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Rural Utilities Service

Title: Public Television Digital Transition Grant Program

OMB Control Number: 0572-0134

Summary of Collection: The Omnibus Appropriations Act (Pub. L. 108-7) provided grant funds in the Distance Learning and Telemedicine Grant Program budget, the Consolidated Appropriations Act (Pub. L. 108-199) and the Consolidated Appropriations Act, 2005 (Pub. L. 108-447) provided additional funds for public broadcasting systems to meet the digital transition. As part of the nation's transition to digital television, the Federal Communications Commission (FCC) required all television broadcasters to initiate the broadcast of a digital television signal and to cease analog television broadcasts on February 18, 2009. While stations must broadcast its main transmitter signal in digital, many rural stations often have translators serving small or isolated areas and some of these have not completed the transition to digital or fully converted its production and studio equipment to digital. Because the FCC deadline did not apply to translators, they are allowed to continue broadcasting in analog. The digital transition also created some service gaps where households receiving an analog signal cannot receive a digital signal. For these reasons the grant program has continued past the FCC digital transition deadline of June 2009. The Rural Utilities Service (RUS) will develop and issue requirements for the grant program to finance the conversion of television

services from analog to digital broadcasting for public television stations serving rural areas.

Need and Use of the Information: Applicants will submit grant applications to RUS for review. The information will consist of the following: Standard Form (SF) 424, "Application for Federal Assistance, executive summary, evidence of eligibility and compliance with other Federal statutes and any other supporting documentation. RUS will use the information to score and rank applications for funding. Scoring will consist of three categories: Rurality; per capita income; and special disadvantaging factors facing the station's transition plans. If this information is not collected, there would be no basis for awarding grant funding.

Description of Respondents: Not-for-profit institutions; State, Local or Tribal Government

Number of Respondents: 40

Frequency of Responses: Reporting: On occasion

Total Burden Hours: 950

Charlene Parker,

Departmental Information Collection Clearance Officer.

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DEPARTMENT OF AGRICULTURE

Davy Crockett National Forest Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of Public Meeting, Davy Crockett National Forest Resource Advisory Committee.

SUMMARY: In accordance with the Secure Rural Schools and Community Self Determination Act of 2000 (Pub. L. 106-393), [as reauthorized as part of Public Law 110-343] and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of Agriculture, Forest Service, Davy Crockett National Forest Resource Advisory Committee (RAC) meeting will meet as indicated below.

DATES: The Davy Crockett National Forest RAC meeting will be held on May 5, 2011.

ADDRESSES: The Davy Crockett National Forest RAC meeting will be held at the Davy Crockett Ranger Station located on State Highway 7, approximately one-quarter mile West of FM 227 in Houston County, Texas. The meeting will begin at 6 p.m. and adjourn at approximately 8 p.m. A public comment period will begin at 7:45 p.m.

FOR FURTHER INFORMATION CONTACT: Gerald Lawrence, Jr., Designated Federal Officer, Davy Crockett National Forest, 18551 State Hwy. 7 E., Kennard, TX 75847; Telephone: 936-655-2299 ext. 225 or e-mail at: *glawrence@fs.fed.us*.

SUPPLEMENTARY INFORMATION: The Davy Crockett National Forest RAC proposes projects and funding to the the Secretary of Agriculture under Section 203 of the Secure Rural Schools and Community Self Determination Act of 2000, (as reauthorized as part of Public Law 110-343). The purpose of the May 5, 2011 meeting is the following: proposal and approval of new Title II and Stewardship proposals, deadlines for obligating funding, and current project status. These meetings are open to the public. The public may present written comments to the RAC. Each formal RAC meeting will also have time, as identified above, persons wishing to comment and time available, the time for individual oral comments may be limited.

Gerald Lawrence, Jr.,

Designated Federal Officer, Davy Crockett National Forest RAC.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2005-0044]

Not Applying the Mark of Inspection Pending Certain Test Results

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice; Request for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing its intention to change its procedures and withhold a determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received. Inspection program personnel periodically sample products for adulterants to verify an establishment's regulatory compliance. The Agency's practice has been to allow these products to bear the mark of inspection, and to enter commerce, even though the test results have not been received. FSIS has asked, but has not required, official establishments to maintain control of products represented by a sample pending test results.

Because establishments, including official import inspection

establishments, are not consistently maintaining control of product, despite FSIS's request that they do so, adulterated product is entering commerce. Therefore, FSIS is announcing its tentative determination not to apply the mark of inspection until negative results are available and received for any testing for adulterants conducted by the Agency. FSIS invites comments on this proposed change in policy and procedures. FSIS will evaluate comments received in response to this notice. In a subsequent **Federal Register** notice, FSIS will respond to the comments it receives. FSIS will make any appropriate changes to the policy and procedures based on comments, and in that subsequent **Federal Register** notice will announce the effective date of the new policy.

DATES: The Agency must receive comments by July 11, 2011.

ADDRESSES: 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 diskettes or CD-ROMs, and hand-delivered 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, Mailstop 5474, Beltsville, MD 20705-5474.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2006-0044. 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 to 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.

All comments submitted in response to this proposal, as well as background information used by FSIS in developing this document, will be available for public inspection in 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: Rachel Edelstein, Director, Policy Issuances Division, Office of Policy and Program Development, FSIS, U.S.

Department of Agriculture, Room 6065, South Building, 1400 Independence Ave., SW., Washington, DC 20250-3700; telephone (202) 720-0399; fax (202) 690-0486.

SUPPLEMENTARY INFORMATION:

Background

FSIS is responsible for protecting the nation's meat and poultry supply by making sure that it is safe, wholesome, not adulterated, and properly labeled and packaged. FSIS operates under authority provided by 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.*) (the Acts). These statutes prohibit anyone from selling, transporting, offering for sale or transportation, or receiving for transportation in commerce, any adulterated or misbranded meat or poultry products (21 U.S.C. 610 and 458).

There are nine parts to the definition of "adulterated" in the FMIA and eight in the PPIA. Most relevant to product testing are subparagraphs (1) and (2)(A) of 21 U.S.C. 601(m) and 453(g). 21 U.S.C. 601(m)(1) and 453(g)(1) provide that product is adulterated if it bears or contains any poisonous or deleterious substance that may render it injurious to health. Therefore, a ready-to-eat meat or poultry product found positive for a pathogen, or a raw ground or other raw non-intact beef product found positive for *E. coli* O157:H7, is adulterated under these statutory provisions. In addition, if food contact surfaces are found positive for *Listeria monocytogenes*, ready-to-eat product produced on these surfaces is adulterated under 9 CFR 430.4(a). 21 U.S.C. 601(m)(2)(A) and 453(g)(2)(A) provide that a meat or poultry product is adulterated if it bears or contains any added poisonous or added deleterious substance by reason of administration of any substance to the live animal. Therefore, if FSIS tests carcasses for residues of animal drugs that have been administered to the live animal and finds unacceptable levels, the product would be adulterated under these statutory provisions. FSIS testing conducted for pathogens and residues that would adulterate product under the provisions above are the primary focus of the actions outlined in this notice.

In addition, the term "adulterated" includes product from which any valuable constituent has been in whole or in part omitted or abstracted; for which any substance has been substituted; or to which any substance has been added or mixed or packed so as to increase its bulk or weight, reduce its quality or strength, or make it appear better or of greater value than it is (21

U.S.C. 601(m)(8) and 453(g)(8)). This type of adulteration is referred to as "economic adulteration". FSIS testing that indicates product is economically adulterated would be subject to the actions outlined in this document. However, because FSIS conducts minimal testing for economic adulteration, this notice does not elaborate on such testing.

The FMIA and PPIA also provide that meat and poultry products must bear an official inspection legend (21 U.S.C. 601(n)(12) and 453(h)(12)) in order to enter commerce. FSIS must be able to determine that product is not adulterated in order to apply the mark of inspection (21 U.S.C. 606 and 457(a)). FSIS inspection personnel conduct a range of activities to determine whether product is adulterated (9 CFR 417.8). Among these activities is testing for adulterants.

FSIS's practice is to allow meat and poultry products to be packaged and labeled with the mark of inspection pending receipt of results of tests done by FSIS. Currently, FSIS requests, but does not require, that establishments maintain control of all product represented by any samples taken until the Agency receives the results of the sampling. Establishments are not required to maintain such control and may ship product before test results are available. If the establishment introduces the product into commerce, and the test result for that product is positive for a pathogen or other adulterant, FSIS will request that the establishment recall the product. If the establishment refuses to recall the product, FSIS will move to detain and, if necessary, seize it.

Reason for This Notice

The Agency has questioned for some time whether it should continue to allow product to leave the establishment, albeit subject to a recall, before relevant test results are received. On December 12, 2002, FSIS held a public meeting in Washington, DC, to both inform the public about the recall process and to solicit recommendations on recalls from establishments whose product is subject to recall, from public health agencies, and from those who represent the public health interests of consumers. The agenda for this meeting included a discussion on withholding the decision to apply the mark of inspection until FSIS test results are available. Presenters and commenters raised concerns about the effect such a policy would have on small and very small establishments. FSIS took these comments into account in the cost

benefit analysis of this policy discussed below.

On June 2–3, 2004, FSIS presented a subcommittee of the National Advisory Committee on Meat and Poultry Inspection (NACMPI) with the following question for discussion: Should FSIS delay a decision on granting the mark of inspection to product that has been tested by FSIS for the presence of an adulterant until it has received the results of the testing? The committee made a number of recommendations to the Agency but was unable to come to consensus on the question of not applying the mark of inspection until FSIS verification test results are available. The committee recommended that the Agency continue to encourage plants to develop a plan for holding products when they are sampled for adulterants. The committee further recommended that FSIS provide guidance to plants regarding holding products, and that FSIS work with the industry on strategies to mitigate some of the practical problems associated with holding products.

In June 2005, the Agency again requested advice from the NACMPI. The Agency asked the committee for suggestions on the most effective way to provide guidance to industry on holding product that has been tested for pathogens by FSIS, especially to small and very small plants. The Committee considered the issue and its impact on small and very small establishments and made a number of recommendations to the Agency. The Committee recommended: (a) That FSIS refrain from issuing any guidance at that time but instead review a draft of voluntary guidelines that representatives from across the meat and poultry industry had written to ensure that they conform to applicable laws, regulations, and policies; (b) that industry issue its guidelines after FSIS review and work with the Agency to ensure widespread distribution of these guidelines, especially to small and very small plants; and (c) that FSIS monitor the effectiveness of the industry guidance on an ongoing basis and take appropriate actions, ranging from recommendations for improving the guidelines to formal Agency action.

In 2005, the Agency carefully considered the committee's recommendations and decided not to pursue a change in policy that would require establishments to hold product pending FSIS test results and to await the outcome of the industry-issued voluntary guidance on best practices for maintaining control of product while awaiting FSIS' test results. The Agency made this decision because of the

difficulties a policy change could present for some small and very small establishments.

In September 2005, a coalition of trade associations issued a guidance document, "Industry Best Practices for Holding Tested Products." This best practices document included, among many other things, suggestions to aid small and very small establishments in planning for and maintaining control of product pending FSIS pathogen test results. FSIS assisted the trade associations in disseminating the guidance document to all official establishments.

The Agency conducted an initial assessment of the voluntary guidance document's effectiveness and presented its findings to the NACMPI at its meeting on May 23–24, 2006. The assessment examined FSIS test data for the calendar years 2003 through 2005 and the first quarter of 2006 and grouped the data by establishment size and pathogen. This initial assessment found that in the first quarter of 2006, establishments were holding between approximately 80% and 100% of all meat and poultry products until receiving Agency test results, and that establishments of all sizes were increasingly holding more product pending receipt of Agency test results every year between 2003 and 2006, with large establishments holding almost all tested product every year since 2003. The brief, 9-month period from the issuance of the industry guidelines was not sufficient for the Agency to ascertain the effectiveness of these guidelines, however.¹ The Agency continues to monitor verification test results and the circumstances that result in recalls. Based on evaluation of 2007–2009 data, the Agency has noted that establishments releasing product into commerce before receiving test results continues to be a problem.

In 2007 there were 14 Class I recalls as a result of FSIS testing; in 2008 there were 19 Class I recalls; and in 2009 there were 11 Class I recalls. In 2007 seven of the Class I recalls were for *E. coli* O157:H7 and seven for *Listeria monocytogenes* (Lm). In 2008, seven of the Class I recalls were for *E. coli* O157:H7 and twelve for Lm. In 2009, eight of the Class I recalls were for *E. coli* O157:H7 and three were for Lm. As discussed in the cost and benefits discussion below, one such recall was associated with two illnesses. There were no recalls for Salmonella in Ready-

to-Eat (RTE) product between 2007–2009. These recalls occurred because establishments that produced the product that tested positive released the product into commerce while test results were pending. Even though the number of Class I recalls went down in 2009 compared to 2007 and 2008, there is still product entering commerce before test results are received. FSIS is currently analyzing the 2010 recall data. 2010 data show the proportion of the industry (by size) that holds product until test results are received to be similar to those from the 2006 study.

These findings have led the Agency to conclude that despite voluntary compliance efforts, adulterated products are continuing to enter commerce and that establishments' failure to hold or maintain control of product pending FSIS test results endangers public health. Not allowing product to move into commerce until the results of any testing for adulterants done by FSIS become available would eliminate this concern.

In June 2008, the American Meat Institute (AMI) sent a letter to the Under Secretary for Food Safety stating that the organization supported the Agency requiring companies to hold or control product tested by FSIS until the results are known. AMI also stated that it did not support Agency retention of any FSIS tested product. Rather, AMI supported requiring a company to utilize its own, effective control measures to ensure the product is not used or distributed for sale before the test results are known.

On October 19, 2009, AMI sent another letter to Secretary of Agriculture Vilsack again stating that the organization supported a policy that would require companies to hold or control product tested by FSIS until the test results are known.

In March of 2010, the USDA Office of Inspector General issued an audit report of the FSIS National Residue Program for Cattle. In that audit, the OIG recommended that establishments should not be allowed to release potentially adulterated product before residue test results are confirmed. The proposed change in policies and procedures will address that recommendation.

FSIS does have a current policy whereby carcasses tested for bovine spongiform encephalopathy (BSE) must be controlled by the establishment and are not permitted to enter commerce until test results are received. FSIS implemented this policy in response to the first discovery of a BSE-positive cow in December 2003. FSIS issued a **Federal Register** notice on January 12,

¹ A summary of the Agency's analysis of the industry guidelines is available electronically at http://www.fsis.usda.gov/OPPDE/NACMPI/May2006/Test_and_Hold_Report_NACMPI.pdf.

2004 (69 FR 1892), announcing that the Agency would not apply the mark of inspection to any animal carcass tested for BSE until after the Agency determined that the test results were negative. This policy, which continues in effect, is consistent with policy and procedures that FSIS has tentatively decided to implement, as discussed in the next section.

New Policy

For the reasons discussed above, FSIS intends to implement a new policy with respect to the application of the mark of inspection that would in effect require establishments to maintain control of product tested for adulterants by FSIS and not allow such products to enter commerce until negative test results are received. Therefore, should FSIS implement this new policy, the policy would cover non-intact raw beef product or intact raw beef product intended for non-intact use that is tested for *E. coli* O157:H7. Also, the policy would cover any ready-to-eat products tested for *Listeria monocytogenes*, *E. coli* O157:H7, or *Salmonella* s. Similarly, this policy would cover ready-to-eat product that passed over food contact surfaces that have been tested for the presence of *Listeria monocytogenes* and *Salmonella*, pending receipt of negative test results. This policy would not cover raw meat or poultry products tested for *Salmonella* or other pathogens that FSIS has not designated as adulterants in those products.

Should FSIS implement this new policy, it would also apply to livestock carcasses subject to FSIS testing for such veterinary drugs as antibiotics, sulfonamides, or avermectins or the feed additive carbadox. Because of the significant number of poultry carcasses in a lot, the economic effect of holding such a lot, and because historically, FSIS has not seen residue problems in poultry tested for residues, such product would not need to be held from commerce pending negative test results.

FSIS requests comments on whether the policy that product cannot be released into commerce before negative test results are received should also apply to tests conducted by establishments.

New Procedures

FSIS recognizes that the mark of inspection is pre-printed on the package label of many products, and that it is most efficient to allow the product to be packaged and labeled with the printed mark of inspection as part of the production process. FSIS intends to continue to allow meat and poultry establishments to package and label

products sampled and tested for adulterants with the mark of inspection pending negative Agency test results, but, if FSIS adopts this change, these products will not be able to enter commerce until negative test results become available. The pre-shipment review of records associated with the production lot will not be complete without the pending test results. Under this new policy, FSIS inspection program personnel will continue to provide each establishment with notification before sampling product or food contact surfaces to allow the establishment time to hold product that is represented by the sample.

Consistent with current policies, should FSIS implement this new policy, establishments would be able to move product to locations other than the production facility so long as the establishment maintains control of the product and maintains the integrity of the lot under company seal. If the establishment moves the product to other locations, it would not be able to transfer ownership of the product until negative test results become available. Inspection program personnel would notify the establishment when product could move into commerce based on negative FSIS test results.

Considerations for Holding Product Tested for Pathogens or Residues

For *E. coli* O157:H7, prior to FSIS's sampling, inspection program personnel inform the establishment that it is responsible for defining the sampled lot. Under current policy and under this new policy, some factors or conditions that the establishment should consider in defining the sampled lot include any scientific, statistically based sampling programs for *E. coli* O157:H7 that the establishment uses to distinguish between segments of production; Sanitation Standard Operating Procedures (Sanitation SOPs) or any other prerequisite programs used to control the spread of *E. coli* O157:H7 cross-contamination between raw beef components during production; processing interventions that limit or control *E. coli* O157:H7 contamination; and the use of beef manufacturing trimmings and other raw ground beef components or rework carried over from one production period to another.

FSIS does not recognize "clean-up to clean-up" alone as a supportable basis for distinguishing one portion of production of raw beef product from another portion of production. Rather, establishments should consider whether the same source materials are used during different production periods.

For testing of ready-to-eat product or contact surfaces for *Listeria monocytogenes* or for testing such product for *Salmonella*, inspection program personnel also inform the establishment that it is responsible for determining the lot. In contrast to *E. coli* O157:H7, for these types of testing, the sampled lot is generally considered the ready-to-eat product that is produced from clean-up to clean-up because the product typically undergoes consistent cooking and other lethality procedures during the production period.

For livestock carcasses subject to scheduled FSIS residue testing or residue testing conducted by the establishment or other entity, establishments would need to hold the sampled carcasses under this new policy. For this testing, the carcasses would not receive the mark of inspection until negative test results are received.

Consistent with current policy, under this new policy, exporting countries would continue to need to complete all forms of inspection (including receiving lab results) before applying the mark of inspection and signing a certificate for export of products to the United States. Also consistent with current policy, the foreign countries would continue to certify on official health certificates how much product in a shipment represents the lot based on the product and its processing method (e.g., HACCP Processing categories, Product Species).

Comments Regarding This New Policy

The National Meat Association (NMA), representing seven other trade associations: The American Association of Meat Processors (AAMP), the Eastern Meat Packers Association (EMPA), the National Cattlemen's Beef Association (NCBA), the National Turkey Association (NTA), the North American Meat Processors Association (NMPA), and the Southwest Meat Association (SMA), submitted a letter in anticipation of this notice to FSIS.

NMA raised a number of issues about the prospective adoption of a revised FSIS hold and test policy. The letter asked how FSIS would address the issue of products with a shelf life less than the amount of time required to conduct the analysis. The letter also asked how small and very small establishments that produce product for same-day delivery would be affected by this policy, and how FSIS could justify economic impacts such as interruption of business and loss of customers.

FSIS recognizes the concern that some very small establishments might lose some product because of a short shelf life, as well as experience some inability

to satisfy customer orders, resulting in a short-term disruption in business activities. FSIS appreciates the concern. However, the Agency believes the new policy would not cause significant loss of product because FSIS inspection program personnel provide establishments with notification before they collect samples to provide the establishment time to plan accordingly. Furthermore, establishments may produce small production lots when they are subject to FSIS testing. In addition, many establishments already maintain control of product pending test results. FSIS welcomes comments on additional ways establishments and FSIS can address this concern. Also, FSIS intends to provide outreach activities for small and very small establishments, such as Webinars or Podcasts, as necessary. FSIS will also make compliance guidelines available.

In addition, NMA asked how FSIS will ensure that all products that should be held have indeed been held. If the policy is adopted after evaluating the comments, FSIS will issue necessary instructions to its field force on how to verify that establishments are maintaining control of product pending test results for adulterants. Similarly, FSIS would develop Agency procedures to promptly inform the establishment

that product is not adulterated and thus may enter commerce when negative results become available.

NMA also noted that some recalls occur because the establishment did not properly hold all products associated with a tested sample. FSIS acknowledges that this new policy, if implemented as planned, will not guarantee establishments correctly identify the sampled lot. However, FSIS will continually evaluate the policy to provide updated instructions to inspection program personnel and guidance to establishments so that lots sampled for pathogens by FSIS do not enter commerce.

Finally, the letter asked whether FSIS intended to mandate 100% testing at establishments that do not currently test but receive tested trim, such as raw ground beef at grinders. FSIS does not require such testing and does not intend to require such testing in the future. However, all establishments are required to conduct on-going verification activities to ensure that their HACCP plans are effectively implemented (9 CFR 417.4(a)(2)).

I. Expected Benefits of the Action

The Agency expects benefits from this policy to accrue to consumers, Government and to industry.

If an establishment fails to hold a product when FSIS tests for a pathogen, and the test is positive, the establishment will be asked to recall the product. Because the pathogens for which FSIS does testing represent an immediate threat to human health, the recall would be classified as a Class I recall.² Table 1 shows Class I recalls (2007–2009) for FSIS testing that are included in the universe for the Test and Hold policy analysis. These recalls were for *E. coli* O157:H7, *Listeria monocytogenes*, and *Salmonella* in RTE product. In 2007 there were 14 Class I recalls as a result of FSIS testing; in 2008 there were 19 Class I recalls; and in 2009 there were 11 Class I recalls. In 2007 seven of the Class I recalls were for *E. coli* O157:H7 and seven for *Listeria monocytogenes* (*Lm*). In 2008, seven of the Class I recalls were for *E. coli* O157:H7 and twelve for *Listeria monocytogenes* (*Lm*). In 2009, eight of the Class I recalls were for *E. coli* O157:H7 and three were for *Listeria monocytogenes* (*Lm*). There were no recalls for *Salmonella* in Ready-to-Eat (RTE) product between 2007–2009 for FSIS testing.

TABLE 1—CLASS 1 RECALLS INCLUDED IN TEST AND HOLD POLICY UNIVERSE DERIVED FROM FSIS TESTS [2007–2009]

| Year and type | <i>E. coli</i> O157:H7 | <i>Listeria monocytogenes</i> | <i>Salmonella</i> | Total |
|---------------|------------------------|-------------------------------|-------------------|-------|
| 2007: | | | | |
| FSIS | 7 | 7 | 0 | 14 |
| 2008: | | | | |
| FSIS | 7 | 12 | 0 | 19 |
| 2009: | | | | |
| FSIS | 8 | 3 | 0 | 11 |
| Total | 22 | 22 | 0 | 44 |

Note: Data source FSIS recall division.

If the combination of industry and government costs per recall on average is \$1 million,³ then the total annual cost of FSIS recalls could be on average as high as \$15 million per year.⁴

Considering costs to retailers as well as manufacturers and State, local, and Federal authorities, a class I recall may cost as much as \$3 million to \$5

million.⁵ Using a conservative estimate, if the actual cost of a recall for industry and government combined is closer to \$3 million than \$5 million,⁶ then the annual cost of the recall (the benefit of avoiding these recalls) could be as high as \$44.0 million annually. FSIS requests comment on these estimates and the

total costs to industry and government associated with USDA Class I recalls.

In addition to the cost savings attributed to avoiding recalls described above, firms generally suffer a loss of sales, at least temporarily, following a Class I or Class II recall. This alone does not result in a social cost, but rather a social transfer, as other firms will step

² There are three classes of recalls. *Class I*: A health hazard situation where there is a reasonable possibility that the use of the product will cause serious, adverse health consequences; *Class II*: A health hazard situation where there is a remote probability of adverse health consequences from the use of the product; and *Class III*: A situation where the use of the product will not cause adverse health consequences.

³ “Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products” (63 FR 24258; May 1, 1998).

⁴ The annual figure of \$15 million is derived by summing the total number of FSIS recalls for 2007–2009 from Table 1, then multiplying the total by \$1 million which is the average cost per recall for

industry and government. That figure is then divided by 3 to get the annual amount. (14 + 19 + 11 = 44 * 1M = 44M/3 = \$14.7 M per year).

⁵ “Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products” (63 FR 24258; May 1, 1998).

⁶ Ibid.

forward to capture sales lost by the recalling firm. However, in addition to the resources invested in recalling the product, the recalling firm may incur additional advertising costs to recapture the loss of sales plus the flow of future sales, which is a social cost. Additionally, there can be a loss of reputation for the manufacturer and the brand associated with recalls that may affect future sales.

Consumer

FSIS expects the consumer to benefit from: (1) Reduced incidence of adulterated product being released into commerce, (2) fewer recalls resulting in higher confidence and acceptability of products, and (3) lower levels of illness. This new policy will lead to increased consumer confidence and acceptance of product through reduced recalls and negative press.⁷

Government

FSIS expects there to be a reduction in the number of recalls, and, therefore, the Agency expects to benefit from lower Agency costs for recalls and recovery of adulterated product because of: (1) Reduced inspection program personnel activities at Federal establishments (2) reduced overtime hours for FSIS staff, and (3) reduced staff travel to establishments after recalls to conduct Food Safety Assessments (FSA) and recall effectiveness checks. These expenses would include air, train, or car travel; lodging; and per diem expenses for meals. In addition, FSIS should have less need to disseminate information about food recalls through press releases and recall releases.

Industry

Under this policy change, the meat and poultry processing and slaughter industries will benefit from fewer recalls and negative press. As the number of recalls declines, there will likely be: (1) An increase in consumers' confidence, (2) reduced costs for recalls,

(3) greater consumer acceptance of products.

Initially, preventing adulterated product from going into commerce should reduce operating costs. Operating costs will be lower because companies will be less likely to have a recall and experience the adverse impacts to business reputation as well as the product loss associated with a recall. Avoiding adverse impacts on business reputation is an indirect benefit.

Imported Product

There were 9 Class I recalls of FSIS tested imported product for the 2007–2009 (Table 1) time period, 4 for *E. coli* O157:H7 and 5 for *Listeria monocytogenes*. One recall occurred in 2007 for *Lm* and eight in 2008 (4 for *E. coli* O157:H7 and 4 for *Lm*). There are no recalls from FSIS testing for imported product in 2009. All of these recalls are included within the universe described in Table 1 and therefore are included in the Benefits section within this analysis.

Human Health Benefits

Introduction

The Centers for Disease Control and Prevention (CDC) has estimated that Shiga toxin-producing *E. coli* O157:H7 infections cause 63,000 illnesses annually in the United States, resulting in more than 2,138 hospitalizations and 20 deaths.⁸ Economic Research Service (ERS) estimates that the annual economic cost of illness caused by *E. coli* O157:H7 is \$478 million (in 2009 dollars) for all cases, not just for foodborne cases.

The occurrence of recalls demonstrates that pathogens have been present on raw meat and poultry products distributed in commerce under FSIS' existing approach. These pathogens represent a hazard to human health. Thus, public health likely will benefit because meat and poultry products will be held until results of pathogen tests are returned as negative. If test results are positive, the product will be destroyed, or further processed to destroy the pathogen, rather than having to be recalled. This change will thus reduce foodborne pathogens in products that are released into

commerce. The economic health benefits are expected to be small relative to the economic benefits of avoided recalls.

To reach this conclusion FSIS analyzed both the actual illnesses from the universe described in Table 1 and estimated future illnesses averted as a result of this change. We discuss in Section A (Potential averted illnesses from this policy using actual case data) the research conducted by the Economic Research Service (ERS) for each of the pathogens, *E. coli* O157:H7, *Listeria monocytogenes*, and *Salmonella*, as well as their associated costs per case.⁹

A. Potential Averted Illnesses From This Policy Using Actual Case Data

(1) During 2007–2009, there were 22 recalls for *E. coli* O157:H7 from FSIS testing. None of these recalls resulted in any illnesses according to the Office of Public Health Science (OPHS) data. The ERS estimate excludes a number of other potential costs, such as those for special education, nursing homes, travel, childcare, and pain and suffering. Illnesses for *E. coli* O157:H7 are divided into seven severity levels depending on whether the patient visits a physician or not, develops Hemolytic Uremic Syndrome (HUS) or not, develops End-stage renal disease or not, and finally whether death occurs. ERS estimates \$6,510 as the average cost per case.¹⁰

(2) During 2007–2009 there were 22 recalls for *Listeria monocytogenes* from FSIS testing. Only one of these recalls was associated with illnesses. In 2008, there were two illnesses, one of which was fatal, when a customer consumed chicken salad that had been released into commerce before the FSIS test results were returned as positive. We know that the cost of *Lm* illnesses with hospitalization ranges from \$10,815 (moderate) to \$30,000 (severe). Ninety-five percent of all hospitalized *Lm* cases are severe. The economic value of a life ranges between \$6 and \$7 million based on the value of statistical life (VSL) economic literature in 2001 dollars. Benefits from averting the two illnesses had the establishment held the product until the test results returned a positive would be \$60,000 (\$30,000 * 2), or \$20,000 annually, and the benefit from averting the fatality would range from \$5.7 to \$6.8 million. The mid-point of the benefit from averting the death is \$6.25 million or \$2.1 million annually.

⁷Ollinger, Michael, working paper. "Many economists have examined the effects of reputation loss and the production of unsafe food. Packman (1998) argues that the negative publicity generated from a recall can erode prior investments in reputation and brand capital. Economists (Thomsen and McKenzie, 2001; Pruitt and Peterson; Salin and Hooker) found that firms that voluntarily recalled contaminated meat and poultry products suffered a decline in long run profitability (*i.e.*, significant declines in stock prices). A number of studies (Piggott and Marsh, 2004; Marsh, Schroeder, and Mintert, 2004) determined that adverse meat and poultry food safety events led to temporary declines in meat and poultry consumption. Thomsen, Shiptsova, and Hamm (2006) established that sales of branded frankfurter products declined more than 20 percent after product recalls."

⁸Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis.* 2011 Jan; [Epub ahead of print] Table 2 of this report provides foodborne STEC O157: H7 illnesses at: 63,153, with 90% confidence of (17,587–149,631). Table 3 of this report provides STEC O157:H7 hospitalizations at 2,138, with 90% confidence of (549–4,614) and deaths of 20, with 90% confidence of (0–113).

⁹ERS cost calculator can be found on their Web site at <http://www.ers.usda.gov>.

¹⁰The cost per illness for the seven severity levels is between \$30 (for an individual who did not obtain medical care) and \$7.2 million for a patient who died from Hemolytic Uremic Syndrome (HUS).

Actual annual benefits during 2007–2009 for *Lm* would be \$2.10 million.

(3) There were no recalls from FSIS testing for *Salmonella* in RTE product during 2007–2009. Research has shown that the cost per case of a *Salmonella* illness is \$18,000.¹¹

B. Estimated Averted Illnesses From This Policy

FSIS has developed a model¹² to estimate annual illnesses averted per positive sample, from holding FSIS tested product until testing results are returned. This model is based on 2007–

2009 recall data, as well as the OPHS illness data occurring from these recalls.¹³ The model estimates expected illnesses by accounting for volume of product recalled and “time in days” between the dates of production of adulterated product until the date of recall of that adulterated product. If the Agency proceeds with this new policy, the FSIS model estimated the upper 95% confidence bound of averted *E. coli* O157:H7 illnesses to be approximately 2.61 for a three-year period (based on the 2007–2009 data). FSIS estimated human health benefits, based on

averting these 2.61 *E. coli* O157:H7 illnesses to be approximately \$5,664 annually. ($\$6,510 \times 2.61/3$)

Using similar methodology and an estimated number of illnesses of 0.18 for *Listeria monocytogenes* and .57 for *Salmonella* in RTE product, the annual cost is \$1,800 and \$3,420, respectively. For the three pathogens, *E. coli* O157:H7, *Listeria monocytogenes*, and *Salmonella*, human health benefits are estimated from the model to be approximately \$10,884 annually. See Table 2.

TABLE 2—HUMAN HEALTH BENEFITS FROM ACTUAL RECALLS AND ESTIMATED MODEL [2007–2009]

| Pathogen | Cost per CASE | Actual CASES 2007–2009 | Actual annual benefit 2007–2009 | FSIS estimated cases averted (Model) 2007–2009** | Annual benefit (Model) |
|-------------------------------------|---------------|------------------------|---------------------------------|--|------------------------|
| <i>E. coli</i> O157:H7 | \$6,510 | 0 | 0 | 2.61 | \$5,664 |
| <i>Listeria Monocytogenes</i> | 30,000 | 2 | \$20,000 | .18 | 1,800 |
| <i>Salmonella</i> | 18,000 | 0 | 0 | .57 | 3,420 |
| Death (Annual)* | 6.25 | 1 | 2.1 M | | |
| Total | | | 2.1 M | 3.36 | 10,884 |

* Note: LM is known to have a high death rate and as such one death is included in the expectation of benefits from illnesses averted. The cost of 2 LM illnesses (\$60,000) is accounted for in the Model.

** Table 3 of the Model (Appendix) estimates illnesses for 10 years. To make the numbers comparable we used estimated illnesses from the model/10 * 3 to derive the numbers in this column.

Total human health benefits from the FSIS model and actual reported illnesses combined would be approximately \$2.11 million annually (\$2.1 M + \$10,884). Differences may be due to rounding.

Residue Benefits

Microbiological hazards are expected to drive the cost-benefit analysis because they result in an attributable short term, low (morbidity) to high (morbidity) impact consequences that can be realistically estimated.

The cost-benefit analysis for chemical hazards on the other hand is difficult to quantify. The negative health effects of exposure to low levels of chemicals are long term and multifactorial. Single exposure to low levels of chemicals or cumulative exposure can contribute to negative health effects 10, 20, or more years later; for example, cancer. Of course, over such long periods of time,

individuals are exposed to a variety of hazards making it impossible to quantify the contribution of the chemical exposure to societal and medical costs. The approach for conducting a cost benefit analysis for single incidents of contamination at levels that cause immediate morbidity/mortality, i.e., where the health effects are readily attributable to the exposure, is comparable to microbiological hazards.

The Environmental Protection Agency (EPA)¹⁴ and the Food and Drug Administration (FDA) conduct risk assessments to establish what level of chemical residues are acceptable.¹⁵ They consider acute and chronic exposure scenarios to set residue limits and include a wide margin of safety in their calculations. Meat, poultry, and egg products with chemical residues that exceed the tolerances or other limits set, or for which no scale level

has been set, by EPA and FDA are adulterated and unsafe for human consumption.

Summary of Benefits

The annual benefits from this policy change come from:

- (1) Reduced costs of recalls, \$15 million to \$44 million,
- (2) Actual averted death, \$2.1 million as shown in Table 2 and
- (3) Estimated Averted illnesses for *E. coli* O157:H7, *Listeria monocytogenes* and *Salmonella* of \$10,884 as shown in Table 2.

Total benefits from this policy change are estimated to range between \$17.1 million and \$46.1 million annually.

II. Expected Costs of the Action

FSIS prepared a paper in September, 2006 to provide data on trends in the industry practice of holding meat and poultry products pending results of

allowable residual levels in the environment, water and air resulting from use, based on the risk to people through direct and indirect exposure to the residues.

¹⁵ See General Accounting Office (GAO) report “Chemical Risk Assessment: Selected Federal Agencies’ Procedures, Assumptions, and Policies”, GAO–01–810, August 2001.

¹⁶ A summary of the FSIS’s analysis is available electronically at <http://www.fsis.usda.gov/OPPDE/>

¹¹ See “Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation” (74 FR 33030, July 9, 2009).

¹² See Appendix 1: “Development of model for predicting averted illnesses due to *E. coli* O157:H7 from Test and Hold” and Appendix 2: “Data used in Analysis.” A copy of these documents is available for viewing in the FSIS Docket Room and on the FSIS Web site as related documents associated with this docket.

¹³ OPHS data was used for the model that contained illnesses from all recalls and all sources. This included Outbreak, Illness, FSIS Test, and Establishment Test. This was done only for the purpose of estimating the rational expectation of future illnesses averted by this policy.

¹⁴ Drugs are used on plants as well as in/on animals, so some of the chemicals regulated by EPA are drugs (for example antibiotics and antifungals). EPA establishes safe methods of use for chemicals (drugs, pesticides, fungicides, etc) and sets the

FSIS microbiological testing.¹⁶ Identifying trends in industry holding practices provides a context and baseline for any future evaluation of the effects of holding product pending test results. FSIS examined test data for the calendar years 2003 through 2005, as well as data for the first eight months of 2006, and grouped data by establishment size and pathogen. Specifically, FSIS examined the hold/release information included with FSIS

testing results for the following pathogens in five different groups: (1) *E. coli* O157:H7 in raw, non-intact beef produced by domestic official establishments,¹⁷ (2) *E. coli* O157:H7 in domestically-produced ready-to-eat (RTE) meat and poultry; (3) *Salmonella* in domestically-produced RTE meat and poultry; (4) *Listeria monocytogenes (Lm)* in domestically-produced RTE meat and poultry; and (5) *Lm* on food-contact

surfaces in establishments that produce RTE meat and poultry products.

A. Domestic Product

(1) Micro Testing

FSIS found the following results of meat and poultry product being held by establishments prior to receiving FSIS test results. Table 3 shows the results by establishment size for the first 8 months of year 2006 for the five test groups described above.

TABLE 3—PERCENT OF PRODUCT BEING HELD BY ESTABLISHMENT SIZE FOR 2006 JAN–AUG
[In percent]

| | Large | Small | Very small | Unknown |
|---------------|-------|-------|------------|---------|
| Group 1 | 100 | 83 | 79 | 57 |
| Group 2 | 100 | 93 | 88 | 100 |
| Group 3 | 100 | 90 | 82 | 93 |
| Group 4 | 99 | 91 | 82 | 93 |
| Group 5 | 100 | 97 | 88 | — |

Group 1: Percent of raw, non-intact beef Products held after Agency *E. coli* O157:H7 Sampling.
 Group 2: Percent of RTE Products held after Agency *E. coli* O157:H7 Sampling.
 Group 3: Percent of RTE Products held after Agency *Salmonella* Sampling.
 Group 4: Percent of RTE Products held after Agency *Lm* Product Sampling.
 Group 5: Percent of RTE Products held after Agency *Lm* Food Contact Surface Sampling.
 Note: This data is the latest available data for product held in establishments from FSIS testing. Study by the Office of Program, Evaluation, Enforcement, and Review (OPEER.).

Based on evaluation of recent data, the Agency has noted that establishments releasing product into commerce before receiving test results continues to be a problem.

However, using the percentage numbers from Table 3 for the first eight

months of 2006 will provide a basis for establishing the costs for 2007–2009 to hold product until test results are returned.

Table 4 shows the number of Federally inspected meat and poultry establishments by establishment size

and illustrates in columns 3 and 4, based on the results from Table 3, the number of establishments currently holding product, as well as the number of establishments that will need to hold product as a result of this policy change.

TABLE 4—FEDERAL INSPECTED MEAT/POULTRY ESTABLISHMENTS.

| Establishment size (1) | Number of establishments* (2) | Holds product (3) | Does not hold product (4) |
|---------------------------|----------------------------------|----------------------|------------------------------|
| LARGE | 362 | 362 | 0 |
| SMALL | 2,366 | 1,964–2,295 | 71–402 |
| VERY SMALL | 2,900 | 2,291–2,552 | 348–609 |
| UNKNOWN | 578 | 329–578 | 0–249 |
| TOTAL | 6,206 | 4,946–5,787 | 419–1,260 |

* Source: Performance Based Inspection System (PBIS) 1/3/2008. There has been no substantial change in establishment numbers. The data provided in Table 3 are used to calculate the number of establishments holding product (column 3) and the number of establishments not holding product (column 4).

Across establishment size, between 79 percent and 100 percent of establishments already hold product pending test results and between zero and 21 percent will need to hold product pending test results.

Based on the percentage results shown in Table 4, FSIS assumes for cost purposes only that all 362 large

establishments are holding all tested product for results. Approximately 71–402 small establishments, 348–609 very small establishments, and between 0 and 249 unknown size establishments do not hold tested product and will be affected by this new policy. Table 4, column 4 shows the range of establishments that will have to hold

product pending negative test results before FSIS will award the USDA mark of inspection. A total of between 419 and 1,260 federally inspected meat and poultry establishments will be affected by this policy change. There will be no additional costs to any of the large establishments as they are assumed to hold all tested product. FSIS expects

that among the remaining establishments that do not hold tested product, there will be an adjustment of lot size to accommodate necessary storage capacity at the establishment prior to an FSIS test.

FSIS conducted further research on all FSIS tests conducted in the year 2007. Combining the percentages of product held from Table 3 and the estimates of common lot sizes from the following Table 5, FSIS reached certain

conclusions about the additional pounds of product that would need to be held by the small and very small establishments, which is shown in Table 6.

TABLE 5—ESTIMATED LOT SIZES BY ESTABLISHMENT SIZE

| Establishment size | Lot (pounds) size produced | Average lot (pounds) size tested * |
|--------------------|----------------------------|------------------------------------|
| LARGE | 2,000–30,000 | 2,000 |
| SMALL | 1,000–10,000 | 1,000 |
| VERY SMALL | 50–2,000 | 50–60 |

Source: Common Industry Practice and expert elicitation.
* Tested lots are smaller than typical production lot sizes.

FSIS estimates the common industry practice for average lot sizes tested to be approximately 2,000 pounds at large establishments, 1,000 pounds at small establishments, and between 50–60

pounds at very small establishments. As a result of the above lot size estimations, there may be a certain number of small and very small establishments that will incur costs relative to additional storage

(recurring costs) or for capital equipment (one-time costs), in order to hold tested product.

TABLE 6—ADDITIONAL COST PER ESTABLISHMENT TO HOLD ESTIMATED POUNDS OF PRODUCT

| | Lbs to be held by establishment | Days product to be held | Cost per establishment store product |
|---------------|---------------------------------|-------------------------|--------------------------------------|
| LARGE | 0 | 3–8 | \$0 |
| SMALL | 4,511 | 3–8 | 5,000 |
| V/SMALL | 1,329 | 3–8 | 1,000 |
| UNKNOWN | 1,011 | 3–8 | 1,000 |

Source: FSIS/OPEER/OCIO data.
Cost per commercial freezer @ \$5,000 per 300 cu. ft. for small establishments. Cost of stand-up freezer for very small establishments @ \$1,000.

Factors affecting this cost impact include: (1) The amount of product needed to be handled and placed into storage; (2) the average number of days of storage; (3) the number of times per year that tests occur; and (4) the cost per day in handling and storage.

The costs shown in Table 6 would predominately be one-time capital expenditures to purchase freezers for storage of tested product. There would be a small amount of electricity charges to operate the refrigeration units, but we do not anticipate that they would be

significant. Labor costs would also be minimal to accommodate the additional product stored. Additionally, FSIS recognizes the concern of some very small establishments that they could lose some product because of the product's short shelf life, and that an establishment could experience some inability to satisfy customer orders, resulting in a short-term disruption in business activities.¹⁸ FSIS does not have sufficient information to include costs associated with this disruption in the

analysis, but we request comments on these costs and on additional ways establishments and FSIS can address the effect this policy may have on small and very small establishments that produce product with a short shelf life.

Table 7 combines the results of tables 4, 5 and 6 and shows that the estimated total costs to all small and very small (and unknown) establishments that do not hold product domestically would range between \$703,000 and \$2.87 million.

TABLE 7—TOTAL ONE-TIME COST PER ESTABLISHMENT SIZE

| Establishment size | Number establishments affected Table 5 (col. 1) | Cost/Est. to store product Table 7 (column 4) | One-time total cost to hold product * | Annualized 7%–10 years |
|--------------------|---|---|---------------------------------------|------------------------|
| Large | 0 | \$0 | \$0 | \$0 |
| Small | 71–402 | 5,000 | \$355K–\$2.01M | \$50,541–\$299,000 |
| Very Small | 348–609 | 1,000 | \$348K–\$609K | \$49,545–\$86,700 |
| Unknown | 0–249 | 1,000 | \$0–\$249K | \$0–\$17,227 |

¹⁷ In this paper, FSIS did not examine results from the recently initiated FSIS baseline testing of beef trim for *E. coli* O157:H7 and Salmonella.

TABLE 7—TOTAL ONE-TIME COST PER ESTABLISHMENT SIZE—Continued

| Establishment size | Number establishments affected Table 5 (col. 1) | Cost/Est. to store product Table 7 (column 4) | One-time total cost to hold product* | Annualized 7%–10 years |
|--------------------|---|---|--------------------------------------|------------------------|
| Total | 419–1,260 | | \$703,000–\$2.87 M | \$100,000–\$408,600 |

* NOTE: Total cost to hold product is result of # of Establishments affected * cost/Est to store product.

(2) Residue Testing

The National Residue Program (NRP) consists of two sampling plans: Domestic and import. These plans are further divided to facilitate the management of chemical residues such as veterinary drugs, pesticides, and environmental contaminants in meat, poultry, and egg products. The domestic sampling plan includes both a scheduled sampling program that is derived statistically by an interagency (FSIS, EPA, and FDA) technical team and by inspector-generated sampling in which samples are collected by in-plant veterinarians when they suspect an animal presented for slaughter may have violative levels of chemical residues. The import re-inspection sampling plan verifies the equivalence of inspection systems of exporting countries. FSIS inspectors collect samples randomly from imported products, and the intensity of sampling increases when products fail to meet U.S. requirements.

Residue Costs

In CY 2008, under the National Residue Plan, there were 22,709 FSIS

residue samples completed. An additional 135,552 inspector-generated samples were taken. The number of samples includes those taken in-plant, taken from show animals, taken by inspectors or OPEER personnel as part of their regular work, and as part of state programs.

The average range of days between a sample arriving at the lab and the report being available is generally 3–10 working days. Some screen results are available the same day by Kidney Inhibition Swab (KIS) tests, while other tests may take longer than 10 days.

The Agency does not anticipate any substantial cost impact from additional storage space requirements for FSIS residue testing. For establishment residue testing, the establishment as part of its HACCP program should already be holding any tested carcasses. The Agency asks for comments on possible additional storage space requirements.

Products will have a reduced shelf-life at retail as a result of carcasses being held pending FSIS and establishment test results. Some beef product that has

been residue tested and held for three to ten days will lose freshness and will need to be frozen. Over the past nine years, on average, the difference in fresh vs. frozen beef prices is approximately \$0.054 a pound.¹⁹ The worst case scenario for loss of business revenue for dairy cows, used for beef estimation purposes, would be approximately \$39,500.²⁰ While these lost revenue estimates are a worst case scenario, we also estimate the range for reduced beef sales to be between \$19,700 and \$39,500. The Agency requests comments on reduced sales.

Additionally, roaster pig carcasses could go rancid and would also need to be frozen. Some product will go to secondary markets, such as renderers, pet foods, and fertilizer product. For roaster pigs, we estimate a worst case scenario loss of business at approximately \$92,400.²¹ The lower estimate for roaster pigs is \$46,200. The Agency requests comments on reduced sales revenues.

TABLE 8—LOSS OF REVENUES FOR DOMESTIC BEEF AND ROASTER PIGS DUE TO RESIDUE TEST AND HOLD POLICY

| Establishment size | Beef number of establishments | Beef \$\$ lost | Roaster pigs number of establishments | Roaster pigs \$\$ lost |
|--------------------|-------------------------------|----------------|---------------------------------------|------------------------|
| Large | 132 | \$1,264 | 4 | \$601 |
| Small | 810 | 7,900 | 85 | 13,860 |
| Very Small | 3,164 | 30,099 | 467 | 77,616 |
| Unknown | 25 | 237 | 2 | 323 |
| Total | 4,131 | 39,500 | 558 | 92,400 |

Source of data: Data Analysis Integration Group (DAIG) and Office of Policy and Program Development (OPPD)/Risk Management Division.

B. Imported Product

Imported Re-Inspection Sampling Plan

Import Inspection Personnel are to sample imported ready-to-eat (RTE) meat and poultry products produced in foreign establishments. Analyses will

include *Listeria monocytogenes* and *Salmonella* testing for all RTE products, and *E. coli* O157:H7 for cooked beef patties and dry or semi-dry fermented sausages.

Ready-to-eat cooked meat or poultry product is subjected to microbial

sampling at the port-of-entry. This includes any product that is intended to be consumed without any further safety preparation steps. Import inspection personnel do not sample products for *Listeria monocytogenes* or *Salmonella* that are labeled with cooking

¹⁹ Beef price data provided by the Economic Research Service, USDA. The data is for 90% lean beef, not carcasses and can be interpreted as cents per pound or dollars per cwt of product.

²⁰ Estimation of worst case business loss for dairy cows: Total number of animals selected for dairy cows (300) * 4 (number of chemicals sampled) * average lbs of animal (609) = total lbs to be held * price difference per lb. from fresh to frozen (\$0.054)

²¹ Estimation of worst case business loss for roaster pigs: Total number of animals selected for roaster pigs 300 * 4 (number of chemicals sampled) * average lbs of animal (70) = total lbs to be held * price per lb. (\$1.10)

instructions or "Not Fully Cooked". These products are not considered RTE and are not sampled under this program.

Table 9 describes the two different types of tests that are conducted on imported product, (1) micro testing, and

(2) residue testing (column 1). Column 2 shows the number of samples where product was held, while column 3 shows the number of samples where the product was not held. Column 4 shows the number of samples for which the

available data do not show whether or not the product was held. Column 5 is the total of all tests taken on imported product (sum of columns 2, 3 & 4). Column 6 is the percentage of tested product that is currently being held.

TABLE 9—PERCENT OF IMPORTED PRODUCT HELD THAT HAS BEEN FSIS TESTED
[By lots]

| Type (1) | Held (2) | Not held (3) | Not indicated (4) | Total (5) | Percentage product currently held (6) |
|----------------|-------------|-----------------|----------------------|--------------|--|
| Micro | 1,994 | 1,799 | 88 | 3,881 | 51.4 |
| Residues | 2,320 | 2,490 | 493 | 5,303 | 43.7 |

Source: FSIS International Policy Division.

Table 10 shows the type of samples (column 1) and the number of FSIS samples taken (column 2). The average lot size derived by dividing the total pounds of product presented for import in 2008 by the total lots presented for

import in 2008 is shown in column 3 (3,270,643,817/210,592). Column 4 and 5 are percentage of product currently held and percentage of product to be held. Column 6 and 7 represent the total pounds to be held and the cost of

holding that product. The cost of holding imported product when this policy becomes effective will range from approximately \$757,000 to \$832,000.²² The Agency asks for comments on costs of storage.

TABLE 10—COST TO HOLD IMPORTED FSIS TESTED PRODUCT

| Type (1) | Number of FSIS samples (2) | Average lot size (3) | Percent product now held (4) | Additional percent of product to be held * (5) | Total pounds to be held (6) | Cost for holding product (7) |
|-----------------|-------------------------------|-------------------------|---------------------------------|---|--------------------------------|---------------------------------|
| Microbial | 3,881 | 15,530 | 51.4 | 48.6 | 29,292,158 | \$292,922 |
| Residue | 5,303 | 15,530 | 43.7 | 56.3 | 46,366,197 | 463,662 |
| Total | | | | | | 756,584 |

Note: Cost is based on storage of product for up to 30 days @ \$.01/pound.

Source: FSIS—International Policy Division.

* Column 5 is the additional percentage of product that will need to be held once this policy becomes effective. (100% – column 4 percentage)

Summary of Annual Costs:

Total Domestic Product—\$100,000–\$408,600.

Loss of Business Revenue—\$66,000–\$131,900.

Total Import Product—\$757,000–\$832,000.

Total Cost: \$923,000–\$1.4 million.

Estimated annual benefits range between \$17.1 million and \$46.1 million and exceed the estimated costs. Annual net benefits range between \$16.2 million and \$44.7 million.

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²²The storage cost data was not robust, therefore a cost + 10% range was cited. Adding the 10% leads to a storage cost of \$832,242.

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.

Done at Washington, DC, on: April 5, 2011.

Alfred V. Almanza,
Administrator.

Appendix 1

FSIS is planning to require product to be held when FSIS test for pathogens. (*E. coli* O157:H7 in ground and trim beef products, and *Salmonella* and *Listeria monocytogenes* (LM) in ready-to-eat (RTE) products), until the test result is reported negative. Benefits from averted illnesses from this policy thus would accrue if it were the case that instead of holding tested product that was contaminated, the product was released before a positive result was found and portions of that product would have been consumed, which would have led to illness. It takes 6 days before samples are confirmed to contain *E. coli* O157:H7 (1 day for sending the sample from the establishment to the laboratory and 5 days once the sample arrives in the laboratory); for

the other two pathogens it takes 8 days. The expected decreased risk of illness (the estimated benefits) to consumers by the execution of this policy is estimated by modeling the observed relationship of reported illnesses due to *E. coli* O157:H7, *Listeria monocytogenes* (LM) and *Salmonella* associated with recent recalls (2007–2009), with the number of days before the recall and the amount of product associated with the recall. From this model, the expected number of illnesses that would occur for product recalled x days after sampling can be estimated. There are many assumptions implicit in the model, for example, the recalled volume might not reflect the actual volume of product for which consumers were exposed. One would expect, though, that the longer time between the recall date and manufactured date, the more the exposure and thus the greater opportunity for illness from the product. Thus, it is expected that illnesses would increase if volume increases or days before recall increase, given everything else being equal; that is, the number of illnesses is an increasing function of volume and days. In Appendix 2 are the data used in the analysis, consisting of 75 cases, within 2007–2009, for which product volume, days between manufactured and recall dates, and illnesses associated with the recall were available.²³

Besides estimates of illnesses associated with potential recalls, there are 4 factors that need to be accounted for in estimating the potential benefits that would be realized from the test and hold policy:

- (1) The number of establishments that would not be holding product if not for the policy;
- (2) The volume of the product being held;

(3) The number of tests expected to be conducted, yearly; and

(4) The expected proportion of tests that would be positive.

Another assumption made is that large establishments (as determined from FSIS' HACCP size classification) already hold product when it is being tested and thus this policy will not result in averted illnesses from this sector of the industry. It is only assumed that some HACCP-size small and very small establishments will need to hold product that otherwise would not have, and thus will have averted illnesses as a result of this policy.

Regarding the proportion of tests expected to be positive, the proportion could be a function of the volume of product per test that is held. However, a test consists of an analysis of a certain amount of material, which is assumed constant; thus for modeling the potential benefits, it is assumed that this proportion is independent of volume. The percentage of positive test results that would be seen in the future is assumed to be equal to that observed for the years 2007–2009 (up to the middle of November). The percentage of positive results depends upon the HACCP size of the establishment (Table 1) as well as the particular test. For LM, since FSIS tests multiple samples per "unit" (unit = a collection of samples for product and food contact surfaces, excluding other environment samples), the results below report the percentage of units that had at least one positive result, since even one positive result from these samples leads to a determination of an adulterated product that would be subject to recall.

TABLE 1—NUMBERS OF TESTS AND NUMBERS AND PERCENTS POSITIVE BY HACCP SIZE AND TEST-TYPE, FROM 2007–2009 (MID-NOVEMBER), COVERING 34.5 MONTHS, FOR ALL FSIS' TESTS ON GROUND AND TRIM BEEF FOR *E. coli* O157:H7 AND READY-TO-EAT (RTE) PRODUCT FOR SALMONELLA AND LISTERIA MONOCYTOGENES (LM)

| Size | <i>E. coli</i> O157:H7 | | <i>Salmonella</i> | | LM* | | Other LM | |
|------------------|------------------------|--------------|-------------------|--------------|------|-------------|----------|-------------|
| | Test | Positive | Test | Positive | Test | Positive | Test | Positive |
| Small | 17,772 | 115 0.65% | 17,898 | 7 0.039% | 671 | 19 2.83% | 17,630 | 90 0.51% |
| Very small | 20,313 | 74 0.36% | 12,821 | 10 0.078% | 125 | 6 4.80% | 12,735 | 41 0.32% |

* LM numbers refer to the number of units (set of product and food contact surface samples, from which any positive would lead to declaration of product adulteration).

For LM, estimating the number of tests and percent of those that would be positive and lead to held product, the numbers for the two types of LM sampling are added together. Thus, for example, for the small size establishments, it is assumed that there are 17,630 + 671 tests for Lm of which 90 + 19 of them were positive.

For *Salmonella* and *Listeria* testing, it is assumed that the number of samples used in the past would remain the same.

In this case, the number of positive results that would lead to holding product that otherwise would not have been is determined by just multiplying the number of test times the expected percentage of positive results, times a factor that represents the fraction of establishments that would not be holding product if not for this rule. This percentage is taken from Table 4 of the main report, which provides the percentages of establishments by

HACCP size category that hold product for the different types of sampling. As mentioned above, it is assumed that all large establishments would hold product and thus do not contribute in the analysis presented here. For *Salmonella*, the assumed percentages of the tested small and very small establishments that hold product are 90% and 82% respectively (Table 4 of the main report). For LM, since either a positive result for a food contact surface

²³ Recalls cited in Table 1 in the main report do not include all *E. coli* O157:H7 recalls. Rather, Table 1 includes only those recalls based on FSIS

or establishment *E. coli* O157:H7 positive test results. The data used for modeling include all recalls of relevant FSIS regulated product besides

those identified in Table 1 of the main report, such as recalls resulting from outbreaks or state laboratory testing.

or product leads to recall, the lower percentages establishments holding product of the groups associated with LM testing from Table 4 of the main report are assumed. That is, it is assumed that percentages of the tested small and very small establishments that hold product are 91% and 82% respectively (Table 4 of the main report, group 4). Thus the number of positive samples over a 10-year period associated with product that would not have been held if not for the proposed regulation is $10Q(1-w)^{12}/34.5$ where Q is the number of positive results for 34.5 months given above in Table 1, and w is the fraction of establishments that already hold product (Table 4 of the main report).

For *E. coli* O157:H7 sampling, since FSIS' sampling plan calls for sampling each establishment once a month, the number of establishments assumed are the number that are being sampled presently. There are 570 and 884 small and very small size establishments, respectively, that were sampled. From Table 4 of the Notice it is assumed that 17% and 21% of them, respectively, are not presently holding product. In addition 5 establishments were sampled

for which the size was not known for which (from Table 4 of the main report) is assumed that an expected 43% did not hold product. These 5 establishments are assumed to be distributed between the small and very small establishments by the ratio of 570/(884 + 570). Thus, after calculations, it is assumed that 98 small and 187 very small establishments presently do not hold product for *E. coli* O157:H7 sampling. Since for *E. coli* O157:H7 testing, it is assumed that every establishment will be tested once a month, for 10 years, the expected number of positive tests in the next 10 years per establishment is $10(12)p$, where p equals 0.65% for small establishments and 0.36% for very small establishments (Table 1 above). This number is multiplied by the number of establishments assumed involved, which would be equal to 98 for the small establishments and 187 for the very small establishments to derive the expected number of positive tests in a 10-year period, K.

Regarding the number of pounds that would be held, FSIS policy permits the number of pounds likely to be subjected to being tested and held to be small

since the establishment will be given prior notification of the test and will, most likely, prepare smaller amounts of product for testing. As discussed in the economic analysis (Table 6), it is anticipated that, for small establishments, the product volume held would be on average 1000 pounds, and for very small establishments, the held volume will be on average 50–60 pounds. In the analysis, 60 pounds was used.

The estimated number of averted illnesses is estimated by multiplying the expected number of positive results in 10 years times the expected number of illnesses averted per positive test resulting in a recall x days after the manufacturing date, where x equals 6 for *E. coli* O157:H7 and equals 8 for the other two pathogens. For modeling this expected number of averted illnesses, as mentioned above, it is assumed that number of illnesses associated with a positive test is an increasing function of the volume of the recalled product and the days after the initial manufactured date of the product. Specifically, a general model considered was:

Illness \sim Poisson(λ)

$$\ln(\lambda) = g(v, x) + \epsilon \quad (1)$$

where v = volume, x = days, g is a function with parameters: a, b, c, * * *, whose values are to be estimated from the data in the appendix, and ϵ is random variable, with expected value equal to 0, and standard deviation equal to σ . Estimated values were obtained

using the non-linear mixed effects model of PC-SAS version 9.1 (PROC NLMIXED). For this procedure, ϵ is assumed to be distributed as a normal distribution, since this is the only option permitted. The procedure maximizes the marginal likelihood

function, integrated over the distribution of ϵ . Thus λ is distributed as a lognormal distribution, and the expected value of the number of illnesses, given v and x, is

$$Ill(v, x) = E(\# \text{ illnesses} | v, x) = e^{g(v, x) + \sigma^2/2} \quad (2)$$

The benefit for a given volume, B(v, x), and days before recall, x, is obtained by:

$$B(v, x) = (Ill(v, x) - Ill(v, 0))K. \quad (3)$$

where K is the number of expected positive tests for the next 10 years for product that would not be held if not for the requirement. For small HACCP size establishments, it is assumed v = 1000 pounds; for very small size establishment, v = 60 pounds. And as mentioned above, for *E. coli* O157:H7, x = 6 days and for *Salmonella* and LM, x = 8 days.

Comparisons of models used to estimate g and σ are based on the log-likelihood ratio test, where the distribution of the difference of statistics, $L = -2 \log(\text{likelihood})$, for two models being compared is approximated by the appropriate chi-square distribution.

To help determine the form of g, the function of independent variables associated with the variable 'days'

between the date of manufacturing and recall and the volume of the recalled product, Figure 1 presents graphs of the natural logarithm of the ratio of the number of illnesses divided by product volume, $\ln(\text{illnesses}/\text{volume})$, versus days (right side) and versus the natural logarithm of days + 1, $\ln(\text{days} + 1)$ (left side). When the number of illnesses was 0, the value assigned was -14. The smooth lines are spline curve,

constructed using the default options of the S-Plus® for Windows, version 8.1. The graph on the right indicates the high degree of influence the data point with days = 365 could have on a model predicting number of illnesses using days as an independent variable. This point would have less influence if ln(days+1) were used instead of days as an independent variable.

Figure 2 provides a graph of ln(#illness/(days+1)) versus ln(volume). When the number of illnesses is zero, a value of -5.5 was assigned. The dark smoothed line is the quadratic fit; the dashed-dotted red line is the curve derived from fitting: $a + \ln(be^{-c \ln(v)} + ce^{b \ln(v)})$, a function borrowed from one used to describe cell population growth assuming two phases: A lag phase and an exponential phase.

These figures suggest a model for estimating the number of illnesses as a function of ln(volume) and ln(days+1) be based on a Poisson regression with log-link a function of ln(days+1) and ln(volume), plus a random error (Equation 1). It is assumed that g is the full quadratic function of these variables:

$$g(v, x) = a + b \ln(v) + c \ln(x+1) + d [\ln(v)]^2 + e [\ln(x+1)]^2 + f \ln(v) \ln(x+1) \quad (4)$$

where b, c, d, e, and f are constants, and a depends upon the pathogen. For the full model in Equation 4, the model has 9 parameters (including σ) since there are three “intercepts” being estimated, one for each pathogen.

Table 2 presents differences of values of L for selected models from the value obtained from the full quadratic model given in Equation 4, excluding the 2 outlier data points identified. All models converged by the G-

convergence criterion (gradient) using the default quasi-Newton optimization technique.

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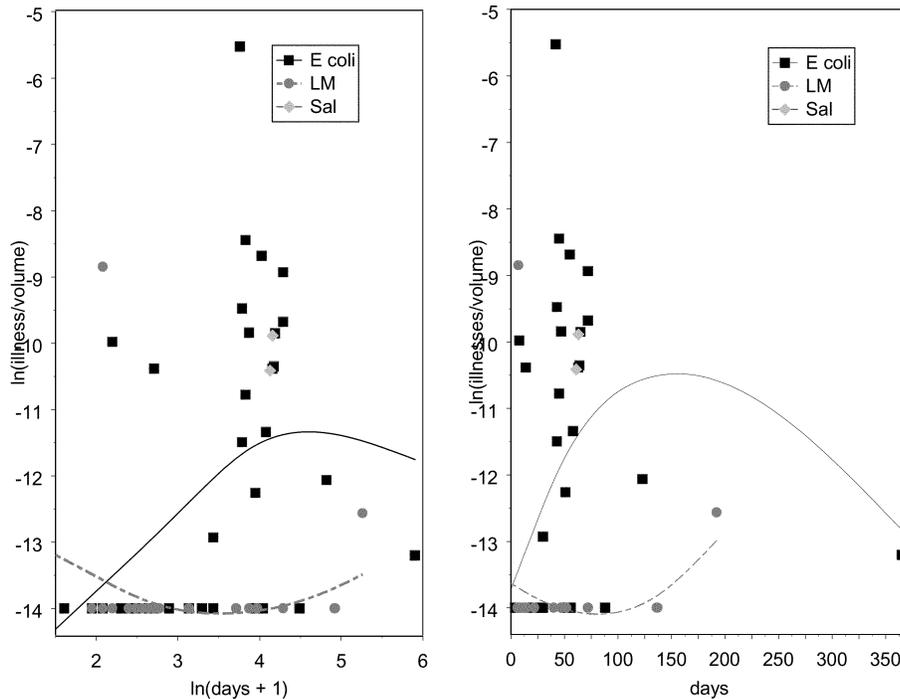


Figure 1: Plot of ln(# illnesses/volume) versus ln(days + 1) and days. When # illnesses = 0, assigned value = -14. Smooth line is the spline fit (from S-Plus ® graphics procedure).

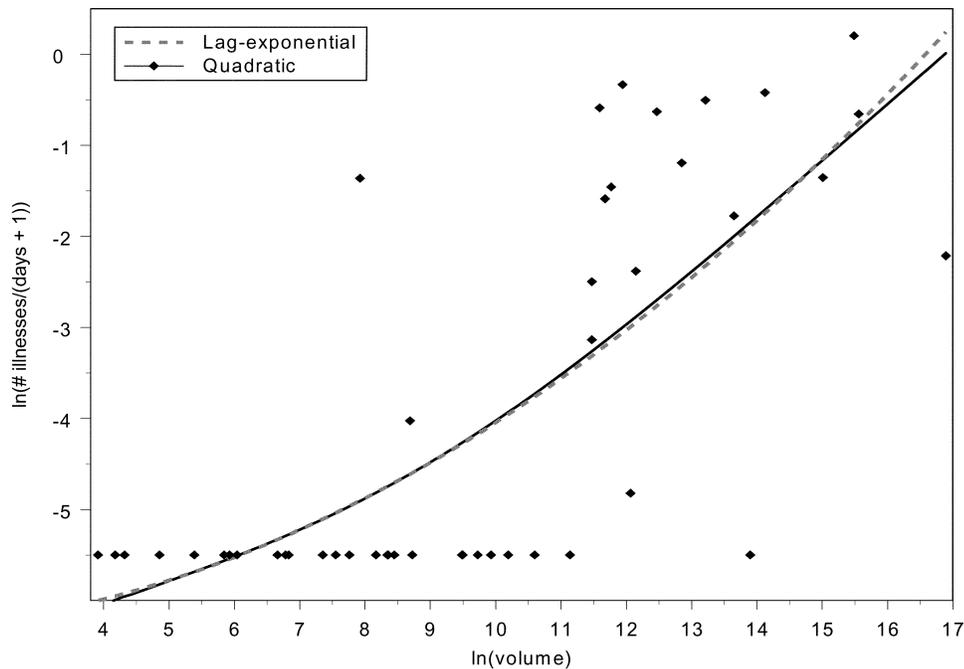


Figure 2: Plot of $\ln(\# \text{ illnesses}/(\text{days} + 1))$ versus $\ln(\text{volume})$ for *E coli* O157:H7 illnesses. When # illnesses = 0, assigned value = -5.5. The dark smoothed line is the quadratic fit and the dotted red line is the curve derived from fitting: $a + \ln(b e^{-c \ln(v)} + c e^{b \ln(v)})$.

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TABLE 2—L = -2 LOG(LIKELIHOOD) FOR SELECTED MODELS FROM THE VALUE OBTAINED FROM THE FULL QUADRATIC MODEL GIVEN IN EQUATION 4. MODELS ARE DESIGNATED BY FREE PARAMETERS NOT ASSIGNED TO BE ZERO, IN EQUATION 4

| Model | Number of parameters | L = -2 log likelihood |
|---|----------------------|-----------------------|
| Linear model (a, b, c, σ) | 6 | 208.8 |
| (a, b, c, d, σ) | 7 | 207.8 |
| (a, b, c, f, σ) | 7 | 207.2 |
| (a, b, c, e, σ) * | 7 | 206.6 |
| (a, b, c, d, f, σ) | 8 | 207.4 |
| (a, b, c, d, e, σ) | 8 | 206.7 |
| (a, b, c, e, f, σ) | 8 | 206.6 |
| Full model | 9 | 206.6 |

* Model M1.

From Table 2, it appears that the linear model provides the best fitting parsimonious model. The model that includes e – the coefficient of the square of $\ln(x+1)$, decreases L by 2.22, with 1 degree of freedom, which under normal theory would be significant with p-value equal to 0.136. The value of e

was estimated to be negative; however the term $c \ln(x+1) + e[\ln(x+1)]^2$ is greater than zero for $x < 4989$ which is well outside the range of concern. Thus, for our purposes, the function g (Equation 4) for M1 is an increasing function of the variable days in the region of concern, and thus can be used. Because

the p-value is not large, this model cannot be rejected, thus an estimate associated with this model, M1, is also considered in order to help evaluate the range of uncertainty of the estimates and to see the impact of the more complicated model. Table 3 provides the estimates of averted illnesses.

TABLE 3—ESTIMATED ILLNESSES AND TOTAL AVERTED COSTS (TAC) OVER 10 YEARS TOGETHER WITH UPPER 95% CONFIDENCE LIMIT FOR THE TWO MODELS CONSIDERED. ESTIMATES DERIVED USING MIXED EFFECT MODEL WITH ASSUMPTION OF LOGNORMAL DISTRIBUTION (SEE EQUATIONS 2 AND 3)

| Statistic | Estimate linear model | Upper 95% limit linear model | Estimate M1 model | Upper 95% limit M1 model |
|-----------------------|-----------------------|------------------------------|-------------------|--------------------------|
| Tot ill for Sal | 0.7 | 1.9 | 0.5 | 1.7 |
| Tot ill for LM | 0.3 | 0.6 | 0.4 | 1.0 |

TABLE 3—ESTIMATED ILLNESSES AND TOTAL AVERTED COSTS (TAC) OVER 10 YEARS TOGETHER WITH UPPER 95% CONFIDENCE LIMIT FOR THE TWO MODELS CONSIDERED. ESTIMATES DERIVED USING MIXED EFFECT MODEL WITH ASSUMPTION OF LOGNORMAL DISTRIBUTION (SEE EQUATIONS 2 AND 3)—Continued

| Statistic | Estimate linear model | Upper 95% limit linear model | Estimate M1 model | Upper 95% limit M1 model |
|--------------------------|-----------------------|------------------------------|-------------------|--------------------------|
| Tot ill for E coli | 5.6 | 8.7 | 4.0 | 10.6 |

The residuals of these models do not appear to be normally distributed, based on the QQ plots (for both the linear and model M1) given in Figure 3, with occasional large residuals. The QQ plots take on the appearance it does because of many results with no illnesses. However, the models provide estimated values of λ (Equation 1) that are close to the actual illnesses, thus, conditionally, the goodness-of-fit, as determined by the closeness of the estimated value of λ and the number of illnesses is good.

Using a chi-square approximation, of the square of the difference between the estimated λ and the actual number of illnesses, divided by λ , for the linear model, the sum of these terms over the 75 observations is 14.3; for all recalls for which the illnesses are reported as zero, the largest estimated value of λ is 1.04, which is not inconsistent; the largest difference is about 2, which occurs for a recall that reported 11 illnesses for which the estimated value of λ is 9.06. This data point is the one with the

largest residual (top right corner of the top graph of Figure 3). For the model M1, the chi-square statistic is slightly larger (20.4 because for one recall with 1 reported illness, the estimated value of λ is 0.06 (whereas for the linear model the estimated value of λ is 0.10); thus the chi-square statistic associated with this observation is large, causing the larger chi-square statistic compared to that for the linear model.

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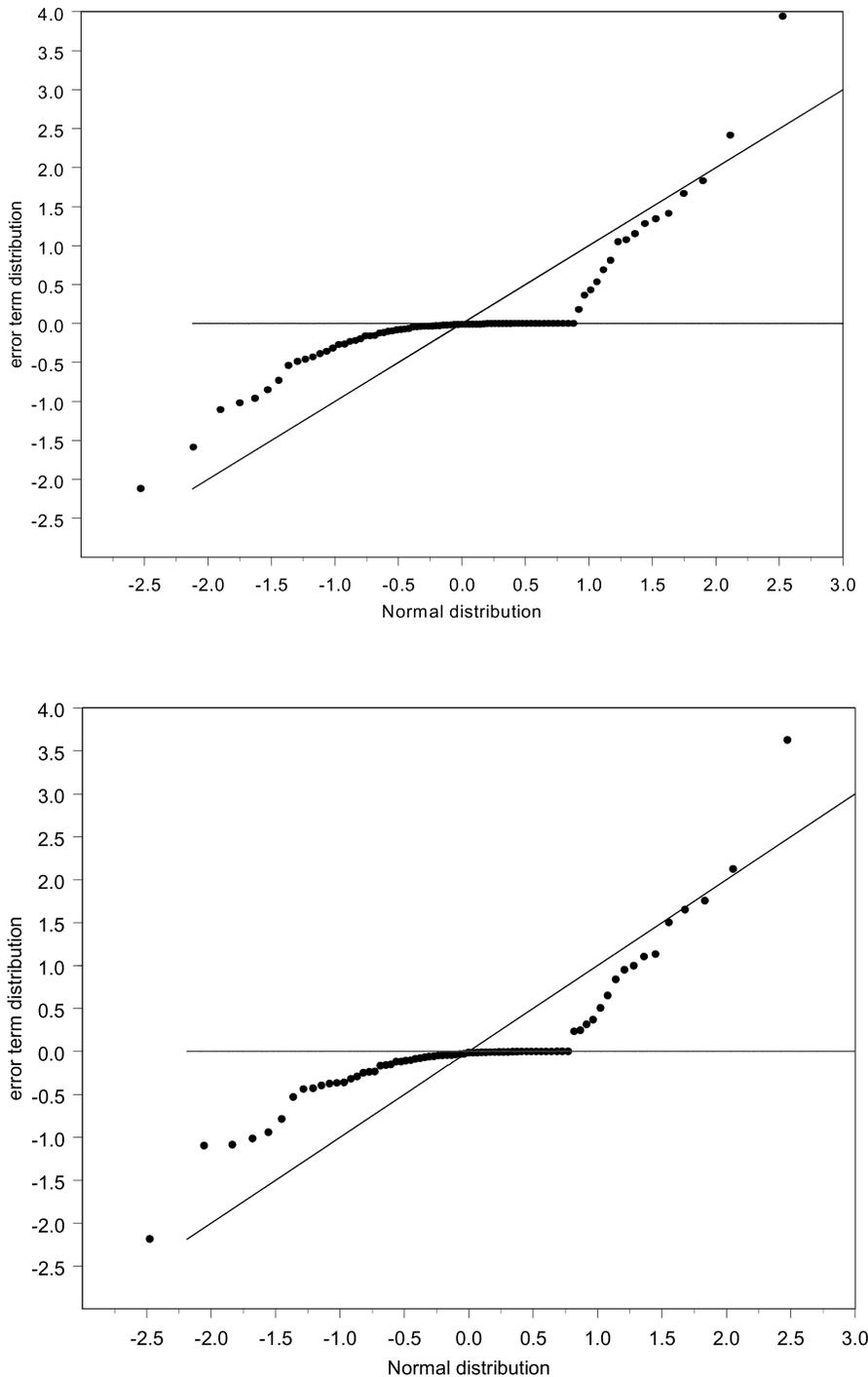


Figure 3: QQ plot of Bayes estimates of ϵ 's of Equation 1, using linear model (top) and model M1 (bottom) (See Table 2 for definition), assuming normal distribution.

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In conclusion, the estimates of the averted illnesses are highly uncertain because of the small number of data points and the high degree of variability of these data, leading to statistical uncertainty regarding the predicted number of illnesses given a model and uncertainty regarding the best model to

use for estimating the number of averted illnesses. However, from the above models, it appears that, with 95% confidence, the expected number of illnesses would be, on average, no more than about 1 illness per year averted, over the 10 years, with expected total averted costs as much as about

\$120,000, depending upon the model used.

These estimates though reflect (only) expectations, and do not include the possibilities of averted cost for a given expected value. There is a distinct probability that one of these averted illnesses could result in severe, long

term illness, or death. In that case the averted costs would be substantially

larger than the expected costs that are being estimated above.

Appendix 2: Data Used in Analysis

| Assigned days before recall | Volume (lbs) | Reported illnesses | Pathogen |
|-----------------------------|--------------|--------------------|----------|
| 4 | 50 | 0 | E coli. |
| 4 | 65 | 0 | E coli. |
| 4 | 375 | 0 | E coli. |
| 6 | 128 | 0 | E coli. |
| 6 | 219 | 0 | E coli. |
| 6 | 345 | 0 | E coli. |
| 6 | 884 | 0 | E coli. |
| 6 | 1900 | 0 | E coli. |
| 6 | 4663 | 0 | E coli. |
| 6 | 6152 | 0 | E coli. |
| 7 | 75 | 0 | E coli. |
| 7 | 925 | 0 | E coli. |
| 9 | 26669 | 0 | E coli. |
| 10 | 4240 | 0 | E coli. |
| 11 | 780 | 0 | E coli. |
| 13 | 13275 | 0 | E coli. |
| 14 | 16743 | 0 | E coli. |
| 17 | 13150 | 0 | E coli. |
| 22 | 1560 | 0 | E coli. |
| 26 | 1084384 | 0 | E coli. |
| 30 | 68670 | 0 | E coli. |
| 50 | 2340 | 0 | E coli. |
| 50 | 4200 | 0 | E coli. |
| 50 | 20460 | 0 | E coli. |
| 52 | 420 | 0 | E coli. |
| 56 | 39973 | 0 | E coli. |
| 88 | 3516 | 0 | E coli. |
| 55 | 5920 | 1 | E coli. |
| 123 | 173554 | 1 | E coli. |
| 45 | 95927 | 2 | E coli. |
| 8 | 107943 | 5 | E coli. |
| 64 | 188000 | 6 | E coli. |
| 72 | 95898 | 6 | E coli. |
| 14 | 259230 | 8 | E coli. |
| 30 | 3300000 | 8 | E coli. |
| 43 | 117500 | 9 | E coli. |
| 58 | 845000 | 10 | E coli. |
| 42 | 2758 | 11 | E coli. |
| 72 | 129000 | 17 | E coli. |
| 65 | 380000 | 20 | E coli. |
| 51 | 5700000 | 27 | E coli. |
| 47 | 545699 | 29 | E coli. |
| 45 | 153630 | 33 | E coli. |
| 365 | 21700000 | 40 | E coli. |
| 63 | 1360000 | 42 | E coli. |
| 43 | 5300000 | 54 | E coli. |

| Assigned days before recall | Volume (lbs) | Reported illnesses | Pathogen |
|-----------------------------|--------------|--------------------|----------|
| 6 | 1591 | 0 | LM. |
| 7 | 16 | 0 | LM. |
| 7 | 285 | 0 | LM. |
| 7 | 290 | 0 | LM. |
| 7 | 4535 | 0 | LM. |
| 7 | 6970 | 0 | LM. |
| 8 | 130 | 0 | LM. |
| 8 | 172 | 0 | LM. |
| 8 | 290 | 0 | LM. |
| 8 | 750 | 0 | LM. |
| 8 | 39514 | 0 | LM. |
| 10 | 6907 | 0 | LM. |
| 11 | 872 | 0 | LM. |
| 11 | 70400 | 0 | LM. |
| 12 | 140 | 0 | LM. |
| 13 | 930 | 0 | LM. |
| 14 | 207 | 0 | LM. |
| 15 | 5250 | 0 | LM. |
| 22 | 564 | 0 | LM. |
| 40 | 2268 | 0 | LM. |

| Assigned days before recall | Volume (lbs) | Reported illnesses | Pathogen |
|-----------------------------|--------------|--------------------|----------|
| 47 | 28610 | 0 | LM. |
| 52 | 3590 | 0 | LM. |
| 72 | 1 | 0 | LM. |
| 136 | 2184 | 0 | LM. |
| 137 | 3780 | 0 | LM. |
| 137 | 10368 | 0 | LM. |
| 192 | 286320 | 2 | LM. |
| 61 | 466236 | 14 | Sal. |
| 63 | 825769 | 42 | Sal. |

[FR Doc. 2011-8408 Filed 4-8-11; 8:45 am]
BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Forest Service

Hiawatha East Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Hiawatha East Resource Advisory Committee will meet in Sault Ste. Marie, Michigan. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110-343) and in compliance with the Federal Advisory Committee Act. The purpose is to hold the first meeting of the newly formed committee.

DATES: The meeting will be held on May 5, 2011, and will begin at 6 p.m.

ADDRESSES: The meeting will be held at Best Western Sault Ste. Marie, 4281 I-75 Business Spur, Sault Ste. Marie, MI 49783. Written comments should be sent to Janel Crooks, Hiawatha National Forest, 2727 North Lincoln Road, Escanaba, MI 49829. Comments may also be sent via e-mail to HiawathaNF@fs.fed.us, or via facsimile to 906-789-3311.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Hiawatha National Forest, 2727 North Lincoln Road, Escanaba, MI. Visitors are encouraged to call ahead to 906-786-4062 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Janel Crooks, RAC coordinator, USDA, Hiawatha National Forest, 2727 North Lincoln Road, Escanaba, Michigan 49862; (906) 786-4062; E-mail HiawathaNF@fs.fed.us.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339

between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The following business will be conducted: (1) Introductions of all committee members, replacement members and Forest Service personnel. (2) Selection of a chairperson by the committee members. (3) Receive materials explaining roles of the RAC and process for considering and recommending Title II projects; and (4) Public Comment. Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting.

Dated: April 4, 2011.

Stevan J. Christiansen,
Designated Federal Officer.

[FR Doc. 2011-8506 Filed 4-8-11; 8:45 am]
BILLING CODE 3410-11-P

DEPARTMENT OF AGRICULTURE

Forest Service

West Virginia Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The West Virginia Resource Advisory Committee will meet in Elkins, West Virginia. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110-343) and in compliance with the Federal Advisory Committee Act. The purpose is for the committee to consider new project proposals.

DATES: The meeting will be held on April 21, 2011, and will begin at 1 p.m.

ADDRESSES: The meeting will be held at the Monongahela National Forest Supervisor's Office, 200 Sycamore Street, Elkins, WV 26241. Written comments should be sent to Kate Goodrich-Arling at the same address. Comments may also be sent via e-mail

to kgoodricharling@fs.fed.us, or via facsimile to 304-637-0582.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Monongahela National Forest, 200 Sycamore Street, Elkins, WV 26241.

FOR FURTHER INFORMATION CONTACT: Kate Goodrich-Arling, RAC coordinator, USDA, Monongahela National Forest, 200 Sycamore Street, Elkins, WV 26241; (304) 636-1800; E-mail kgoodricharling@fs.fed.us.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The following business will be conducted: (1) Review and approval or amendment of notes from previous meeting (2) Consider new project proposals; and (3) Public Comment. Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting.

Dated: April 4, 2011.

Clyde N. Thompson,
Designated Federal Officer.

[FR Doc. 2011-8505 Filed 4-8-11; 8:45 am]
BILLING CODE 3410-11-P

DEPARTMENT OF AGRICULTURE

Forest Service

Madera County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Madera County Resource Advisory Committee will be meeting in North Fork, California on April 20th 2011. The purpose of the meeting will be to review the funding schedule for projects identified for approval at the