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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 304, 381, 417 and 418

[FDMS Docket No. FSIS-2008-0025]

RIN: 0583-AC34

Requirements for Official Establishments to Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain Hazard Analysis and Critical Control Points System Plan Reassessments

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final Rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is implementing provisions of the Food, Conservation, and Energy Act of 2008 by amending the Federal meat and poultry products inspection regulations to 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 written procedures for the recall of all meat and poultry products produced and shipped by the establishment; and require official establishments to document each reassessment of the

establishment's Hazard Analysis and Critical Control Point (HACCP) plans.

DATES: Effective Date: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Applicability Dates: Amendments to §§ 304.3, 381.22, 417.4, 418.2, and 418.4 are applicable beginning [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. For more information on applicability dates, see the section titled "Section 418.3 Effective Dates" in the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, Room 349-E, Jamie L. Whitten Building, 1400 Independence Avenue, SW., Washington, DC 20250; Telephone (202) 205-0495, Fax (202) 720-2025.

SUPPLEMENTARY INFORMATION:

I. Section 418.3 Effective Dates

The regulations in § 418.3 are applicable as follows:

- In large establishments, defined as all establishments with 500 or more employees, [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

- In small establishments, defined as all establishments with 10 or more employees but fewer than 500, May 8, 2013.

- In very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than $2.5 million, May 8, 2013.

II. Background

The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) to protect the health and welfare of consumers. The Agency is responsible for ensuring that the nation's commercial supply of meat and poultry is safe, wholesome, and correctly 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 to require establishments subject to inspection under these Acts that believe or have reason to believe that an adulterated or misbranded meat or poultry product received by or originating from the establishment has entered into commerce to promptly notify the Secretary with regard to

the type, amount, origin, and destination of the meat or poultry product. The 2008 Farm Bill also requires that inspected establishments: (1) prepare and maintain written 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.

In the Federal Register of March 25, 2010 (75 FR 14361), FSIS proposed regulations to implement the new provisions of the 2008 Farm Bill. FSIS proposed to amend 9 CFR 417.4(a)(3) to require official establishments to make a written record of each reassessment of the adequacy of their HACCP plan, or to document the reasons for not making a change to their HACCP plan based on the reassessment. For annual reassessments, if an establishment determines that no changes to its HACCP plans are necessary, the establishment does not have to document the reasons for this determination. Furthermore, FSIS proposed to establish a new 9 CFR part 418, Recalls, under which official establishments would be required to prepare and maintain procedures for the recall of all meat and poultry

products produced and shipped by the establishment, and to promptly notify FSIS within 48 hours if the establishment believes or has reason to believe that an adulterated or misbranded product received by or originating from the establishment has entered into commerce. Interested persons were invited to submit written comments by May 24, 2010.

After review and consideration of all comments, FSIS is finalizing, with three changes, the provisions in the March 2010 proposed rule. Specifically, the Agency is amending the proposal to require official establishments to promptly notify FSIS within 24 hours if the establishment believes or has reason to believe that an adulterated or misbranded product received by or originating from the establishment has entered into commerce. In addition, the Agency is amending the proposal to require new establishments to develop their written recall procedures at the same time as their HACCP plans in order to receive a Federal Grant of Inspection.

Also in response to comments, FSIS has decided to stagger the applicability date for 9 CFR part 418 based on establishment size. Existing large establishments, defined as all establishments with 500 or more employees, will have six months from the date of publication of this final rule

in the Federal Register to prepare their written recall procedures. Existing small establishments (those with 10 or more employees but fewer than 500) and very small establishments (those with fewer than 10 employees or annual sales of less than $2.5 million) will have one year from publication of this final rule in the Federal Register to prepare their written recall procedures. These changes are discussed in detail in the Agency's responses to comments.

III. Summary of and Response to Comments

FSIS received 31 comments from hospitality supply companies, supply management companies, trade groups representing meat packing and processing establishments, a trade group representing the turkey industry, a trade group representing food and beverage companies, a trade group representing organic agriculture products, a representative from a state department of agriculture, a small processing plant, a rancher, a farmer, and 14 consumers.

A summary of issues raised by commenters and the Agency's responses follows.

A. Notification Requirement

Comment: A few comments addressed 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. A consumer and a trade group representing the turkey industry stated that 48 hours is a reasonable timeframe to give establishments to notify District Offices. A trade group representing meat packing and processing establishments also stated that the proposed time period was reasonable, but was concerned that 48 hours may be an arbitrary figure. Three consumer groups and an individual consumer argued the proposed timeframe is too lax, and that establishments should notify District Offices within 24 hours if they may have shipped or received adulterated or misbranded product. One consumer group argued that allowing official establishments to wait as long as 48 hours before reporting this information to the appropriate District Office will unnecessarily delay efforts to remove adulterated or misbranded product from commerce. Another consumer group argued that 24 hours is sufficient time for establishments to notify District Offices that they may have shipped or received adulterated or misbranded product because establishments may notify the District Office by phone.

Agency's Response: FSIS agreed with commenters that 48 hours may be too long. The Agency has concluded that

because notification can be made with a phone call, 24 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. Therefore, the final rule requires official establishments to notify the appropriate District Office within 24 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.

Comment: A few comments requested that the Agency provide more guidance on when the 48-hour period would officially begin. One comment from a consumer group argued that the proposed requirement was vague and confusing. The commenter asked that the Agency explain how much investigation an establishment owner will be required to make before the notification requirement is triggered. Another comment from a trade group representing meat packing and processing establishments recommended that the Agency work with industry on establishing the timeline. They requested that the Agency develop specific guidance that outlines a step-by-step reaction process. They also

requested that FSIS consider factors such as microbial test data recovery, weekends, and Federal holidays when deciding when the 48-hour period should officially begin.

Agency's Response: The 24-hour period begins when the establishment has reason to believe that a product that is in commerce is adulterated or misbranded under the FMIA or PPIA. For example, if the results of a laboratory analysis show that raw ground beef contains E. coli O157:H7, or that a ready-to-eat product contains Listeria monocytogenes or any other pathogen, the product would be adulterated. However, there also may be situations in which laboratory results are not available, but, based on epidemiological evidence, there may be a probability of harm from consuming the product. Under these circumstances, the establishment is to consider the strength of the epidemiological evidence to determine whether there is reason to believe that the product is adulterated or misbranded.

Comment: Two comments argued that the notification requirement is "overly broad," and that minor labeling errors do not misbrand product and should be excluded from the notification requirement. They suggested that the Agency follow the standard established for the U.S. Food and Drug Administration's (FDA's) Reportable Food Registry or incorporate a de minimis standard. The FDA standard

requires notification when there is a reasonable probability that the use of, or exposure to, the article of food will cause serious adverse health consequences or death (21 U.S.C. 350(d)).

Agency's Response: FSIS did not accept suggestions to follow the standard established for the FDA's Reportable Food Registry (RFR) or to incorporate a de minimis standard. FSIS assesses the public health concern or hazard presented by a product being recalled, or considered for recall, and classifies the concern as one of the following: (1) Class I, a health-hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death; (2) Class II, a health-hazard situation where there is a remote probability of adverse health consequences from the use of the product; or (3) Class III, a situation where the use of the product will not cause adverse health consequences. If the Agency adopted the RFR standard or a similar de minimis standard, establishments may not be required to notify FSIS about product that could trigger a Class II or Class III recall. Furthermore, the 2008 Farm Bill provisions do not provide for a de minimis standard concerning the notification requirements for establishments that may have shipped or received adulterated or misbranded

product. Consistent with the statute, and because the notification requirement is a preventive measure that will allow FSIS to determine more quickly whether a recall action is necessary (including detention and seizure of product by FSIS), thereby protecting public health, the final rule requires official establishments to notify the appropriate District Office of all product that is believed to be adulterated or misbranded.

FSIS is aware, however, that there can be misbranding situations because of minor labeling deficiencies, and that these deficiencies do not create health or safety issues or impart an economic advantage. If a District Office, when notified by an establishment that it has shipped or received or may have shipped or received misbranded product, identifies the violation as one that does not create a health or safety issue or economic impact, it will contact FSIS's Labeling and Program Delivery Division (LPDD) about the misbranding situation. LPDD will then contact the establishment and work with it to resolve the situation.

Comment: Two comments submitted by consumer groups requested that the final rule require official establishments to notify both the appropriate District Office and FSIS headquarters in Washington, D.C. They

argued that because the legislation refers to notifying the Secretary of Agriculture, and given the potential health impacts of the recall information, data should be sent to headquarters in addition to the local District Office.

Agency's Response: The Agency does not believe it is necessary for official establishments to contact both the appropriate District Office and FSIS headquarters in Washington, D.C. The Secretary of Agriculture has delegated to the Under Secretary for Food Safety the responsibility for exercising the functions of the Secretary of Agriculture under various statutes (Section 4(a) of Reorganization Plan No. 2 of 1953 (5 U.S.C. App.) and Section 212(a)(1) of the Department of Agriculture Reorganization Act of 1994, Pub. L. No. 103-354, 7 U.S.C. 6912(a)(1)), while the Under Secretary for Food Safety has delegated that authority to the Administrator of the Food Safety and Inspection Service (7 CFR 2.7, 2.18, and 2.53). In turn, each District Office, under the direction of a District Manager, has been given the authority to manage a farm-to-table food safety program of regulatory oversight and inspection in a district consisting of a State or several States and territories. Thus, the District Offices have the authority, and are fully competent, to receive and

analyze information from official establishments about adulterated or misbranded product.

Comment: A trade group representing meat packing and processing establishments and a trade group that represents food and beverage companies noted that the proposed rule provides that establishments must notify FSIS of the destination of the adulterated or misbranded product. The two trade groups suggested that the Agency clearly state in the preamble to the final rule that while the statutory language specified notification of the "destination" of the adulterated or misbranded product, shipping establishments only have knowledge of, and therefore, need only provide notification about their direct consignees.

Agency's Response: Under this rule, establishments must provide all available information about the "destination" of adulterated or misbranded product. This rule does not create a duty to seek out new information; however, if establishments have information about the destination of adulterated or misbranded product beyond their direct consignees, they must provide it to the Agency.

B. Recall plans

Comment: Several comments expressed concerns about the security of plant recall information and whether recall

plans would be subject to the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)).

Agency's Response: FSIS understands the nature of these comments and that many meat and poultry establishments view the data in recall procedures as confidential commercial information. Pursuant to USDA's Freedom of Information Act (FOIA) regulations (7 CFR 1.1 et seq.), FSIS is responsible for making the determination with regard to the disclosure or nondisclosure of information in records obtained from businesses. When, in the course of responding to an FOIA request, FSIS cannot readily determine whether the information obtained from a person is confidential business information, the Agency seeks to obtain and carefully consider the views of the business and provide the business an opportunity to object to any decision to disclose the information.

Under this final rule, establishments are not required to submit their recall procedures to FSIS. They must, however, make the written recall procedures available for copying. FSIS will verify that all establishments maintain the required written recall procedures. FSIS will also protect establishments' confidential business information from public disclosure to the extent authorized under FOIA and in conformity with USDA's FOIA regulations.

Comment: Two comments questioned whether the language of the proposed rule exceeded the provisions of the Farm Bill because it requires official establishments to specify in their written recall procedures how they will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.

Agency's Response: FSIS has the authority to require official establishments to specify in their written recall procedures how they will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.[1] These requirements are also consistent with the legislation and with longstanding Agency guidance on recall plans.[2]

Comment: Several comments suggested that the Agency execute the rule in incremental stages based on business size, similar to the plan used when HACCP was implemented. Two stated that six months to one year is a reasonable time to give establishments to develop recall procedures. One comment suggested that current establishments should be given six months to develop recall procedures, but new

[1] See 21 U.S.C. 621, "… and said Secretary shall, from time to time, make sure rules and regulations as are necessary for the efficient execution of the provisions of this Act, …" and 21 U.S.C. 463(b), "The Secretary shall promulgate such other rules and regulations as are necessary to carry out the provisions of this chapter."
[2] See "FSIS Directive 8080.1, Rev. 6, 10/26/10, Recall of Meat and Poultry Products, Attachment 1".

establishments should be required to prepare their recall procedures at the same time as their HACCP plans. Another comment recommended that large establishments be required to prepare their recall procedures as soon as possible, but that small and very small establishments be given more time to comply. Yet another comment suggested that the Agency implement the rule for large establishments and review the results for one year before requiring small and very small establishments develop recall procedures.

Agency's Response: FSIS has sought to make this rule as fair and equitable as possible, regardless of an establishment's size. Therefore, the Agency asked for comments on when, after the effective date of this final rule, written recall procedures must be completed in accordance with proposed 9 CFR 418.3. Based upon the comments received, FSIS has determined that existing large establishments will have six months from the date of publication of this final rule to implement it and prepare recall plans. To minimize the burden on small businesses, small and very small establishments will have one year from the date of publication to comply.

FSIS believes that the suggestion to require new establishments to have prepared their recall procedures at the same time as their HACCP plans in order to receive a

Federal Grant of Inspection has merit. Therefore, the Agency is amending 9 CFR part 304.3 and 9 CFR part 381.22 to require that before being granted Federal inspection, an establishment must have developed written recall procedures as required by part 418 of Title 9, Chapter III. The Office of Outreach, Employee Education and Training has model recall plans available to industry.

Reassessment of HACCP Plans

Comment: Several comments supported the documenting of HACCP reassessments, as proposed. One consumer group argued that documentation is vital because it provides a needed safeguard against evasion of reassessment requirements. The commenter stated that by making records of reassessment available for official review and copying, FSIS has the ability to preempt an outbreak by identifying overlooked hazards.

Agency's Response: The Agency agrees with comments that the documenting of HACCP reassessments is beneficial. The Agency believes that documenting HACCP reassessments will facilitate verification that establishments have appropriately reassessed their HACCP plans. It will also help FSIS personnel to identify whether there are emerging hazards that the establishment has decided not to address.

Comment: One comment submitted by a trade group representing meat packing and processing establishments requested that the Agency clarify in the final rule that simple formatting or grammar changes of a HACCP plan do not need to be documented as reassessments.

Agency's Response: While establishments are required to document each reassessment of their HAACP plans, the Agency does not consider formatting and grammar changes to be reassessments.

Costs

Comment: The Agency received several comments addressing the cost of implementing the proposed rule. One consumer group argued that the cost of implementing the proposed rule is reasonable. The commenter argued that if the first-year industry costs will be $5 million dollars, that cost is far less than the billions of dollars the United States incurs as a result of foodborne illnesses per year.

A few comments from very small processors or supporters of very small processors or local processors claimed that additional regulation will be an undue financial burden on small and very small establishments. One trade group representing meat packing and processing establishments believed that FSIS's estimated initial cost

is already a significant cost to many small and very small establishments, and that the actual cost could potentially be much higher. The trade group suggested that the initial cost to small and very small establishments might be $2,000; however, the trade group did not offer any data to support its claim. Another comment submitted by a consumer suggested creating waivers or exemptions for small and very small establishments.

Agency's Response: While the Agency agrees with the commenter that $2,000 in initial cost for small and very small establishments may be a significant cost, FSIS estimates that the average initial (first-year) cost of implementing this final rule for these establishments will not be $2,000 but would be between $700 and $900, with a midpoint of $800[3], for each small or very small establishment.

IV. Executive Orders 12866 and 13563 and Regulatory Flexibility Act

Executive Orders 13563 and 12866 direct agencies to assess all 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 health and safety

[3] See, Table 2 (columns 7, 8, and 9), which is the updated Table 3, Federal Register, Vol. 75, No. 57, March 25, 2010, page 14365.

effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action" under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

FSIS has carefully evaluated the comments submitted in response to the proposed rule and has concluded that it is appropriate to adopt the Preliminary Regulatory Impact Analysis and the initial Regulatory Flexibility Act (RFA) assessment as final. This Final Regulatory Impact Analysis (FRIA) and final RFA assessment have changed from the Preliminary Regulatory Impact Analysis and the initial RFA assessment that were published in the proposed rule on March 25, 2010, though the methodology remains the same.

A. Baseline

FSIS expects that this final rule will affect about 6,300 official federally-inspected establishments that slaughter or process meat, meat products, poultry, and poultry products, based on FSIS's Performance Based Inspection System (PBIS) of 2011. Based on HACCP

classification, about 400 are large establishments, 3,044 are small, and 2,856 are very small.[4]

B. Expected Costs

Under the current regulations, the development and maintenance of recall procedures and the written documentation of HACCP reassessments are voluntary. This final rule will make them mandatory. Costs will be incurred because about 6,300 official establishments will need to develop recall procedures and maintain written documentation of HACCP reassessments. Cost estimates are updated to reflect the most recent available data[5].

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

[4] Very small establishments have fewer than 10 employees or generate less than $2.5 million in annual sales; and small establishments have 10 or more but fewer than 500 employees and generate more than $2.5 million in annual sales.

[5] This includes USDA, FSIS Performance Based Inspection System Volume Database 2011, and 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.

In addition to the extra establishment labor cost, FSIS estimates that the extra establishment material cost would be about 1 percent of the labor cost of the development of the recall procedures and the documentation of each reassessment of the HACCP plan. The first year estimated average total costs to the industry are about $5.2 million for labor (shown in Table 1) and $52 thousand (0.01 x $5.2M = $52,000) for materials.

FSIS believes that the estimated cost of developing recall procedures is an overestimate because: (1) Some unknown number of establishments already have plans that 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. Given the uncertainty of incurred labor cost in different regions and with various experience levels, FSIS assumes a 20% range, plus and minus 10%, of the estimated average-compliance cost. The estimated cost summary is shown in Table 1.

FSIS expects that in the first year of the final rule, one-time costs for developing recall procedures would cost

the industry of approximately 6,300 establishments $4.6 million, in an estimated range of $4.1 and $5.0 million, 10% lower and upper bound, respectively. Furthermore, the final rule would have first year costs of approximately $0.5 million for documenting periodic reassessments of HACCP plans, and $0.1 million for records backup and storage, although these costs may well be overstated. The recurring costs of developing and updating recall procedures, documenting periodic reassessments of HACCP plans, and records backup and storage for the second through the tenth year are estimated at $610,000, $66,000, and $11,000, respectively (see Table 3).

The total cost for the first year is $5.2 ($4.6 + $0.5 +$0.1) million, in an estimated range of $4.7 and $5.7 million, 10% lower and upper bound, respectively. Considering the subsequent years cost of $687,000, the annualized cost over ten years using 3% and 7% discount rates is $1.20 million ($1.08 million and $1.31 million, 10% lower and upper bound), and $1.28 million ($1.15 million and $1.41 million, 10% lower and upper bound), respectively (Table 3).

The present value of total costs with a 3% discount rate for 10 years would be $10.2 million, in an estimated range of $9.2 and $11.2 million. The present value of

total costs with a 7% discount rate for 10 years would be $9.0 million, in an estimated range of $8.1 and $9.9 million.

Table 2 shows the first year total costs by 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 first year cost per official establishment is between $700 and $900, 10% lower and upper bound, respectively.

Table 3 gives the estimated annualized cost and the present value of total cost by establishment size classes for ten years. Table 3, column 4, shows all cost categories of the first year (assumed to be 2013) and comes from Table 2, column 6, distributed by the counts of establishment size classes. The costs for years 2 – 10 are based on constant dollar assumption and are shown in Table 3, column 5.

TABLE 1 – FIRST YEAR COST BREAKDWON, IN DOLLARS, FOR 6,300 ESTABLISHMENTS (LABOR AND MATERIALS)

Cost Component	Response Rate	Required Man-hours	Wage Rate	Factor for paper, ink, and media cost	Material (paper, ink and media) Cost (x$1,000)	Total Cost (x$1,000)	Low Range (-10%) of Total Cost	High Range (+10%) of Total Cost
Recall-Procedures Development (one-time)	1	20	36	1.01	46	4,582	4,124	5,040
Document Reassessment (First Year)	5	0.25	63	1.01	5	501	451	551
Records Backup and Storage (First Year)	1	0.25	36	1.50	28	85	77	94
Total					79	5,168	4,651	5,685

TABLE 2 – NUMBER OF ESTABLISHMENTS, TOTAL AND AVERAGE COSTS IN SIZE (x$1,000)

HACCP Class	Number of Establish-ments	Recall Procedures Development (one-time)	Docu-menting HACCP Re-assessment	Records backup and storage	Total Cost	Cost per establish-ment	Low estimate (-10%)	High estimate (+10%)
Very Small	2,856	2,077	227	39	2,343	0.8	0.7	0.9
Small	3,044	2,214	242	41	2,497	0.8	0.7	0.9
Subtotal	5,900	4,291	469	80	4,840	0.8	0.7	0.9
Large	400	291	32	5	328	0.8	0.7	0.9
Total	6,300	4,582	501	85	5,168	0.8	0.7	0.9

TABLE 3 - ESTIMATE ANNUALIZED AND PRESENT VALUE OF THE TOTAL COST BY ESTABLISHMENT SIZE CLASS, ASSUMING CONSTANT DOLLARS

HACCP Class	Number of establish-ments	Activities	1st Year 2013	2nd-10th Years 2014-22	Annual-ized Cost at 3%	Annual-ized Cost at 7%	Present Value of Total Cost at 3%	Present Value of Total Cost at 7%
Very Small	2,856	Recall-Procedures development & updating	2,077	278	483	517	4,118	3,634
		Documenting HACCP Reassessment	227	30	52	56	447	395
		Records backup and storage	39	5	9	10	76	67
		Subtotal	2,343	313	544	583	4,641	4,096
Small	3,044	Recall-Procedures development & updating	2,214	296	514	551	4,387	3,872
		Documenting HACCP Reassessment	242	32	56	60	477	421
		Records backup and storage	41	5	9	10	78	69
		Subtotal	2,497	333	579	621	4,942	4,361
Small and Very Small	5,900	Subtotal of Small & Very Small	4,480	646	1,123	1,204	9,582	8,457
Large	400	Recall-Procedures development & updating	291	36	65	70	555	491
		Documenting HACCP Reassessment	32	4	7	8	61	54
		Records backup and storage	5	1	1	2	12	11
		Subtotal	328	40	74	79	628	556
Total	6,300	Recall-Procedures development & updating	4,582	610	1,062	1,139	9,060	7,997
		Documenting HACCP Reassessment	501	66	116	124	985	870
		Records backup and storage	85	11	19	21	166	146
Total			5,168	687	1,197	1,283	10,211	9,013

C. Expected Benefits

The expected benefits likely to result from this final rule are improvements in the effectiveness of the nation's food safety system for meat and poultry products and improved protection of public health. These benefits are not monetized because quantified data on benefits attributable to this final rule are not available to FSIS. The expected benefits include:

HACCP Reassessment and Documentation of Reassessments

Under this final rule, establishments must document each reassessment, the reasons for any changes to the HACCP plan, or the reasons for not changing the HACCP plan. For annual reassessments, if the establishment determines that no changes are necessary, documentation of this determination is not necessary. These provisions will allow FSIS personnel to better verify and track that establishments are, in fact, reassessing those plans at least annually, as required by 9 CFR 417.4(a)(3), and that they are appropriately responding to their findings.

Notification Requirement

This final rule is a preventive measure that will result in FSIS being alerted to potential meat and poultry recall situations earlier than would otherwise be the case. Under this rule, establishments will be required to notify

the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded product received by or originating from the establishment has entered commerce. This notification, in turn, will allow FSIS to initiate its preliminary inquiries more quickly and to determine more quickly whether a recall is necessary.

Improve Recall Effectiveness with Documented Procedures

FSIS expects that this final rule will 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 be able to act more effectively to remove adulterated or misbranded products from commerce. This added efficiency and effectiveness will help establishments to move quickly to disseminate information about the need to return the product to it and thus maximize the amount of recalled product they will actually recover. Table 4 gives a summary of the benefits discussed above.

TABLE 4-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 documentation of the HACCP plans available to inspection program personnel.	• Improved HACCP systems for establishments.
Notification Requirement	• Establishments are to notify local FSIS District Office within 24 hours of having reason to believe that an adulterated or misbranded product received 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 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 be able to act more effectively to remove adulterated or misbranded products from consumers. • Establishments will be able to move quickly to disseminate information about the need to return product to it. • Establishments will be able to maximize the amount of product they will be able to receive.

D. Regulatory Flexibility Act Analysis

The FSIS Administrator has certified that this final 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 number about 5,900 federally-inspected establishments. The average cost to small and very small businesses will be in the range of $700 to $900, (Table 2).

Based on data recorded in the PBIS (2011)[6] volume database, and slaughter volume recorded in the FSIS Animal Disposition Reporting System (ADRS, 2008)[7] database, and volume estimates of the USDA Economic Research Service (ERS, 2009)[8], 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 final rule to small entities will be less than one tenth of one cent (e.g., $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 $1.50 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.

E. Alternatives

[6] USDA, FSIS Performance Based Inspection System Volume Database 2011. The number of establishments is the number of Federally-inspected processing and slaughter establishments.
[7] USDA, FSIS Animal Disposition Reporting System Database 2008.
[8] 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 .

The option of no rulemaking is unavailable. FSIS was directed to conduct this rulemaking by Congress. As discussed above, FSIS considered a longer time period (48 hours) for establishments to notify FSIS when they have reason to believe that adulterated or misbranded products of theirs may have entered commerce. This option was rejected in response to comments received. Also in response to comments, FSIS is providing a phased-in implementation period, with more time allowed for small and very small establishments than for larger establishments, rather than a uniform implementation period. This latter amendment should lessen the burden on smaller entities.

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.

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 rule have been submitted for approval to OMB.

Title: Requirements for Official Establishments to Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain HACCP Plan Reassessments.

Type of Collection: New.

Abstract: Under this final rule, FSIS is requiring three information collection activities. First, FSIS requires 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 requiring that this notification occur as quickly as possible, but within 24 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 requiring that establishments prepare and maintain 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 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 requiring that establishments document each reassessment of the establishment's HACCP plans. FSIS requires establishments to reassess their HACCP plans annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Under this rule, establishments must document each reassessment, the reasons for any changes to the HACCP plan, or the reasons for not changing the HACCP plan. For annual reassessments, if the establishment determines that no changes are necessary, documentation of this determination is not necessary. 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.

E-Government Act Compliance

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.

Executive Order 13175

This final rule has been carefully evaluated for potential tribal implications in accordance with Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. FSIS has concluded based on its evaluation that this final rule will not have any direct or substantial effects on Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power or responsibilities between the Federal Government and Indian Tribes because there are currently no federally-inspected meat or poultry

establishments owned or operated by Indian Tribes in tribal areas or on tribal reservations.

USDA Nondiscrimination Statement

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To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW., Washington, DC 20250-9410 or call 202-720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this rule online through the FSIS Web page located at

http://www.fsis.usda.gov/regulations_&_policies/Interim_&_Final_Rules/index.asp.

FSIS will also make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/News_&_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 304, 381, 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 amending 9 CFR Chapter III, as follows:

PART 304—APPLICATION FOR INSPECTION; GRANT OF INSPECTION

1. The authority citation for part 304 continues to read as follows:

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

2. In § 304.3, paragraph (a) is revised to read as follows:

§ 304.3 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment must have developed written sanitation Standard Operating Procedures, as required by part 416 of this chapter, and written recall procedures as required by part 418 of this chapter.

* * * * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

3. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451-470; 7 CFR 2.7, 2.18, 2.53

4. In § 381.22, paragraph (a) is revised to read as follows:

§ 381.22 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment must have developed written sanitation Standard Operating Procedures, as required by part 416 of this chapter, and written recall procedures as required by part 418 of this chapter.

* * * * *

PART 417—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

5. 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.

6. 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 must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must 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 is not required to document the basis for this determination.

* * * * *

7. 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 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 must promptly notify the local FSIS District Office within 24 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 must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.

§ 418.3 Preparation and maintenance of written recall procedures.

Each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official establishment. These written procedures must 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, must be available for official review and copying.

Done in Washington, DC, on: May 1, 2012

Alfred V. Almanza

Administrator.

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