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The USDA's Authority to Recall Meat and Poultry Products

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SUMMARY

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The USDA's Authority to Recall Meat and Poultry Products

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) has monitored numerous recalls of meat and poultry products sold in the United States. The recalls have involved beef products possibly contaminated with *E. coli* O157:H7, beef and poultry products possibly contaminated with *Salmonella*, and canned meat products possibly contaminated by botulism. These recalls raise issues of consumer confidence in the meat industry and questions about the adequacy of the USDA oversight of these products.

In February 2008, USDA announced the largest-ever recall, of 143.4 million pounds of fresh and frozen beef products from a California slaughterer-processor. The Class II recall (meaning only a remote possibility of adverse health effects) was in response to evidence that nonambulatory ("downer") cattle had been mistreated and periodically slaughtered for food, in violation of a federal humane slaughter law and of meat safety regulations, respectively.

Following these recalls, Congress included in the 2008 farm law (P.L. 110-246) new requirements for establishments to promptly notify USDA about potentially adulterated or mislabeled meat and poultry products and also to develop and maintain plans for conducting a recall. Other recall-related issues for Congress include whether USDA should be given mandatory recall authority; whether notification and/or recall planning rules should be more prescriptive; and whether new recordkeeping and product traceability requirements are needed.

Currently, USDA does not have authority to mandate a recall of meat and poultry products. Rather, USDA, through FSIS, monitors food companies' recalls. When FSIS learns of a potential recall, it convenes a recall committee, which makes recommendations based on information such as any pertinent production and distribution data provided by the company. Once the company initiates a recall, FSIS immediately issues a press release to notify the public, posts it on its website, and provides information directly to stakeholders—including Congress, the media, federal, state, and local officials, and constituents—via e-mail and faxes. At the conclusion of the recall, FSIS conducts an effectiveness check to determine whether all appropriate parties were properly notified and all reasonable efforts were made to retrieve, destroy, or return the recalled product to the firm.

This report provides an overview of USDA's authority to regulate meat, poultry, and their products. Specifically, it discusses the requirements of USDA inspections and import regulations, as well as USDA's role in product recalls. This report also addresses some of the issues that arise when considering possible changes to recall authority that may be of interest as the 112th Congress may consider related food safety issues. The **Appendix** of this report provides information regarding recent recalls and the significance of the recall data.

Contents

Background 1
Current Statutory Authority to Regulate Meat and Poultry Products 2
Authority to Regulate Imports 2
Inspection Authority 3
Current USDA Regulations and Guidance Regarding Recalls 4
Authority for Detentions and Seizures 4
Industry-Initiated Recalls 4
Recall Recommendations 5
Recall Classifications 5
Extent of Recall 6
Communication Regarding Recalls 6
Monitoring and Termination of Recalls 7
Selected Issues and Bills 7
Is Mandatory Authority Needed? 8
Responsibility Questions 8
Notification Requirements 9
Traceability 9
Recovery Rates and Recall Effectiveness 9
Significance of Recall Data 10

Figures

Figure A-1. Annual FSIS Meat and Poultry Recalls, 1994-2009 (Number) 12
Figure A-2. Annual FSIS Meat and Poultry Recalls, 1994-2009 (Volume) 12

Tables

Table A-1. Total Recalls, 2004-2009, by Reason 13
Table A-2. Total Recalls, 2004-2009, by Product Type 13
Table A-3. Largest Recalls Since 1994 14

Appendixes

Appendix. Information Regarding Meat and Poultry Product Recalls 11

Contacts

Author Information 17

Background

The Food Safety and Inspection Service (FSIS) within the U.S. Department of Agriculture (USDA) has monitored numerous recalls of meat and poultry products sold in the United States.[1] The recalls have involved beef products possibly contaminated with *E. coli* O157:H7, beef and poultry products possibly contaminated with *Salmonella*, and canned meat products possibly contaminated by botulism. A recall is "a firm's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded...."[2]

Recalls received heightened attention in February 2008, when USDA announced the largest-ever recall—143.4 million pounds of fresh and frozen beef products from a California slaughterer-processor. The Class II recall was in response to evidence that nonambulatory ("downer") cattle had been mistreated and periodically slaughtered for food, in violation of a federal humane slaughter law and of meat safety regulations, respectively.[3] (See "Recall Classifications," below, for a definition of Class II.)

Recalls raise issues of consumer confidence in the meat industry and questions of the adequacy of the USDA oversight. A 2004 Government Accountability Office (GAO) report criticized the adequacy of efforts to monitor and ensure compliance with recalls, noting that "concerns that contaminated food could reach consumers have also intensified because of the potential susceptibility of food to deliberate contamination."[4]

Although recalls are voluntary, USDA may withhold products from the food supply through its regulation of imports, its inspection and approval process, and its power to seize and detain products that are in violation of its regulations.[5] This report provides an overview of USDA's statutory authority to regulate meat, poultry, and their products. Specifically, the report discusses the requirements of USDA relating to inspections and import regulations, as well as USDA's role in product recalls, including its power to seize and detain products in commerce. This report also addresses issues surrounding the debate over expansion of USDA authority to require recalls of products known or suspected to be adulterated and legislative proposals to change the current

[1] The FSIS has authority to regulate the safety and proper labeling of most meat, poultry, and their products and of some egg products. The Food and Drug Administration (FDA), within the Department of Health and Human Services, is responsible for the safety of all other foods. For a broader overview of issues relating to USDA's role in meat and poultry regulation, *see* CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, by Renée Johnson. For more information on federal authority to regulate other food products, *see* CRS Report RL34167, *The FDA's Authority to Recall Products*, by Vanessa K. Burrows. For more information on food safety issues generally, *see* CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Renée Johnson.

[2] Recall of Meat and Poultry Products, FSIS Directive 8080.1, Revision 6, October 26, 2010, *available at* http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1.pdf. FSIS does not include market withdrawals or stock recoveries in the definition of recall. A market withdrawal is "a firm's removal or correction, on its own initiative, of a distributed product that involves a minor company quality program or regulatory program infraction that would not cause the product to be adulterated or misbranded." *Id*. A stock recovery is "a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm." *Id*.

[3] In March 2009, FSIS published a final rule that required non-ambulatory disabled cattle offered for slaughter to be condemned and disposed of according to regulations, which eliminated the discretion provided to FSIS inspectors to determine the disposition of such cattle on a case-by-case basis. *See* 74 Fed. Reg. 11463.

[4] Government Accountability Office, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food* (October 2004), http://www.gao.gov/new.items/d0551.pdf.

[5] For general information about FSIS recalls and links to various agency resources, see FSIS Food Recalls Fact Sheet, available at http://www.fsis.usda.gov/fact_sheets/FSIS_Food_Recalls/index.asp.

recall process. Information about recent recalls and analysis of recall data can be found in the **Appendix** of the report.

Current Statutory Authority to Regulate Meat and Poultry Products

USDA does not currently have statutory authority to issue mandatory recalls of contaminated products. Recalls, which withdraw products from the food supply, must be voluntarily initiated by a manufacturer or distributor, and these entities generally bear the cost of any recall. USDA does have statutory authority to perform other regulatory functions involving meat and poultry under the Federal Meat Inspection Act (FMIA)[6] and the Poultry Products Inspection Act (PPIA),[7] respectively.[8]

These acts authorize USDA to regulate the safety, wholesomeness, and proper labeling of domestic and imported meat, poultry, and their products sold for human consumption. USDA has assigned its authority to FSIS, which carries out USDA's authority under the acts.[9] Though FSIS may not mandate recalls, it can keep some products from entering the food supply through its role in importation regulation and inspections.

Authority to Regulate Imports

Meat, poultry, and their products may not be imported if they do not comport with the standards provided by U.S. law. FMIA prohibits importation of any carcasses, meat or meat food products that are meant for human consumption if they are adulterated,[10] misbranded,[11] or do not comply with other inspection and facilities standards provided in the act.[12] PPIA prohibits importation of "slaughtered poultry, or parts or products thereof" if they are not healthful, wholesome, unadulterated or fit for human consumption or if they do not comply with the standards provided in the act.[13]

Imported items must comply with U.S. domestic sanitary protection standards. Specifically, poultry imports must be "subject to inspection, sanitary, quality, species verification, and residue standards" and must have been "processed in facilities and under conditions that achieve a level

[6] 21 U.S.C. § 601 et seq.

[7] 21 U.S.C. § 451 et seq.

[8] USDA also has authority to regulate egg products under the Egg Products Inspection Act (EPIA). 21 U.S.C. § 1031 et seq. USDA shares this authority with FDA. The statutory provisions governing regulation of imports and inspection of egg products that fall under the jurisdiction of USDA are similar to the provisions relating to meat, poultry, and their products. However, because USDA does not have exclusive authority to regulate eggs, this report does not address these provisions.

[9] The Secretary delegates this authority to FSIS under 9 C.F.R. § 300.2.

[10] A product can be considered "adulterated" if it "bears or contains any poisonous or deleterious substance which may render it injurious to health"; contains any additives considered unsafe; "consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food"; or "has been prepared, packed, or held under insanitary conditions." *See* 21 U.S.C. § 601(m).

[11] A product can be considered "misbranded" if its label is false or misleading; contains an inaccurate description of the product; does not identify manufacturer, packer, or distributor and an accurate statement of quantity of the contents; or does not contain other information that may be required by the act. *See* 21 U.S.C. § 601(n).

[12] 21 U.S.C. § 620(a).

[13] 21 U.S.C. § 466(a).

of sanitary protection equivalent to that achieved under United States standards."[14] Meat imports are subject to the same standards.[15] These requirements are enforceable through random inspection and testing of products by FSIS.[16]

Imported items that do not comply with these requirements can be refused entry into the United States. Items that are refused entry into the United States and not exported within the designated time period are subject to destruction by FSIS.[17]

Inspection Authority

The FMIA requires FSIS to inspect all cattle, sheep, swine, goats, horses, mules, and other equines before they enter any plant to be slaughtered and processed for human consumption.[18] The PPIA requires inspection of any domesticated birds that might be processed for human consumption.[19]

These statutes provide for ante mortem and post mortem inspections. Livestock and poultry covered under the statutes must be examined and inspected before entry into a plant for slaughtering or processing (ante mortem inspection).[20] The carcasses must also be examined after the animals are slaughtered (post mortem inspection).[21] Inspectors are responsible for inspecting the methods of slaughtering, handling, and processing, as well as the facilities in which these activities take place.[22] They also inspect the establishment's sanitation quality.[23] In order to conduct these inspections, inspectors must have access at all times to the entire facility in which the animals are slaughtered or processed.[24]

This inspection process regulates the entry of meat and poultry products into the food supply. If inspectors find that an establishment or animals do not meet FSIS standards, the FSIS may cease or refuse inspection services.[25] Products inspected and approved as unadulterated must be clearly labeled before entry into the food supply.[26] Products inspected and not approved must be destroyed.[27]

[14] 21 U.S.C. § 466(d).

[15] 21 U.S.C. § 620(f).

[16] 21 U.S.C. § 466(d)(4); 21 U.S.C. § 620(f).

[17] *See* 21 U.S.C. § 620(b); 21 U.S.C. § 466(b).

[18] 21 U.S.C. § 601 et seq.

[19] 21 U.S.C. § 451 et seq.

[20] *See* 21 U.S.C. § 603; 21 U.S.C. § 455(a).

[21] *See* 21 U.S.C. § 604; 21 U.S.C. § 455(b).

[22] 21 U.S.C. § 603.

[23] 21 U.S.C. § 608; 21 U.S.C. § 456.

[24] 21 U.S.C. § 606; 9 C.F.R. § 300.6.

[25] 21 U.S.C. § 603(b); 21 U.S.C. § 467.

[26] 21 U.S.C. § 606; 21 U.S.C. § 457.

[27] 21 U.S.C. § 604; 21 U.S.C. § 455.

Current USDA Regulations and Guidance Regarding Recalls

While USDA has statutory authority to prevent meat and poultry products from entering the food supply, it lacks authority to withdraw products already in the food supply. Rather, recalls of meat and poultry products are voluntary actions taken by food companies. USDA has long relied on this voluntary, cooperative approach between FSIS and meat and poultry establishments. If an establishment conducts the recall, FSIS provides assistance and monitors the recall. If an establishment does not conduct the recall, FSIS is limited to its authority to detain and seize the products in question. Recall policies are spelled out in FSIS Directive 8080.1.[28]

Authority for Detentions and Seizures

If a firm does not follow FSIS' recommendation to conduct a recall, "FSIS personnel are to detain any product found in commerce that would have been subject to a recall as set out [by an internal procedure directive]."[29] FSIS has the authority to detain any meat or poultry product after making two determinations. First, it must find that the product is being held for distribution, in the process of being distributed, or already distributed in commerce.[30] Second, FSIS must have reason to believe that any such article: (a) "is adulterated or misbranded and is capable of use as human food;" (b) "has not been inspected;" or (c) "has been or is intended to be, distributed in violation of [any federal or state law]."[31]

Under these regulations, the authorized detention period cannot exceed 20 days.[32] If FSIS detains a product, the agency will "issue a Press Release informing the public that product that appears to be adulterated or misbranded has been shipped by the responsible firm and that the Agency is detaining the product in commerce."[33]

Industry-Initiated Recalls

FSIS provides recall guidelines for firms that wish to voluntarily recall a product. The guidelines suggest identifying a recall coordinator, developing a recall plan, and issuing recall communications and notifications.[34] FSIS also notes that it "expects that, once it is determined that a recall will be undertaken, the recalling firm will immediately notify FSIS."[35] The enacted 2008 farm bill included a requirement that an establishment subject to inspection "promptly notify" FSIS when it believes or has reason to believe that adulterated or misbranded products have entered commerce.[36]

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[28] Recall of Meat and Poultry Products, FSIS Directive 8080.1, Revision 6, October 26, 2010, *available at* http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1.pdf (hereinafter FSIS Directive 8080.1).

[29] FSIS Directive 8080.1, part VIII.B.

[30] 9 C.F.R. § 329.1.

[31] *Id. See also* 9 C.F.R. 381.210.

[32] *See* 9 C.F.R. 329.1; 9 C.F.R. § 381.210.

[33] FSIS Directive 8080.1, part VIII.B.

[34] FSIS Directive 8080.1, Attachment 1, part 2.

[35] FSIS Directive 8080.1, Attachment 1, part 3.

[36] P.L. 110-246, title XI, § 11017(a), codified at 21 U.S.C. § 612.

FSIS notes that "[t]here is no regulatory requirement that an establishment includes this recall plan in its HACCP plan or as a prerequisite program; however, FSIS believes that prudent establishments will."[37] HACCP (Hazard Analysis and Critical Control Points) is the safety prevention plan that FSIS requires of every inspected establishment.

Recall Recommendations

FSIS monitors and oversees voluntary recalls. FSIS oversight begins when it learns of a potential recall. FSIS may learn of a potential recall from various sources: (1) the manufacturer or distributor of the product; (2) test results from FSIS sampling programs; (3) observations or inquiries by FSIS inspection program personnel; (4) consumer complaints; (5) epidemiological data submitted by various federal, state, and local agencies; or (6) information from other agencies.[38] If a recall may appear appropriate, FSIS assembles a Recall Committee and responds to any threats or hazards posed by the recall.[39]

The Recall Committee makes a preliminary evaluation to determine whether to recommend a recall of the product. In this evaluation, FSIS considers the nature of the defect, the actual occurrence of any illnesses or injuries, and the likelihood and type of illness or injury that may result.[40] If FSIS issues a recall recommendation, the recommendation will contain the following information: (1) the reason for the recall and any reason to believe the product is adulterated or misbranded; (2) the recall classification; (3) the ability of distributors and consumers of the product to identify it; and (4) the estimated amount of the product in distribution.[41]

Recall Classifications

Recall classifications are based on the public health risk posed by the product in question. One of three levels, or classes, of recalls can be designated. Class I recalls are the most serious and would involve a "situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death."[42] Pathogens like *Listeria monocytogenes* or *Salmonella* on ready-to-eat products, or *E. coli* O157:H7 on raw beef products are examples of Class I recalls.

Class II recalls would involve a "situation where there is a remote probability of adverse health consequences from the use of the product."[43] The undisclosed presence of a small amount of a potentially allergenic substance or the presence of a nonsharp-edged foreign material like plastic are examples of Class II recalls. Class III recalls would involve a "situation where the use of the product will not cause adverse health consequences."[44] The presence of excess water in a product might lead to a Class III recall.

[37] FSIS Directive 8080.1, Attachment 1, part 1.

[38] FSIS Directive 8080.1, part VII.

[39] FSIS Directive 8080.1, part VI.I.

[40] FSIS Directive 8080.1, part VII.B.

[41] FSIS Directive 8080.1, part VII.C.

[42] FSIS Directive 8080.1, part VI.D.

[43] *Id*.

[44] *Id*.

Extent of Recall

The depth of the recall identifies the level of distribution to which the recall extends. If a recall extends to the consumer level, the recall applies to household consumers, as well as all other levels of distribution.[45] If the recall extends to the retail level, the product is recalled from all retail sales.[46] If it extends to the HRI level (formerly known as the user level), the recall applies to user entities, including "hotels, restaurants, and other food service institutional customers."[47] If the recall applies to the wholesale level, it involves "the distribution level between the manufacturer and the retailer."[48]

Communication Regarding Recalls

FSIS uses press releases and recall notification reports to inform the public of recalled products.[49] FSIS issues press releases known as recall releases for Class I or Class II recalls but generally not for Class III recalls.[50] The press release and a photo of the product are posted on FSIS' website, and the information is disseminated to stakeholders (including Congress), news media, and public health officials.[51]

The press release includes a detailed description (and photo, if possible) of the product, the reason it is being recalled and the risk associated with the product's use.[52] It also instructs the public about the appropriate responses to be taken after the product is identified and provides contact information for questions.[53] The press release also indicates the product's destination to better alert potential consumers.[54]

If FSIS verifies that "the recalled product has not been distributed beyond the wholesale level and ... it is not likely to be sold directly to consumers," FSIS issues recall notification reports with general information about the recall, including information similar to recall recommendations.[55] Recall notification reports are issued for all classes of recalls and are also posted on the FSIS website.[56]

Under a regulation effective in August 2008, FSIS now publishes on its website the retail stores receiving meat and poultry products involved in Class I recalls.[57] Some of the retail stores subject to the regulation include supermarkets and grocery stores, convenience stores, meat markets,

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[45] FSIS Directive 8080.1, part VI.E.

[46] *Id*.

[47] *Id*.

[48] *Id*.

[49] A list of all FSIS recalls since 1994, and related information, can be accessed at http://www.fsis.usda.gov/Fsis_Recalls/.

[50] FSIS Directive 8080.1, part IX.A.

[51] To Review Recent Recalls in the Meat Industry: Hearing before the H. Comm. On Agriculture, 110th Cong. 11 (2007) (statement of Richard Raymond, Under Secretary for Food Safety, U.S. Department of Agriculture), http://agriculture.house.gov/testimony/110/h71107/DrRaymond.doc.

[52] FSIS Directive 8080.1, part IX.A.

[53] *Id*.

[54] *Id*.

[55] *Id*.

[56] FSIS Directive 8080.1, part IX.B.

[57] 9 C.F.R. § 390.10; 73 Fed. Reg. 40948. *See also* News Release, U.S. Dept. of Agriculture, USDA Will List Retail Stores Receiving Recalled Meat and Poultry Products (July 11, 2008).

wholesale clubs and supercenters.[58] FSIS noted that the listing is intended to better inform consumers about products that have the greatest potential for serious health consequences.[59]

Monitoring and Termination of Recalls

FSIS monitors the recall process through effectiveness checks. The effectiveness checks verify the diligence and success of the recalling firm in notifying consignees (those entities or individuals to whom the product has been delivered) of the recall and the response of the consignees.[60] They are based on the risk involved, the recall classification, and the number of consignees.[61]

FSIS personnel contact consignees to determine the effectiveness of a recall.[62] When the number of consignees that are found to have the product available to the public exceeds the critical limit provided in FSIS sampling plans, the recall cannot be deemed effective.[63] If the number is equal to or less than the critical limit, the recall is deemed effective.[64]

If FSIS finds a lack of prompt action by a firm or a lack of response by consignees to a firm's request, the agency may exercise its authority to detain any product found in commerce.[65] When a firm does not or cannot implement a proper recall strategy, FSIS may intervene under its detention authority or provide public warnings in order to mitigate the risk posed by the product.[66]

FSIS issues a recall termination report after it completes effectiveness checks and determines that all reasonable efforts have been made to recall the product.[67] FSIS may close a recall case "if data indicate that no additional illnesses associated with the recalled product are being reported, and there are no signs that recalled product remains in commerce."[68]

Selected Issues and Bills[69]

Proposals have been debated in past sessions of Congress to provide FSIS with the authority to order companies to recall meat and poultry. However, none has been enacted. Following is a brief discussion of selected issues that have been raised in the debate about amending FSIS recall authority.

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[58] 73 Fed. Reg. 40946.

[59] 73 Fed. Reg. 40940.

[60] FSIS Directive 8080.1, part XI.

[61] *Id*.

[62] *Id*. For specific information on effectiveness checks (including tables that provide the critical limits), see Attachment 3 of the FSIS Directive 8080.1.

[63] FSIS Directive 8080.1, part XI.C.

[64] *Id*.

[65] FSIS Directive 8080.1, part XI.E.

[66] *Id*.

[67] FSIS Directive 8080.1, part XII.

[68] *Id*.

[69] Among the sources for the pro-con arguments in this section is Roberts, Michael T., *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*, bepress Legal Series, Working Paper 258 (April 27, 2004), available at http://law.bepress.com/expresso/eps/258/.

Is Mandatory Authority Needed?

Consumer and food safety advocacy groups have long argued that FSIS (as well as FDA) should be granted explicit statutory authority to impose mandatory recalls of adulterated and misbranded products. These advocates contend that FSIS (and FDA) needs such authority to ensure products can be quickly removed from the market any time a company declines to do so voluntarily, is reluctant to act swiftly, or fails to conduct a comprehensive recall. Mandatory authority would expedite the current process, make it clear that public health is the agencies' top priority, reduce companies' exposure to lawsuits, and bolster consumer confidence in the food supply, they maintain. In 2004, GAO concluded that FSIS and FDA do not know how well companies carry out recalls, and have not effectively tracked them. As a result, most recalled food products are not recovered and thus may be consumed, GAO found.[70]

Others, including meat and poultry industry trade associations, have countered that current authorities are sufficient. Few if any meat or poultry establishments have refused to comply with an FSIS recommendation to recall a suspected contaminated product, they argue. (Critics contend that this claim is based upon anecdotal reports rather than a factual accounting.) Industry representatives assert that FSIS's existing authority to suspend or withdraw its inspection service, which effectively denies a plant the right to market its products, is a strong incentive for establishments to ensure their products are safe to consume. FSIS' authority also enables it to detain meat and poultry products of concern for up to 20 days, and the agency can, with a court's permission, seize, condemn and destroy unsafe food as well. These implicit threats, along with the potential for adverse publicity and legal liability, make the current system effective, its proponents maintain.

It is also argued that voluntary procedures encourage cooperation between industry and its regulators, whereas mandatory recall authority might discourage it. Mandatory authority would foster a more adversarial system of mistrust and possible litigation, making recalls less rather than more effective, they argue.

Responsibility Questions

Among other components that might be considered for a "sensible" mandatory food recall system, according to the Roberts article,[71] are: extension of due process protection to food companies (i.e., a hearing before an administrative law judge); and possibly some limitation on the liability of companies that comply with a government recall request, to protect them from civil actions.

These particular aspects of the issue apparently have not been widely discussed among stakeholders, at least not publicly. More specifically, if Congress empowered FSIS with mandatory recall authority, would it also be shifting—whether implicitly or explicitly—the burden of proof from the companies to the agency? Might FSIS's reasons for ordering a recall be subject to protracted challenge during the hearing proceedings, potentially undermining the recall's effectiveness? What if FSIS erroneously ordered a recall "out of an abundance of

[70] Government Accountability Office, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food* (October 2004), http://www.gao.gov/new.items/d0551.pdf. An earlier GAO (then called the General Accounting Office) report critical of current recall policies was *Food Safety: Actions Needed by USDA and FDA to Ensure That Companies Promptly Carry Out Recalls*, GAO/RCED-00-195, August 2000, http://www.gao.gov/archive/2000/rc00195.pdf.

[71] *See* Roberts, *supra* note 69.

caution" that ultimately caused a business to fail, on the one hand? If, on the other hand, FSIS waited until it had additional evidence of problems, would it be jeopardizing consumer safety?

Notification Requirements

FSIS does not have explicit statutory authority to require a company to notify it when the company has distributed an unsafe product or knows that such a product is in commerce. Many, including Roberts,[72] believe that such a mandate for prompt notification is a prerequisite for an effective recall policy.

In the enacted 2008 farm bill, Section 11017 ("Food Safety Improvement") amends both the FMIA and PPIA to require any establishment subject to inspection to "promptly notify" USDA if it believes, or has reason to believe, that an adulterated or misbranded meat or poultry product has entered commerce.[73] Section 11017 also requires meat and poultry establishments to prepare and maintain recall plans and any reassessments of their process control plans and to have them available for USDA inspectors to review and copy.

Traceability

Effective recalls require that industry and government officials have the means to easily trace the movement of products. Some argue that improved traceability capabilities would facilitate determining a product's source and whereabouts, and better prevent or contain foodborne illness outbreaks.[74]

Recovery Rates and Recall Effectiveness

Recalls rarely recover all products.[75] Between 1994 and 2007, for example, the quantity of products actually found have constituted anywhere from 17% to 28% annually of the total pounds recalled. (Recoveries did reach 64% in 2004, 40% in 1997 and 58% in 1996.) Among the reasons that many products are not recovered is that they likely have been consumed or destroyed by purchasers, according to FSIS. One issue is whether recoveries offer evidence that recalls are effective. FSIS officials have asserted on several occasions that "pounds recovered" is not a reliable measure of recall effectiveness, preferring to evaluate its success on such factors as whether the number of illnesses associated with an outbreak has been halted since a recall was announced and "whether or not the product has stopped flowing through the distribution chain."[76]

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[72] *Id*.

[73] This notification requirement is in lieu of a somewhat more prescriptive provision in the Senate-passed version that would have created "reportable" meat and poultry registries. The registries would have been similar in concept to the registry in the Food and Drug Administration Amendments Act of 2007 (P.L. 110-85), which now requires the Secretary of HHS to create a registry for reporting FDA-regulated foods with safety problems.

[74] Traceability has also been debated in connection with protecting against agroterrorism, and for verifying the U.S. origin of live animals and their products for marketing, trade and/or animal health purposes. *See* CRS Report R40832, *Animal Identification and Traceability: Overview and Issues*, by Joel L. Greene.

[75] According to one analysis of FSIS recall data, "for five recalls that followed reports of consumer illness, recovery rates per recall averaged just 20%." Julie Schmit and Barbara Hansen, "Most Recalled Meat Isn't Recovered," *USA Today*, December 3, 2007, at 1B.

[76] *See*, for example, "Recalls v. Recoveries," USDA responses to questions by Representative Kaptur, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2007, Hearings before a House Appropriations Subcommittee (Part 1), pp. 292-293, 2006.

Notwithstanding these assertions, the 2004 GAO report claims that both FSIS and FDA "told us recovery was an important indicator of a successful recall."[77]

FSIS testified that it has improved the effectiveness of the recall process since the release of the critical OIG report. The agency also stated that it has increased the number of effectiveness checks and shortened their completion times. Such checks rely on

> ... a risk-based statistical sampling plan to determine the number of consignees that FSIS program personnel will contact during the effectiveness checks. For a recall to be deemed effective or successful, the number of consignees found to have a product in commerce must be equal to or less than a critical number established in the FSIS risk-based recall effectiveness checks sampling plan.[78]

FSIS also published a final rule on July 17, 2008, providing for the agency to post on its website a list of all retail outlets to which a recalled product has been distributed. In response to comments received, FSIS limited the application of the rule to Class I recalls only. The agency believes that this would enable consumers to identify, and return or destroy, more products than currently are found.[79]

Significance of Recall Data

Another issue is the usefulness of recall data generally. Does a high number of recalls indicate that current food safety measures are ineffective in keeping unsafe products off the market? Or, rather, does it signify that industry and the federal government have heightened testing, improved their ability to find the sources of more foodborne illness outbreaks, and have otherwise become more vigilant in their oversight, even after the products leave the plants?

In arguing that their own inspection programs provide at least as much safety at the federal program, states have long made the claim that they experience far fewer recalls of their inspected products than does FSIS. However, might it be argued that states conduct fewer recalls because they maintain a different level of vigilance than FSIS? One consumer advocate told CRS that most recalls of federally inspected products are announced after routine FSIS or plant testing finds instances of bacterial contamination or potential contamination—not necessarily in response to a foodborne illness outbreak. By contrast, she asserted, neither states nor state-inspected plants have done as much testing.[80] A representative of the state agencies, on the other hand, speculated that states tend to hold products until testing is completed and verified, so that contamination may more likely be discovered before a product enters commerce.[81]

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[77] *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, p. 15.

[78] USDA responses to questions by Chairman DeLauro, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2008, Hearings before a House Appropriations Subcommittee (Part 4), pp. 3358-359, 2007. These pages contain additional details on how FSIS checks effectiveness, but does not appear to shed light on how the agency arrives at its "critical number" benchmarks.

[79] 73 Fed. Reg. 40939 - 40948.

[80] Carol Tucker Foreman, Consumer Federation of America, personal communication, October 15, 2007.

[81] National Association of State Departments of Agriculture, personal communication, October 15, 2007. States also are responsible for inspecting significantly fewer pounds of meat and poultry. For example, FSIS inspected a total of 96.4 billion pounds of meat and poultry in FY2004. Another 4.2 billion pounds were imported meat and poultry that were subject to border re-inspection by FSIS. By contrast, states inspected approximately 500 million pounds of meat and poultry in FY2004, or 5% of the volume of FSIS-regulated products. *See also* CRS Report RL34202, *State-Inspected Meat and Poultry: Issues for Congress*, by Geoffrey S. Becker.

Appendix. Information Regarding Meat and Poultry Product Recalls

Recent Recalls

FSIS reported approximately 890 meat and poultry recalls, representing nearly 323 million pounds of products, from January 1, 1994, through December 31, 2009, the period of time examined by CRS. Of the total, approximately three-fourths were Class I recalls, with the remainder either Class II or Class III recalls (CRS calculation based on FSIS recall data).

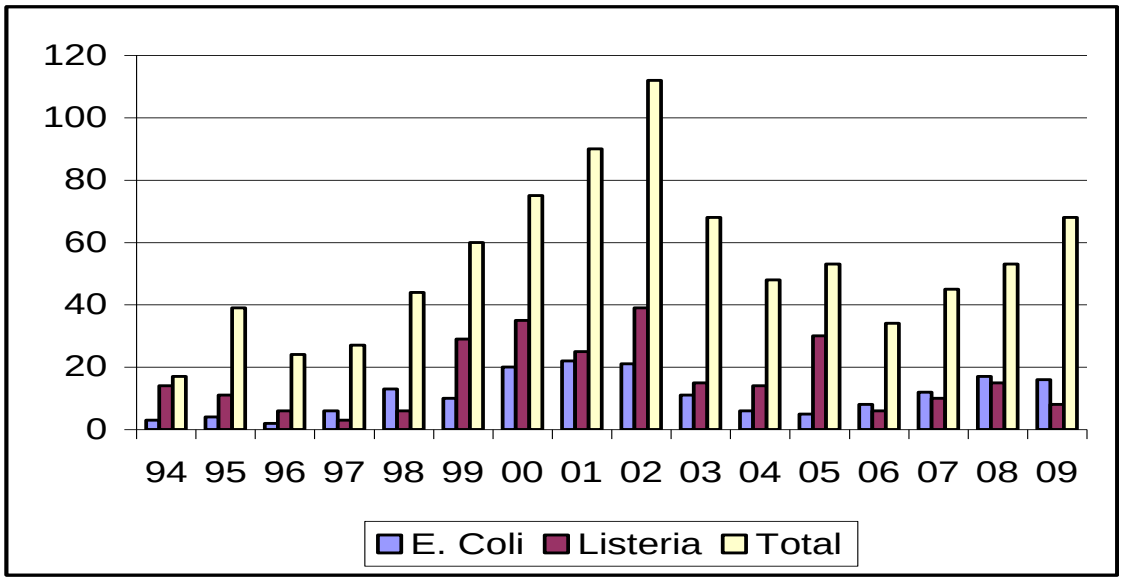
Listeria monocytogenes, usually on various ready-to-eat products, and *E. coli* O157:H7, almost always involving ground beef, hamburger patties, and other raw cuts of beef, together constitute the majority of reasons for recalls. Measured by volume of products, these two pathogens alone accounted for nearly 80% of the total pounds recalled during the period. More specifically, *Listeria* concerns were associated with 266 or 30% of all recalls (and by volume, nearly 109 million pounds or 45%) from 1994 through 2009. *E. coli* O157:H7 concerns were associated with 176 or 20% of all recalls (and a total of nearly 109 million pounds or 34%).[82]

Of the total number of recalls, 191 or 21% were a variety of products found to be misbranded, often because they contained an undeclared substance or ingredient. These substances were frequently allergens such as undeclared nuts in a processed product. Another 75 or 9% of all recalls during the period, again of a variety of products, were due to reports of foreign materials—from sharp objects such as glass or metal to potentially less hazardous matter such as pieces of plastic wrap. Another 179 recalls or 20% were from a number of different causes, ranging from processing defects like undercooking to ineligible imports (i.e., from countries or foreign plants not determined to have equivalent safety systems).

As **Figure A-1** shows, recall volumes have varied significantly from year to year. Years with large overall volumes typically were because just one or two of the total recalls for that year involved a large quantity of products produced by a single company. For example, 25 million pounds, of the total of 28.3 million pounds of recalled products in 1997, can be attributed to a Hudson Foods recall of ground beef products on August 12 of that year due to *E. coli* O157:H7 contamination. This was one of the eight largest recalls during the period examined (see **Table A-3**). Four of these recalls are discussed following the tables.

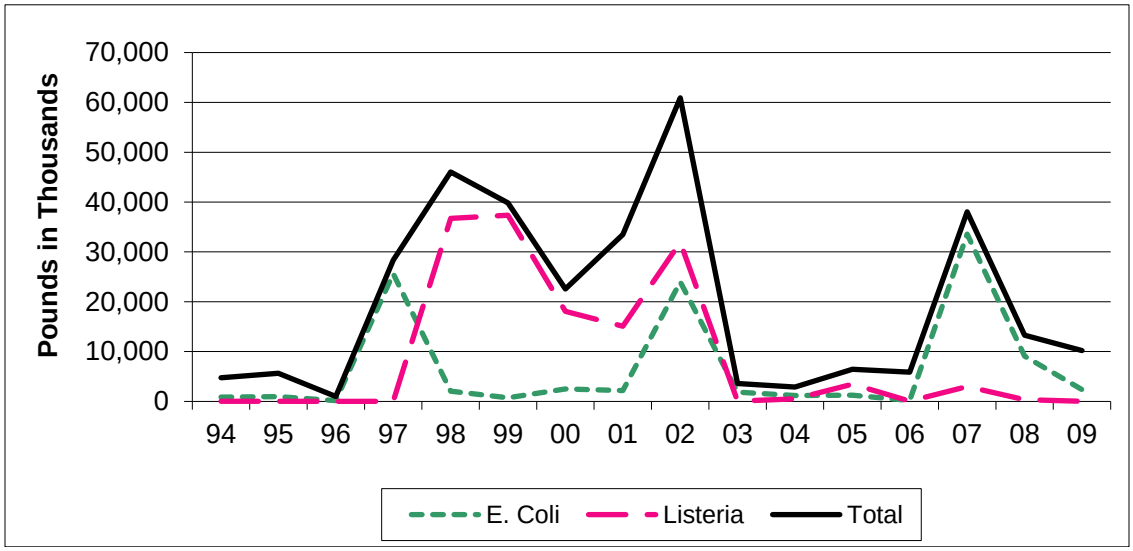
[82] Volume data excludes 143 million pounds of fresh and frozen beef products recalled in February 2008 by Hallmark/Westland Meat Packing Co. of California.

Figure A-1. Annual FSIS Meat and Poultry Recalls, 1994-2009 (Number)



Source: Prepared by CRS based on FSIS data.

Figure A-2. Annual FSIS Meat and Poultry Recalls, 1994-2009 (Volume)



Source: Prepared by CRS based on FSIS data.

Note: Data for 2008 exclude 143.4 million pounds of fresh and frozen beef products recalled in February 2008 by Hallmark/Westland Meat Packing Co. of California. This Class II recall, the largest U.S. meat recall ever, came after FSIS found that for at least two years the facility had not always notified inspectors about cattle that had become nonambulatory after they had been inspected and approved—but before they were actually slaughtered—for food. FSIS regulations explicitly prohibit most nonambulatory cattle which are presented for ante-mortem inspection, because of their higher risk of BSE. Excluding the Hallmark/Westland data makes the historical trend lines in this figure easier to discern.

Table A-1. Total Recalls, 2004-2009, by Reason

	Percent of Total Number (890)	Percent of Total Volume (323 million pounds)
Foreign Material	8.5%	4.9%
E. coli O157:H7	19.8%	33.6%
Listeria	30.0%	45.4%
Misbranded or undeclared substance	21.5%	8.9%
Other	20.2%	7.1%

Source: Prepared by CRS based on FSIS data.

Note: Totals for 2004-2009 are rounded. Total volume (323 million pounds) does not include 143 million pounds of fresh and frozen beef products recalled in February 2008 by Hallmark/Westland Meat Packing Co. of California. Including the 143 million pounds would increase the percentage for "Other" to 35.6% and decrease the percentages for other categories proportionally.

Table A-2. Total Recalls, 2004-2009, by Product Type

	Percent of Total Number (890)	Percent of Total Volume (323 million pounds)
Beef and processed beef products	33.3%	37.9%
Poultry and processed poultry products	21.3%	24.4%
Pork, ham and processed pork products	11.9%	1.7%
Franks (all species)	7.7%	13.2%
Sausage (all species)	11.2%	1.4%
Mixed, other, or unspecified	14.7%	21.4%

Source: Prepared by CRS based on FSIS data.

Note: Totals for 2004-2009 are rounded. Total volume (323 million pounds) does not include 143 million pounds of fresh and frozen beef products recalled in February 2008 by Hallmark/Westland Meat Packing Co. of California. Including the 143 million pounds would increase the percentage for beef and processed beef products to 57% and decrease the percentages for other categories proportionally.

Table A-3. Largest Recalls Since 1994

Date	Company	Product	Reason	Pounds (millions)
August 1997	Hudson Foods	ground beef	*E. coli* O157:H7	25
December 1998	Bil Mar Foods	franks; packaged meats	*Listeria*	35
January 1999	Thorn Apple Valley	packaged meats	*Listeria*	35
December 2000	Cargill	ready-to-eat poultry	*Listeria*	17
April 2001	Bar-S Foods	meat & poultry products	*Listeria*	14
June 2002	ConAgra	ground beef	*E. coli* O157:H7	18
October 2002	Pilgrim's Pride	poultry products	*Listeria*	27
September 2007	Topps	ground beef	*E. coli* O157:H7	22
February 2008	Westland/Hallmark	raw & frozen beef products	downer cattle not cleared for slaughter	143

Source: USDA, FSIS, Recall Archives.

Note: Pounds rounded to nearest million.

Recall 005-2008, Beef Products

On February 17, 2008, USDA announced that Westland/Hallmark Meat Co. of Chino, California, was recalling 143.4 million pounds of fresh and frozen beef products dating to February 1, 2006. Approximately 50 million pounds were distributed to the school lunch and several other federal nutrition programs in 45 states.

This was the largest U.S. meat or poultry recall ever. It came after FSIS found evidence that the establishment had a practice of occasionally allowing the slaughter of cattle that had become nonambulatory after they had been inspected, but before they were slaughtered for human food. FSIS regulations explicitly prohibit nonambulatory ("downer") cattle in human food because they are more likely to have bovine spongiform encephalopathy (BSE, or "mad cow disease").

The recall was so-called Class II, indicating a remote possibility that consumption of the products could cause adverse health effects. (Most large recalls are Class I, with a reasonable probability that the product could cause serious health consequences or death.) USDA stated that most of the recalled beef likely had been consumed, and that schools and other nutrition outlets had been instructed to hold and eventually destroy all remaining products.

FSIS had suspended inspection at the plant on February 4, 2008, three days after the plant voluntarily ceased operations pending an investigation of inhumane practices there. These came to light after animal welfare advocates secretly videotaped what they described as employees inhumanely handling downer cattle before slaughter. USDA inspectors reportedly had failed to detect that these animals became nonambulatory after they had received antemortem inspection—causing some to question the effectiveness of recent increased appropriations from Congress for more aggressive enforcement of the federal Humane Methods of Slaughter Act (7 U.S.C.1901 *et seq*.). The act requires meat establishments to handle and kill livestock using prescribed humane practices.[83]

[83] For additional background, *see* CRS Report RS22819, *Nonambulatory Livestock and the Humane Methods of Slaughter Act*, by Geoffrey S. Becker.

Recall 040-2007, Ground Beef Products

On September 25, 2007, FSIS announced that Topps Meat Company, LLC, an Elizabeth, NJ, establishment, was voluntarily recalling approximately 331,582 pounds of frozen ground beef products because they might be contaminated with *E. coli* O157:H7. On September 29, the recall was expanded to 21.7 million pounds; on October 6, FSIS notified the public that several more product labels (but no additional pounds of products) were being added to the recall. FSIS officials said that this recall case was unusual in that it arose from a patient-reported illness (forwarded on August 31, 2007) thought to be caused by *E. coli*. The same day, according to FSIS, a field investigator collected a sample of leftover product from the patient's freezer for testing, and the laboratory returned a positive finding of *E. coli* O157:H7 from that sample on September 7. It took a series of follow-up tests and meetings before FSIS was ready to tie the illness—and other similar illnesses—to the Topps plant, with the recall announced on September 25. By October 6, the Centers for Disease Control (CDC) had cited 32 illnesses that appeared to be related to the recall.

According to trade press reports, the initial (September 25) recall covered three days of ground beef production (June 22, July 12, and July 23, 2007). The expansion to 21.7 million pounds covered one year of production (back to September 25, 2006), because the plant was carrying over (reworking) each day's production to the next, rather than processing the ground meat in separate batches, which would create a clean break in production, a critical control stressed by industry experts and FSIS officials. In addition, the plant had not followed its own HACCP plan, according to the reports.[84] More specifically, for example, reports indicated that the plant appeared to be grinding meat that did not carry the necessary documentation showing that it had been tested by the supplier for contamination. At the same time, the FSIS inspector who visited the plant daily (but was not there continuously), did not uncover the problem, either. As of this writing, it is not clear whether the company, which has since ceased operations, had a recall plan in the plant's HACCP plan.[85]

Recall 055-2002, Beef Trim and Fresh and Frozen Ground Beef Products

On June 30, 2002, FSIS announced that ConAgra Beef Company of Greeley, CO, was voluntarily recalling approximately 354,200 pounds of fresh and frozen ground beef products that may have been contaminated with *E. coli* O157:H7. On July 19, 2002, FSIS announced that the recall had been expanded to approximately 19 million pounds (later re-estimated to be 18 million pounds) of fresh and frozen ground beef products, along with beef trim. The recall was initiated after at least 46 people in 16 states became ill from contaminated meat, beginning in mid-June 2002. Testing confirmed that many of the illnesses were from the same strain of *E. coli* that had been found in beef tested at the Greeley plant as early as April 12, 2002 and as late as July 12, 2002.[86]

The USDA Office of Inspector General (OIG) report critiqued FSIS's oversight of the recall, characterizing it as "ineffective and inefficient because adequate controls and processes were not in place to timely identify the source (establishment) of the contaminated product or provide reasonable assurance that recovery of the recalled product was maximized or enforcement actions taken, as necessary." OIG noted that only about 3 million pounds of 18 million pounds were

[84] *See*, for example, *Cattle Buyers Weekly*, October 8, 2007; *Feedstuffs*, October 8, 2007.

[85] *See* the recall announcements at http://www.fsis.usda.gov/Fsis_Recalls/Open_Federal_Cases/index.asp.

[86] USDA, Office of Inspector General (OIG) Audit Report, *Food Safety and Inspection Service Oversight of Production Process and Recall at Conagra Plant (Establishment 969)* (Report. No. 24601-2-KC) at ii, September 2003, *available at* http://www.usda.gov/oig/webdocs/24601-2-KC%20conagra%20091603.pdf.

recovered. Among problems observed by OIG: "Neither FSIS nor the processing plants involved ... were prepared for the possibility of a recall. Although FSIS encourages all establishments to prepare recall plans, HACCP plans for two of the grinders using ConAgra beef did not address recall procedures. One of these grinders was unable to readily determine from its records which of its customers received the recalled product."[87]

Recall 090-2002, Turkey and Chicken Products

On October 9, 2002, FSIS announced that Pilgrim's Pride Corporation (Wampler Foods) of Franconia, PA, was recalling 295,000 pounds of fresh and frozen ready-to-eat poultry products due to possible contamination with *Listeria monocytogenes*. The announcement came after FSIS found that a sample taken from the plant on October 2 had tested positive for *Listeria*. On October 12, the recall was expanded to approximately 27.4 million pounds of the products, produced between May 1 and October 2, 2002, which Pilgrim's Pride had distributed throughout the country and overseas. Some went to school feeding agencies. Although product samples from various days of production were all negative for the bacteria, environmental sampling in the plant itself matched the strain of *Listeria* found in the October 9 recalled product, according to FSIS. Operations had been suspended at the plant but resumed on November 14, 2002.

This recall was terminated on July 11, 2003, after the reported recovery of more than 5.5 million pounds (much of the rest was likely consumed or discarded by consumers), and FSIS declared it effective. However, OIG found that FSIS's oversight was ineffective, finding "an overwhelming number of significant discrepancies on the agency's effectiveness check forms that call [FSIS's] conclusion into question."[88]

Recall 015-1997, Frozen Ground Beef Patties

On August 12, 1997, FSIS announced that Hudson Foods of Rogers, AR, was recalling approximately 20,000 pounds of frozen ground beef patties distributed nationwide because the product might be contaminated with *E. coli* O157:H7. This occurred after several Colorado consumers were reported to have become ill from the bacterium after consuming the Hudson product, and subsequent testing found the same strain in a Hudson patty. The recall was expanded to over 1.2 million pounds on August 15 and reached 25 million pounds by the time it was officially ended on February 9, 1999. The plant that produced the patties in Columbus, NE, was closed. Approximately 10.1 million pounds of beef were eventually recovered.

The initial recall was limited to 20,000 pounds even though the plant produced 400,000 pounds per shift—and though meat from one day was being reworked into hamburger being produced on subsequent days, which led to the greatly expanded recall. (This was the same problem that re-emerged 10 years later in the Topps recall.) "The Hudson recall was viewed as an example of the breakdown of the voluntary food recall system. Critics noted that FSIS's lack of recall authority results in dangerous delays when companies such as Hudson question the extent or basis for a recall and wait before acting," Roberts wrote, suggesting it was an argument for mandatory recall authority.[89]

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[87] *Id.* at iv.

[88] USDA, Office of Inspector General (OIG) Audit Report, *Food Safety and Inspection Service Effectiveness Checks for the 2002 Pilgrim's Pride Recall* (Report. No. 24601-02-Hy) at i, June 2004, available at http://www.usda.gov/oig/webdocs/24601-03-HY.pdf.

[89] *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*.

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