



# Association of Food and Drug Officials

2550 Kingston Road, Suite 311, York, PA 17402  
 Telephone (717) 757-2888 • Fax (717) 650-3650  
 E-Mail: [afdo@afdo.org](mailto:afdo@afdo.org) • Internet: [www.afdo.org](http://www.afdo.org)

## Official Comments from the Association of Food and Drug Officials

Date:	9/19/2014
Subject:	Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products
Docket ID:	FSIS-2009-0011
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### President

Stephen Stich  
 NY Dept. of Agriculture & Markets  
 10B Airline Dr.  
 Albany, NY 12235  
 (518) 457-4492  
 (518) 457-8892 FAX  
[stephen.stich@agriculture.ny.gov](mailto:stephen.stich@agriculture.ny.gov)

### President-Elect

Stan Stromberg  
 OK Dept. of Agriculture  
 P.O. Box 528804  
 Oklahoma City, OK 73152-8804  
 (405) 522-6119  
 (405) 522-1060 FAX  
[Stan.stromberg@ag.ok.gov](mailto:Stan.stromberg@ag.ok.gov)

### Vice-President

Steven Mandernach  
 IA Dept. of Inspection & Appeals  
 3rd F. Lucas State Office Building  
 321 E. 12th Street  
 Des Moines, IA 50310  
 (515) 281-8587  
 (515) 281-3291 FAX  
[steven.mandernach@dia.iowa.gov](mailto:steven.mandernach@dia.iowa.gov)

### Secretary-Treasurer

Steven Moris  
 KS Dept. of Agriculture  
 109 SW 9th St., 3rd Floor  
 Topeka, KS 66612  
 (785) 296-5600  
 (785) 296-0673 FAX  
[steve.moris@kda.ks.gov](mailto:steve.moris@kda.ks.gov)

### Executive Director

J. Joseph Corby  
 Association of Food and Drug  
 Officials  
 2550 Kingston Road, Suite 311  
 York, PA 17402  
 (518) 860-2838  
 (717) 650-3650 FAX  
[jjcorby@afdo.org](mailto:jjcorby@afdo.org)

### Association Manager

Denise C. Rooney  
 Association of Food and Drug  
 Officials  
 2550 Kingston Road, Suite 311  
 York, PA 17402  
 (717) 757-2888  
 (717) 650-3650 FAX  
[drooney@afdo.org](mailto:drooney@afdo.org)

The Association of Food & Drug Officials [AFDO] is a national organization that represents state, local, and federal government food, drug, and medical device safety regulatory officials. Within the food protection arena, AFDO is well known for promoting uniformity and cooperation among the regulatory community and has participated in numerous collaborative projects to advance these objectives. AFDO's vision for an integrated food safety system nearly two decades ago remains a foundational goal today for improving government's oversight of our global and domestic food supply. Additionally, AFDO continues to develop a host of model codes and guidance documents that state and local regulatory agencies can utilize for promulgating their own specific regulations and for improving their field staff's inspection skills. Because of AFDO's strong allegiance to state and local food safety programs, we routinely intervene in matters we feel are important to government regulators and which can have an important impact on public health.

The USDA's Food Safety and Inspection Service has proposed amending 9 CFR Part 320 by including a rule designed to improve the traceability of ground beef by requiring all producers of these products to keep extensive records. Under the proposed new requirements, ground beef producers would have to record the source, supplier and names of all materials used in producing ground beef. FSIS officials have indicated that ground beef sold at retail is often produced by combining cuts from multiple beef sources, which becomes problematic during foodborne illness investigations when the agency attempts to identify the source of the illness outbreak.

As the proposed rule would apply to both official processing establishments and retail facilities, its application is most significant at the retail area where FSIS does not maintain an oversight presence. Government oversight at retail facilities is conducted by state and local government agencies that license or permit, conduct inspection and investigation, and collect and test food products for safety. All of these agencies are, therefore, impacted by this proposed rule. The proposed rule, if finalized, will require such facilities to maintain clear records identifying the source, supplier, and names of all materials used in the preparation of raw ground beef products.

AFDO is pleased to offer the following comments on the proposed new requirements:

September 19, 2014

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It appears USDA/FSIS is seeking to broaden its regulation of retail-exempt facilities, which have traditionally come under the purview of state and local regulatory authorities. If adopted, this rule could very well set a precedent for USDA/FSIS to expand its regulatory activities with regard to retail and grocery facilities that are not currently subject to ongoing federal inspection. AFDO would not be supportive if this were to be true but would welcome a more collaborative system of addressing FMIA requirements in retail-exempt establishments through Memorandums of Understanding [MOU's] or Cooperative Agreements with state or local food safety regulatory agencies.

FSIS should indicate how they plan to enforce the requirements of the proposed rule should they be approved. Will FSIS have their Compliance staff conduct inspections at retail, and, if so what types of enforcement actions would they take for non-compliant retail establishments? Here, again, AFDO believes FSIS should consider collaborating with state and local agencies on enforcement activities since these agencies currently license and permit them to operate.

It would seem appropriate for FSIS to submit the proposed rule to the Conference for Food Protection [CFP] for adoption into the FDA Food Code and eventually into state rules.

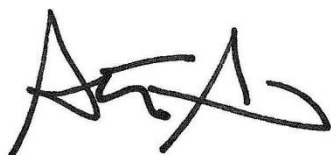
The proposed rule would provide access to records by FSIS personnel because of the importance of these records during foodborne illness investigations. FSIS investigators, however, are seldom the first responders to illness outbreaks. Local and state health officials are the first to respond and generally conduct the majority of the illness investigation in the early stages. While AFDO supports the proposed requirement for providing FSIS investigators access to records, we would strongly recommend the wording be amended in such a way to provide record access by state and local officials as well. If this proposed rule is truly intended to impact foodborne illness by helping to improve effective trace-back and trace-forward activities at retail establishments, this amended language is necessary, in our view.

Under 9 CFR 320.2, a person or business that conducts business at multiple locations are allowed to maintain required records at the business's office location. Since these records are critical in foodborne illness and recall investigations, we believe the proposed rule should require the records to be maintained at the business where ground beef is produced. In a number of circumstances, major retail grocery chains operate in multiple states with their main offices located in one location. It is not unreasonable to expect the records to be maintained at the location of production which could help speed any investigation that might occur.

AFDO is very supportive of the proposed rule as we believe it will assist regulators in the oftentimes difficult task of identifying contaminated product. Furthermore, our experience with voluntary recordkeeping indicates it is ineffective and not uniformly accepted. This proposed rule can have an impact on creating improved investigation and identification capabilities for regulatory officials.

AFDO appreciates the opportunity to comment on this important proposed rule.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Stephen Stich', written in a cursive style.

Stephen Stich  
AFDO President

# Rules and Regulations

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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.

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## 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:** Final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is amending its recordkeeping regulations to require that all official establishments and retail stores that grind raw beef products for sale in commerce maintain the following records: The establishment numbers of establishments supplying material 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 date and time each lot of raw ground beef product is produced; and the date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized. These requirements also apply to raw beef products that are ground at an individual customer's request when new source materials are used.

**DATES:** Effective June 20, 2016.

**FOR FURTHER INFORMATION CONTACT:** Dr. Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250; Telephone: (202) 205-0495; Fax (202) 720-2025.

**SUPPLEMENTARY INFORMATION:**

#### 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 proposed rule, FSIS is finalizing the rule and making several changes in response to comments. Most of the proposed requirements are retained in this final rule. This final rule requires establishments and retail facilities that grind raw beef to keep the following records: The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef; 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 date and time each lot of raw ground beef is produced; and the date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized. These requirements also apply when official establishments and retail stores grind new source materials at an individual customer's request.

In response to comments, FSIS is not adopting two proposed requirements. First, under this final rule, establishments and retail stores that grind raw beef products will not have to maintain records concerning the weight of each source component used in a lot of ground beef. After considering comments, FSIS concluded that weighing each component in a lot of ground beef was time-consuming and offered little food safety benefit because contamination in a lot of ground beef is

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 conducted at multiple locations. In response to comments, however, this rule requires the grinding records to be kept at the location where the beef is ground. This change in the final rule will save investigators valuable time and will reduce the risk that records will be lost or misplaced. Finally, in response to comments, for purposes of this rule, FSIS is including the definition of a lot as set out in the regulatory text at the end of this document (9 CFR 320.1(b)(4)(iii)).

Under the proposed rule, based on existing regulations (9 CFR 320.3(a)), the required grinding records would have been required to be maintained for up to three years. However, in response to comments, FSIS concluded that because the records required by this rule are needed primarily to investigate foodborne illness outbreaks, their utility diminishes over time. FSIS consulted with its investigators and public health experts and determined that the records would rarely be needed after one year. Considering this fact and comments concerning the burden of keeping records on-site, particularly at retail stores, FSIS shortened the retention period in the final rule to one year after the date of the recorded grinding activity.

The final rule will result in storage and labor costs to official establishments and retail stores that grind raw beef for sale in commerce. Benefits will accrue

in terms of averted foodborne illnesses, less costly outbreaks and recalls, and increased consumer confidence when

purchasing ground beef. These costs and benefits are listed in Table 1.

TABLE 1—EXECUTIVE SUMMARY TABLE

<p><b>Costs:</b></p> <ul style="list-style-type: none"> <li>Labor .....</li> <li>Storage .....</li> <li>Unquantified Costs .....</li> </ul> <p><b>Benefits:</b></p> <ul style="list-style-type: none"> <li>Unquantified Benefits .....</li> </ul>	<ul style="list-style-type: none"> <li>▪ \$56.6 million annually (\$45.8 million to \$67.4 million).</li> <li>▪ \$2.7 million annually.</li> <li>▪ Non-labor costs associated with recordkeeping for customer-requested grinds.</li> <li>▪ Potential for slight costs to consumers in the form of ground beef price increases.</li> </ul> <ul style="list-style-type: none"> <li>▪ Benefits to consumers in the form of averted foodborne illnesses as a result of contaminated ground beef.</li> <li>▪ Benefits to retailers and official establishments grinding raw beef in the form of less costly food safety events, such as outbreaks and recalls.</li> <li>▪ Benefits to official establishments supplying ground beef components in the form of less costly recalls and insulation from costly spillover effects during food safety events.</li> </ul>
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**Background**

Under the authority of the Federal Meat Inspection Act (FMIA) and its implementing regulations (9 CFR 329.1 and 329.6), FSIS investigates reports of consumer foodborne illness associated with FSIS-regulated products. FSIS investigators and other public health officials use records kept at all levels of the food distribution chain, including the retail level, to identify the sources of outbreaks.

FSIS has often been impeded in these efforts when an outbreak involves ground beef because of a lack of documentation identifying all source materials used in its preparation (79 FR 42464). In some situations, official establishments and retail stores have not kept adequate records that would allow effective traceback and traceforward activities. Without such records, FSIS cannot conduct timely and effective consumer foodborne illness investigations and other public health activities throughout the stream of commerce.

As FSIS also explained in the proposed rule, 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 business that are subject to the FMIA (see 21 U.S.C. 642) (79 FR 42465). Businesses must also provide access to, and permit inspection of, these records by FSIS personnel.

The proposed rule also explained that under 9 CFR 320.1(a), every person, firm, or corporation required by 21 U.S.C. 642 to keep records must keep records that will fully and correctly disclose all transactions involved in the aspects of their business 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. With respect to each transaction, the records must provide the name or description 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.

The recordkeeping requirements contained in the FMIA and 9 CFR part 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 consumer purchased the product, back through its distribution chain to the establishment that was the source of the product. Having this information available will make it easier to determine where the contamination 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 the proposed rule, FSIS explained past efforts it has made to ensure that official establishments and retail stores that produce raw ground beef maintain necessary records. For example, the proposal explained that in 2002, FSIS published a **Federal Register** notice that listed the data that FSIS intended to collect when any samples of raw ground beef produced at an official establishment tested positive for *E. coli* O157:H7 (67 FR 62325, Oct. 7, 2002). FSIS also listed the information it intended to gather from retail stores at the time it collected a sample of raw ground beef for *E. coli* O157:H7 testing,

In the proposed rule in the present rulemaking, FSIS explained that shortly after issuing the 2002 **Federal Register** notice, the Agency began collecting the information listed in the **Federal Register** notice from official establishments and retail stores (79 FR 42465).<sup>1</sup> However, as the proposal explained, some retail stores and official establishments still did not maintain records sufficient for traceback, and some retail stores did not document or maintain supplier information at times other than when FSIS collected samples of ground raw beef product from the stores for *E. coli* O157:H7 testing.<sup>2</sup> As a result, FSIS was, and remains, disadvantaged in its foodborne disease investigations.

In 2009, FSIS provided guidance to a retail industry association, which was made available on the FSIS Web site, stating that retail stores should keep appropriate records to aid in investigations involving FSIS-regulated products associated with foodborne illnesses and other food safety incidents.

To further address the issue, on December 9–10, 2009, the Food and Drug Administration (FDA) and FSIS held a 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>3</sup> This meeting was followed on

<sup>1</sup> FSIS Notice 47–02, November 20, 2002, “FSIS Actions Concerning Suppliers that may be Associated with *Escherichia coli* (*E. coli*) O157:H7 Positive Raw Ground Beef Product.”

<sup>2</sup> On June 4, 2012, FSIS implemented routine verification testing for six Shiga toxin-producing *E. 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).

<sup>3</sup> Comments from this hearing are available at: <http://www.regulations.gov/#!searchResults:rpp=10;po=0;s=FDA-2009-N-0523;dc=PS>. A transcript of this meeting is

March 10, 2010, by an FSIS public meeting that discussed its procedures for identifying suppliers of source material used to produce raw beef product that FSIS found positive for *E. coli* O157:H7. FSIS sought input from meeting participants on ways to improve its procedures for identifying product that may be positive for *E. coli* O157:H7.

Despite these actions, as explained in the proposed rule, some official establishments and retail stores still did not keep and maintain the records necessary for effective investigation by FSIS. With this history in mind, FSIS conducted a retrospective review of 28 foodborne disease investigations from October 2007 through September 2011 in which beef products were ground or re-ground at retail stores.<sup>4</sup> When records were available and complete, enabling FSIS to identify specific production in an official establishment, the Agency was able to request a recall of product from the supplying establishment in six of eleven investigations. In contrast, when records were not available or incomplete, FSIS was able to request a product recall only two of seventeen times. These results confirmed FSIS's experience in specific cases where the presence of records at the retail level was often instrumental in identifying the source of an outbreak, as well as the implicated products that should be recalled. The proposed rule includes a fuller description of this review,

including specific examples (79 FR 42464).

Since the review in the proposed rule, FSIS has completed nine ground beef outbreak investigations. Of these nine investigations, grinding records were available and complete in four of them and incomplete or not available in five. When records were available and complete, FSIS was able to request a recall of product from the supplying establishment in one of four investigations. For the remaining three, two led to store level recalls. For these two, FSIS did not request recalls at supplier establishments because in one investigation, the trim for retail product had over ten suppliers, and in the other, FSIS was not able to narrow down the list of suppliers because the retailer did not clean up in between grinding different products. FSIS did not request a recall for the third case in which records were available and complete because there were multiple products and multiple federal establishments involved, and FSIS was not able to identify the product associated with the illnesses or the supplying establishment. In the five investigations where records were not available or incomplete, FSIS was unable to request a recall from a supplying establishment.

The investigations reviewed in the proposed rule, and those reviewed since the proposed rule, confirm the Agency's findings that the records kept by official establishments and retail stores vary in type and quality and are often incomplete or inaccurate. Overall, FSIS has concluded that voluntary recordkeeping by retail stores that grind raw beef has been insufficient, as evidenced by continuing outbreaks linked to pathogens in raw ground beef that FSIS cannot trace back to the source. The lack of specific information about supplier lot numbers, product codes, production dates, and the cleaning and sanitizing of grinding

equipment has prevented or delayed FSIS in identifying the source of outbreaks, as well as other product that might be adulterated. 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.

#### Proposed Rule

On July 22, 2014 (79 FR 42464), FSIS proposed to amend the Federal meat inspection regulations to require that all official establishments and retail stores that grind raw beef for sale keep records disclosing the following: The names, points of contact, phone numbers, and establishment numbers of suppliers of source materials used in the preparation of each lot of raw ground beef; the names of each source material, including any components carried over from one production lot to the next; the supplier lot numbers and production dates; the weight of each beef component used in each lot (in pounds); the date and time each lot was produced; and the date and time when grinding equipment and other related food-contact surfaces were cleaned and sanitized. FSIS also proposed that official establishments and retail stores would have to comply with these requirements with respect to raw beef products ground at an individual customer's request when new source materials are used.

FSIS posted the sample grinding log record below (Table 2) on its Web site in late 2011 and included it with the 2009 guidance and the proposed rule. FSIS proposed requiring the items in the sample record marked with asterisks. The proposed rule specifically stated that the information under the other column headings would not be required, but that some official establishments and retail stores might choose to keep and maintain this information.

available at: <http://www.regulations.gov/#!searchResults;rpp=10;po=0;s=FDA-2009-N-0523;dc=O>.

<sup>4</sup> Ihry, T., White, P., Green, A., and 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, June 4–6; Omaha, NE. A copy of this document is available at: <http://www.fsis.usda.gov/wps/wcm/connect/87caa3f9-0c76-45c7-be4e-84d73151ed9e/RD-2009-0011-072114.pdf?MOD=AJPERES>.

Table 2: Grinding log record that FSIS posted (2009)

<p><b>NEW WAVE STORE</b></p> <p>123 Main Street</p> <p>Anytown, USA, Zip Code</p> <p><b>FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST</b></p> <p>Employee Name _____ Today's Date _____</p>										
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
<p>_____ Signature of Store Management Reviewer</p> <p style="text-align: right;">_____ Date</p>										

\*Information that would have been required by the proposed rule.

**Final Rule**

As stated above, the final rule is mostly consistent with the proposed rule. It requires official establishments and retail stores that grind raw beef products to maintain the following records: The establishment numbers of the establishments supplying the material used to prepare each lot of raw ground beef; all supplier lot numbers and production dates; the names of the supplied materials, including beef components and any materials carried over from one production to the next; the date and time each lot is produced; and the date and time when grinding equipment and other related food-

contact surfaces are cleaned and sanitized. These requirements also apply to raw ground beef products that are prepared at an individual customer's request when new source materials are used. If new source materials are not used, there is no reason to record the customer-requested grind separately.

The final rule will not require records concerning the names, points of contact, and phone numbers of each official establishment supplying source material or the weight of each source component. In consideration of comments that it received, FSIS has concluded that the records concerning the names, points of contact, and phone numbers of each

official establishment supplying source material were unnecessary given that FSIS already possesses this information through the establishment profiles in PHIS. In addition, FSIS concluded, in response to the comments submitted, that weighing each component in a lot of ground beef was time-consuming and offered little food safety benefit. Contamination occurs in a lot of ground beef regardless of the weight of the contaminated component.

In conformance with these changes, FSIS has updated its sample grinding log as pictured in Table 3 below to reflect the requirements of this final rule.

Table 3: Sample Grinding log with final rule requirements.

<p><b>NEW WAVE STORE</b></p> <p>123 Main Street</p> <p>Anytown, USA, Zip Code</p> <p><b>FRESH GROUND BEEF PRODUCTION LOG/TRACKING LIST</b></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 <span style="float: right;">Date</span></p>					

The final rule also differs from the proposed rule with respect to the place of maintenance and the retention period of the required records. Based on 9 CFR 320.2, the proposed rule would have required records to be kept at the place



where the business, in this case the grinding activity, is conducted, unless the business is conducted at multiple locations, in which case the proposal would have allowed the records to be maintained at a business's headquarters office. In response to comments, FSIS has concluded that keeping the required information at the location where the beef is ground will save investigators time and reduce the risk that records are misplaced when they are moved. This rule, therefore, establishes a new 9 CFR 320.2(b), which requires that all the information required by this final rule be kept at the location where the beef is ground.

Based on 9 CFR 320.3(a), the proposed rule would have required that the proposed grinding records be retained for a period of two years after December 31 of the year in which the transaction giving rise to the record (grinding) occurred. In response to comments discussed below, FSIS concluded that because the vast majority of ground beef is consumed within several months of its production, a one-year retention period is adequate to trace the source of any foodborne disease outbreak involving raw ground beef. Accordingly, this final rule creates a 9 CFR 320.3(c) which requires that official establishments and retail stores covered by this rule retain the required records for one year.

The final rule also makes technical changes to 9 CFR 320.2 and 320.3 to improve readability.

### Summary of Comments and Responses

FSIS received 40 comments on the proposed rule from individuals, retailers, beef producers and processors, beef industry and retail trade groups, consumer advocacy groups, an organization representing food and drug officials, a State department of agricultural and rural development, a food technology company, and two members of Congress. Most of the commenters supported the proposed rule. Industry groups supported recording information for effective investigation in the event of a foodborne illness outbreak but stated that the costs of compliance were higher than estimated, and that several pieces of information were unnecessary or overly burdensome. A summary of the relevant issues raised by the commenters and the Agency's responses follows.

#### 1. Covered Entities

*Comment:* Consumer and retail trade groups stated that the rule should apply to supermarkets, grocery stores, meat markets, warehouse clubs, cooperatives,

supercenters, convenience stores, wholesalers, and restaurants.

*Response:* This final rule applies to all official establishments and retail stores that grind raw beef products for sale to consumers in normal retail quantities. The rule covers supermarkets and other grocery stores, meat markets, warehouse clubs, cooperatives, supercenters, convenience stores, and wholesalers, if they grind raw beef product.

FSIS is not applying this final rule to restaurants. Only a small percentage of all raw beef grinding occurs at restaurants and only on a very small scale. It is thus likely that any outbreak traced to a restaurant that grinds its own raw beef will be traceable to a specific supplier.

#### 2. Content of Records

*Comment:* Retail organizations, a food technology company, and a beef brand recommended reducing costs by removing from the proposed rule the requirement to weigh each source component. These commenters stated that the proposed requirement was time-consuming, disruptive to workflow, unfeasible with current equipment, and offered no public health benefit.

*Response:* FSIS agrees that the requirement to weigh each source component is not necessary. If a foodborne illness outbreak occurs, the weight of a source component in a lot of ground beef is not significant in tracing the material back to the suppliers. Also, any amount of adulterated source material in a lot of ground beef would adulterate the product. Accordingly, FSIS has removed this provision from the final rule and has adjusted the paperwork burden estimates and costs accordingly.

*Comment:* An independent grocers' trade group suggested removing the requirement to record supplier lot numbers and production dates.

*Response:* Supplier lot numbers and production dates are necessary to identify product at a supplier's location that may be associated with an outbreak. By including supplier lot numbers and production dates, investigators can more easily and quickly determine the source of a foodborne illness outbreak and limit the amount of product recalled.

*Comment:* Industry groups generally opposed recordkeeping for customer-requested grinds. They stated that it was impractical to clean grinding equipment between customer requests, meat case items usually lack supplier information, and public health benefits from logging these grinds would be limited. One meat industry trade group suggested only requiring the proposed recordkeeping provisions for customer-requested

grinds over thirty pounds. A retail trade group recommended that its members perform customer-requested grinds at the end of the day or during a clear production cycle break.

*Response:* Customer-requested grinds present the same food safety risk as other raw ground beef. Retailers should keep customer-requested grinds separate and must record the information required in this rule when new source materials are used for customer-requested grinds. It is also in the store's interest to perform a clean up before and after customer-requested grinds. If the source is not clear, or if there is no clean up, traceback to the supplier will be impossible. The retailer would have produced the product associated with the outbreak, and in such circumstances, FSIS will have to request that the retailer recall product. Also, if the source is not clear, FSIS will likely have to request that the retailer recall more product than would be necessary if the retailer had recorded the necessary information.

FSIS agrees that customer-requested grinds present unique challenges but estimates that the benefits of being able to rapidly identify a customer-grind associated with an outbreak outweigh the recordkeeping and clean-up costs.

*Comment:* Two food-safety non-profits, a grocery store chain, and a consumer group stated that the name of the retail product should be recorded to assist in identifying product subject to recall. One individual and a food-safety non-profit stated that retail products should include specific day or production lot codes to assist in tracing products back to specific grinding lots.

*Response:* FSIS does not believe that including retail product names on records listing source materials used to produce those products is practical. Products from different source materials may have the same name, e.g., 80/20 Ground Chuck. In addition, products from the same source materials may be marketed differently. For example, packages of "Bob's Ground Beef" and "Jan's Ground Beef" may originate from the same lot of source materials, despite bearing different retail names.

FSIS is also not requiring official establishments and retail stores to label retail products with timestamps or production lot codes to identify them with the specific lot or lots of ground beef from which they were produced. Retail ground beef products can usually be traced back to their specific grinding lots through stores' inventory data, the product's date and time of sale, and information stored on customers' shopper cards. Once a retail product is traced back to the grinding lot or lots,

the records required by this final rule will enable FSIS investigators to identify the source materials, suppliers, and production lots from which the product was produced.

*Comment:* Industry groups opposed recording the names, points of contact, and phone numbers of suppliers because FSIS already has this information through PHIS.

*Response:* FSIS agrees that the names, points of contact, and phone numbers of official establishments supplying source materials are already located in the establishment profiles within PHIS. Therefore, the establishment numbers of suppliers provide sufficient information to FSIS, and FSIS has removed those pieces of information from the recordkeeping requirements, leaving the requirement that official establishments and retail stores keep the establishment number of their suppliers of source materials. FSIS has updated its paperwork burden and costs estimates to reflect this change.

### 3. Use of Sample Grinding Log

*Comment:* A consumer group recommended that FSIS provide a sample grinding log containing all of the required information. A grocery store chain and retail trade group stated that grinders should be able to create their own logs, so long as all required information is included. A retail trade group questioned whether grinders would be required to use the sample log shown above.

*Response:* While FSIS has provided a sample grinding log that is depicted above, FSIS is not specifying in the final rule how official establishments and retail stores must record the required information. Entities may record the required information as they see fit, so long as the records of the required information are maintained in accordance with 9 CFR 320.2 and 320.3.

### 4. Imports

*Comment:* One individual stated that the proposed rule should apply to imported beef.

*Response:* FSIS' regulations do not apply directly to establishments in foreign countries, and retail stores in foreign countries are not eligible to export product to the United States. To be eligible to export raw beef product to the United States, countries must maintain an equivalent inspection system for beef. Therefore, in the event of *Salmonella* or shiga-toxin producing *E. coli* (STEC) outbreaks, countries that ship beef to the United States will need to have traceback and traceforward systems for beef products that allow the country to identify the source of

contamination. Countries that export beef to the United States may choose to establish recordkeeping requirements consistent with this rule. However, they may also have other means to track the necessary information.

### 5. Other Species

*Comment:* Individual commenters and food safety groups believed that the rule should apply to ground product produced from swine, poultry, lamb, and turkey.

*Response:* FSIS issued the proposed rule to address deficiencies in recordkeeping that hampered investigations into foodborne illness investigations involving raw ground beef. 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. FSIS did not propose that new records be maintained for ground products other than beef because the Agency is most often impeded in its efforts to trace back and identify sources of human illness when beef ground in retail stores is the vehicle for those illnesses. FSIS considers the comments requesting similar requirements for other ground product to be outside the scope of this rule.

### 6. Consumer Education

*Comment:* A meat processor, a meat products company, and two individuals stated that more outreach was needed to educate consumers on how to properly handle and cook meats.

*Response:* FSIS promotes consumer awareness of food safety issues and encourages proper food preparation practices. For example, FSIS posts consumer food safety information on its Web page.<sup>5</sup> The posted information includes the kind of bacteria that can be found in ground beef, specific information as to why the *E. coli* O157:H7 bacterium is of special concern in ground beef, and the best way to handle raw ground beef when shopping and when at home. This Web page also contains the *Food Safe Families Campaign* guidelines to keep food safe, which tells consumers to cook ground beef to a safe minimum internal temperature of 160 °F (71.1 °C) as measured with a food thermometer. FSIS also provides food safety education in other forms (e.g., FSIS has continued to work with the Ad Council to launch food safety public service announcements, and FSIS staff provide

<sup>5</sup> FSIS food safety guidance for meat preparation, available at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/meat-preparation>.

in-person food safety education through the mobile Food Safety Discovery Zone).

Nonetheless, recordkeeping by retail establishments will more quickly and efficiently address the concerns (i.e., traceback and identifying sources of human illness when beef ground in retail stores is the vehicle for those illnesses) raised in this final rule.

### 7. Supplier Process Control Actions

*Comment:* One individual urged official establishments to improve contamination control at slaughter. A meat products company that did not support the rule believed that suppliers cannot control *E. coli*, but that the answer is not more recordkeeping because that does not address the core problem, which is the interdependent relationship between animals and *E. coli*.

*Response:* FSIS is continuing to address process control actions that should be taken by beef suppliers to control *E. coli*. For example, FSIS made available updated guidance on testing and high event periods<sup>6</sup> in 2013 and implemented new traceback activities in 2014.<sup>7</sup> However, while better process control may reduce the incidence of *E. coli* O157:H7-adulterated ground beef, it will not address the issue of official establishments and retail stores not keeping adequate records that allow effective traceback and traceforward activities. Without the records required by this final rule, FSIS cannot conduct timely and effective consumer foodborne illness investigations and other public health activities through the stream of commerce.

### 8. Implementation

*Comment:* An independent grocers' trade group recommended a two-year delayed effective date for small businesses to comply with the rule. Alternatively, the commenter stated that small businesses should be exempt from the rule's requirements altogether. Similarly, a retail trade group believed that small retailers would need more time for outreach and training and that implementation would take longer than anticipated by the proposed rule

<sup>6</sup> Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing *Escherichia coli* (STEC) Organisms or Virulence Markers, available at: <http://www.fsis.usda.gov/wps/wcm/connect/e0f06d97-9026-4e1e-a0c2-1ac60b836fa6/Compliance-Guide-Est-Sampling-STEC.pdf?MOD=AJPERES>.

<sup>7</sup> FSIS Directive 10,010.3, Traceback Methodology for *Escherichia coli* (*E. coli*) O157:H7 in Raw Ground Beef Products and Bench Trim, available at: <http://www.fsis.usda.gov/wps/wcm/connect/ae5e81d0-c636-4de1-93f3-7a30d142ae69/10010.3.pdf?MOD=AJPERES>.

because of the need to create or modify records forms.

*Response:* FSIS has provided sample grinding logs in this rule and the proposed rule. Small businesses may use these logs, or any other recordkeeping system they wish, to record the required information. FSIS believes that the recordkeeping requirements are straightforward and do not require extensive training or guidance materials. FSIS has also not adopted the proposed requirements that grinders record and maintain records of the weight of each source material used in a grinding lot, and the names, points of contact, and phone numbers of each official establishment supplying source material.

In addition, as is discussed above, FSIS has advised official establishments and retailers to maintain these types of records since 2002. Nonetheless, in response to comments, this final rule provides that retailers and official establishments will have 180 days from the date of publication of this final rule to comply with its requirements. This effective date should provide industry sufficient time to comply with the requirements because FSIS has simplified the requirements originally proposed, and FSIS will ensure that establishments and retailers are aware of the new requirements through the outreach activities discussed below and through partnering with the States and other organizations, such as retail organizations.

### 9. Training

*Comment:* One consumer group recommended face-to-face contact by FSIS with entities that grind raw beef to explain the rule's requirements. A beef producers' trade group encouraged FSIS to conduct outreach through webinars and by attending industry meetings. One individual stated that operators should be trained to understand the risks of *E. coli* in grinding. Another individual suggested more training on keeping logs, proper attire, and hand-washing. A State agriculture department believed it would incur costs associated with responding to questions from grinders and training State personnel to field such questions appropriately.

*Response:* As noted above, the recordkeeping requirements in the final rule are straightforward and do not require extensive training or guidance materials. FSIS will update its Sanitation Guidance for Beef Grinders,<sup>8</sup> which includes sample grinding logs and instructions, and will hold

webinars to explain the requirements of this final rule and answer questions from official establishments, retailers, and other organizations. FSIS will also provide guidance to small businesses through its Small Plant Help Desk and *Small Plant News* newsletter, and at industry conferences, exhibitions and workshops.

### 10. Retention and Maintenance of Records

*Comment:* A food-safety non-profit organization suggested that records required under this rule be retained for at least ninety days. A grocery store chain believed six-to-twelve months would be adequate. A retail trade group believed six months was appropriate. The latter two commenters mentioned that frozen beef should be consumed within three to four months.

*Response:* While ground beef is safe indefinitely if kept frozen, it will lose quality over time. FSIS recommends consuming fresh ground beef within two days and frozen ground beef within four months.<sup>9</sup> These recommendations suggest that records documenting the grinding of raw beef need only be kept for a short period of time. However, the Agency is aware that consumers do not always follow such recommendations, sometimes keeping ground beef in their freezers for up to a year, for example. FSIS is therefore requiring in the final rule that official establishments and retailers maintain the prescribed records for one year (9 CFR 320.3).

*Comment:* A trade group representing food safety officials stated that records should always be maintained at the location where the beef was ground.

*Response:* This final rule amends 9 CFR 320.2 to require that official establishments and retail stores maintain the required records at the place where the raw beef is ground. This approach, along with the shorter record retention period being required in 9 CFR 320.3, balances the burden on retailers of storing records for the necessary period of time with the needs of investigators to have such records available at the grinding location.

### 11. Enforcement

*Comment:* Three individuals stated that FSIS should assess additional fines or penalties to enforce the final rule's requirements. A consumer group recommended FSIS perform verification checks at retailers to monitor compliance. A trade group representing

food safety officials asked how FSIS would enforce the rule and urged FSIS to work more cooperatively with State and local food safety agencies. The commenter also recommended that local officials have access to the new records, as they are often involved at the earliest stages of an outbreak.

*Response:* The FMIA provides FSIS with authority to require specified persons, firms, and corporations to keep records that will fully and correctly disclose all transactions involved in their businesses subject to the FMIA and to provide access to facilities, inventory, and records (21 U.S.C. 642). If official establishments do not maintain the required records, FSIS will issue noncompliance records. FSIS may also take any regulatory control actions as defined in 9 CFR 500.1(a), including the tagging of product, equipment, or areas.

FSIS personnel conduct in-commerce surveillance related to wholesomeness, adulteration, misbranding, sanitation, and recordkeeping.<sup>10</sup> When this rule becomes final, FSIS compliance investigators will verify that retail grinders meet the recordkeeping requirements. If compliance investigators find they do not, they may issue a Notice of Warning to the retail store.

If FSIS personnel find noncompliance at an official establishment, the Agency could issue non-compliance reports, letters of warning, or request the Department of Justice to initiate a civil proceeding in Federal court to enjoin the defendant from further violations of the applicable laws and regulations. If FSIS personnel find noncompliance at a retail facility, the Agency may issue notices of warning or request the Department of Justice to initiate a civil proceeding to enjoin the defendant from further violations of the applicable laws and regulations.

States with their own meat and poultry inspection (MPI) programs will need to be aware of the requirements of this rule and are required to enforce requirements "at least equal to" the Federal inspection program. Therefore, they will need to require that establishments under State inspection maintain records consistent with what FSIS is requiring.

FSIS will also explore ways to partner with States, with or without MPI programs, so that State employees can provide information about the recordkeeping requirements to grocery stores, help them to keep logs in the most efficient and effective way

<sup>8</sup> Available at: [http://www.fsis.usda.gov/shared/PDF/Sanitation\\_Guidance\\_Beef\\_Grinders.pdf](http://www.fsis.usda.gov/shared/PDF/Sanitation_Guidance_Beef_Grinders.pdf).

<sup>9</sup> FSIS Ground Beef and Food Safety, available at: [http://www.fsis.usda.gov/wps/portal/portal/food-safety-education/get-answers/food-safety-factsheets/meat-preparation/ground-beef-and-food-safety/CT\\_Index](http://www.fsis.usda.gov/wps/portal/portal/food-safety-education/get-answers/food-safety-factsheets/meat-preparation/ground-beef-and-food-safety/CT_Index).

<sup>10</sup> FSIS Directive 8080.1, Rev. 4, *Methodology for Conducting In-Commerce Surveillance Activities*, April 24, 2014.

possible, and provide other information that will enhance the efficiency and effectiveness of store efforts. FSIS intends to provide information to State officials about the grinding logs requirement during regular monthly Webinars that FSIS conducts for State MPI Directors and State HACCP Contacts and Coordinators.

FSIS also routinely cooperates with State and local authorities to conduct effective foodborne illness investigations, including by sharing epidemiological data, records, and investigative resources. FSIS intends to provide information to State and local authorities during the course of these illness investigations about the role that grinding logs can play in facilitating these investigations.

#### 12. Grinding Frequency and Time Burden

*Comment:* To reduce costs, a grocers' trade group stated that FSIS should require records only for all source materials used in grinds during a single production day, requiring a new log for production that would begin only after the end-of-day full cleaning of the grinding equipment. Several commenters also stated that many retail stores grind several times per day and may use several different suppliers, significantly increasing recordkeeping costs.

*Response:* In the proposed rule, FSIS considered requiring documentation of information on a weekly basis, but rejected this approach because it would be difficult to differentiate between lots ground from different suppliers throughout the week (79 FR 42469). The same holds true for daily logs. In either situation, investigators would be unable to effectively conduct traceback and traceforward activities in the event of an outbreak because of limited detail. FSIS is not dictating how often the required information must be physically recorded. Under the final rule, the required information must be recorded whenever any of the information required for the lot of product being ground changes. For example, if an entity uses the same source material for multiple grinds throughout the day, it would only need to record the source material information (9 CFR 320.1(b)(4)(i)(A)–(C)) once but would need to record the date and time of each grind (9 CFR 320.1(b)(4)(i)(D)). However, if a store or establishment were to start using a different supplier or lot number during the day, it would need to document that change (9 CFR 320.1(b)(4)(i)(B)). This approach minimizes the recordkeeping burden

but preserves the information needed by investigators.

*Comment:* A grocery store chain disagreed with FSIS's estimates of grinds per day and average number of suppliers at retail, suggesting that beef is ground every day, several times per day as needed, and with several different cases of raw material. A retail trade group estimated more average grinds at retail per day than FSIS's estimate, stating that its average member grinds four times per day. A State agriculture department and a beef producers' trade group urged further study of the economic impact of the rule on small businesses, including feedback from industry. A retail trade group estimated that the time needed for the proposed recordkeeping is much higher per respondent per year than estimated by FSIS, suggesting that a conservative estimate would be 214 hours per year.

*Response:* FSIS has taken into account comments on the amount of time required for recordkeeping and made adjustments to its cost estimate. For the final estimates, FSIS adjusted the average number of recordkeeping tasks per day at official establishments and retail stores from one to a range of four-to-five-and-a-half, plus an additional task if an entity conducts a grind composed of only trim. FSIS also adjusted the assumed time required to complete a record at official establishments and retail stores to account for multiple source materials, from 30-to-90 seconds to one minute for grinds not including trim, two minutes for grinds including trim and other ground beef components, and six-to-ten minutes for trim-only grinds. Trim-only grinds are usually composed of trim from different suppliers and production lots. Therefore, more time is needed to document the required information as compared to other grinding activities. In updating these estimates, FSIS has taken into account, in addition to the comments, the changes in the final rule concerning required records. Specifically, FSIS is using the low end of time estimates from the comments because, for the final rule, FSIS has significantly reduced the information required to be kept compared to the proposed rule.

#### 13. Waste

*Comment:* Two individuals and an independent grocers' trade group stated that retailers would simply throw out bench trim to avoid the recordkeeping requirements.

*Response:* In its proposed rule, FSIS considered a 2008 study that found that recording grinding information is already prevalent among official

establishments and retail stores that grind raw beef. The 2008 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 that 78 percent of those logs were incomplete (79 FR 42471). Although insufficient voluntary recording is one impetus for this rule, FSIS is not aware of any instance when official establishments and retail stores that were keeping necessary records discarded source material in lieu of recording necessary records. Therefore, FSIS concludes that the costs of recordkeeping will rarely be greater than the costs of discarding bench trim, and that the amount of product discarded as a result of the rule should be negligible.

#### 14. Effect on Small Businesses

*Comment:* An independent grocers' trade group stated that the proposed rule would have a significant economic impact on a substantial number of small entities, and, therefore, FSIS must conduct an initial regulatory flexibility analysis.

*Response:* While the rule will affect a substantial number of small businesses, the cost of complying with the proposed regulations will be relatively small on a per firm basis. FSIS has provided guidance and a sample grinding log, which FSIS will update as appropriate. Similar guidance is available from other providers, including industry associations.<sup>11</sup> Entities can use these materials to minimize the costs of their recordkeeping programs. In addition, as is discussed above, FSIS will hold webinars to provide small businesses additional information on the rule and will publish information through its Small Plant Help Desk and *Small Plant News* newsletter. The fact that a number of small firms already maintain adequate grinding records suggests that the cost of the practice is not prohibitive to doing business.

#### 15. Definition of a Lot of Ground Beef

*Comment:* A beef industry trade group commented that some ground beef producers have different definitions for "lots" or "batches" of ground beef.

<sup>11</sup> Food Marketing Institute, Comprehensive Guide Meat Ground at Retail Recordkeeping and Sanitation, available at: <http://www.fmi.org/docs/default-source/food-safety-best-practice-guides/meat-ground-at-retail-comprehensive-guide.pdf?sfvrsn=6>. Conference for Food Protection, Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments, available at: <http://www.foodprotect.org/media/guide/CFP%20Beef%20Grinding%20Log%20Template%20Guidance%20Document%20-%208-2014.pdf>.

*Response:* FSIS did not propose a definition for a “lot” of ground beef in the proposed rule. In response to this comment, and for the sake of consistency in implementing this final rule, FSIS has added a new 9 CFR 320.1(b)(4)(iii), which defines a lot.

### Implementation

All retailers and official establishments will have 180 days from the date of publication of this final rule to comply with its requirements.

As is discussed above, this rule does not prescribe the method by which official establishments and retail stores must keep the required information but does require that the information be kept at the location where the beef is ground. The records must be retained for one year after the transaction giving rise to the record (grinding) occurred. FSIS will update its Sanitation Guidance for Beef Grinders,<sup>12</sup> which currently includes sample grinding logs and instructions, and hold webinars to explain the requirements of the final rule and answer questions from official establishments, retailers, and other organizations. FSIS will also provide information to small businesses through its Small Plant Help Desk and *Small Plant News* newsletter. FSIS will provide guidance to State MPI programs on the requirements of this rule and seek to partner with States to ensure that the requirements of this rule are communicated to official establishments inspected by State MPI programs and to retail stores that grind raw beef. FSIS will also work with States and universities around the nation to conduct outreach workshops targeted to retailers and official establishments to explain the requirements of the rule. Records of the required information must be made available to authorized USDA officials upon request (9 CFR 300.6(a)(2)). These officials may examine and copy such records (9 CFR 320.4). At official establishments, FSIS inspection personnel will verify compliance. As is discussed above, if FSIS personnel find noncompliance at an official establishment, the Agency could issue non-compliance reports, letters of warning, or request the Department of Justice to initiate a civil proceeding in Federal court to enjoin the defendant from further violations of the applicable laws and regulations. At retail stores, FSIS compliance investigators will verify that retail grinders meet the recordkeeping requirements. If compliance investigators find they do not, the

Agency may issue notices of warning or request the Department of Justice to initiate a civil proceeding to enjoin the defendant from further violations of the applicable laws and regulations.

### 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 “non-significant regulatory action” under section 3(f) of Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget.

In updating the preliminary regulatory impact analysis of the proposed rule, FSIS has made several changes in response to public comments and newly available information. Specifically, FSIS has made the following changes in the final regulatory impact analysis:

- Increased the number of retail firms in the baseline using new U.S. Census Bureau data;
- Added assumptions about the percentage of retail firms that grind raw beef;
- Incorporated new distributions relating to source materials used to reflect the complexity of grinding operations;
- Adjusted the time estimates for recordkeeping activities, the frequency of recordkeeping tasks, and the number of active grinding days per week based on comments received;
- Added estimates of labor to incorporate recordkeeping for grinds, including pieces of trim and customer-requested grinds;
- Updated the wage rate and benefits factor for firm employees that record or maintain required records based on the newest available information;
- Added discussion about unquantified costs associated with maintaining records for customer-requested grinds; and
- Expanded the benefits discussion to include benefits not previously addressed, such as the mitigation of costly spillover effects from foodborne illness outbreaks, and the incentive traceability provides to produce safe product.

### Need for the Rule

During investigations of foodborne illness outbreaks attributed to ground beef, grinding records are an important part of the traceback and traceforward processes. Without accurate records, it is difficult to identify where ground beef components originated. If investigators cannot identify a source, it is likely that adulterated product will remain in commerce and more consumers will eat the product and become ill. Delays in identifying the source of contamination can also negatively affect sales of ground beef due to loss in consumer confidence. Despite efforts by FSIS, industry associations, and other regulators to provide retailers and official processing establishments with guidance and examples of best practices, the current level of recordkeeping is still less than what is needed for timely and accurate traceability investigations.

Traceability systems are a potential way to lessen the costs of foodborne illness outbreaks and other food safety events. In the case of private regulation, each firm will ultimately decide what level of traceability to implement on the basis of costs and potential benefits, such as smaller losses of reputation and reduced liability costs during foodborne illness outbreaks.<sup>13</sup> Some firms may decide not to invest at all. Insufficient traceability, however, is not optimal for the industry as a whole.<sup>14</sup> In some cases industry associations and third parties can influence firms to adopt traceability measures, but in the case of grinding records, these efforts have not achieved an acceptable level.<sup>15</sup>

Forms of private regulation, such as those currently in place for raw beef grinding entities, are vulnerable to firms that do not invest their fair share to the detriment of others, commonly referred to as the “free rider” problem.<sup>16</sup> In the event of a foodborne illness outbreak

<sup>13</sup> Hobbs, Jill E., (2004) “Information Asymmetry and the Role of Traceability Systems,” *Agribusiness*, Vol. 20 (4), 397–415, available at: <http://onlinelibrary.wiley.com/doi/10.1002/agr.20020/pdf>.

<sup>14</sup> McEvoy, David M. and Souza-Monteiro, Diogo M., (2008) “Can an Industry Voluntary Agreement on Food Traceability Minimize the Cost of Food Safety Incidents?” *12th Congress of the European Association of Agricultural Economists*, Gent, Belgium, July 26–29, available at: <http://ageconsearch.umn.edu/bitstream/43860/2/397.pdf>.

<sup>15</sup> Gould, Hannah L. et al. (2011) “Recordkeeping Practices of Beef Grinding Activities at Retail Establishments,” *Journal of Food Protection*, Vol. 74 (6), 1022–1024, available at: <http://www.ncbi.nlm.nih.gov/pubmed/21669085>.

<sup>16</sup> Havinga, Tetty, (2006) “Private Regulation of Food Safety by Supermarkets,” *Law and Policy*, Vol. 28 (4), 515–533, available at: <http://www.ru.nl/publish/pages/552245/havingasupermarketslapo2006.pdf>.

<sup>12</sup> Available at: [http://www.fsis.usda.gov/shared/PDF/Sanitation\\_Guidance\\_Beef\\_Grinders.pdf](http://www.fsis.usda.gov/shared/PDF/Sanitation_Guidance_Beef_Grinders.pdf).

attributed to ground beef, if traceback is conducted at an entity that maintains adequate records, there is a strong chance that the source of contamination will be identified. When this happens, losses in reputation, consumer confidence, and sales are generally limited to the firm supplying the adulterated product. Other firms, such as the retailers (both those that invest in traceability and those that do not), are to some degree insulated from negative spillover effects. In this case, free-rider firms—those that do not invest in traceability—benefit from the investments of others.

If, however, traceback occurs at a firm that does not invest in recordkeeping, the chances of investigators successfully tracing adulterated product to its source are low. An illness outbreak attributed to ground beef in which the source is unidentified will negatively affect ground beef producers and retailers indiscriminately. In this case, firms that have invested in traceability will bear costs that could have been avoided were it not for the free-rider firm. Mandatory recordkeeping requirements will help to eliminate insufficient traceability systems and therefore mitigate the free rider problem.

Inadequate traceability systems can also contribute to moral hazard, which, in the case of ground beef, is a lack of incentives to produce a safe product.<sup>17</sup> Producers of ground beef components endeavor to produce safe product because the consequences of producing unsafe product are great. However, if adulterated ground beef is often unable to be traced back to its source, producers face less risk when the components they produce are unsafe.

Mandatory recordkeeping requirements can help to reduce moral hazard by increasing the chances that adulterated product is traced back to its source, thereby strengthening the incentives for fabricators of ground beef components to supply the safest product that they can produce.

**Industry Baseline**

FSIS has identified four groups of businesses that will be subject to the final rule.

1. Official, federally-inspected establishments that grind beef: FSIS used information from PHIS to determine the number of federally inspected establishments subject to FSIS sampling of ground beef product for *E. coli* O157:H7 and *Salmonella* in the past calendar year (2014). To ensure that only those establishments that receive ground beef components from a supplier are included in the total, FSIS excluded those establishments that also slaughtered beef in the past calendar year.<sup>18</sup> Using the Hazard Analysis and Critical Control Point (HACCP) size categories available in PHIS, FSIS determined that there are 12 large establishments and 1,132 small (including HACCP size small and HACCP size very small) establishments that fall into this category.

2. Supermarkets and other grocery stores that grind beef: FSIS used data from the U.S. Census Bureau to determine the number of grocery stores in the U.S. Specifically, FSIS used the 2012 Statistics of U.S. Business (SUSB) data set<sup>19</sup> to determine the number of stores under the North American Industry Classification System (NAICS) code 445110—Supermarkets and Other

Grocery (except Convenience) Stores. FSIS found that there are 21,543 stores owned by large firms (≥500 employed), and 44,504 stores owned by small firms (<500 employed). FSIS is aware that not all supermarkets and grocery stores grind beef in store. However, for the purposes of the cost estimate, FSIS assumed that 100 percent of supermarkets and grocery stores grind beef. While this results in a minor overestimate, FSIS lacks the data needed to support a different assumption.

3. Meat markets that grind beef: FSIS used the 2012 SUSB Census data to determine the number of stores under the NAICS code 445210—Meat Markets. FSIS found that there are 123 stores owned by large firms, and 5,105 stores owned by small firms. The NAICS code for meat markets includes six subcategories, three of which do not grind beef, including Baked Ham Stores, Frozen Meat Stores, and Poultry Dealers. To account for these stores, FSIS assumed that 50 percent of large stores and 50 percent of small stores in this category grind beef.

4. Warehouse clubs and supercenters that grind beef: FSIS used the 2012 SUSB Census data to determine the number of stores under the NAICS code 452910—Warehouse Clubs and Supercenters. FSIS determined that there are 5,124 such stores owned by large firms, and 40 stores owned by small firms. FSIS is aware that not all warehouse clubs and supercenters grind beef in store. To account for this, FSIS assumed that 20 percent of large stores and 100 percent of small stores grind beef.<sup>20</sup>

TABLE 4—ENTITIES THAT GRIND RAW BEEF

Entity type Establishment type	Total entities		Percent grinding		Entities grinding	
	Large	Small	Large	Small	Large	Small
Official Establishments .....	12	1,132	100	100	12	1,132
Supermarkets and Other Grocery Stores	21,543	44,504	100	100	21,543	44,504
Meat Markets .....	123	5,105	50	50	62	2,553
Warehouse Clubs and Supercenters .....	5,124	40	20	100	1,025	40
Total .....	26,802	50,781	.....	.....	22,641	48,229

Values in Table may not sum to totals because of rounding.

<sup>17</sup> Starbird, S. A., Amanor-Boadu, V., and Roberts, T. (2008) "Traceability, Moral Hazard, and Food Safety," *12th Congress of the European Association of Agricultural Economists*, available at: [http://ageconsearch.umn.edu/bitstream/43840/2/EAAE\\_0398.pdf](http://ageconsearch.umn.edu/bitstream/43840/2/EAAE_0398.pdf).

<sup>18</sup> If an official establishment slaughters beef, then it is likely the only source of components for its own ground beef production, and therefore it would

not need to keep records pertaining to suppliers. While it is possible that some official establishments both slaughter beef and receive components from other official establishments for grinding, the number of such establishments is likely very small.

<sup>19</sup> U.S. Census Bureau, (2012), *Statistics of U.S. Businesses*, accessed January 28, 2015, available at: <http://www.census.gov/econ/susb/>.

<sup>20</sup> FSIS was able to determine that the majority of large stores in this category do not grind beef in store because two large firms which account for approximately 80 percent of supercenters have ceased this practice. These firms purchase beef pre-ground and pre-packaged from federally inspected establishments or have it shipped from one of their other branded chains.

To estimate the number of entities that are already maintaining adequate records, FSIS used a Centers for Disease Control and Prevention (CDC) study of ground beef recordkeeping practices at retail stores and applied the distributions in the study to the entities 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>21</sup> For the purposes of this estimate, FSIS used the chain stores surveyed in the study as a proxy for large retailers and official establishments, and the independent stores as a proxy for small retailers and official establishments. Therefore, the recordkeeping distribution of large entities 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 entities, 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 applied these distributions to the set of all grinding entities in Table 4, above. The current recordkeeping practices of beef grinding entities are displayed in Table 5.

TABLE 5—BASELINE RECORDKEEPING PRACTICES AT ENTITIES THAT GRIND RAW BEEF

Entity size	Recordkeeping	Distribution (percent)	Entities
Large .....	Complete .....	16	3,686
	Incomplete .....	58	13,069
	No Records .....	26	5,887
	Total .....		22,641
Small .....	Complete .....	3	1,273
	Incomplete .....	9	4,514
	No Records .....	88	42,441
	Total .....		48,229

Values in table may not sum to Totals because of rounding.

**Alternative Regulatory Approaches**

FSIS considered a number of alternatives designed to achieve the regulatory objective outlined in the Need for the Rule section. The final rule was chosen as the least burdensome, technically acceptable regulatory approach to ensure that adequate grinding records are maintained for the purposes of outbreak investigation and product trace back. While some alternatives would result in lesser costs to industry, and some alternatives would result in more complete information for outbreak investigators, in FSIS’s judgment the final rule is the alternative that maximizes net benefits. Cost estimates were developed for the final rule but not for the rejected alternatives because the costs for these alternatives are discernibly higher or lower because of the amount of time spent on recordkeeping.

**Alternatives Considered**

(1) Encouraging rather than requiring grinding records: FSIS provided industry voluntary guidelines (see Table 2) in 2009. As stated previously, the Agency has concluded that a policy of voluntary guidelines for recordkeeping has not ensured that all official establishments and retail stores maintain complete records that will ensure quick identification of contaminated product.

(2) Regulated Daily Recordkeeping Program: FSIS considered requiring that retail stores and official establishments maintain grinding records such that each producer recorded grinding activities once per day, and information on all suppliers that were used during that day but not on when during the day those suppliers were used. Daily recording may have been sufficient if entities typically cleaned their equipment once a day, rarely changed suppliers, and conducted few grinds per day, but FSIS has found that the majority of retailers grind product and clean their equipment multiple times per day. A single daily recordkeeping task is, therefore, insufficient to provide the necessary information for traceback and could inhibit FSIS’s ability to identify suppliers during ongoing outbreaks. In addition, the time savings of daily recordkeeping over per-grind recordkeeping is likely low since most of the same information will need to be kept. Therefore, FSIS rejected this alternative.

(3) The Final Rule: The chosen alternative requires that retail stores and official establishments maintain grinding records such that each producer must record the required information whenever any of the required information for the lot of product being ground changes. To minimize the burden placed on these entities, FSIS has removed certain

pieces of information from the requirements that were included in the proposed rule, ensuring that only the necessary information for traceability is maintained. Requiring records that pertain to each individual grind guarantees that investigators will be able to identify the components included in an adulterated package of ground beef, creating a narrower list of potential sources of adulterated product and increasing the chances that the source of contamination is identified. FSIS has determined that this alternative is the least burdensome option that achieves the regulatory objective.

(4) More Detailed Recordkeeping Program: FSIS also considered expanding the proposed recordkeeping requirements to include all fields suggested in the 2009 FSIS guidance (all fields in the Table 2 sample log). This approach would provide FSIS with more detailed records to use during an investigation, which may improve traceability slightly. However, the small improvement in the trace back process provided by the additional level of detail would place an unnecessarily large burden on those entities that grind product and must keep records. Any such small improvement would not outweigh the costs incurred for keeping the more detailed records. For this reason, FSIS decided to require that only the most critical information be recorded. Other information, including

<sup>21</sup> See footnote 3.

that which appears on the sample log, is voluntary.

The costs and benefits of the final rule and each regulatory alternative are displayed in Table 6.

TABLE 6—REGULATORY ALTERNATIVES CONSIDERED

Alternative	Costs	Benefits
(1) Encouraging Voluntary Recordkeeping.	No additional costs .....	No additional benefits.
(2) Regulated Daily Record-keeping.	Slightly less costly alternative to industry due to small time savings over per-grind recordkeeping.	Improvement over voluntary recordkeeping because records are required and must be created every day of grinding, but the records will in most cases not be detailed enough to facilitate traceability. Therefore, any benefits that can realistically be expected will be minimal, and the objective of facilitating traceability will not be met.
(3) The Final Rule .....	\$59.3 million (\$48.5 million to \$70.2 million) annual costs to the industry, plus additional costs associated with recording the source of trim and customer-requested grind components. Potential slight costs to consumers.	Achievement of regulatory objective resulting in benefits to consumers in the form of averted foodborne illness, to retailers and official establishments grinding components from suppliers in the form of less costly outbreaks and recalls, and to official establishments supplying ground beef components in the form of less costly recalls and insulation from costly spillover effects during food safety events.
(4) More Detailed Record-keeping.	Most costly alternative to industry .....	Achievement of regulatory objective resulting in the benefits described above. Potential for small increase in traceback speed and therefore small increase in avoided illnesses.

**Expected Costs of the Final Rule**

*Costs to Industry*

Retailers and official establishments that grind raw beef will incur costs to comply with the final rule. These include the labor cost of employees who record and maintain the records, storage costs, and those costs associated with trim and customer-requested grinds. FSIS has attempted to estimate the cost of labor and storage using information obtained from industry associations, the U.S. Census Bureau, the U.S. Bureau of Labor Statistics, a commercial real estate services firm report, and public comments.

In order to keep adequate records when grinding trim, entities will need to keep track of the source of each cut of beef from which the trim was separated. If not all of the trim is ground in a single batch, then entities will need to record each lot in which the trim is used. Similarly, if retail stores grind beef at the request of customers, they will need to record the required information for that small grind if new source materials are used. How entities choose to deal with the requirements will differ, and the costs associated with these requirements will vary greatly because of differences in firm size, component ordering practices, and grinding practices. FSIS used labor-time estimates from a grocery store chain’s public comments to estimate additional costs related to grinding trim. FSIS left additional costs related to customer requested grinds unquantified because

of the many variations in how retail stores will deal with the requirements and the relatively small number of customer grinds that take place.

Entities may incur other costs for training and investment should they choose to implement complex recordkeeping systems. Electronic recordkeeping options exist, which are likely more expensive than paper records but provide additional benefits such as improved accuracy, lower labor requirements, useful reporting and recall management tools, and supply-side management functions. Firms will decide individually whether these systems are suitable to their needs, and the proportion of those choosing more complex systems is uncertain. For the purposes of the cost estimate, FSIS has only estimated costs and benefits of the basic, paper-based system of recordkeeping. FSIS assumes that if firms choose to invest more in their recordkeeping systems, they will do so because the benefits achieved outweigh the costs.

Model records are available in the preamble of this final rule, on the FSIS Web site,<sup>22</sup> and on the Web sites of industry associations. Best practices and guidance for beef grinders are also available from a number of sources.<sup>23</sup>

<sup>22</sup> FSIS, (2012) Sanitation Guidance for Beef Grinders, available at: [http://www.fsis.usda.gov/wps/wcm/connect/b002d979-1e1e-487e-ac0b-f91ebd301121/Sanitation\\_Guidance\\_Beef\\_Grinders.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/b002d979-1e1e-487e-ac0b-f91ebd301121/Sanitation_Guidance_Beef_Grinders.pdf?MOD=AJPERES).

<sup>23</sup> Food Marketing Institute, (2013) “Comprehensive Guide Meat Ground at Retail

Therefore, FSIS does not anticipate that entities will incur significant costs for the development of records and standard operating procedures. FSIS also believes that training for recordkeeping can be done informally, on the job, and will therefore result in minimal costs. Also, as noted above, FSIS will conduct webinars and provide guidance to help inform industry of the new requirements, which will help minimize training costs.

To estimate the labor costs associated with recordkeeping, FSIS divided the entities keeping no records and incomplete records into categories based on three basic types of grinding activities:

1. No trim—grinds in which no trim is used, only chubs of ground beef;
2. With trim—grinds in which trim is added to chubs of ground beef; and
3. Trim-only—grinds consisting only of trim.

Using distributions from the CDC recordkeeping study, FSIS was able to estimate the number of official establishments and retail stores that do not use trim in their grinds (no trim), that use trim in their grinds (with trim), and that use no trim in some grinds and

Recordkeeping and Sanitation,” accessed February 12, 2015, available at: <http://www.fmi.org/docs/default-source/food-safety-best-practice-guides/meat-ground-at-retail-comprehensive-guide.pdf?sfvrsn=6>. Beef Industry Food Safety Council, (2005) “Best Practices For Retailer Operations Producing Raw Ground Beef,” accessed February 12, 2015, available at: <https://www.bifsc.org/CMDocs/BIFSCO/Best%20Practices/bestpracticesforretail4-05.pdf>.



only trim in others (trim-only). While there are likely other combinations of practices, and not all entities will fall

into the three defined categories, these categories are sufficient for the purposes

of the cost estimate. The categorization of entities is displayed in Table 7.

TABLE 7—ENTITIES CATEGORIZED BY TYPES OF GRINDING PERFORMED

Size	Recordkeeping	Entities	Trim or no trim	Trim practices	Entities
Large ...	Incomplete .....	13,069	Using Trim (91%) .....	Trim-Only (90%) .....	10,703
			No Trim (9%) .....	With Trim (10%) .....	1,189
	No Records .....	5,887	Using Trim (91%) .....	Trim-Only (90%) .....	4,821
			No Trim (9%) .....	With Trim (10%) .....	536
Small ....	Incomplete .....	4,514	Using Trim (61%) .....	Trim-Only (52%) .....	1,432
			No Trim (39%) .....	With Trim (48%) .....	1,322
	No Records .....	42,441	Using Trim (61%) .....	Trim-Only (52%) .....	13,462
			No Trim (39%) .....	With Trim (48%) .....	12,427
				16,552	

Values in table may not sum to Totals because of rounding.

FSIS assigned time estimates for each of the three types of grinds based on public comments. For no trim grinds, FSIS assumed that recordkeeping would take approximately 1 minute per grind.<sup>24</sup> For with trim grinds, FSIS assumed that the number of components would approximately double, and therefore recordkeeping would take about 2 minutes. For trim-only grinds, FSIS assumed that recordkeeping would vary depending on the number of sources and take approximately 6 to 10 minutes per grind.<sup>25</sup> If an entity is keeping complete records, FSIS assumed that it would not incur any additional costs; if an entity is keeping no records, it would incur costs associated with the full labor time estimate, and if an establishment is keeping incomplete records, FSIS assumed it would incur costs associated with half of the labor time estimate.

FSIS also relied on public comments to estimate the number of grinding activities completed per day. FSIS consequently estimated that the average entity grinds 4 to 5.5 times per day,<sup>26</sup> with the exception of those that do trim-only grinding. For those entities, FSIS estimated that they would complete no

trim grinds 4 to 5.5 times per day and then perform an additional trim-only grind (for a total of 5 to 6.5 per day). Further, FSIS estimated that approximately 90 percent of retailers perform customer-requested grinds, and that those grinds make up 1 percent of the total grinds.<sup>27</sup> FSIS estimated that the recordkeeping for customer-requested grinds would take about 1 minute. Customer-requested grinds were not applied to official establishments. Finally, FSIS estimated that the average retailer grinds 6 days per week.<sup>28</sup>

To illustrate the time estimate, FSIS has provided the following example of a retail store that does trim-only grinds, performs customer-requested grinds, and has incomplete records:

- Low Estimate: [4 grinds per day × 1 min per grind (no trim) + 1 grind per day × 6 min per grind (trim-only) + {5 grinds (no trim + trim-only) \* 1/99<sup>29</sup>} grinds per day × 1 min per grind (customer request)] × 6 days per week × 50 percent (incomplete records) = 30.2 minutes per week.

- High Estimate: [5.5 grinds per day × 1 min per grind (no trim) + 1 grind per day × 10 min per grind (trim-only) + {6.5 grinds (no trim + trim-only) \* 1/99} × 1 min per grind (customer request)] ×

6 days per week × 50 percent (incomplete records) = 46.7 minutes per week.

If the store in the example above started with no records, the 50-percent factor would be removed, increasing the time burden to 60.3 to 93.4 minutes per week. If instead the store were an official establishment, the customer grinds would be removed, resulting in a burden of 30 to 46.5 minutes per week.

Time estimates were calculated for each entity in Table 7 and then multiplied by 52 weeks for an annual estimate. To calculate the cost of this added labor, FSIS estimated that the recordkeeping would be performed by an employee paid at the Bureau of Labor Statistics “Butchers and Meat Cutters” (occupation code 51–3021) mean hourly wage rate of \$14.40.<sup>30</sup> To account for benefits paid to these employees, such as paid leave and retirement contributions, FSIS applied a benefits factor of 1.412<sup>31</sup> to the wage rate, resulting in a total compensation rate of \$20.33 per hour. FSIS then multiplied the labor time estimates by the total compensation rate estimate to get the total annual cost of labor, displayed in Table 8.

<sup>24</sup> “60 seconds to fill each grind log entry”—Docket ID# FSIS–2009–0011–0035, available at: <http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0035>.

<sup>25</sup> “8 minutes per day to log beef trim,” ± 2 minutes to account for varying number of components—Docket ID# FSIS–2009–0011–0035, available at: <http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0035>.

<sup>26</sup> Low estimate: “Grinds raw beef 4x per day”—Docket ID# FSIS–2009–0011–0034, available at: <http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0034>. High estimate: Midpoint of “3–8 batches a day”—Docket ID# FSIS–2009–0011–0040, available at: <http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0040>.

[www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0040](http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0040).

<sup>27</sup> “90 percent of the retailers that grind beef in store perform grinds at a consumer’s request . . . the figure is 1 percent or less”—Docket ID# FSIS–2009–0011–0047, available at: <http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0047>.

<sup>28</sup> “6x per week”—Docket ID# FSIS–2009–0011–0034, available at: <http://www.regulations.gov/#!documentDetail;D=FSIS-2009-0011-0034>.

<sup>29</sup> (1/99) is the factor used to calculate the number of customer-requested grinds as 1 percent of the total grinds.

<sup>30</sup> Bureau of Labor Statistics, May 2013 National Occupational Employment and Wage Estimates, accessed February 2, 2015, available at: [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm).

<sup>31</sup> Bureau of Labor Statistics, Employer Costs for Employee Compensation, September 2014, accessed February 2, 2015, available at: <http://www.bls.gov/news.release/ecec.t06.htm>. Wages and salaries as a percentage of total compensation are estimated at 70.8% for all service-providing industries, with total benefits accounting for the other 29.2%. To estimate total compensation, FSIS applied a benefits factor of (29.2%/70.8% + 1) = 1.412 to the hourly wage rate.

TABLE 8—ANNUAL LABOR COSTS

Entity size	Low estimate (\$mil)	High estimate (\$mil)	Midpoint estimate (\$mil)
Large .....	12.24	18.70	15.47
Small .....	33.54	48.74	41.14
Total .....	45.78	67.44	56.61

Values in table may not sum to Totals because of rounding.

To account for record storage costs, FSIS again used distributions of recordkeeping practices from the aforementioned CDC study.<sup>32</sup> According to the study, 36 percent of retailers that maintain records keep them for greater than 1 year, 39 percent keep records for 6 months to 1 year, and 25 percent keep records for less than 6 months. FSIS assumed that grinding records for a full year could be kept in 3 square feet of storage space, and that the cost of that storage would be approximately \$15.50 annually.<sup>33</sup> FSIS then assumed that those retail stores that already kept records, but for less than 6 months, would incur \$46.50 in costs for a full

year of storage (3 sq. ft. × \$15.50), and those entities that already kept records for 6 months to 1 year would pay half the annual cost, or \$23.25. Those entities keeping records for greater than 1 year would have no additional costs because they are already maintaining records at the minimum level.

The distribution from the CDC study was applied to the number of retail stores keeping complete or incomplete records, and then multiplied by the assumed annual cost of storage. The retail stores that do not keep records will incur the \$46.50 in costs for a full year of storage.

For official establishments, FSIS assumed that those already maintaining

records would be keeping those records for at least 2 years, as required by 9 CFR 320.3(a). For these establishments there would be cost savings associated with one year of reduced storage time equivalent to \$46.50. For official establishments not maintaining records, there would be an additional cost of \$46.50. FSIS applied the cost savings to those official establishments keeping records and the additional costs to those official establishments keeping no records, and added those costs and savings to the recordkeeping costs estimated for retail stores. The results are displayed in Table 9.

TABLE 9—ANNUAL RECORD STORAGE COSTS

Entity size	Affected entities	Storage costs (\$mil)
Large .....	16,613	0.62
Small .....	46,194	2.08
Total .....	62,807	2.70

Values in table may not sum to Totals because of rounding.

The total cost to industry was calculated as a sum of the previously estimated costs. The results of the

annual industry cost estimate are displayed in Table 10.

TABLE 10—TOTAL ANNUAL INDUSTRY COSTS

Entity size	Low estimate (\$mil)	High estimate (\$mil)	Midpoint estimate (\$mil)	Unqualified costs
Large .....	12.86	19.32	16.09	Additional costs associated with the grinding of trim and customer requested grinds.
Small .....	35.63	50.83	43.23	
Total .....	48.48	70.15	59.32	

Values in table may not sum to Totals because of rounding.

**Cost to Consumers**

This rule will not result in any direct costs to consumers. It is possible that retailers and official establishments that grind raw beef will pass on a portion of the increased cost of grinding to

consumers. In most cases these costs should be small. In the case of customer-requested grinds, consumers may end up paying a small fee, as is presently customary at some retail stores. While this practice may

discourage some consumers, the facts that customer-requested grinds are so infrequent, and fees are already applied at some locations, suggest that fees will not cause major disruptions to ground beef sales. Therefore FSIS expects that

<sup>32</sup> See footnote 3.  
<sup>33</sup> Cassidy Turley, National Retail Review Winter 2014, accessed February 3, 2015, available at: <http://dtz.cassidyurley.com/DesktopModules/>

[CassidyTurley/Download/Download.aspx?contentId=3926&fileName=Cassidy\\_Turley\\_National\\_Retail\\_Review\\_Winter\\_2014.pdf](#). FSIS used the national average quoted rate for Community/

Neighborhood/Strip Shopping Centers (see page 11) to approximate the cost of storing records at a retail store.

any indirect costs to consumers will be minimal.

#### Cost to Agency

FSIS does not anticipate that the Agency or other regulators will incur additional costs as a result of this rule. FSIS has provided guidance to retailers that grind raw beef and will continue outreach efforts to ensure that retailers are aware of the rule and are able to comply. FSIS will also hold webinars and provide guidance on the new recordkeeping requirements.

FSIS will conduct a retrospective analysis to quantify what effects, if any, the final rule has on Agency resources. To do so, FSIS will examine the following:

- 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).

We determined to not examine the overtime hours for enforcement, district office, and recall staff on a per-outbreak basis, as suggested in the proposed rule. The overtime hours cannot directly link to outbreaks.

#### Expected Benefits of the Final Rule

##### Public Health Benefits

Mandatory grinding logs with a minimum level of necessary information will improve FSIS investigators' ability to trace implicated product to its source, recommend timely and accurate recalls, remove adulterated product from commerce, and prevent illnesses at later stages of outbreaks.<sup>34</sup>

Mandatory grinding logs will increase the likelihood that adulterated product is able to be traced back to its source. When FSIS identifies official establishments producing adulterated product, it takes steps to assess their production processes through comprehensive food safety assessments and follow-up evaluations. In doing so, FSIS is able to identify poor practices and deficiencies in process control and to require changes to resolve these issues. In some cases these assessments lead to findings that are valuable to industry as a whole, and the lessons learned can be documented and disseminated in the form of guidance. Improvements to production practices and process control, whether at implicated official establishments or

other establishments that have benefited from lessons learned, will result in reductions in foodborne illness outbreaks.

Firms that supply ground beef components will have incentives to apply the guidance developed as a result of previous outbreak investigations and to improve the safety of their product in general. As traceability systems improve as a result of better recordkeeping, liability for food safety events will be shifted from retailers to suppliers. This shift will reduce the prevalence of moral hazard—explained previously in the Need for the Rule section—thereby incentivizing supplier firms to produce safer product through the potential for adverse consequences of supplying unsafe product, such as reputation loss and litigation.<sup>35</sup> Therefore, by improving traceability through better recordkeeping, this rule has the potential to promote a safer supply of ground beef for consumers.

##### Benefits to Retailers and Official Establishments That Grind Raw Beef

Retailers and official establishments that grind raw beef products purchased from a supplier will benefit from mandatory recordkeeping because investigators have a better chance of tracing the adulterated product back to the supplier. Investigations that end at the retail level often result in recalls that are very costly for retailers because they bear the burden of product loss and compensating customers for returned product. These recalls can also negatively affect the brand of the store or chain, resulting in a loss in consumer confidence and a loss in sales. In some cases outbreak investigations that end at the retail level could result in exposure to legal liability.<sup>36</sup> Accurate records increase the likelihood that contaminated product is traced to its source, lessening the impact of recalls on retailers and official establishments that purchase ground beef components from suppliers.

For retailers that are already maintaining accurate records, there will be benefits from the reduction in free rider firms, as explained previously in the Need for the Rule section. Fewer free rider firms will decrease the chances that outbreak investigations go unresolved, which can greatly reduce

the cost to retailers. When a source is not identified, an outbreak may indiscriminately affect firms selling and producing ground beef. The fresh spinach outbreak in 2006 is a prime example of the consequences of an outbreak where the source of contamination is in doubt. Bagged spinach was associated with infections of *E. coli* O157:H7, but because no individual processor could be identified as having been the source of the outbreak, FDA and CDC issued a public alert advising consumers not to eat bagged spinach and eventually advised consumers not to eat all fresh spinach. Six companies issued voluntary recalls in September 2006. Sales of spinach plummeted from \$14.3 million in September to \$3.7 million in October and did not recover fully until January 2008.<sup>37</sup> An outbreak caused by a single firm, which was identified weeks after public warnings and recalls took place, ended up causing serious losses to the entire industry. Mandatory recordkeeping increases the chances that an investigator identifies the source of contamination, thereby increasing the chances that an outbreak will have minimal impact on uninvolved firms.

##### Benefits to Official Establishments That Supply Ground Beef Components

Official establishments supplying retail stores and processing establishments with ground beef components will also benefit from the increased ability of FSIS investigators to identify sources of contamination. When individual establishments are found to be suppliers of adulterated product, other uninvolved establishments are insulated from large spillover effects such as those illustrated in the spinach recall described above. Identifying the source establishment will likely be even more significant for official establishments because ground beef components make up a greater portion of their sales than ground beef would at a retail store. Mandatory recordkeeping could help to preserve consumer confidence and ground beef sales in the event of a foodborne illness outbreak, benefiting all firms that are uninvolved in the outbreak, while penalizing the establishment that supplied the adulterated product.

Another potential benefit for official establishments is a reduction in the scope of ground beef recalls. All else being equal, more accurate grinding records should result in the

<sup>34</sup> For a visual representation of the potential for averted illnesses due to quicker investigations and an earlier recall, please refer to Figure 1 of the FDA *Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002* final rule, available at: <https://federalregister.gov/a/04-26929/#p-674>.

<sup>35</sup> See footnote 9.

<sup>36</sup> See *Financial Exposures* section of: Grocery Manufacturers Association (GMA), Covington & Burling, and Ernst & Young "Capturing Recall Costs," 2011, accessed January 15, 2015, available at: [http://www.gmaonline.org/file-manager/images/gmapublications/Capturing\\_Recall\\_Costs\\_GMA\\_Whitepaper\\_FINAL.pdf](http://www.gmaonline.org/file-manager/images/gmapublications/Capturing_Recall_Costs_GMA_Whitepaper_FINAL.pdf).

<sup>37</sup> University of Minnesota Food Industry Center, (2009) "Natural Selection: 2006 *E. coli* Recall of Fresh Spinach," accessed January 20, 2015, available at: <http://ageconsearch.umn.edu/bitstream/54784/2/Natural%20Selection.pdf>.

identification of specific lots of implicated product and therefore a narrower recall.<sup>38</sup> Smaller recalls will result in lower costs from product loss and reimbursement and recall execution costs such as advertising and public relations management. In some cases, smaller recalls as a result of better recordkeeping could even minimize sales losses, because a recall could be limited to a smaller geographical region

thereby reducing losses in consumer confidence. Finally, official establishments will benefit from lessons learned during recalls and follow-up assessments at entities linked to foodborne illness outbreaks. As recordkeeping practices at retail and official processing establishments improve, more outbreaks will be able to be traced to their source. This traceback will initiate further

examination of current practices and could lead to the identification of significant issues that, if corrected, would benefit official establishments generally.

**Net Benefits of the Final Rule**

The total costs and benefits achieved as a result of the final rule are displayed in Table 11.

TABLE 11—NET BENEFITS OF THE FINAL RULE

Costs:	
Labor .....	\$56.6 million annually (\$45.8 million to \$67.4 million).
Storage .....	\$2.7 million annually.
Unquantified Costs .....	Non-labor costs associated with recordkeeping for the grinding of trim and customer requested grinds. Potential slight costs to consumers in the form of ground beef price increases.
Benefits:	
Unquantified Benefits .....	Benefits to consumers in the form of averted foodborne illnesses as a result of contaminated ground beef. Benefits to retailers and official establishments grinding raw beef in the form of less costly food safety events, such as outbreaks and recalls. Benefits to official establishments supplying ground beef components in the form of less costly recalls and insulation from costly spillover effects during food safety events.

**Regulatory Flexibility Analysis**

The FSIS Administrator certifies that, for the purpose of the Regulatory Flexibility Act (5 U.S.C. 601–602), the final rule will not have a significant economic impact on a substantial number of small entities in the United

States. While the rule does affect a large number of small businesses, the average per entity annual cost is relatively low, at approximately \$905 (746 to 1,064). This estimate does not include unquantified costs associated with customer-requested grinds. These costs

will vary by retail store, but the total cost of compliance across the industry will be low because of the relatively small number of customer requested grinds. Table 12 provides a summary of the small entities affected by the final rule and the average annual cost.

TABLE 12—TOTAL COSTS AND AVERAGE COST PER ENTITY FOR SMALL BUSINESSES

Entity type	Entities	Total annual cost (\$mil)	Average annual cost (\$)
Retailer .....	46,649	42.22	905.16
Official .....	1,132	1.00	885.63
Total .....	47,781	43.23	904.70

Values in table may not sum to Totals because of rounding.

There is a multitude of guidance already available that small businesses can use, and FSIS has provided a sample grinding log in this final rule that can be used. These resources will help to keep the cost of implementing a new recordkeeping program low. In general, as the size of the business and the amount of ground product sold gets smaller, so too will the number of suppliers and components used, and the number of grinds performed. The smaller scale of production should contribute to lower average costs for smaller businesses. Moreover, the fact that some small firms are already

maintaining adequate records shows that the cost of the practice is not prohibitive to doing business.

**Paperwork Reduction Act**

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

*Title:* Records to be Kept by Official Establishments and Retail Stores that Grind Raw Beef Products.

*Type of Collection:* New.

*Abstract:* Under this final rule, all official establishments and retail stores that grind raw beef products for sale in commerce, including products ground at a customer’s request, will have to maintain certain records.

The required records will have to include the following information:

- (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

<sup>38</sup>Resende-Filho, Moises A. and Buhr, Brian L. “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, available at: [http://ageconsearch.umn.edu/bitstream/126193/2/IAAE\\_2012\\_Paper.pdf](http://ageconsearch.umn.edu/bitstream/126193/2/IAAE_2012_Paper.pdf). 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 (see Table 3).

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.

In response to comments, FSIS removed requirements for entities covered by this rule to provide names, points of contact, and phone numbers for official establishments. Also in response to comments, the Agency eliminated the requirement that the weight of each source component used in a lot of ground beef be kept. However, in response to other public comments, FSIS increased the time estimates for recordkeeping activities, the frequency of recordkeeping tasks, and the number of active grinding days per week. FSIS also increased the number of retail stores that will be affected by the rule. These changes resulted in a significant increase in the number of burden hours initially estimated in the proposed rule.

**Estimate of Burden:** FSIS estimates that it would take a maximum of 50.33 hours per respondent annually.

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

**Estimated Number of Respondents:** 65,911.

**Estimated Maximum Annual Number of Responses per Respondent:** 1,878.

**Estimated Maximum Total Annual Recordkeeping Burden:** 3,317,493 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 Ave. SW., Room 6065 South Building, Washington, DC 20250-3700; (202) 720-5627.

#### Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (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) no administrative proceedings will be required before parties may file suit in court challenging this rule.

#### Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that

have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, the Food Safety and Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

#### E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this 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 our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email 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/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

#### USDA Nondiscrimination 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).

#### List of Subjects in 9 CFR Part 320

Meat inspection, Reporting and recordkeeping requirements.

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

#### PART 320—RECORDS, REGISTRATION, AND REPORTS

■ 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. Amend § 320.1 by adding paragraph (b)(4) to read as follows:

#### § 320.1 Records required 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 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.

(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.

\* \* \* \* \*

■ 3. Revise § 320.2 to read as follows:

**§ 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 § 320.1(b)(4) must be kept at the location where the raw beef was ground.

■ 4. Revise § 320.3 to read as follows:

**§ 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 part 318 of this chapter, 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 § 320.1(b)(4) must be retained for one year.

Done in Washington, DC, on: December 14, 2015.

**Alfred V. Almanza,**

*Acting Administrator.*

[FR Doc. 2015-31795 Filed 12-18-15; 8:45 am]

**BILLING CODE 3410-DM-P**

**FEDERAL DEPOSIT INSURANCE CORPORATION**

**12 CFR Parts 348 and 390**

**RIN 3064-AE20**

**Removal of Transferred OTS Regulations Regarding Management Official Interlocks and Amendments to FDIC's Rules and Regulations**

**AGENCY:** Federal Deposit Insurance Corporation.

**ACTION:** Final rule.

**SUMMARY:** The Federal Deposit Insurance Corporation ("FDIC") is adopting a final rule to rescind and remove from the Code of Federal Regulations the transferred OTS regulation entitled "Management Official Interlocks." This subpart was included in the regulations that were transferred to the FDIC from the Office of Thrift Supervision ("OTS") on July 21, 2011, in connection with the implementation of applicable provisions of title III of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act"). The requirements for State savings associations in the transferred OTS regulation are substantively similar to those in the FDIC's regulation, which is also entitled "Management Official Interlocks" and is applicable for all insured depository institutions ("IDIs") for which the FDIC has been designated the appropriate Federal banking agency.

**DATES:** The final rule is effective on January 20, 2016.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Maree, Counsel, Legal Division, (202) 898-6543; Mark Mellon, Counsel, Legal Division, (202) 898-3884; Karen Currie, Senior Examination Specialist, (202) 898-3981.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. The Dodd-Frank Act*

The Dodd-Frank Act<sup>1</sup> provided for a substantial reorganization of the regulation of State and Federal savings associations and their holding companies. Beginning July 21, 2011, the

transfer date established by section 311 of the Dodd-Frank Act, codified at 12 U.S.C. 5411, the powers, duties, and functions formerly performed by the OTS were divided among the FDIC, as to State savings associations, the Office of the Comptroller of the Currency ("OCC"), as to Federal savings associations, and the Board of Governors of the Federal Reserve System ("FRB"), as to savings and loan holding companies. Section 316(b) of the Dodd-Frank Act, codified at 12 U.S.C. 5414(b), provides the manner of treatment for all orders, resolutions, determinations, regulations, and advisory materials that had been issued, made, prescribed, or allowed to become effective by the OTS. The section provides that if such materials were in effect on the day before the transfer date, they continue to be in effect and are enforceable by or against the appropriate successor agency until they are modified, terminated, set aside, or superseded in accordance with applicable law by such successor agency, by any court of competent jurisdiction, or by operation of law.

Section 316(c) of the Dodd-Frank Act, codified at 12 U.S.C. 5414(c), further directed the FDIC and the OCC to consult with one another and to publish a list of the continued OTS regulations that would be enforced by the FDIC and the OCC, respectively. On June 14, 2011, the FDIC's Board of Directors approved a "List of OTS Regulations to be Enforced by the OCC and the FDIC Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act." This list was published by the FDIC and the OCC as a Joint Notice in the **Federal Register** on July 6, 2011.<sup>2</sup>

Although section 312(b)(2)(B)(i)(II) of the Dodd-Frank Act, codified at 12 U.S.C. 5412(b)(2)(B)(i)(II), granted the OCC rulemaking authority relating to both State and Federal savings associations, nothing in the Dodd-Frank Act affected the FDIC's existing authority to issue regulations under the Federal Deposit Insurance Act ("FDI Act") and other laws as the "appropriate Federal banking agency" or under similar statutory terminology. Section 312(c) of the Dodd-Frank Act amended the definition of "appropriate Federal banking agency" contained in section 3(q) of the FDI Act, 12 U.S.C. 1813(q), to add State savings associations to the list of entities for which the FDIC is designated as the "appropriate Federal banking agency." As a result, when the FDIC acts as the designated "appropriate Federal banking agency" (or under similar terminology) for State

<sup>1</sup> Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111-203, 124 Stat. 1376 (2010).

<sup>2</sup> 76 FR 39247 (July 6, 2011).