

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## 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.

**ACTION:** Proposed rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is proposing to amend its recordkeeping regulations to specify that all official establishments and retail stores that grind raw beef products for sale in commerce must keep records that disclose the identity and contact information of the supplier of all source materials that they use in the preparation of each lot of raw ground beef. They must also record the names of those supplied source materials, including any beef components and any carryover from one production lot to the next. The records would also be required to document lot numbers, the amount of the beef component used in each lot (in pounds), the date and time each lot of raw ground beef product was produced, and the date and time when grinding equipment and other related food-contact surfaces were cleaned and sanitized. Official establishments and retail stores would also have to comply with the proposed recordkeeping requirements with respect to raw beef products that are ground at an individual customer's request.

**DATES:** Comments must be received on or before September 22, 2014.

**ADDRESSES:** FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type

short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the online instructions at that site for submitting comments.

- *Mail, including CD-ROMs:* Send to U.S. Department of Agriculture (USDA), FSIS, 1400 Independence Avenue SW., Mailstop 3782, 8–163B, Washington, DC 20250–3700.

- *Hand- or courier-delivered items:* Send to U.S. Department of Agriculture (USDA), FSIS, OPPD, RIMD, Docket Clearance Unit, Patriots Plaza 3, 355 E Street SW., 8–163B, Washington, DC 20250–3700 20024–3221.

*Instructions:* All comments submitted by mail or electronic mail must include the Agency name and docket number FSIS–2009–0011. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

*Docket:* For access to background documents or comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

#### FOR FURTHER INFORMATION CONTACT:

Contact Victoria Levine, Program Analyst, Issuances Staff, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250; (202) 720–5627; Fax (202) 690–0486.

**SUPPLEMENTARY INFORMATION:** Under the authority of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and its implementing regulations, FSIS investigates complaints and reports of consumer foodborne illness associated with FSIS-regulated meat products. Many such investigations into consumer foodborne illnesses involve those linked to the consumption of raw beef ground<sup>1</sup> by official establishments or retail stores.<sup>2,3</sup>

<sup>1</sup> Raw ground beef products are ground and chopped beef (9 CFR 319.15(a)), hamburger (9 CFR 319.15(b)), beef patties (9 CFR 319.15(c)), ground or chopped veal, veal patties, veal or beef patty mix, ground veal or beef product with added seasonings, and beef manufacturing trimmings produced at an official establishment or at retail. Raw ground beef products are also ground intact steaks/roasts, bench trim ground from intact steaks/roasts, or a mix these components with trim or coarse ground beef derived from official establishments.

<sup>2</sup> See 9 CFR 303.1(d)(2)(iii)(a) through (f) for the definition of a retail store. While retail stores are

FSIS investigators and other public health officials typically use records kept at all levels of the food distribution chain, including the retail level, to identify and trace back product that may be the source of the illness to the suppliers that produced the source material for the product. The Agency, however, has often been impeded in its efforts to trace back ground beef products to the suppliers' products due to the lack of documentation identifying all source materials used in its preparation.

In some situations, official establishments and retail stores have not kept adequate records that would allow effective traceback<sup>4</sup> and traceforward activities.<sup>5</sup> Without such records, FSIS cannot conduct timely and effective consumer foodborne illness investigations and other public health activities throughout the stream of commerce.

The President's Food Safety Working Group (FSWG), which was formed on March 14, 2009, recommended a new public health-focused approach to food safety based on three core principles: (1) Prioritizing prevention; (2) strengthening surveillance and enforcement; and (3) improving response and recovery.<sup>6</sup>

One of the objectives of the third principle is to quickly identify and stop outbreaks of foodborne illness. When people become ill because of consuming product from the same source material, it is important to identify all remaining source material and remove it as quickly

exempt from the provisions of the FMIA and the meat inspection regulations with regard to inspection of the preparation of products, they are not exempt from their sanitary or recordkeeping requirements.

<sup>3</sup> Of the 130 outbreaks that FSIS investigated from 2007 through 2013, 74 were determined to be caused by the consumption of ground beef. Of those 74, 31 were linked to beef ground at a retail venue.

<sup>4</sup> Traceback actions are those actions taken to identify and document the flow of product back to the official establishment from which the suspect product originated from other official establishments, retail stores, warehouses, distributors, restaurants, or other firms in commerce.

<sup>5</sup> Traceforward actions are those actions taken to identify other potentially contaminated batches of meat that might have originated from the same official establishment and other establishments, retail stores, warehouses, distributors, restaurants, or other firms in commerce that might have been affected by contaminated product.

<sup>6</sup> <http://www.foodsafetyworkinggroup.gov/ContentKeyFindings/HomeKeyFindings.htm> and FSIS News Release No. 0292.09 dated July 8, 2009.

as possible in order to prevent more illnesses. The FSWG has recommended the establishment of a food tracing system that shortens the time between outbreak detection, resolution, and recovery. A system that permits rapid traceback to the source would protect consumers and help industry recover contaminated product more quickly and accurately.

### FMIA Recordkeeping Requirements

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 subject to the Act (*see* 21 U.S.C. 642). This is because they engage in the business of preparing <sup>7</sup> products of an amenable species <sup>8</sup> for use as human food, and they engage in the business of buying or selling (as meat brokers, wholesalers or otherwise) in commerce products of carcasses of an amenable species. These businesses must also provide access to, and permit inspection of, these records by FSIS personnel.<sup>9</sup>

### Current Regulatory Requirements

Under 9 CFR 320.1(a), every person, firm, or corporation required by section 642 of the FMIA to keep records must keep records that will fully and correctly disclose all transactions involved in businesses subject to the Act. Records specifically required to be kept under § 320.1(b) include, but are not limited to: bills of sale, invoices, bills of lading, and receiving and shipping papers. With respect to each transaction, the records must provide, but are not limited to: the name or description of the livestock or article, the net weight of the livestock or article, the number of outside containers, the name and address of the buyer or seller of the livestock or animal, and the date and method of shipment.<sup>10</sup>

Under 9 CFR 320.2, every person engaged in any business described in § 320.1 and required by part 320 to keep records must maintain them at the place where the business is conducted. However, a person who conducts business at multiple locations may

maintain those records at his or her headquarters' office. 9 CFR 300.6(b)(2) requires any person (including any firm or corporation or other business unit) subject to the recordkeeping requirements in section 642 of the FMIA to allow representatives of the Secretary of Agriculture to enter his or her place of business to examine and copy the records specified in § 320.1. Therefore, if records relevant to an outbreak or recall investigation are being maintained at a headquarters' office rather than at the place where the business is conducted, i.e., the location where raw beef is being ground, those records must be made available to FSIS personnel conducting traceback and traceforward activities. Records required to be maintained under part 320 must be retained for a period of two years after December 31 of the year in which the transaction to which the record relates has occurred (9 CFR 320.3)).

The recordkeeping requirements contained in the FMIA and 9 CFR 320 are intended to permit FSIS to trace product, including raw ground beef product associated with consumer foodborne illness, from the consumer, or the place where the product was purchased, back through its distribution chain to the establishment that was the source of the product. This will make it easier to determine, if possible, where the contamination originally occurred. Investigators should also be able to conduct effective traceforward investigations so as to identify other potentially contaminated product that has been shipped from the point of origin of its contamination to other official establishments, retail stores, warehouses, distributors, restaurants, or other firms. FSIS must be able to carry out these investigations using records that should be kept routinely by official establishments and retail stores.

In 2002, FSIS published a **Federal Register** notice explaining the Agency's views with regard to the records and information it considered important for effective traceback and traceforward activities involving *E. coli* O157:H7 contamination of beef products.<sup>11</sup> Specifically, the notice stated that if the Agency confirmed positive *E. coli* O157:H7 samples of raw ground products produced at an official establishment, the Agency intended to collect the following information from the official establishment:

1. The name, point of contact, and phone number for the official establishments supplying the source

materials for the lot of ground beef sampled;

2. The supplier lot numbers and production dates; and any other information that would be useful to suppliers that may have supplied *E. coli* O157:H7-positive product to official establishments.

FSIS also stated that it intended to gather the following information from retail stores at the time it collected a sample of raw ground beef for *E. coli* O157:H7 testing:

1. The names and establishment numbers of the establishments supplying the source materials for the lot of ground beef sampled;
2. The supplier lot numbers and production dates; and
3. Any other information that would be useful to suppliers if they are later notified of an *E. coli* O157:H7 positive finding.

Shortly after issuing the 2002 **Federal Register** notice, FSIS began collecting the information listed in the notice from official establishments that produced ground raw beef products that FSIS confirmed positive for *E. coli* O157:H7 and from retail stores at the time the Agency collected samples of ground raw beef product from the stores for *E. coli* O157:H7 testing.<sup>12</sup> FSIS has also been collecting supplier information from official establishments at the time FSIS collects a sample, just as the Agency does when it collects retail samples.

Retail stores, however, often do not document and maintain supplier information at times other than when FSIS collects samples of ground raw beef product from the stores for *E. coli* O157:H7 <sup>13</sup> testing. As a result, the Agency is unable to respond quickly during foodborne disease investigations. This information, which the Agency expects businesses to obtain from their suppliers pursuant to the requirements contained in 9 CFR 320.1, is essential for effective traceback and traceforward activities.

In 2009, FSIS provided guidance to a retail industry association requesting appropriate records that retail stores should keep to aid in identifying traceback and traceforward on FSIS-regulated products associated with foodborne illnesses and other food safety incidents. The Agency

<sup>7</sup> Prepared means slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

<sup>8</sup> The term "amenable species," 21 U.S.C. 601(w), was added by section 798(2) of Pub. L. 109–97, Nov. 10, 2005. Section 798(1) of that law amended the FMIA by striking the words "cattle, swine, goats, horses, mules, and other equines" in each place it appeared in the Act and inserting "amenable species" in its place. *See also* 21 U.S.C. 642(a)(2) and 9 CFR 320.1(a)(2).

<sup>9</sup> 21 U.S.C. 642(a). *See also* 9 CFR 300.6(a)(1).

<sup>10</sup> 9 CFR 320.1(b)(1).

<sup>11</sup> "E. coli O157:H7 Contamination of Beef Products" (67 FR 62325, Oct. 7, 2002).

<sup>12</sup> FSIS Notice 47–02, dated 11/20/02, "FSIS Actions Concerning Suppliers that may be Associated with *Escherichia coli* (*E. coli*) O157:H7 Positive Raw Ground Beef Product"

<sup>13</sup> On June 4, 2012, FSIS implemented routine verification testing for six Shiga toxin-producing *Escherichia coli* (STEC), in addition to *E. coli* O157:H7, in raw beef manufacturing trimmings. *See Shiga Toxin-Producing Escherichia coli in Certain Raw Beef Products* (77 FR 31975, May 31, 2012).

recommended that retail stores keep records of the lot/batch number of the source materials used to prepare the raw ground beef, as well as the exact name/type of product produced, the manufacturer name of the source material used for the product produced, the product code or pack date of the source material used, and the establishment number of the source product used. FSIS then made the guidance available on the Agency's Web site.

To further address the issue, on December 9 and 10, 2009, FDA and FSIS held a joint public meeting to discuss the essential elements of product tracing systems, gaps in then-current product tracing systems, and mechanisms to enhance product tracing systems for food.<sup>14</sup> This meeting was followed on March 10, 2010, by an FSIS public meeting that discussed the Agency's procedures for identifying suppliers of source material used to produce raw beef product that FSIS has found positive for *E. coli* O157:H7. FSIS also discussed additional verification activities that the Agency planned to conduct at suppliers' establishments in response to positive *E. coli* O157:H7 results. Moreover, FSIS sought input from meeting participants on ways to improve the Agency's procedures for identifying product that may be positive for *E. coli* O157:H7.

Despite these FSIS actions, the Agency has continued to experience significant impediments in connection with tracebacks of FSIS-regulated products, associated with consumer foodborne illness, to the suppliers that

produced the source materials. Some official establishments and retail stores still do not keep and maintain the records necessary to allow effective traceback activities. FSIS has found that the records kept by these businesses vary in type and quality, and are often incomplete or inaccurate.

Overall, FSIS has concluded that voluntary recordkeeping by retail facilities that grind raw beef has not been sufficiently effective, as evidenced by continuing outbreaks linked to pathogens in raw ground beef that FSIS cannot trace back to the source.<sup>15</sup> The lack of specific information about supplier lot numbers, product codes, pack dates of source materials used to produce lots of raw ground beef, and when and whether grinding equipment has been cleaned and sanitized has prevented or delayed FSIS from identifying businesses that produced the source materials for product that was positive, the specific product responsible for an outbreak and, therefore, to accurately identify other product that might also be adulterated. The cleaning and sanitization of equipment used to grind raw beef between lots or batches is important because it prevents the transfer of *E. coli* O157:H7 and other bacteria from one lot of product that may be contaminated to another lot of product ground on the same equipment that is not.

FSIS conducted a retrospective review of 28 foodborne disease investigations from October 2007 through 2012 in which beef products were ground or re-ground at retail stores to describe their beef grinding and recordkeeping

practices.<sup>16</sup> Twenty-two of these investigations were for outbreaks that occurred in 2009 or earlier, and the remainder occurred after 2009.

Among the 22 investigations that took place in 2009 or earlier, seven had complete records, four had incomplete records, and 11 had no records. Among the six investigations that took place after 2009, four had complete records and two had incomplete records. Additionally, in 2013, FSIS participated in three outbreaks. In two investigations, no records had been kept, while in the third complete records were available. Therefore, while the evidence suggests improvement, there remain retail stores or establishments that do not maintain complete records.

Complete records are important for successfully identifying adulterated product and initiating a recall. FSIS was assisted in its traceback and traceforward activities by records in each of the 11 investigations identified in the study where complete records were available. In situations where complete records were not available, the inability to identify product suppliers in a timely fashion, or at all, hindered FSIS in identifying the source of adulteration.

When records were available and complete, such that FSIS could identify specific production in an establishment, the Agency was able to institute a recall of product from the supplying establishment in six of 11 investigations. In contrast, when records were not available or incomplete, FSIS was able to do so only two of 17 times.

| 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                                    |

For example, in July 2007, an epidemiologic investigation conducted by the Suffolk County Health Department, Suffolk County, New York, identified two ill persons who reported consuming pre-formed, 80/85-percent lean ground beef patties purchased from

a retail store in New York. Leftover products collected from the homes of the case-patients and tested by the Outbreaks Section of FSIS's Eastern Laboratory were found to have *E. coli* O157:H7 with pulsed-field gel electrophoresis (PFGE) <sup>17</sup> pattern

combinations indistinguishable from those of the case-patients. Even with purchase dates and store invoices, FSIS and local health officials were unable to definitively identify the supplier of the beef that was processed into the pre-formed patties because the source

<sup>14</sup> Comments and a transcript of this meeting are available at [www.regulations.gov](http://www.regulations.gov) at <http://www.regulations.gov/#?searchResults;rpp=10;po=0;s=FDA-2009-N-0523>.  
<sup>15</sup> Recall.  
<sup>16</sup> Ihry, T., White, P., Green A., Duryea, P. Review of the Adequacy of Ground Beef Production Records at Retail Markets for Traceback Activities During Foodborne Disease Investigations. Poster presented at: Annual Conference of the Council of

State and Territorial Epidemiologists; 2012, Jun 4–6; Omaha, NE. A copy of this document is available for viewing in the FSIS Docket Room. FSIS selected 28 investigations because the illnesses were presumptively or definitely caused by the consumption of ground beef. Beef was ground or re-ground at one or more retail meat markets, and the name of the retail market that sold the ground beef, the name of the product, and the date that it was purchased were available. Since the time of the

original survey, FSIS has added two more investigations.  
<sup>17</sup> Pulsed-field gel electrophoresis (PFGE) is a standardized method used to subtype (or fingerprint) foodborne disease-causing bacteria. PFGE can be used to distinguish strains of organisms such as *E. coli* O157:H7, STECs, *Salmonella*, *Listeria*, or *Campylobacter* at the DNA level.

materials for the product associated with the outbreak were re-ground and packaged by the retail store, which did not identify the supplier of the raw beef used to produce the patties. The inability of public health officials to identify the supplier of the ground beef prevented them from identifying other possibly adulterated product produced by the supplier, or other establishments, retail stores, warehouses, distributors, restaurants, or other firms in commerce that might have received contaminated product from the supplier.

In November 2007, a similar situation occurred when FSIS was unable to identify a source of *Salmonella* contamination that accounted for nearly 40 human illnesses associated with fresh ground beef products produced at a single retail grocery chain with stores nationwide. In this case, records kept by the grocery chain's raw ground beef grinding facility were missing, had no entries on the dates of interest, or had incomplete or inaccurate entries. The records also did not document all of the suppliers of the raw beef ground at the facility.

More recently, in December 2011, a Maine-based grocery chain recalled an undetermined amount of fresh ground beef products that may have been contaminated with a multiple drug-resistant strain of *Salmonella* Typhimurium. This recall was initiated by the grocery chain in response to illnesses caused by an outbreak of salmonellosis that was associated with the use of fresh in-store ground beef prepared in and purchased at the grocery chain's stores. In its examination of the chain's records, FSIS was unable to determine suppliers of the beef, which accounted for 15 human illnesses. In this case, records kept by the grocery chain's raw ground beef grinding facility did not list all of the suppliers of the raw beef ground at the facility. As a result, FSIS could not definitively identify products subject to a recall.

Correspondingly, complete records are more likely to result in efficient recalls. In May 2007, officials from the Minnesota and Virginia state departments of health and FSIS investigated an outbreak involving nine ill persons. These nine individuals had an indistinguishable strain of *E. coli* O157:H7. A case-control study showed consumption of ground beef purchased at a local grocery chain was significantly associated with illness. Left-over ground beef from a case-patient's home was tested and found positive. Investigators used purchase date and store location information from case-patients along with complete, accurate grinding logs

from the stores to definitively identify a single supplying establishment and the production date of implicated product. Successful traceback resulted in a recall of 117,500 lbs. of potentially adulterated ground beef from an official establishment.

In May and June 2009, officials from FSIS, the Centers for Disease Control and Prevention (CDC), and health departments in several states investigated an outbreak that involved 20 persons with an indistinguishable strain of *E. coli* O157:H7. Eleven people were hospitalized; one developed hemolytic uremic syndrome. The case-patients resided in nine states throughout the U.S. All 18 who provided food histories reported consuming some type of beef; 16 reported consumption of ground beef. Ground beef samples from a retail store and a small, regulated processing establishment were also positive with the outbreak strain. Twelve case-patients provided consumption histories that included purchases at nine supermarkets. Using purchase information from the case-patients, investigators were able to determine a common supplier for the stores and the small processing establishment. The source establishment had supplied trim and primal or sub-primal cuts to several companies which processed them into ground beef or intact retail cuts. Using information from the retail grinding logs, investigators were able to determine a specific production day at the source establishment. The establishment recalled approximately 421,000 lbs. of various potentially adulterated beef cuts.

In June 2012, FSIS learned of an outbreak that ultimately involved 46 persons, 12 of whom were hospitalized. The patients resided in nine states, primarily in the northeastern U.S. The CDC determined that all were ill with an indistinguishable strain of *Salmonella* Enteritidis. Seven of eight case-patients from two states reported consuming ground beef prior to illness. A case-control study showed that shopping in the Maine-based grocery chain described earlier was statistically significant. State investigators collected leftover ground beef from several case-patients and from retail supermarkets or their distribution center. Ground beef from case-patients' homes tested positive for the outbreak strain. Eight case-patients who shopped at the grocery chain provided purchase information. The grocery chain had implemented improvements in their record system and grinding logs for products purchased by five case-patients conclusively showed they

purchased 85 percent lean ground beef from a regulated federal establishment with a known production date. This time, the establishment recalled approximately 29,000 lbs. of adulterated product. In all of the examples above, grinder records were necessary in identifying the official establishments that supplied source materials and retailers that distributed the product.

To better ensure that FSIS will be able to conduct effective traceback and traceforward investigations, or foodborne illness investigations, or to monitor product recalls, the records kept and maintained by official establishments and retail stores that grind raw beef products must disclose the identity of the supplier, the source of all materials that they use in the preparation of each lot of raw ground beef product, including any carryover from one production lot to the next, the amount of the beef component used in each lot (in pounds), and the date and time each lot of raw ground beef product is produced. The records also must document the date and time when cleaning and sanitizing occurs because cleaning and sanitizing of food-contact equipment after grinding beef may help define the lot and limit the scope of a recall.

FSIS is proposing to amend the Federal meat inspection regulations to require that official establishments and retail stores that grind raw beef products keep records that fully disclose the names, points of contact, phone numbers, and establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product; all supplier lot numbers and production dates; the names of the supplied materials, including beef components and any materials carried over from one production lot to the next; the amount of the beef component used in each lot (in pounds); the date and time each lot of raw ground beef product is produced; and the date and time when grinding equipment and related food-contact surfaces are cleaned and sanitized.<sup>18</sup> Note that for materials purchased from a broker or distributor, the establishment number would be on the shipping container of the product.

Official establishments and retail stores that prepare raw beef products that are ground at an individual customer's request would also be required to comply with the proposed recordkeeping requirements with respect to such product. Keeping complete records for all grinding activity will enable FSIS to conduct

<sup>18</sup> Proposed 9 CFR 320.1(b)(4)(i).

effective recalls in a timely manner thereby reducing illnesses or deaths.

Grinding logs at retail stores are a good example of a type of record that can easily be used to identify the source, supplier, and names of all materials used in the preparation of raw ground beef products. Below is the grinding log

record that FSIS posted with this 2009 guidance. As shown in the sample grinding log (Table 1) below, the date and time of grind, the amount of carryover, the name of the source material, supplier establishment information from the label of the source material, and the date and time of

cleaning and sanitizing would be the information required to be kept, if this rule is finalized. Information under the other column headings would not be required, but some official establishments and retail stores may choose to keep and maintain such information.

NEW WAVE STORE

123 Main Street

Aytown, USA, Zip Code

FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST

Employee Name\_\_\_\_\_Today's Date\_\_\_\_\_

| Date and Time of Grind* | Lot/Batch # (lot = same source material) | Exact Name/ Type of Product Produced | Package Size of Product Produced | Amount (in lbs.) of Source Material Used in Each Lot, including Carryover* | Production Code of Product Produced | Manufacturer Name of Source Material Used for Product Produced* | Supplier Lot #s, Product Code and/or Pack Date of Source Material Used* | Estab. Info. from Label of Source Material Used (Est. #, ph #, contact info)* | Date and Time Grinder and Related FCSs Cleaned and Sanitized* | Comments |
|-------------------------|--|--------------------------------------|----------------------------------|--|-------------------------------------|---|---|---|---|----------|
|                         |  |                                      |                                  |  |                                     |   |   |   |   |          |
|                         |  |                                      |                                  |  |                                     |   |   |   |   |          |

Signature of Store Management Reviewer

Date

Table 1: Grinding log record that FSIS posted (2011)

\* This information will be required if this proposed rule is finalized.

**Executive Orders 12866 and 13563 and Regulatory Flexibility Act**

Executive Orders 12866 and 13563 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of

harmonizing rules, and of promoting flexibility. This rule has been designated a “significant regulatory action” under section 3(f) of Executive Order 12866. Accordingly, this rule has been reviewed by the Office of Management and Budget.

**I. Background**

FSIS is proposing a rule that would require official establishments and retail stores that grind raw beef products for sale in commerce to keep records that will fully and correctly disclose details

of all transactions involved in their businesses subject to the FMIA, including the identity and supplier of all materials used in the preparation of each lot of raw ground product. The required records are essential to conduct efficient foodborne illness investigations. The proposal would affect retail stores and official establishments.

If adopted, the proposed rule will require records to include lot-specific information (i.e., a lot number, a code number, or other identifier). Lot-specific

information distinguishes one production batch from another and can be a number printed on the packaging or some other identifier.<sup>19</sup>

Recordkeeping systems are designed to track the flow of product or product attributes through production processes or the supply chain. Traceability is the ability to follow the movement of a food product through the stages of production, processing, and distribution.<sup>20</sup> Records are necessary for a good product traceback (traceforward) system.

Public and private sector officials often lack information about the sources of foods or ingredients, making traceback processes inefficient, which results in missed opportunities to identify contaminated product. This proposed rule, if adopted, will strengthen traceback systems, leading to quicker identification of adulterated product and quicker, more targeted recalls, an outcome in keeping with the objectives of the FSWG.

## II. Need for Rule

Voluntary recordkeeping at retail stores and official establishments has not been sufficiently effective. Incomplete and nonexistent grinding records have impeded traceback and traceforward activities by FSIS investigators during food safety events, limiting their ability to identify implicated product and sources of contamination. This rule is needed to enhance FSIS' ability to protect public health by conducting recalls quickly and efficiently, thereby reducing illnesses associated with contaminated ground beef product.

## III. Alternatives Considered

### (1) Existing Voluntary Recordkeeping Program

FSIS provided industry voluntary guidelines (see Table 1) in 2009. As

<sup>19</sup> FSIS acknowledges that most firms use lot or code numbers to identify specific batches of their products. However, some may use other technologies such as barcodes. The term 'other identifier' is intended to capture any other methods that the food industry may be using to identify specific lots of product.

<sup>20</sup> Codex Alimentarius Commission, "Procedural Manual, Seventeenth Edition," 2007. The Codex Alimentarius Commission was created in 1963 by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to develop food standards and guidelines. Available online at: <http://ftp.fao.org/docrep/fao/010/a1472e/a1472e.pdf>.

stated above, the Agency has concluded that a policy of voluntary guidelines for recordkeeping has not ensured that all establishments and retail outlets maintain complete records that will ensure quick identification of contaminated product.

### (2) Regulated Weekly Recordkeeping Program

FSIS considered requiring that retail stores and official establishments maintain grinding records such that each producer recorded grinding activities once per week. This would be an improvement over the current voluntary recordkeeping program in that those establishments and retail stores which are not recording grinding activities would now be required to do so, and a weekly recordkeeping task would be less burdensome than the recordkeeping being proposed, which requires firms to record activities approximately two to five times per week. However, a weekly record would make it difficult to differentiate between lots of product ground from different suppliers throughout the week, and would therefore result in many of the same traceback obstacles currently experienced under voluntary recordkeeping. Therefore, FSIS rejected this alternative.

### (3) More Detailed Recordkeeping Program

FSIS also considered expanding the recordkeeping requirements to include all fields suggested in the 2011 FSIS guidance (all fields in the Table 1 proposed log). This would provide FSIS with more detailed records to use during an investigation, which may be particularly useful in instances where product is ground multiple times per day from multiple sources. However, this level of detail would place an unnecessary burden on those establishments that do not grind product multiple times per day. For this reason, FSIS decided to require that only the most critical information be recorded while leaving the remaining possible fields as a voluntary component.

## IV. Baseline

FSIS expects that this proposed rule could affect a total of 76,093 retail stores and official establishments. These

include 64,380 supermarkets, 5,924 meat markets, 4,544 warehouse clubs and supercenters, and 1,245 official establishments that engage in grinding raw beef products. The number of retail stores is based on 2010 Census data<sup>21</sup> for establishments that grind beef, while the number of official establishments was obtained from the Public Health Information System (PHIS). Some of these establishments and retail stores already maintain the records required in the proposed rule, and would therefore not incur any additional costs.

Table 2 distinguishes between large establishments, defined as those with 500 or more employees, and small establishments, defined as those with fewer than 500 employees. FSIS assumes that retail establishments with 500 or more employees will grind beef and create a record approximately five times per week, thus assuming 260 records per year for these large entities. For small retail entities, with fewer than 500 employees, FSIS assumes that these establishments on average would grind beef and create a record approximately twice a week for 50 weeks for the year, for 100 records per year. For official FSIS processing establishments, FSIS examined data from a 2008 FSIS survey,<sup>22</sup> and found that, on average, large official establishments processed ground beef product 258 days a year and the small establishments processed ground beef about 164 times a year. Small official establishments grind more often than small retail establishments because official establishments rely more heavily on ground beef production than retail establishments, which have a wider variety of products for sale. FSIS used these values to estimate the number of grinding log records per year for retail establishments.

<sup>21</sup> Source: U.S. Department of Commerce, U.S. Bureau of the Census—Number of Firms, Number of Establishments, Employment, and Annual Payroll by Enterprise Employment Size for the United States, All Industries: 2010.

<sup>22</sup> Results of Checklist and Reassessment of Control for *Escherichia coli* O157:H7 in Beef Operations. 2008, available at [http://www.fsis.usda.gov/wps/wcm/connect/9ce5ce22-f609-4990-bd9a-ce2c323d229b/Ecoli\\_Reassessment\\_Checklist.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/9ce5ce22-f609-4990-bd9a-ce2c323d229b/Ecoli_Reassessment_Checklist.pdf?MOD=AJPERES), accessed July 24, 2013.

TABLE 2—NUMBER OF RETAIL FIRMS AND OFFICIAL ESTABLISHMENTS AFFECTED BY RECORDKEEPING REQUIREMENTS ASSOCIATED WITH GROUND RAW BEEF PRODUCTS

| NAICS codes  | NAICS description  | Number of firms by size <sup>1</sup> |        |        | Number of establishments by firm size <sup>2</sup> |        |        |
|--------------|--|--------------------------------------|--------|--------|--|--------|--------|
|              |  | Large                                | Small  | Total  | Large  | Small  | Total  |
| 445110 ..... | Supermarket and other grocery (except convenience) stores. | 314                                  | 40,713 | 41,027 | 21,028   | 43,352 | 64,380 |
| 445210 ..... | Meat Markets .....   | 9                                    | 5,415  | 5,424  | 274  | 5,650  | 5,924  |
| 452910 ..... | Warehouse clubs and Supercenters .....                     | 11                                   | 13     | 24     | 4,531  | 13     | 4,544  |
| PHIS .....   | Official establishments .....                              | .....                                | .....  | .....  | 35   | 1,210  | 1,245  |
| Total ..     | .....  | 334                                  | 46,141 | 46,475 | 25,868   | 50,225 | 76,093 |

<sup>1</sup> Large: 500 or more employees; Small: 499 or fewer employees.

<sup>2</sup> For official establishments, size category based on establishment HACCP size class distinguishing Large (500 or more employees) from Small and Very Small.

Note: NAICS is the North American Industry Classification System. A “firm” refers to the parent company and an “establishment” refers to each distinct facility.

Source: U.S. Department of Commerce, U.S. Bureau of the Census—Number of Firms, Number of Establishments, Employment, and Annual Payroll by Enterprise Employment Size for the United States, All Industries: 2010.

The kinds of businesses identified as potentially subject to the final regulation are:

- Supermarkets and other grocery (except convenience) stores. This industry comprises establishments generally known as supermarkets and grocery stores primarily engaged in retailing a general line of food, such as canned and frozen foods; fresh fruits and vegetables; and fresh and prepared meats, fish and poultry. Included in this industry are delicatessen-type establishments primarily engaged in retailing a general line of food.

- Meat Markets. This industry comprises establishments primarily engaged in retailing fresh, frozen, or cured meats. Meat markets may butcher animals for their own account, or they may buy bulk from others. Delicatessen-type establishments primarily engaged in retailing fresh meat are included in this industry.

- Warehouse clubs and supercenters. This industry comprises establishments known as warehouse clubs, superstores or supercenters primarily engaged in retailing a general line of groceries in combination with general lines of new merchandise, such as apparel, furniture, and appliances. Official federal—inspected establishments that grind raw beef products are included in this group.

There are three major kinds of businesses FSIS does not consider to be retail establishments, and thus are not affected by the proposed rule: convenience stores, meat and meat product merchant wholesalers, and full-service and limited-service restaurants. The convenience store or food mart (except those with fuel pumps) industry comprises establishments that primarily engage in retailing a limited line of goods that generally includes milk,

bread, soda, and snacks, but do not engage in the business of grinding raw beef. The meat and meat product merchant wholesalers industry comprises establishments primarily engaged in the merchant wholesale distribution of meats and meat products (except canned and packaged frozen) or lard, but do not engage in the business of grinding raw beef. Most, if not all supermarkets, meat markets, and warehouse clubs sell product from federally inspected establishments and derive a significant share of revenue from those products. The full-service restaurant industry comprises establishments primarily engaged in providing food services to patrons who order and are served while seated (i.e., waiter/waitress service) and pay after eating. Limited service refers to fast food restaurants, delis, pizza shops, carry out restaurants, and other similar establishments.

#### V. Costs

FSIS estimated the costs to industry and the Agency for ensuring compliance with the regulation.

##### Industry Costs

Under the current regulations (9 CFR 320.1(a)(2) and (b)), official establishments are required to keep records that fully and correctly disclose all transactions involved in their business. These records must show the name or description of the articles handled (section 320.1(b)(1)(i)) and the name and address of the sellers and buyers of the articles (section 320.1(b)(1)(iv)). Official establishments must provide FSIS access to these records (section 320.4, 21 U.S.C. 642). FSIS believes that supplier lot numbers and production dates are normally made available to official establishments. FSIS

also expects that these businesses normally obtain buyer and seller contact information during the course of business. In determining cost to industry for this rule, though, FSIS did not assume that all these establishments had complete records that would satisfy the provisions of this rule. FSIS requests comments on the extent to which this is already being done.

Costs would occur because many of the estimated 76,093 retail stores and official establishments would need to implement new recordkeeping activity and make those records available for the Agency's review. To estimate costs to industry, the Agency used information based on existing literature and discussions with FSIS experts. The annual recurring cost is due to the time requirement for recording information for each daily set of entries. FSIS assumed that, for establishments that currently maintain a complete grinding log, there would be no additional time requirement. For establishments that presently keep a log, but do not include all of the information required under the proposed regulation, FSIS assumed that it would take an additional 30 to 60 seconds per daily recordkeeping to comply with the rule, and, for establishments that presently do not maintain a grinding log, it would take 60 to 90 seconds to record each daily record. FSIS seeks comments on these recordkeeping time assumptions.

To estimate the numbers of logs that are presently incomplete and the number of logs that presently do not exist but would under the provisions of this proposed rule, FSIS used a published 2008 study<sup>23</sup> that reported on

<sup>23</sup> “Recordkeeping Practices of Beef Grinding Activities at Retail Establishments.” (2011) Hannah Gould, Scott Seys, Karen Everstine, Dawn Norton,

the recordkeeping practices of retail stores that grind raw beef. The study found that 74 percent of chain retail stores and 12 percent of independent retail stores kept grinding logs. Of the stores that kept grinding logs, the study reported 78 percent of those logs as incomplete.<sup>24</sup> For the purposes of the cost estimate, FSIS used the chain stores surveyed in the study as a proxy for large retail and official establishments, and the independent stores as a proxy for small retail and official establishments. Therefore, the recordkeeping distribution of large establishments based on the survey results is approximately 16 percent complete (74 percent\*(1–78 percent)), 58 percent incomplete (74 percent\*78 percent), and 26 percent no records. For small establishments, the distribution is

approximately 3 percent complete (12 percent\*(1–78 percent)), 9 percent incomplete (12 percent\*78 percent), and 88 percent no records. FSIS is seeking comment on these distributions and the current recordkeeping practices of retail stores.

FSIS multiplied the percentages by the number of grinding logs that will exist under this rule to determine the present numbers of incomplete and non-existing grinding logs. FSIS multiplied these numbers 30 to 60 seconds and 60 to 90 seconds respectively, to estimate the total number of additional hours, and then multiplied this estimated range by the average hourly compensation rate, derived below, of \$19.18.

To estimate the hourly cost of recordkeeping, FSIS assumed that, primarily, employees that are in the

Bureau of Labor Statistics labor category of “Butchers and Meat Cutters” would perform the recordkeeping. FSIS assumed a wage per hour from the most recent mean wage rate for this labor category, \$14.42.<sup>25</sup> In addition to the base wage, FSIS assumed an additional benefit cost factor of 33 percent<sup>26</sup> to account for benefits that the employee may receive in addition to the mean hourly wage. These include, but are not limited to, vacation time, sick time, and health care. Consequently, FSIS assumed a total hourly compensation rate of \$14.42 (1+0.33)=\$19.18. Table 3 presents the total costs by establishment/retail store (entity) size class and estimated current recordkeeping practices. This results in an estimated total cost to industry of about \$2.69 million to \$4.39 million.

TABLE 3—ANNUAL ESTIMATED COSTS BY ENTITY SIZE AND CURRENT RECORDKEEPING PRACTICES <sup>1</sup>

| Size        | Current logs     | Annual records | Added time/record (s) | Added time (h) |         | Annual cost (\$1,000) |       |
|-------------|------------------|----------------|-----------------------|----------------|---------|-----------------------|-------|
|             |                  |                |                       | Low            | High    | Low                   | High  |
| Large ..... | None .....       | 1,726,846      | 60–90                 | 28,781         | 43,171  | 552                   | 828   |
|             | Incomplete ..... | 3,909,648      | 30–60                 | 32,580         | 65,161  | 625                   | 1,250 |
|             | Complete .....   | 1,089,116      | 0                     | 0              | 0       | .....                 | ..... |
| Small ..... | None .....       | 4,499,947      | 60–90                 | 74,999         | 112,499 | 1,438                 | 2,158 |
|             | Incomplete ..... | 469,268        | 30–60                 | 3,911          | 7,821   | 75                    | 150   |
|             | Complete .....   | 130,725        | 0                     | 0              | 0       | .....                 | ..... |
| Total ..... | .....            | 11,825,550     | .....                 | 140,271        | 228,652 | 2,690                 | 4,385 |

<sup>1</sup> Numbers in table may not sum to totals due to rounding.

**Agency Enforcement Costs:** This proposed rule will result in no impact on the Agency’s operational costs because the Agency will not need to add any staff or incur any non-labor expenditures.

#### Total Costs

FSIS estimates the total cost for the rule to be about \$2.69 million to \$4.39 million.

#### VI. Benefits

Expected benefits would likely result from this proposed rule, for consumer health, the ground beef processing industry, and for the Agency.

Under this rule, FSIS expects the industry to benefit from lower direct costs for recalls because compliance

with this proposed rule will lead to more efficient, accurate, and quicker identification of potentially adulterated product. Given everything else being equal, FSIS, therefore, expects a decrease in the average volume of product recalled,<sup>27</sup> resulting in decreased costs for recalls and for the proper disposal of the product, i.e., relabeling, re-cooking, reworking, or destroying product. The Agency notes, however, that the expected benefit for any individual establishment would be less than (perhaps substantially less than) the rule-induced cost borne by that establishment; otherwise, the establishment would voluntarily keep complete records even in the absence of a regulatory requirement to do so. FSIS

is requesting data on the impact of recordkeeping on reducing the volume of product recalled for official establishments and retail outlets.

The ground beef industry will also benefit from reduced damage to reputation during food safety events. The ability of FSIS to trace adulterated product back to its source ensures that in events such as recalls, the number of firms implicated is kept to a minimum. By limiting the scope of recalls, traceability through better recordkeeping will reduce negative spillover effects which could unnecessarily burden a large group of otherwise uninvolved ground beef producers.<sup>28</sup> This level of accountability insulates the industry as a whole from

Danny Ripley, David Reimann, Moshe Dreyfuss, Wu San Chen, and Carol A. Selman. *Journal of Food Protection*, Vol. 74 (6), 1022–24.

<sup>24</sup> The study defined a complete log as one that included, at minimum, the date and time the grind was performed, the type of product produced, the lot and establishment code of the source beef, whether cleanup was performed between grinds, and the whether beef trimmings were included in the grind. An incomplete log was defined as one that was only partially completed (missing records), or did not record all of the listed data elements.

While some fields identified in the survey are not those required in the rule, and some fields required in the rule are not identified in the survey, FSIS determined that there was enough of an overlap to make use of the survey results.

<sup>25</sup> BLS Occupational Employment and Wages, May 2013.

<sup>26</sup> BLS Employer Costs for Employee Compensation, June 2013.

<sup>27</sup> Resende-Filho, Moises A. and Brian L. Buhr. “Economics of Traceability for Mitigation of Food

Recall Costs,” prepared for presentation at the *International Association of Agricultural Economists (IAAE) Triennial Conference*, Foz do Iguaçu, Brazil, 18–24 August, 2012. This paper presents simulation results of a model that indicated that that presence of a traceability system decreased volumes of recalls by over 90 percent.

<sup>28</sup> Pouliot, Sebastien and Sumner, Daniel A. “Traceability, recalls, industry reputation, and product safety.” *European Review of Agricultural Economics*. (2013) Volume 40 (1): 121–142.



losses to reputation and consumer confidence.

In addition, FSIS expects to benefit from lower Agency costs for recalls and recovery of adulterated product because the expected increased efficiency of identifying potentially adulterated product will lead to: (1) reduced inspection program personnel activities at Federal meat establishments and (2) reduced overtime hours for FSIS personnel not employed in official establishments, including enforcement, district office, and recall staff. As recalls become more effective because of better recordkeeping, FSIS could reduce staff travel for conducting recall effectiveness checks.

FSIS will conduct an ongoing retrospective analysis to confirm that the rule positively affects Agency resources and to quantify those benefits. To do so, FSIS will examine the following:

- Overtime hours for enforcement, district office, and recall staff, on a per-outbreak basis.
- Number, length, and outcome of recall effectiveness checks.
- Regulatory noncompliance citations at official establishments for the proposed revisions to 9 CFR 320.1(b)(4).

This review will enable FSIS to better quantify the benefits of the proposed recordkeeping requirements and identify areas where the regulation could be further improved.

## VII. Public Health Benefits and Related Costs

FSIS expects public health benefits in the form of averted illnesses due to better recordkeeping practices at official and retail establishments. Epidemiologic, environmental, and microbiologic findings and assessments link illnesses to contaminated food. Typically, distributions of outbreak illnesses caused by contaminated raw beef produced in FSIS-regulated establishments are geographically and temporally dispersed. Working together, epidemiologists and microbiologists may determine that ill persons share a common bacterial strain (outbreak strain) and common food exposure. When these researchers find a common exposure, environmental specialists identify food and practices associated with production, transportation, and preparation of the food to determine the possibility of contamination of the common-source food. In some investigations, microbiologists test samples of implicated foods and find the outbreak strain. Investigators use such findings to support the causal association of ill people with the food they consumed. If epidemiologic and

environmental information is sufficiently convincing to link consumption of a specific food to a cluster of illnesses, investigators can identify the contaminated product without finding the bacterial strain in the consumed food. In any circumstance, without adequate records, rapid identification of the contaminated product is not likely to occur. When FSIS identifies a food product causing illness in commerce, FSIS takes action to remove it through a voluntary product recall.

It is FSIS' experience that, before a recall takes place, many ill people have already been confirmed ill from the specific pathogen (STECs or *Salmonella* bacteria) through a laboratory test. One ill person could lead to a recall if investigators identify the consumed product that led to illness and where the consumer purchased the product, the point of purchase (POP), and confirm through microbiological tests that the identified unconsumed product contained the same bacterial strain as that that caused the illness. If complete records existed at the POP, investigators would be able quickly to identify the supplier and the lots involved. With the lot numbers, a supplier would be able to identify implicated product, enabling earlier recalls and a higher proportion of product recovered. This would result in averted illnesses and limited outbreaks.

In addition to identifying implicated product, complete records will also allow investigators to identify product source establishments, resulting in a better chance of determining the cause of adulteration. The ability of FSIS to determine process failures will help establishments take corrective actions to prevent future contamination, resulting in a reduction in future illnesses. Both the costs and benefits of corrective actions would be attributable to this rule if the actions would not have occurred without being facilitated by the proposed new recordkeeping requirements.

Beyond establishment-level improvements, a better understanding of product adulteration through investigations can serve as education for the entire industry as well as regulatory organizations. The identification of potentially hazardous practices can lead to improved guidance, and the linking of such practices to outbreaks and recalls motivates establishments to refrain from risky behavior. Lessons learned from successful investigations can also lead to improvements in the decision making process for recalls and regulatory actions.

For example, in August 1997, a Federal establishment recalled 25

million pounds of frozen ground beef patties due to *E. coli* O157:H7 contamination. The recalled product, consisting of only six lots but distributed to all 48 contiguous states, led to thirteen PFGE confirmed illnesses by the time the product was recalled. As a result of the recall investigation, FSIS identified the establishment's practice of carry-over—the process of reworking the previous day's product into the next day's product—as one of the major reasons for the large amount of contamination. Following the investigation, FSIS promulgated guidance to establishments producing ground beef instructing them to implement lot designation procedures and refrain from practicing carry-over.<sup>29</sup> As a result of the improved guidance and the incentive to not sustain losses like those seen at this Federal establishment (sold to a competitor three weeks after the recall), there was a major response from producers of ground beef.<sup>30</sup>

Better recordkeeping will facilitate outbreak investigations and enable FSIS to identify deficiencies in industry practices and government policy. This type of evidence results in improvements at the establishment level by helping to identify source establishments and affording these establishments the opportunity to diagnose and correct process failures. FSIS expects improvements due to lessons learned from outbreak investigations to prevent future outbreaks. Consumers would also benefit from the prevention of future foodborne illnesses which are not a part of outbreaks, since lessons learned from outbreak investigations will likely lead to improvements which may reduce isolated foodborne illnesses as well.

FSIS requests information that could help quantify the above or any other benefits or costs from this rule.

## VIII. Net Benefits

FSIS estimates annual costs of approximately \$2.69 million to \$4.39. Costs associated with newly-occurring public health interventions that would be facilitated by the proposed recordkeeping requirements have not been quantified. Benefits would accrue to industry due to an expected smaller volume of recall, given everything else being equal, and due to reduced industry vulnerability to reputation

<sup>29</sup> Ground Beef Processing Guidance Material (January 19, 1999, 64 FR 2872).

<sup>30</sup> 82 percent of establishments with grinding operations reported using a robust testing program in their rework process. Results of Checklist and Reassessment of Control for *Escherichia coli* O157:H7 in Beef Operations (2008) See footnote 25.

damaging food safety events. The Government would benefit in that the rule would enable the Government to operate in a more efficient manner in identifying and tracking recalls of adulterated raw ground beef products. Consumers would benefit from a reduction in foodborne illnesses due to quicker recalls, correction of process failures at ground beef producing establishments, and improved guidance and industry practices.

FSIS estimates that the average cost per *E. coli* O157:H7 illness is \$3281,<sup>31</sup> and the average cost per *Salmonella* illness is \$2423.<sup>32</sup> Given the cost savings incurred for each ground beef-linked foodborne illness that is averted, and the potential for this rule to prevent outbreaks and illnesses, FSIS asserts that the benefits accrued to industry, Government, and consumers from this proposed rule may result in net economic benefits.

### IX. Regulatory Flexibility Analysis

The FSIS Administrator made a preliminary determination that this proposed rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601).

The Agency analyzed the potential impact of this proposed rule on affected small entity retail stores and official establishments that grind raw beef products. The number and type of small entity retail stores and official establishments potentially affected by the final rule is shown in Table 2 to be 50,225, based on number of employees. Costs would accrue for maintaining the required records based on the volume of ground raw beef products produced by the business. The average annual cost to small establishments for this rule depends on whether the establishment

is already maintaining complete records and the number of days of production. For official establishments presently with no records, FSIS estimates an annual cost of \$52.42 to \$78.63; with incomplete records, FSIS estimates an annual cost of \$26.21 to \$52.42. For retail establishments, FSIS estimated annual costs are \$31.96 to \$47.95 for establishments presently with no records and \$15.98 to \$31.96 for those with incomplete records. Establishments that are already keeping records as required by the proposal would incur no costs because of this rule.

Based on the above analysis, the Agency has concluded that the rule will not have a significant economic impact on a substantial number of small entities.

#### Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. When this proposed rule is adopted: (1) All state and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

#### Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this proposed regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

#### Paperwork Requirements

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this proposed rule have been submitted for approval to OMB.

**Title:** Records to be kept by Official Establishments and Retail Stores Grinding Raw Beef Products.

**Type of Collection:** New.

**Abstract:** Under this proposed rule, FSIS is requiring several information activities. FSIS is proposing to amend its recordkeeping regulations to specify that all official establishments and retail stores that grind raw beef products for sale in commerce must keep records, for a period of two years, that disclose the identity of the supplier of all source materials that they use in the preparation of each lot of raw ground

product and identify the names of those source materials.

The required records would have to include the following information:

(A) The names, points of contact, phone numbers, and 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 amount of the beef component used in each lot (in pounds),

(E) The date and time each lot of raw ground beef product is produced, and

(F) The date and time when grinding equipment and related food-contact surfaces cleaned and sanitized.

**Estimate of Burden:** FSIS estimates that it would take 3.00 hours per respondent annually.

**Respondents:** Official establishments and retail stores that grind raw beef products.

**Estimated Number of Respondents:** 76,093.

**Estimated Number of Responses per Respondent:** 155.

**Estimated Total Annual Burden on Respondents:** 228,652 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW., Room 6077, South Building, Washington, DC 20250.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to both Gina Kouba, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. To be most effective, comments should be sent to OMB

<sup>31</sup> The FSIS estimate for the cost of *E. coli* O157:H7 (\$3,281 per case—2010 dollars) was developed using the USDA, ERS Foodborne Illness Cost Calculator: STEC O157 (June 2011) <http://webarchives.cdlib.org/sw1rf5mh0k/http://www.ers.usda.gov/Data/FoodborneIllness/> (archived link—calculator currently being updated). FSIS updated the ERS calculator to incorporate the Scallan (2011) case distribution for STEC O157. Scallan E. Hoekstra, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, et al. 2011 January. "Foodborne Illness Acquired in the United States—Major Pathogens". *Emerg. Infect. Dis.* 17: 7–15.

<sup>32</sup> The FSIS estimate for the cost of *Salmonella* (\$2,423 per case—2010 dollars) was developed using the USDA, ERS Foodborne Illness Cost Calculator: *Salmonella* (June 2011) <http://webarchives.cdlib.org/sw1rf5mh0k/http://www.ers.usda.gov/Data/FoodborneIllness/> (archived link—calculator currently being updated). FSIS updated the ERS calculator to incorporate the Scallan (2011) case distribution for *Salmonella*. Scallan E. Hoekstra, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, et al. 2011 January. "Foodborne Illness Acquired in the United States—Major Pathogens". *Emerg. Infect. Dis.* 17: 7–15.

within 60 days of the publication date of this proposed rule.

#### *E-Government Act Compliance*

The Food Safety and Inspection Service is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

#### *USDA Non-Discrimination Statement*

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

#### *How To File a Complaint of Discrimination*

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at [http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain\\_combined\\_6\\_8\\_12.pdf](http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf), or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

#### *Mail*

U.S. Department of Agriculture,  
Director, Office of Adjudication, 1400  
Independence Avenue SW.,  
Washington, DC 20250-9410.

#### *Fax*

(202) 690-7442

#### *Email*

[program.intake@usda.gov](mailto:program.intake@usda.gov)

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

#### *Additional Public Notification*

FSIS will announce this proposed rule online through the FSIS Web page located at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/proposed-rules>.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices,

FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email-subscription-service>. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

#### **List of Subjects**

Meat inspection, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR part 320, as follows:

- 1. The authority citation for part 320 continues to read as follows:

**Authority:** 21 U.S.C. 601-695; 7 CFR 2.7, 2.18, 2.53.

- 2. In § 320.1, add paragraph (b)(4) to read as follows:

#### **§ 320.1 Records to be kept.**

\* \* \* \* \*

(b) \* \* \*

(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 names, points of contact, phone numbers, and 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 amount of the beef component used in each lot (in pounds);

(E) The date and time each lot of raw ground beef product is produced; and

(F) The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.

(ii) Official establishments and retail stores covered by this regulation that prepare raw beef products that are

ground at an individual customer's request must keep records that comply with paragraph (4)(i) of this section.

\* \* \* \* \*

Done in Washington, DC on July 16, 2014.

**Alfred V. Almanza,**

*Administrator.*

[FR Doc. 2014-17128 Filed 7-21-14; 8:45 am]

**BILLING CODE 3410-DM-P**

## **NUCLEAR REGULATORY COMMISSION**

### **10 CFR Parts 26 and 73**

**[NRC-2014-0118]**

**RIN 3150-AJ41**

### **Enhanced Security at Fuel Cycle Facilities; Special Nuclear Material Transportation**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Draft regulatory basis; extension of comment period.

**SUMMARY:** On June 18, 2014, the U.S. Nuclear Regulatory Commission (NRC) published a request for public comment on a draft regulatory basis to support the potential amendments to revise a number of existing security related regulations relating to physical protection of special nuclear material (SNM) at NRC-licensed facilities and in transit, as well as the fitness-for-duty programs for security officers at certain fuel cycle facilities. The public comment period originally was scheduled to close on August 4, 2014. The NRC has decided to extend the public comment period on this document to allow more time for members of the public to develop and submit their comments.

**DATES:** The due date for comments requested in the document published on June 18, 2014 (79 FR 34641) is extended. Comments must be filed no later than October 17, 2014. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received before this date.

**ADDRESSES:** You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search for Docket ID NRC-2014-0118. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For