Proposed Rules

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

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 417 and 418

[FDMS Docket Number FSIS–2008–0025]

RIN 0583–AD34

Notification, Documentation, and Recordkeeping Requirements for Inspected Establishments

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to implement provisions of the Food, Conservation, and Energy Act of 2008 by adopting regulations that require official establishments to promptly notify the appropriate District Office that an adulterated or misbranded meat or poultry product has entered commerce; require official establishments to prepare and maintain current procedures for the recall of meat and poultry products produced and shipped by the establishment; and require official establishments to document each reassessment of the establishment's process control plans, that is, its Hazard Analysis and Critical Control Point plans.

DATES: Comments due on or before May 24, 2010.

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

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov*. Follow the online instructions at that site for submitting comments.
- *Mail, including CD–ROMs, and hand- or courier-delivered items:* Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Room 2–2127 George Washington Carver Center, 5601 Sunnyside Avenue, Beltsville, MD 20705.

Instructions: All items submitted by mail or via Regulations.gov must include the Agency name and docket number FSIS–2008–0025. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

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

FOR FURTHER INFORMATION CONTACT: Philip Derfler, Assistant Administrator, Office of Policy and Program Development, Room 350–E, Jamie L. Whitten Building, 1400 Independence Avenue, SW., Washington, DC 20250; Telephone (202) 720–2709, Fax (202) 720–2025.

SUPPLEMENTARY INFORMATION:

Background

FSIS administers the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601–695), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451–470), and the regulations that implement these Acts. Under these statutes and rules, the Agency is responsible for ensuring that the nation's commercial supply of meat and poultry is safe, not adulterated, wholesome, and properly marked, labeled, and packaged.

On June 18, 2008, section 11017 of the Food, Conservation, and Energy Act of 2008, Public Law 110–246, 122 Stat 1651, 448–49, otherwise known as the 2008 Farm Bill, amended the FMIA and the PPIA by adding new sections 12 and 13 to the FMIA (21 U.S.C. 612 and 613) and amending section 10 of the PPIA (21 U.S.C. 459). Section 12 of the amended FMIA and section 10(b) of the amended PPIA require establishments subject to inspection under the Acts that believe, or have reason to believe, that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the establishment has entered into commerce, to promptly notify the Secretary of Agriculture of that belief. They also require these establishments to inform the Secretary of the type, amount, origin, and destination of the adulterated or misbranded product.

Section 13 of the amended FMIA and section 10(c) of the amended PPIA also require establishments subject to inspection under these statutes to: (1) Prepare and maintain current procedures for the recall of all meat, meat food, poultry, and poultry products produced and shipped by the establishment; (2) document each reassessment of the establishment's process control plans, *i.e.,* its Hazard Analysis and Critical Control Point (HACCP) plans; and (3) make the recall procedures and written records of the establishment's HACCP plan reassessments available for official review and copying.

FSIS is proposing regulations to implement these new statutory provisions. Establishments subject to inspection under the Acts are official meat [1] and poultry products [2] establishments.

I. Notification Requirement

The FMIA and PPIA, and their implementing regulations, prohibit the sale, transport, offer for sale or transportation, or receipt for transportation in commerce of any meat, meat food, poultry, or poultry products (hereinafter referred to as meat or poultry products) that are capable of use as human food and are adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation by any person,[3] firm,[4] or corporation.[5] The FMIA also prohibits the importation of adulterated or misbranded [6] meat and meat food products, while the PPIA prohibits the importation of adulterated [7] poultry or poultry products. Imported meat and poultry products must also "* * *

[1] 9 CFR 301.2. *Official establishment* means any slaughtering, cutting, boning, meat canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations in this subchapter.

[2] 9 CFR 381.1. *Official establishment* means any establishment as determined by the Administrator at which inspection of the slaughter of poultry, or the processing of poultry products, is maintained pursuant to the regulations.

[3] 21 U.S.C. 453(j). A person is "any individual, partnership, corporation, association, or other business unit."

[4] 21 U.S.C. 601(b). A firm is "any partnership, association, or other unincorporated business organization."

[5] 21 U.S.C. 610(c)(1) and 9 CFR 320.7, and 21 U.S.C. 458(a)(2) and 9 CFR 381.181.

[6] 21 U.S.C. 620(a)

[7] 21 U.S.C. 466(a)

comply with the rules and regulations made by the Secretary of Agriculture to assure that they comply with the standards provided for in * * *" the Act, including the misbranding provision found in 21 U.S.C. 458(a)(2).

While the Federal meat and poultry products inspection regulations have provisions that address the receipt of adulterated or misbranded products by an official establishment or consignee under specific circumstances,[8] they do not explicitly require establishments subject to inspection under the FMIA or PPIA to notify FSIS[9] when an adulterated or misbranded product received by or originating from the establishment has entered commerce. Therefore, in accordance with section 11017 of the 2008 Farm Bill and the newly enacted sections 12 of the FMIA and 10(b) of the PPIA, FSIS is proposing to require that official establishments promptly notify the appropriate District Office that an adulterated or misbranded product received by or originating from the establishment has entered commerce, if the establishment believes or has reason to believe that this has happened. FSIS is also proposing to require that the establishment inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.[10]

If this proposed rule becomes final, the required information concerning the type of product will need to include the product name, any code or lot numbers on the individual packages or cases, and the type and size of the packages. Information concerning the origin and destination of the product will need to include the official establishment numbers and addresses of both the producing establishment and the receiving establishment, or, if the product is not going, or is not only going, to an official establishment, the names and addresses of any facilities to which the product has been shipped.

The new notification provisions of the FMIA and PPIA do not provide an explicit timeframe within which notification must be given. However, the purpose of notification is to ensure that potentially adulterated or misbranded product is removed from commerce as quickly as possible. Thus, FSIS is proposing to require that official establishments notify the appropriate District Office as quickly as possible, but within 48 hours of learning or determining that an adulterated or misbranded product received by or originating from the establishment has entered commerce. FSIS requests comment on whether 48 hours is an appropriate time in which to expect official establishments that have shipped or received, or have reason to believe that they have shipped or received, adulterated or misbranded product, to notify the appropriate District Office of that situation.

II. Documentation and Recordkeeping

A. Recall Procedures

The FMIA and PPIA require Federal inspection[11] and provide for Federal regulation of meat and poultry products prepared for distribution in commerce for use as human food.[12] Before enactment of the 2008 Farm Bill, there was no requirement that official establishments prepare and maintain written procedures for the recall of meat and poultry products produced and shipped by them, although FSIS strongly recommended that establishments do so. Such a plan involves preparing and maintaining detailed, written recall plans or procedures that specify how the firm will decide whether to conduct a product recall, and how the establishment will effect the recall should it decide that one is necessary.[13]

Under newly enacted section 13 of the FMIA and section 10(c) of the PPIA, the preparation and maintenance of written, up-to-date recall procedures are mandatory. Therefore, FSIS is proposing to require that official meat and poultry establishments prepare and maintain written procedures for the recall of meat or poultry products produced or shipped by an establishment for use should it become necessary for the establishment to remove such products from commerce. FSIS is proposing to require that these written procedures specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall. Consistent with the 2008 Farm Bill, the proposed rule requires that these procedures be available for official review and copying.

Under the proposed rule, recall procedures will not have to be included in an establishment's HACCP plan or used as a prerequisite program, as long as each official establishment has procedures that meet the requirements of 9 CFR 418.2. These could, however, be incorporated into HACCP plans or prerequisite programs as corrective actions to be followed to address deviations that resulted in the shipment of adulterated or misbranded product in commerce. 9 CFR 417.3 requires that HACCP plans identify corrective actions to be followed in response to a deviation from a critical limit.

FSIS requests comment on when, after the effective date of this rule, assuming it becomes final, written recall procedures must be completed in accordance with proposed § 418.3. FSIS is also seeking comment as to within what time from new establishments must prepare written recall procedures.

B. Process Control Plans

HACCP is a science-based process control system for food safety that promotes systematic prevention of biological, chemical, and physical hazards. HACCP plans are establishment-developed process control plans designed to identify and prevent hazards before they occur and to correct problems if they are detected.

FSIS requires every official establishment to develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur in the production process.[14] Official establishments must reassess the adequacy of their HACCP plans at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan.[15] 9 CFR 417.4(a)(3) contains examples of changes that could affect the hazard analysis or alter the HACCP plan.

FSIS has, on occasion, notified the public when changes have occurred that could affect the hazard analysis or alter the HACCP plans for particular products. For example, FSIS notified the public of the availability of new scientific data indicating that

[8] *See, e.g.,* 9 CFR 318.1(j), "If any slaughtered poultry or poultry products or other articles are received at an official establishment and are suspected of being adulterated or misbranded under the Poultry Products Inspection Act or the Federal Food, Drug, and Cosmetic Act, or applicable State law, the appropriate governmental authority will be notified." *See also* 9 CFR 320.7 and 381.181, which require the consignee of any product that bears an official inspection legend that refuses to accept the delivery of the product on the grounds that it may be adulterated or misbranded to notify the Inspector in Charge of the kind, quantity, source, and present location of the product and the respects in which it is alleged to be adulterated or misbranded.

[9] The functions of the Secretary of Agriculture contained in the FMIA and the PPIA are delegated to the Under Secretary for Food Safety in 7 CFR 2.18. These functions, in turn, are delegated to the Administrator, Food Safety and Inspection Service in 7 CFR 2.53.

[10] Proposed 9 CFR 418.2.

[11] 21 U.S.C. 603(a), 604, 606, and 455.

[12] 21 U.S.C. 602 and 451.

[13] *See* Attachment 1 to FSIS Directive 8080.1, Revision 5, *Product Guidelines for Firms,* which discusses the elements that should be addressed by a recall plan.

[14] 9 CFR 417.2(b)(1).

[15] 9 CFR 417.4(a)(3).

Escherichia coli (*E. coli*) O157:H7 was more prevalent than was previously thought (67 FR 62326, Oct. 7, 2002) and notified the public of *E. coli* O157:H7 outbreaks associated with the consumption of mechanically tenderized beef (70 FR 30331, May 26, 2005).

Under FSIS's regulations, the reassessment required by 9 CFR 417.4(a)(3) does not have to be documented. The 2008 Farm Bill changes this situation. It requires that official establishments document each reassessment of their process control plans. Therefore, this rule proposes to require that official establishments make a written record when they perform reassessment as required by 9 CFR 417.4(a)(3) or for any other reason. The Agency is proposing to require that establishments document the reasons for any changes that they made to their HACCP plans based on the reassessment, or, if they did not make any changes, that they document the reasons that they did not. If, however, an establishment performs its annual reassessment and determines that no changes are needed to its HACCP plan, it may briefly state this fact in lieu of more extensive documentation. Consistent with the statute, official establishments must make all documentation of the reassessment available for official review and copying.[16]

Documenting reassessments is important for a number of reasons. It will facilitate verification that establishments are actually reassessing their HACCP plans. Without a record, this has proven difficult to do. It will also help FSIS personnel to identify whether there are emerging hazards that the establishment has decided not to address. Finally, a record of reassessments will help an establishment to track the situation in its operation over time.

If this proposed rule becomes final, official establishments will be able to maintain these records on computers (9 CFR 417.5(d)), and establishments will be required to retain the records for up to two years, as prescribed in 9 CFR 417.5(e).

If this proposed rule becomes final, foreign countries that export meat and poultry products to the United States will be expected to establish requirements equivalent to those that FSIS is proposing in this rulemaking, or to establish why their system remains equivalent if they fail to do so.

[16] *See* § 417.5(f).

Executive Order 12866 and Regulatory Flexibility Act

This rule was reviewed by the Office of Management and Budget (OMB) under Executive Order 12866 and was determined to be significant.

I. Background

The Food, Conservation, and Energy Act of 2008 (Pub. L. 110–246, Sec. 11017), known as the 2008 Farm Bill, amended the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) to require establishments subject to inspection under these Acts to promptly notify the Secretary of Agriculture that an adulterated or misbranded product received by or originating from the establishment has entered into commerce, if the establishment believes or has reason to believe that this has happened. Section 11017 also requires establishments subject to inspection under the FMIA and PPIA to: (1) Prepare and maintain procedures for the recall of all products produced and shipped by the establishment; (2) document each reassessment of the process control plans of the establishment (*i.e.,* HACCP plans); and (3) upon request, make the procedures and reassessed control plans available for inspectors appointed by the Secretary to review and copy.

II. What Is Being Proposed

This proposed action will amend 9 CFR 417.4 (a)(3) to require that every establishment make a written record of each reassessment of the adequacy of its process control plan, *i.e.,* HACCP plan, or to document the reasons for not making a change to the HACCP plan based on the reassessment (except for annual reassessments of the HACCP plan, for which, if no change is found necessary, only the fact that the reassessment occurred need be documented). It will also establish a new 9 CFR Part 418, *Recalls,* under which official establishments will have to promptly notify FSIS that an adulterated or misbranded product received by or originating from the establishment has entered into commerce, if the establishment believes or has reason to believe that this has happened, and prepare and maintain current procedures for the recall of products produced and shipped by the establishment if there is a reason to believe that its product are adulterated or misbranded.

III. Need for the Proposed Rule

- FSIS believes that prompt notification that adulterated or misbranded product has entered commerce is an important prerequisite for effective action to prevent such product from causing harm.
- Having established procedures will help establishments to conduct effective and efficient recalls, should it be necessary for them to do so.
- Moreover, records of reassessments will help establishment and Agency personnel to assess the adequacy and appropriateness of what has been done.

IV. Baseline

FSIS expects that this proposed rule will affect about 6,300 official establishments that slaughter or process meat, meat food, poultry, and poultry products, based on FSIS's Performance Based Inspection System (PBIS) of 2008. Based on HACCP classification, about 400 are large establishments, 3,044 are small, and 2,856 are very small (Table 3).

V. Expected Costs

Under the current regulations, the development and maintenance of recall procedures and the written documentation of HACCP reassessments are voluntary. This proposed rule will make them mandatory. Costs occur because about 6,300 official establishments will need to develop recall procedures, maintain written documentation of HACCP reassessments, and make the records accessible to the Agency's review. The Agency used in this analysis the best available data, based on discussions with FSIS experts. FSIS solicits costs data from other sources to be sure that the Agency is using the best available data. The methodology of the labor cost estimates is as follows:

(1) Developing Recall Procedures = Number of establishments[17] × hours[18] × wage rate[19]

(2) Documenting HACCP Reassessment = Number of establishments × hours × response rate[20] × wage rate

(3) Records Backup and Storage = Number of establishments × hours × response rate × wage rate

Since estimates of all of the above factors are provided by experts in the related fields, not collected directly from related establishments, FSIS invites comments and inputs from industries likely to improve the cost

[17] The number of establishments is the number of Federally-inspected processing and slaughter establishments.

[18] Hours are labor hours likely spent on the required provisions.

[19] The wage rate is estimated according to the current labor market and the nature of work, including all non-salary benefits to workers.

[20] Response rate is the projected frequencies of an action within a year.

estimation. In particular, FSIS welcomes comments on the total cost and the annual cost estimation related to the notification, documentation, and recordkeeping provisions affected by this proposed rule.

The cost of notifying FSIS, with a few phone calls, facsimiles, and e-mails about questionable products in commerce is negligible. FSIS certifies that there will be no impact on the Agency's operational costs resulting from this proposed rule, because the Agency will not need to add any staff or incur any non-labor expenditure if the proposed rule is adopted.

In addition to the labor cost, FSIS estimates that the extra material cost would be about 1 percent of the labor cost of the development of the recall procedures and the documenting of each reassessment or the documenting that no changes to the HACCP plan were found necessary based on the reassessment. For the cost estimation of records backup and storage, the ratio of labor cost versus material cost was estimated to be 2:1, or 2 thirds labor cost versus 1 third material cost. These costs are significantly mitigated by the fact that FSIS has guidance materials on preparing recall plans available. *See* footnote 16, above. The material cost would mostly be paper, ink, and electronic storage media. The estimated total average costs of about $5 million for labor and $76 thousand for materials are shown in Table 1.

Considering the facts that: (1) Some unknown number of establishments already have plans which could likely be adequate with little or no change, (2) establishments in the meat and poultry industries have differing levels of expertise in writing HACCP plans, (3) the Agency makes model recall plans available to the industry, and (4) establishments have a range of different processes for producing meat and poultry products, FSIS believes that the estimated cost of developing recall procedures tends to be overstated by using the maximum number of establishments. However, given the uncertainty of incurred labor cost in different regions and with various experience levels, FSIS assumes a 20% range, or plus and minus 10%, of the estimated average-compliance cost. The estimated cost summary is shown in Table 2.

FSIS expects that in the first year of the proposed rule, one-time costs for developing recall procedures would cost the industry of approximately 6,300 establishments $4.5 million, in an estimated range of $4.0 and $4.9 million, 10% lower and upper bound, respectively. Furthermore, the proposed rule would have first year and recurring costs of approximately $0.5 million for documenting periodical reassessments of HACCP plans, and $0.1 million for records backup and storage, although these costs may well be overstated. Thus, the total cost for the first year is $5.0 ($4.4 + $0.5 +$0.1) million, in an estimated range of $4.6 and $5.6 million, 10% lower and upper bound, respectively. The average cost adjusted with a 3% inflation rate of following years would be $0.7 ($0.5 + $0.2) million, in an estimated range of $0.6 and $0.8 million, 10% lower and upper bound, respectively (Table 2).

The present value of total estimated costs with a 3% discount rate for 10 years would be $4.3 million, in an estimated range of $3.9 and $4.8 million, 10% lower and upper bound, respectively. The present value of estimated costs with a 7% discount rate for 10 years would be $3.6 million, in an estimated range of $3.2 and $3.9 million, 10% lower and upper bound, respectively. The above present values of estimated costs were calculated in year 2003 dollars, with 7% and 3% discount rates, in accordance with OMB Circular A–4 requirements (Table 2).

Table 3 shows the drilled-down costs in establishment size, of which $0.3 million is attributed to large, $2.5 million to small, and $2.3 million to very small establishments. The cost per official establishment is between $700 and $900, 10% lower and upper bound, respectively.

Table 4 gives the estimated annual and total cost by establishment size classes for the first five years. Table 4, column 4, shows all cost categories of the first year (assumed to be 2010) and comes from Table 3 column 3, distributed by the counts of establishment size classes. The costs of following year, in Table 4, columns 5–8, are based on annual recurring costs (Table 2), compounded at the 3% inflation rate for the following four years. FSIS expects that the first five years of the proposed rule, if adopted, would cost the industry of approximately 6,300 establishments $7.9 million, in an estimated range of $7.1 and $8.7 million, 10% lower and upper bound, respectively. The present value of a 2009 dollar at 7% is $5.6 million, in the range of $5.1 million to $6.2 million, minus and plus 10%, respectively. The present value of a 2009 dollar at 3% is $6.8 million, in the range of $6.1 million to $7.5 million, minus and plus 10%, respectively. Total costs of the first five years for small/very small and large establishments as a central estimate are $7.4 million and $0.5 million, respectively; the average recurring cost after the first year for small/very small and large establishments will be $0.7 million and $0.04 million, respectively.

TABLE 1—FIRST YEAR COST BREAK-DOWN, IN DOLLARS, FOR 6,300 ESTABLISHMENTS

Cost component	Response rate	Required man hours	Wage rate	Factor for paper, ink & media cost	Material (paper, ink & media) cost (×$1,000)	Total cost (×$1,000)
	(1)	(2)	(3)	(4)	(5)=(4)×(6)	(6)=(1)×(2)×(3)×(4)×6.3
Recall-Procedures development (one-time)	1	20	35	1.01	44	4,454
Documenting Reassessment	5	0.25	60	1.01	5	477
Records backup and storage	1	0.25	35	1.5	28	83
Total					77	5,014

TABLE 2—ESTIMATED FIRST YEAR TOTAL COST AND AVERAGE COST OF FOLLOWING YEAR

	Total cost (×$ million)	Low-range estimate (−10%)	High-range estimate (+10%)
(A) Recall-Procedures development (one-time)	4.4	4.0	4.9
(B) Documenting Reassessment	0.5	0.4	0.5
(C) Records backup and storage	0.1	0.1	0.1
(D) First Year Cost (Total) (D=A+B+C)*	5.0	4.6	5.6
Average Cost of Following Years (for next 10 years)	0.7	0.6	0.8
Present Value (2003) at 3%	4.3	3.9	4.8
Present Value (2003) at 7%	3.6	3.2	3.9

* Note: Summation is subject to rounding error.

TABLE 3—NUMBER OF ESTABLISHMENTS, AND TOTAL AND AVERAGE COST IN SIZE (× $1,000)

HACCP class	Number of establishments	Recall procedures development (one-time)	Documenting HACCP reassessment	Records backup and storage	Total cost	Cost per establishment	Low estimates (−10%)	High estimates (+10%)
Very Small	2,856	2,030	218	38	2,285	0.8	0.7	0.9
Small	3,044	2,164	232	40	2,436	0.8	0.7	0.9
Subtotal	5,900	4,194	449	78	4,721	0.8	0.7	0.9
Large	400	260	28	5	293	0.8	0.7	0.9
Total	6,300	4,454	477	83	5,014	0.8	0.7	0.9

TABLE 4—ESTIMATED ANNUAL AND 5-YEAR TOTAL COST BY ESTABLISHMENT SIZE CLASSES (×$1,000), ASSUMING INFLATION RATE = 3%

HACCP Class	Number of Establishments	Activities	1st Year (2010)	2nd Year (2011)	3rd Year (2012)	4th Year (2013)	5th Year (2014)	5-Year Total
Very Small	2,856	Recall-Procedures development & updating	2,030	278	286	295	304	3,193
		Documenting HACCP Reassessment	218	30	31	32	33	342
		Records backup and storage	38	5	5	5	6	59
		Subtotal	2,285	313	322	332	342	3,594
Small	3,044	Recall-Procedures development & updating	2,164	296	305	314	324	3,403
		Documenting HACCP Reassessment	232	32	33	34	35	365
		Records backup and storage	40	5	6	6	6	63
		Subtotal	2,436	333	343	354	364	3,831
Small & Very Small	5,900	Subtotal	4,721	646	666	686	706	7,425
Large	400	Recall-Procedures development & updating	260	36	37	38	39	409
		Documenting HACCP Reassessment	28	4	4	4	4	44
		Records backup and storage	5	1	1	1	1	8
		Subtotal	293	40	41	43	44	461
Total All	6,300	Recall-Procedures development & updating	4,454	610	628	647	666	7,005
		Documenting HACCP Reassessment	477	65	67	69	71	751
		Records backup and storage	83	11	12	12	12	130
		Total	5,014	686	707	728	750	7,886

VI. Expected Benefits

Expected benefits will likely result from this proposed rule, which is intended to improve the effectiveness of the nation's food safety system for meat and poultry products. These benefits will not be monetized in this section because quantified data on benefits attributable to this proposed rule are not available to FSIS. FSIS solicits data that would permit the monetization of the expected benefits. However, without discussing monetized benefits, FSIS would expect to gain the following benefits related to:

HACCP Reassessment and Documentation of Reassessments

While HACCP reassessment is already required by 9 CFR 417, requiring establishments to document in writing each reassessment of their HACCP plans or the reasons for not making changes to the HACCP plan based on the reassessment will allow establishment supervisory and audit personnel, as well as FSIS personnel, to verify that establishments are, in fact, reassessing those plans at least annually, as required by § 417.4(a)(3), and that they are appropriately assessing their findings when they do (although FSIS is proposing not to require an explanation if no change is made to the HACCP plan on the basis of the annual reassessment). Requiring these written reassessments to

be made available to inspection program personnel ensures that the records are prepared and available.

Notification Requirement

In addition, this proposed rule will likely be a preventive measure that will result in FSIS being alerted to potential meat and poultry recall situations earlier than otherwise is the case today. If this proposed rule is adopted, establishments will be required to notify the local FSIS District Office within 48 hours of learning or determining that an adulterated or misbranded product received by or originating from the establishment has entered commerce, if the establishment believes or has reason to believe that this has happened. This notification, in turn, will allow FSIS to begin coordinating more rapidly preliminary inquiries to determine whether a recall is necessary.

Improve Recall Effectiveness With Documented Procedures

FSIS expects that this proposed rule will likely assist meat and poultry establishments during recalls. By requiring these establishments to prepare and maintain recall procedures for all products they produce, FSIS expects that establishments that do not currently have such plans will likely be able to act more effectively to remove adulterated or misbranded products from commerce. This added efficiency and effectiveness should help establishments to move quickly to disseminate information about the need to return the product to it and thus maximize the amount of product it will be able to recover. Table 5 gives a summary of the benefits discussed above.

TABLE 5—SUMMARY OF BENEFITS

Benefit related to:	Required actions:	Expected benefits:
Document Reassessment	• Establishments are to document all reassessments of HACCP plans. • Establishments are to make the documentation of the HACCP plans available to inspection program personnel. • FSIS is to verify that establishments are, in fact, reassessing their HACCP plans at least annually.	• Improved HACCP systems for establishments.
Notification Requirement	• Establishments are to notify the local FSIS District Office within 48 hours of learning or determining that an adulterated or misbranded product received by or originating from the official establishment has entered commerce.	• FSIS will be alerted to potential meat or poultry recall situations earlier than otherwise is the case today. • FSIS will be able to begin coordinating more rapidly preliminary inquiries to determine whether a recall is necessary.
Improve Recall Effectiveness	• Establishments are to prepare and maintain recall procedures for all products they produce.	• Establishments will likely be able to act more effectively to remove adulterated or misbranded products from commerce. • Establishments may be able to move more quickly to disseminate information about the need to return the product to it. • Establishments may be able to maximize the amount of product they will be able to recover.

VII. Flexibility Analysis

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

These small entities are about 5,900 federally-inspected establishments. The average cost to small and very small businesses will be in the range of $700 to $900, 10% lower and upper bound, respectively (Table 3). FSIS invites small (with more employees than 10 but less than 500) and very small (with fewer than 10 employees) establishments to comment on the cost estimation of documentation and reassessment required under the proposed rule.

Based on data recorded in the PBIS (2007) [21] volume database, and slaughter volume recorded in the FSIS Animal Disposition Reporting System (ADRS, 2008) [22] database, and volume estimates of the USDA Economic Research Service (ERS, 2009),[23] these 5,900 small entities process about 12 percent or about 8 billion pounds of the U.S. meat and poultry food supply per annum. Further, FSIS estimated that the average processing volume per establishment of 5,900 small entities was about 1.4 million pounds (8,000,000,000/5,900) per annum. Thus, the average cost for the first year of this proposed rule to small entities will be less than one tenth of one cent (*i.e.,* $0.0006 = $800/1,400,000) of meat and poultry food products per pound. This is a relatively insignificant cost to the small entities because most of their meat and poultry food products are valued at more than $1.00 per pound. The average cost for the following years, based on annual recurring costs, decreases to less than one hundredth of one cent per pound.

VIII. Alternatives

The option of no rulemaking is unavailable. FSIS was directed to conduct this rulemaking by Congress.

Executive Order 12988

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

[21] USDA, FSIS Performance Based Inspection System Volume Database 2007.

[22] USDA, FSIS Animal Disposition Reporting System Database 2008.

[23] USDA, Economic Research Service, Food Availability (Per Capita) Data System—Per capita food availability data compiled reflect the amount of food available for human consumption in the United States. March 2009, *http://www.ers.usda.gov/Data/FoodConsumption.*

Paperwork Requirements

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

Title: Notification, and Recall Procedure and HACCP Reassessment Documentation Requirements.

Type of Collection: New.

Abstract: Under this proposed rule, FSIS is requiring three information collection activities. First, FSIS is proposing to require that official establishments notify the appropriate District Office that an adulterated or misbranded product received by or originating from the establishment has entered commerce, if the establishment believes or has reason to believe that this has happened. FSIS is proposing that this notification occur as quickly as possible, but within 48 hours of the establishment learning or determining that an adulterated or misbranded product received by or originating from it has entered commerce. Second, FSIS is also proposing that establishments prepare and maintain current, written procedures for the recall of meat and poultry products produced and shipped by the establishment for use should it become necessary for the establishment to remove product from commerce. These written recall procedures will have to specify how the establishment will decide whether to conduct a product recall and how the establishment will effect the recall, should it decide that one is necessary. Finally, FSIS is proposing that establishments document each reassessment of the establishment's HACCP plans. The Agency is proposing to require that establishments document the reasons for any changes that they make to their HACCP plans based on the reassessment, or if they did not make any changes, that they document the reasons that they did not (although FSIS is proposing not to require an explanation if no change is made to the HACCP plan on the basis of the annual reassessment). The recall procedures and reassessment documentation will have to be made available for official review and copying.

Estimate of Burden of Average Hours per Response: 1.159.

Respondents: Official meat and poultry products establishments.

Estimated Number of Respondents: 6,300.

Estimated Number of Responses: 40,960.

Estimated Number of Responses per Respondent: 6.5.

Estimated Total Annual Burden on Respondents: 47,475.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, Room 6081, South Agriculture Building, 1400 Independence Avenue, SW., Washington, DC 20250.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

E–Government Act Compliance

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

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations/2010_Proposed Rules_Index/*. FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an e-mail subscription service that provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/.* Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects in 9 CFR Parts 417 and 418

Hazard Analysis and Critical Control Point (HACCP) Systems, Meat inspection, Poultry and poultry products inspection, Reporting and recordkeeping requirements, Recalls.

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

1. The authority citation for part 417 continues to read as follows:

Authority: 7 U.S.C. 450; 21 U.S.C. 451–470, 601–695; 7 U.S.C. 1901–1906; 7 CFR 2.18, 2.53.

2. In § 417.4, paragraph (a)(3) is redesignated as paragraph (a)(3)(i), and a new paragraph (a)(3)(ii) is added to read as follows:

§ 417.4 Validation, Verification, Reassessment.

* * * * *

(a) * * *

(3) *Reassessment of the HACCP plan.*

(i) * * *

(ii) Each establishment shall make a record of each reassessment required by paragraph (a)(3)(i) of this section and shall document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment; for annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it may briefly document this determination.

* * * * *

3. A new part 418 is added to read as follows:

PART 418—RECALLS

Sec.
418.1 [Reserved]
418.2 Notification.
418.3 Preparation and maintenance of current, written recall procedures.
418.4 Records.

Authority: 7 U.S.C. 450; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

§ 418.1 [Reserved]

§ 418.2 Notification.

Each official establishment shall promptly notify the local FSIS District Office (*see* 9 CFR 300.3(c)) within 48 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment shall inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.

§ 418.3 Preparation and maintenance of current, written recall procedures.

Each official establishment shall prepare and maintain written procedures for the recall of any meat, meat food, poultry, and poultry product produced and shipped by the official establishment for use should it become necessary for the official establishment to remove product from commerce. These written procedures shall specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.

§ 418.4 Records.

All records, including records documenting procedures required by this part, shall be available for official review and copying.

Done in Washington, DC, on March 19, 2010.

Alfred V. Almanza,

Administrator.

[FR Doc. 2010–6629 Filed 3–24–10; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF ENERGY

10 CFR Part 431

[Docket No. EERE–2008–BT–STD–0006]

RIN 1904–AB47

Energy Conservation Standards for Residential Central Air Conditioners and Heat Pumps: Public Meeting and Availability of the Preliminary Technical Support Document

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of public meeting and availability of preliminary technical support document.

SUMMARY: The U.S. Department of Energy (DOE) will hold a public meeting to discuss and receive comments on the product classes that DOE plans to analyze for purposes of establishing energy conservation standards for residential central air conditioners and heat pumps; the analytical framework, models, and tools that DOE is using to evaluate amended standards for these products; the results of preliminary analyses performed by DOE for these products; and potential energy conservation standard levels derived from these analyses that DOE could consider for these products. DOE also encourages written comments on these subjects. DOE has prepared a preliminary technical support document (TSD), which is available at: *http://www1.eere.energy.gov/buildings/appliance_standards/residential/central_ac_hp.html.*

DATES: DOE will hold a public meeting on Wednesday, May 5, 2010, from 9 a.m. to 5 p.m. in Washington, DC. Any person requesting to speak at the public meeting should submit such request, along with an electronic copy of the statement to be given at the public meeting, before 4 p.m., Wednesday, April 21, 2010. Written comments are welcome, especially following the public meeting, and should be submitted by May 10, 2010.

ADDRESSES: The public meeting held at the U.S. Department of Energy, Forrestal Building, Room GE–086, 1000 Independence Avenue, SW., Washington, DC 20585–0121. Please note that foreign nationals participating in the public meeting are subject to advance security screening procedures. If a foreign national wishes to participate in the public meeting, please inform DOE of this fact as soon as possible by contacting Ms. Brenda Edwards at (202) 586–2945 so that the necessary procedures can be completed. Interested persons may submit comments, identified by docket number EERE–2008–BT–STD–0006, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov* Follow the instructions for submitting comments.
- *E-mail: Brenda.Edwards@ee.doe.gov* Include EERE–2008–BT–STD–0006 in the subject line of the message.
- *Postal Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, Public Meeting for Residential Central Air Conditioners and Heat Pumps, EERE–2008–BT–STD–0006, 1000 Independence Avenue, SW., Washington, DC 20585–0121. Telephone (202) 586–2945. Please submit one signed paper original.
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Sixth Floor, 950 L'Enfant Plaza, SW., Washington, DC 20024. Telephone (202) 586–2945. Please submit one signed paper original.

Instructions: All submissions must include the agency name and docket number.

Docket: For access to the docket to read background documents or a copy of the transcript of the public meeting or comments received, go to the U.S. Department of Energy, Sixth Floor, 950 L'Enfant Plaza, SW., Washington, DC 20024, (202) 586–2945, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Please call Ms. Brenda Edwards at (202) 586–2945 for additional information regarding visiting the Resource Room.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information to Mr. Wes Anderson, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE–2J, 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–7335. E-mail: *Wes.Anderson@ee.doe.gov.* In the Office of General Counsel, contact Ms. Elizabeth Kohl, U.S. Department of Energy, Office of General Counsel, GC–71, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–7796. E-mail: *Elizabeth.Kohl@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

A. Statutory Authority

Part A of Title III of the Energy Policy and Conservation Act (42 U.S.C. 6291 *et seq.*) (EPCA) established the Energy Conservation Program for Consumer Products Other than Automobiles. Amendments expanded Title III of