Date?", "Entry type 02 - Consumption Quota/Visa must be filed in ACE", "Definition of Food Contact Surface", "What is the Definition of a Processing Aid?", "Confirmation of establishment screening tests for non-O157 STEC", "HACCP 'step' of a Flow Chart", "Condensation", "Inspection Coverage Requirements for Poultry Chilling", "How would a manufacturer label product consisting of 1-pound packages of links weighing between 2.6 and 3.2 ounces apiece?", "Positive or Presumptive Positive E. coli O157:H7 or non-O157 STEC Raw Beef", and "The Requirement for addressing E. coli O157:H7 in a Slaughter/Processing Establishment".

On the right side of the page, there is a "Contact Us" section with three sub-sections: "Ask a Question" (with a question mark icon), "Contact Us" (with a telephone icon), and "Give Feedback" (with a document icon). Each sub-section includes a brief description of the service.

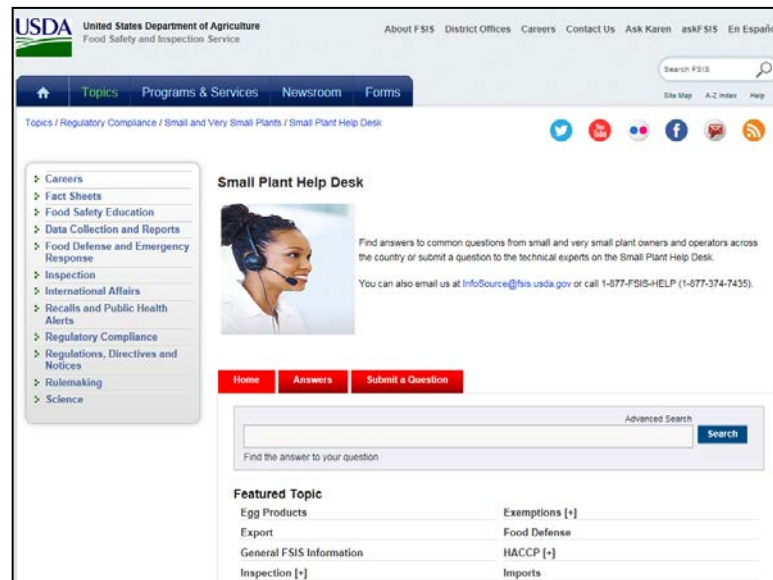
Submit questions to *askFSIS*:
www.askfsis.custhelp.com

Food Safety and Inspection Service: Small Plant Help Desk

Telephone: 1-877-FSIS-Help (1-877-374-7435)

Web site: <http://www.fsis.usda.gov/sphelpdesk>

Email: sphelpdesk@custhelp.com



The screenshot shows the USDA Small Plant Help Desk website. The header includes the USDA logo, "United States Department of Agriculture", "Food Safety and Inspection Service", and navigation links for "About FSIS", "District Offices", "Careers", "Contact Us", "Ask Karen", "askFSIS", and "En Español". A search bar is located in the top right. Below the header is a navigation menu with "Topics", "Programs & Services", "Newsroom", and "Forms". The main content area is titled "Small Plant Help Desk" and features a photo of a woman wearing a headset. Text on the page reads: "Find answers to common questions from small and very small plant owners and operators across the country or submit a question to the technical experts on the Small Plant Help Desk. You can also email us at InfoSource@fsis.usda.gov or call 1-877-FSIS-HELP (1-877-374-7435)." Below this text are three buttons: "Home", "Answers", and "Submit a Question". A search box is present with the text "Find the answer to your question" and a "Search" button. At the bottom, there is a "Featured Topic" section with a grid of links: "Egg Products", "Export", "General FSIS Information", "Inspection [+]", "Exemptions [+]", "Food Defense", "HACCP [+]", and "Imports".

8:00 a.m. – 5:00 p.m. Monday through Friday ET

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Food Safety and Inspection Service: Final Rule

Rules and Regulations

Federal Register

Vol. 80, No. 244

Monday, December 21, 2015

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 320

[Docket No. FSIS-2009-0011]

RIN 0583-AD46

Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products

AGENCY: Food Safety and Inspection Service, USDA

Executive Summary

This rule requires official establishments and retail stores that grind raw beef for sale in commerce to maintain specific information about their grinding activities. This rule is necessary to improve FSIS's ability to accurately trace the source of foodborne illness outbreaks involving ground beef and to identify the source materials that need to be recalled. The recordkeeping requirements in this final rule will greatly assist FSIS in doing so.

FSIS has often been impeded in its efforts to trace ground beef products back to a supplier because of the lack of documentation identifying all source materials used in their preparation. On July 22, 2014, FSIS published a proposed rule (79 FR 42464) to require official establishments and retail stores to maintain records concerning their suppliers and source materials received. Having reviewed and considered all comments received in response to the

not dependent on the weight of any contaminated component. FSIS is also not requiring that establishments and stores that grind raw beef products maintain records of the names, points of contact, and phone numbers of each official establishment supplying source material because FSIS already has this information in its Public Health Information System (PHIS). Any marginal benefit presented by these two proposed requirements would be outweighed by the time burden associated with recording the information. In response to comments, this rule also differs from the proposed rule in terms of the place where the records must be maintained and the retention period. Under the proposed rule, based on existing recordkeeping requirements (9 CFR 320.1), establishments and retail stores would have been allowed to keep the required records at a business headquarters location if the grinding activity is

www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules

Food Safety and Inspection Service:

Retail Recordkeeping for Establishments and Retail Stores That Grind Raw Beef Products

Adjournment