

# CRS Report for Congress

## The USDA's Authority to Recall Meat and Poultry Products

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Cynthia Brouger  
Legislative Attorney  
American Law Division

Geoffrey S. Becker  
Specialist in Agricultural Policy  
Resources, Science, and Industry Division



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Committees of Congress

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## Summary

In recent months, 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 U.S. 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 of the adequacy of the USDA oversight of these products.

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 the USDA's authority to regulate meat, poultry, and their products. Specifically, the report discusses the requirements of USDA inspections and import regulations, as well as the USDA's role in product recalls. This report also addresses some of the issues that arise when considering possible changes to recall authority and reviews proposed legislation regarding the role of the USDA in the recall process. The Appendix of this report provides information regarding recent recalls and the significance of the recall data.

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# The USDA's Authority to Recall Meat and Poultry Products

## Background

In recent months, 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 U.S.<sup>1</sup> 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...”<sup>2</sup>

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.”<sup>3</sup>

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<sup>1</sup> 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 RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, by Geoffrey S. Becker. For information on federal authority to regulate other food products, see 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 Geoffrey S. Becker and Donna V. Porter; and CRS Report RS22734, *Food Safety: Oversight and Current Issues*, by Geoffrey S. Becker.

<sup>2</sup> Recall of Meat and Poultry Products, FSIS Directive 8080.1, Revision 4, May 24, 2004, part VI, available at [<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev4.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 volition of a distributed product that involves a minor infraction that would not warrant legal action by FSIS and constitutes no health hazard.” *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.*

<sup>3</sup> 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>].

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.<sup>4</sup> This report provides an overview of the 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 the 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 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**

The 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. The USDA does have statutory authority to perform other regulatory functions involving meat and poultry under the Federal Meat Inspection Act (FMIA)<sup>5</sup> and the Poultry Products Inspection Act (PPIA),<sup>6</sup> respectively.<sup>7</sup>

These acts authorize the USDA to regulate the safety, wholesomeness, and proper labeling of both domestic and imported meat, poultry, and their products sold for human consumption. Under FMIA and PPIA, the USDA is given the responsibility of administering the provisions of the acts. USDA has assigned this authority to FSIS, which carries out USDA's authority under the acts.<sup>8</sup> Though FSIS may not mandate recalls, it can keep some products from entering the food supply through its role in inspections and importation regulation.

**Authority to Regulate Imports.** Meat, poultry, and their products may not be imported if they do not comport with the standards provided by law. FMIA prohibits importation of any carcasses, meat or meat food products that are meant for

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<sup>4</sup> 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](http://www.fsis.usda.gov/fact_sheets/FSIS_Food_Recalls/index.asp)].

<sup>5</sup> 21 U.S.C. § 601 et seq.

<sup>6</sup> 21 U.S.C. § 451 et seq.

<sup>7</sup> The USDA also has authority to regulate egg products under the Egg Products Inspection Act (EPIA). 21 U.S.C. § 1031 et seq. The USDA shares this authority with the FDA. The statutory provisions governing regulation of imports and inspection of egg products that fall under the jurisdiction of the 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.

<sup>8</sup> The Secretary delegates this authority to FSIS under 9 C.F.R. § 300.2.

human consumption if they are adulterated,<sup>9</sup> misbranded,<sup>10</sup> or do not comply with other inspection and facilities standards provided in the act.<sup>11</sup> 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.<sup>12</sup>

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 of sanitary protection equivalent to that achieved under United States standards.”<sup>13</sup> Meat imports are subject to the same standards.<sup>14</sup> These requirements are enforceable through random inspection and testing of products by FSIS.<sup>15</sup>

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.<sup>16</sup>

**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.<sup>17</sup> The PPIA requires inspection of any domesticated birds that might be processed for human consumption.<sup>18</sup>

These statutes provide for ante mortem and post mortem inspections. Livestock and poultry covered under the statutes must be examined and inspected before entry

<sup>9</sup> 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).

<sup>10</sup> 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).

<sup>11</sup> 21 U.S.C. § 620(a).

<sup>12</sup> 21 U.S.C. § 466(a).

<sup>13</sup> 21 U.S.C. § 466(d).

<sup>14</sup> 21 U.S.C. § 620(f).

<sup>15</sup> 21 U.S.C. § 466(d)(4); 21 U.S.C. § 620(f).

<sup>16</sup> *See* 21 U.S.C. § 620(b); 21 U.S.C. § 466(b).

<sup>17</sup> 21 U.S.C. § 601 et seq.

<sup>18</sup> 21 U.S.C. § 451 et seq.

into a plant for slaughtering or processing (ante mortem inspection).<sup>19</sup> The carcasses must also be examined after the animals are slaughtered (post mortem inspection).<sup>20</sup> Inspectors are responsible for inspecting the methods of slaughtering, handling, and processing, as well as the facilities in which these activities take place.<sup>21</sup> They also inspect the establishment's sanitation quality.<sup>22</sup> 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.<sup>23</sup>

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.<sup>24</sup> Products inspected and approved as unadulterated must be clearly labeled before entry into the food supply.<sup>25</sup> Products inspected and not approved must be destroyed.<sup>26</sup>

## 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 does not conduct the recall, FSIS is limited to its authority to detain and seize the products in question. If an establishment conducts the recall, FSIS provides assistance and monitors the recall. Recall policies are spelled out in FSIS Directive 8080.1.<sup>27</sup>

**Authority for Detentions and Seizures.** If a firm does not follow FSIS' recommendation to conduct a recall, "FSIS will detain any product that would have been subject to a recall that it finds in commerce."<sup>28</sup> 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

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<sup>19</sup> See 21 U.S.C. § 603; 21 U.S.C. § 455(a).

<sup>20</sup> See 21 U.S.C. § 604; 21 U.S.C. § 455(b).

<sup>21</sup> 21 U.S.C. § 603.

<sup>22</sup> 21 U.S.C. § 608; 21 U.S.C. § 456.

<sup>23</sup> 21 U.S.C. § 606; 9 C.F.R. § 300.6.

<sup>24</sup> 21 U.S.C. § 603(b); 21 U.S.C. § 467.

<sup>25</sup> 21 U.S.C. § 606; 21 U.S.C. § 457.

<sup>26</sup> 21 U.S.C. § 604; 21 U.S.C. § 455.

<sup>27</sup> Recall of Meat and Poultry Products, FSIS Directive 8080.1, Revision 4, May 24, 2004, available at [<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev4.pdf>] (hereinafter "FSIS Directive 8080.1").

<sup>28</sup> FSIS Directive 8080.1, part VIII.B.

already distributed in commerce.<sup>29</sup> 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].”<sup>30</sup>

Under these regulations, the authorized detention period cannot exceed 20 days.<sup>31</sup> 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 firm has refused to recall it.”<sup>32</sup>

**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.<sup>33</sup> FSIS also notes that it “expects that, once it is determined that a recall will be undertaken, the recalling firm will immediately notify FSIS.”<sup>34</sup>

FSIS notes that “[t]here is no regulatory requirement that an establishment [include] this recall plan in its HACCP plan or as a prerequisite program; however, FSIS believes that prudent establishments will.”<sup>35</sup> HACCP stands for Hazard Analysis and Critical Control Points, 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; or (5) epidemiological data submitted by various federal, state, and local agencies.<sup>36</sup> If a recall may appear appropriate, FSIS assembles a Recall Committee and responds to any threats or hazards posed by the recall.<sup>37</sup>

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

<sup>29</sup> 9 C.F.R. § 329.1.

<sup>30</sup> *Id.* See also 9 C.F.R. 381.210.

<sup>31</sup> See 9 C.F.R. 329.1; 9 C.F.R. § 381.210.

<sup>32</sup> FSIS Directive 8080.1, part VIII.B.

<sup>33</sup> FSIS Directive 8080.1, Attachment 1.

<sup>34</sup> FSIS Directive 8080.1, Attachment 1, part 3.

<sup>35</sup> FSIS Directive 8080.1, Attachment 1, part 1.

<sup>36</sup> FSIS Directive 8080.1, part V.B.

<sup>37</sup> FSIS Directive 8080.1, part VII.



type of illness or injury that may result.<sup>38</sup> If FSIS issues a recall recommendation, the recommendation will contain the following information: (1) whether the firm is voluntarily recalling the product; (2) the reason for the recall and any reason to believe the product is adulterated or misbranded; (3) the recall classification; (4) the depth of the recall; (5) the scope of the recall, which “defines the amount and kind of product in question”; (6) the ability of distributors and consumers of the product to identify it; and (7) the estimated amount of the product in distribution.<sup>39</sup>

**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 involve “situation[s] where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.”<sup>40</sup> 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 involve “situation[s] where there is a remote probability of adverse health consequences from the use of the product.”<sup>41</sup> The undisclosed presence of a small amount of a potentially allergenic substance or the presence of a non-sharp edged foreign material like plastic are examples of Class II recalls. Class III recalls involve “situation[s] where the use of the product will not cause adverse health consequences.”<sup>42</sup> The presence of excess water in a product might lead to a Class III recall.

**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.”<sup>43</sup> If the recall extends to the retail level, the product is recalled from all retail sales.<sup>44</sup> If it extends to the user level, the recall applies to user entities, including “hotels, restaurants, and other food service institutional consignees.”<sup>45</sup> If the recall applies to the wholesale level, it involves “the distribution level between the manufacturer and the retailer.”<sup>46</sup>

**Communication Regarding Recalls.** FSIS uses press releases and recall notification reports to inform the public of recalled products.<sup>47</sup> FSIS issues press

<sup>38</sup> FSIS Directive 8080.1, part VII.B.

<sup>39</sup> FSIS Directive 8080.1, part VII.C.

<sup>40</sup> FSIS Directive 8080.1, part VI.D.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> FSIS Directive 8080.1, part VI.E.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> A list of all FSIS recalls since 1994, and related information, can be accessed at (continued...)

releases for Class I or Class II recalls but generally not for Class III recalls.<sup>48</sup> 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.<sup>49</sup>

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.<sup>50</sup> It also instructs the public about the appropriate responses to be taken after the product is identified and provides contact information for questions.<sup>51</sup> The press release also indicates the product's destination to better alert potential consumers.<sup>52</sup>

If FSIS verifies "that all products in question were removed from commerce and brought under the firm's control before FSIS requested a recall," FSIS issues recall notification reports with general information about the recall, including information similar to recall recommendations.<sup>53</sup> Recall notification reports are issued for all classes of recalls and are also posted on the FSIS website.<sup>54</sup>

**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.<sup>55</sup> They are based on the risk involved, the recall classification, and the number of consignees.<sup>56</sup>

FSIS personnel contact or visit consignees to determine the effectiveness of a recall.<sup>57</sup> 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

<sup>47</sup> (...continued)

[[http://www.fsis.usda.gov/Fsis\\_Recalls/](http://www.fsis.usda.gov/Fsis_Recalls/)].

<sup>48</sup> FSIS Directive 8080.1, part IX.A.

<sup>49</sup> To Review Recent Recalls in the Meat Industry: Hearing before the H. Comm. On Agriculture, 110<sup>th</sup> 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>].

<sup>50</sup> FSIS Directive 8080.1, part IX.A.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> FSIS Directive 8080.1, part IX.B.

<sup>55</sup> FSIS Directive 8080.1, part X.

<sup>56</sup> *Id.*

<sup>57</sup> FSIS Directive 8080.1, part X.E. For specific information on effectiveness checks (including tables that provide the critical limits), see Attachment 3 of the Directive.

cannot be deemed effective.<sup>58</sup> If the number is equal to or less than the critical limit, the recall is deemed effective.<sup>59</sup>

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.<sup>60</sup> 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.<sup>61</sup>

FSIS issues a recall termination report after it completes effectiveness checks and determines that all reasonable efforts have been made to recall the product.<sup>62</sup> These reports may also be issued if the firm disposed of the product that was in commerce during the recall or if the product is held under FSIS control.<sup>63</sup> Termination reports indicate the amount of recovery and method of disposition.<sup>64</sup>

## Selected Issues and Bills<sup>65</sup>

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 have been enacted. A number with recall-related provisions are pending again in the 110<sup>th</sup> Congress.<sup>66</sup> Following is a brief discussion of selected issues and bills.

**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 needs (as does FDA) 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

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<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> FSIS Directive 8080.1, part X.F.

<sup>61</sup> FSIS Directive 8080.1, part X.G.

<sup>62</sup> FSIS Directive 8080.1, part XI.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> 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/>].

<sup>66</sup> Not discussed here are a number of other bills that also have been introduced with mandatory recall language, but they appear to affect FDA exclusively. These include the Food and Drug Import Safety Act of 2007 (H.R. 3610), the Consumer Food Safety Act of 2007 (H.R. 3624), and the Food Import Safety Act of 2007 (H.R. 3937).

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.<sup>67</sup>

Others, including meat and poultry industry trade associations and some Administration officials, 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.

The House Agriculture Subcommittee on Livestock, Dairy, and Poultry held a November 7, 2007 hearing to review recent FSIS recalls. Responding to questions from several subcommittee members, USDA Under Secretary for Food Safety Dr. Richard Raymond reiterated the Department's view that it does not need additional enforcement tools, including mandatory recall authority. A day earlier, the Bush Administration had announced a new food safety strategy proposing such authority for FDA, however.<sup>68</sup>

Several pending bills would provide mandatory recall authority for products currently regulated by FSIS. Under the Safe and Fair Enforcement and Recall for Meat, Poultry, and Food Act of 2007 (H.R. 3484), all appropriate persons first would be given the opportunity to cease distribution of a potentially unsafe product, recall it, and to notify all others in the marketing chain including consumers, and state and

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<sup>67</sup> 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>].

<sup>68</sup> U.S. Department of Health and Human Services, FDA, *Food Protection Plan: an integrated strategy for protecting the nation's food supply*, November 2007, accessed November 21, 2007 at: [<http://www.fda.gov/oc/initiatives/advance/food/plan.html>].

local health officials. The bill further directs FSIS to mandate such actions if voluntary actions are not undertaken in a timely fashion. Comparable provisions in the bill would cover poultry and poultry products.

Several other bills would authorize the new agency to mandate a recall, if voluntary recall actions are not sufficient. These include the Safe Food Act of 2007 (H.R. 1148/S. 654), which is a much broader proposal to consolidate all federal food safety responsibilities under a new Food Safety Administration (FSA), and the Food and Product Responsibility Act of 2007 (S. 2081). The latter proposal also would require anyone who distributes food products — including meat and poultry products — to have certification that he/she is financially capable of paying for the entire cost of a recall of that product if necessary, including any associated administrative costs.

**Responsibility Questions.** Among other components that might be considered for a “sensible” mandatory food recall system, according to the Roberts article,<sup>69</sup> 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 caution” that ultimately caused a business to fail, on the one hand? If, on the other hand, FSIS waited until it had additional (presumably more legally-defensible) 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,<sup>70</sup> believe that such a mandate for prompt notification is a prerequisite for an effective recall policy.

Before passing its version of the omnibus farm bill (H.R. 2419) in December 2007, the Senate adopted a managers’ amendment that establishes reportable food registries for FSIS-regulated meat and poultry products. A House-Senate conference is pending; it may determine the outcome of these registries, which are not in the House version.

The Senate-passed H.R. 2419 would require FSIS to establish Reportable Meat and Poultry Food Registries within one year of enactment, to which inspected establishments, or those who inspect them, would have to provide information on any “reportable food event” generally within 24 hours. The bill would define a

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<sup>69</sup> See Roberts, *supra* note 65.

<sup>70</sup> *Id.*

“reportable food” as meat (poultry) or meat (poultry) food product “for which there is a reasonable probability that the use of, or exposure to, the meat (poultry) or meat (poultry) food product will cause serious adverse health consequences or death to humans or animals.”<sup>71</sup>

Earlier legislation in the 110<sup>th</sup> Congress now requires FDA, but not FSIS, to establish, by September 2008, a Reportable Food Registry for the products it regulates. More specifically, Title X of P.L. 110-85, which was signed into law September 27, 2007, will require responsible parties and importers to report to this FDA registry detailed information (outlined in the bill) about cases of actual or suspected food adulteration, generally within 24 hours.<sup>72</sup> The measure contains a number of explicit provisions regarding the types of records that must be maintained and the specific data that must be provided. Another recall-related provision, in Title VI of the bill, requires FDA to work with companies, professional associations, and other organizations to collect and communicate information about recalls of human or pet food and to post information regarding the products on an accessible FDA Internet website.

Other pending bills also include mandatory notification language. For example, H.R. 1148/S. 654 would require any person with reason to believe that a food entering commerce is in violation of the law to immediately notify the newly-established FSA. H.R. 3484 and S. 2081 also would require persons (other than household consumers) to notify the Department as soon as practicable if they had reason to believe that a carcass, carcass part, meat, or meat food product they are handling is adulterated or misbranded. Another somewhat different measure, the Ending Agricultural Threats: Safeguarding America’s Food for Everyone (EAT SAFE) Act of 2007 (S. 2418), would provide for mandatory public notification of food products that have been fraudulently brought into the United States.

**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.<sup>73</sup>

Several pending bills would require FSIS to establish programs to achieve these goals. The Tracing and Recalling Agricultural Contamination Everywhere (TRACE) Act of 2007 (H.R. 3485) would require FSIS to establish a system enabling it to

<sup>71</sup> A related provision in the Senate’s version would require meat and poultry establishments to include a written recall plan as part of their HACCP plans. Currently recall plans are encouraged by FSIS Directive 8080.1 Rev. 4.

<sup>72</sup> Responsible parties are defined to mean facilities that have to register with FDA under Section 415 of the FFDCA, i.e., “... any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States ...” Exempted are farms, restaurants, and other retail establishments.

<sup>73</sup> 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 also CRS Report RS22653, *Animal Identification: Overview and Issues*, by Geoffrey S. Becker.

retrieve the history, use and location of a meat or poultry food, from the animal of origin and its locations prior to slaughter, through processing and distribution to the ultimate consumer. The system would include recordkeeping and auditing elements. The Meat and Poultry Products Traceability and Safety Act of 2007 (S. 1292) also would require FSIS to establish a meat and poultry traceability system covering all stages of production, processing, and marketing, from live animals before slaughter to distribution of finished products to the ultimate consumer. S. 1292 would require persons and companies to maintain records and allow access to them when needed to trace products. H.R. 1148/S. 654 also contains traceability requirements.

**Recovery Rates and Recall Effectiveness.** Recalls rarely recover all products.<sup>74</sup> Since 1994, 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.”<sup>75</sup> Notwithstanding these assertions, the 2004 GAO report claims that both FSIS and FDA “told us recovery was an important indicator of a successful recall.”<sup>76</sup>

FSIS testified that it has improved the effectiveness of the recall process since the release of the critical OIG report. In 2004, FSIS included revisions in Directive 8080.1 designed to enhance recall verification instructions to agency officials. 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.<sup>77</sup>

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<sup>74</sup> According to one analysis of FSIS recall data, the average recovery rate per recall is 44% over the past two years and “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, Dec. 3, 2007, at 1B.

<sup>75</sup> 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.

<sup>76</sup> *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, p. 15.

<sup>77</sup> USDA responses to questions by Chairman DeLauro, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2008, Hearings (continued...)

FSIS also published a proposed rule on March 7, 2006 providing for the agency to post on its website a list of all retail outlets to which a recalled product has been distributed. The agency believes that this would enable consumers to identify, and return or destroy, more products than currently are found.<sup>78</sup>

**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?

USDA Under Secretary Raymond was asked at a House Appropriations subcommittee hearing about the significance of recall numbers. He responded that the number had declined in recent years, and that “... it tells me that our food safety system has improved dramatically.”<sup>79</sup>

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.<sup>80</sup> 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.<sup>81,82</sup>

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<sup>77</sup> (...continued)

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.

<sup>78</sup> 71 *Federal Register* 11326 — 11328. The final rule was pending in early January 2008.

<sup>79</sup> Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2008, Hearings before a House Appropriations Subcommittee (Part 4), p. 289, 2006. Others have pointed out that even the record 60.9 million pounds recalled in 2002 represented only 0.06% of the 92.3 billion pounds of meat and poultry inspected at slaughter that year.

<sup>80</sup> Carol Tucker Foreman, Consumer Federation of America, personal communication, October 15, 2007.

<sup>81</sup> National Association of State Departments of Agriculture, personal communication, October 15, 2007.

<sup>82</sup> 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 (continued...)



## Appendix. Information Regarding Meat and Poultry Product Recalls

### Recent Recalls

FSIS reported 773 meat and poultry recalls, representing nearly 300 million pounds of products, from January 1, 1994 through November 30, 2007, the period of time examined by CRS because the data were readily available. Of the total, 73% were Class I recalls, 19% Class II recalls and 8% Class III recalls (CRS calculation based on FSIS recall data).

*Listeria monocytogenes*, usually on 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 more than 80% of the total pounds recalled during the period. More specifically, *Listeria* concerns were associated with 243 or 31.4% of all recalls (and a total of more than 146 million pounds or 48.9%) from 1994 through November 2007. *E. coli* O157:H7 concerns were associated with 150 or 19.4% of all recalls (and a total of more than 97 million pounds or 32.4%).

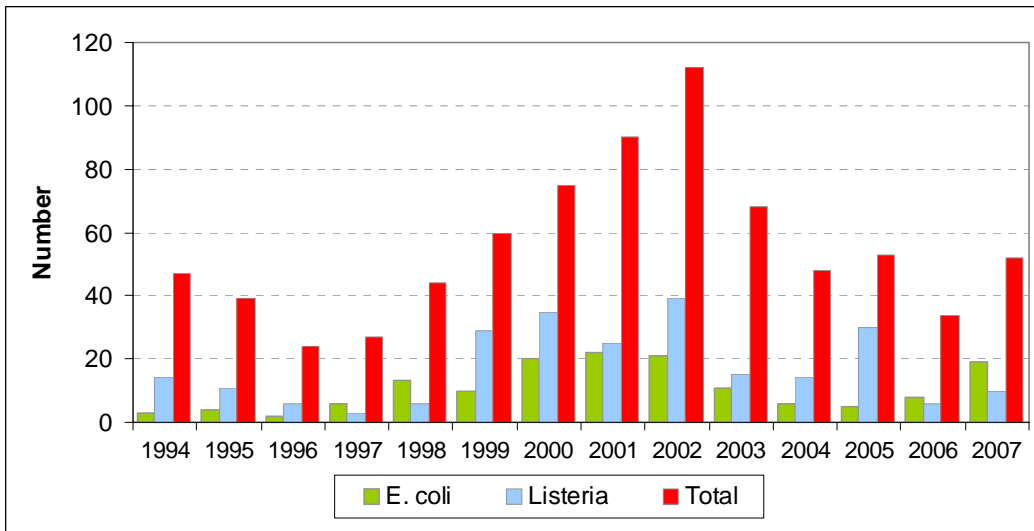
Of the total number of recalls, 164 or 21.2% were a variety of products found to be misbranded, often because they contained an undeclared substance or ingredient. These substances were frequently allergens such as undeclared nuts in a processed product. Another 67 or 8.7% of all recalls during the period, 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 149 recalls or 19.3% 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).

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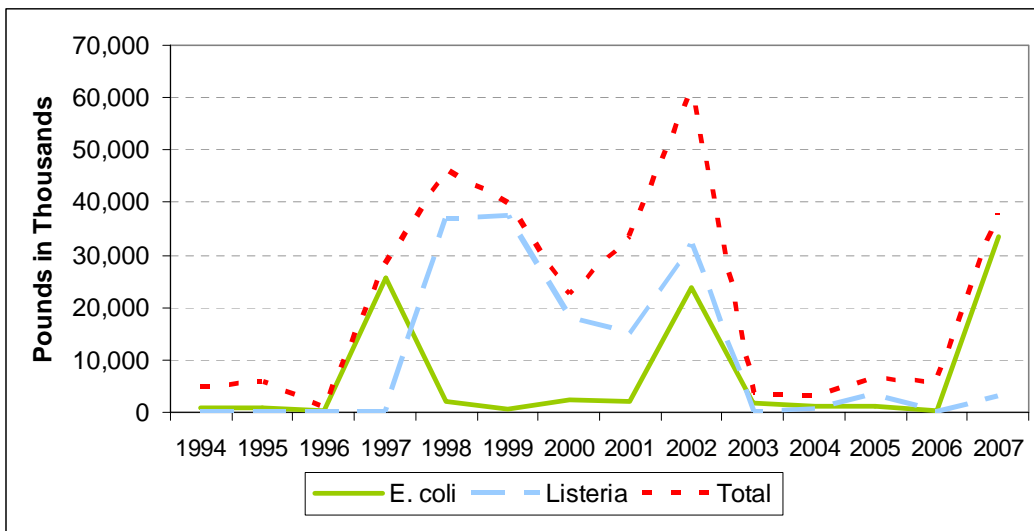
<sup>82</sup> (...continued)

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.

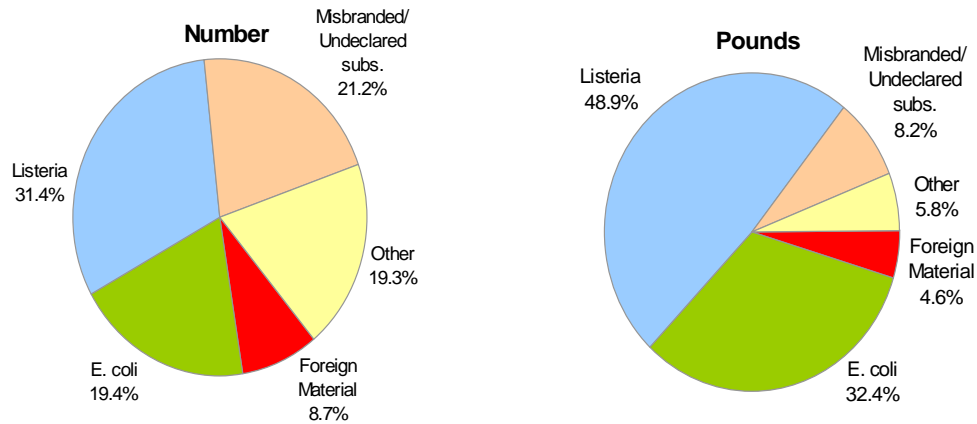
**Figure 1. FSIS Meat & Poultry Recalls  
January 1994 - November 2007**



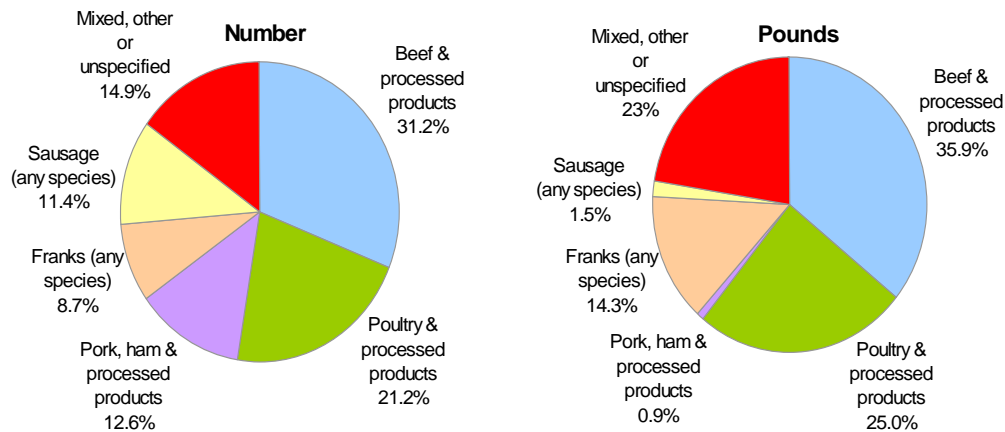
**Figure 2. FSIS Meat & Poultry Recalls  
January 1994 - November 2007**



**Figure 3. Recalls by Reason  
Percent, January 1994 - November 2007**



**Figure 4. Recalls by Product Type  
Percent, January 1994 - November 2007**



As Figure 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 1**). Four of these recalls are discussed following the table.

**Table 1. Largest Recalls Since 1994**

<b>Date</b>	<b>Company</b>	<b>Product</b>	<b>Reason</b>	<b>Pounds (millions)</b>
Aug. 1997	Hudson Foods	ground beef	<i>E. coli</i> O157:H7	25
Dec. 1998	Bil Mar Foods	Franks; packaged meats	<i>Listeria</i>	35
Jan. 1999	Thorn Apple Valley	packaged meats	<i>Listeria</i>	35
Dec 2000	Cargill	ready to eat poultry	<i>Listeria</i>	17
Apr. 2001	Bar-S Foods	meat & poultry products	<i>Listeria</i>	14
June 2002	ConAgra	ground beef	<i>E. coli</i> O157:H7	18
Oct. 2002	Pilgrim's Pride	poultry products	<i>Listeria</i>	27
Sept. 2007	Topps	ground beef	<i>E. coli</i> O157:H7	22

**Source:** USDA, FSIS, Recall Archives. Pounds rounded to nearest million.

**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.<sup>83</sup> 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.<sup>84</sup>

**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.<sup>85</sup>

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 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."<sup>86</sup>

**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

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<sup>83</sup> See for example, *Cattle Buyers Weekly*, October 8, 2007; *Feedstuffs*, October 8, 2007.

<sup>84</sup> More extensive details on the Topps recall can be found in the recent press briefing transcript, included here as Attachment A. Also see the recall announcements at: [[http://www.fsis.usda.gov/Fsis\\_Recalls/Open\\_Federal\\_Cases/index.asp](http://www.fsis.usda.gov/Fsis_Recalls/Open_Federal_Cases/index.asp)].

<sup>85</sup> 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>].

<sup>86</sup> *Id.* at iv.

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."<sup>87</sup>

**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.<sup>88</sup>

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<sup>87</sup> 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>].

<sup>88</sup> *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*.