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"Improving the Recall Process"
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My name is Caroline Smith DeWaal, and I am director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a non-profit advocacy and education organization focusing on food safety, nutrition, and alcohol issues. We are supported principally by 800,000 subscribers to its *Nutrition Action Healthletter*.

The summer of 2002 may well become known as the US Department of Agriculture's (USDA) "Summer of Recalls." The past six months have clearly demonstrated the weaknesses in the current "voluntary" recall policy. The recalls have affected numerous meat and poultry producers and repeatedly sent consumers rushing to their refrigerators in search of plant numbers and production dates. There are a number of lessons that illustrate the need for a mandatory recall policy:

First, too many recalls are initiated only after people become ill. Both outbreaks and recalls signal a failure of the HACCP system to prevent well-known food hazards from entering the food supply in the first place. FSIS must initiate earlier testing programs to ensure that the meat and poultry companies are focused on finding and fixing contaminated products in the plant, rather then releasing and recalling them after they are in consumers' homes. Ongoing testing for hazards like *E. coli* O157:H7 and *Listeria* at the plant level would mean that USDA wouldn't have to wait days for

test results to come in before taking action, as it did with the ConAgra recall. The agency would have a better basis to prevent recalls, and could act more quickly when a recall was needed.

Second, too many recalls begin with an announcement that grossly underestimates the amount of product that poses a risk to the public. Each new recall announcement appears to be just the beginning of an arduous process of further investigation followed by additional announcements that dramatically increase the recall size (see Appendix I). Under a voluntary recall policy, companies all too frequently minimize the size of the initial recall. Once USDA sends investigators to the plant, the size of the recall sometimes increases by several orders of magnitude. But, as we have seen numerous times, days can elapse before the expansion is announced, during which time the hazardous products remain on the market. Civil penalties are clearly needed for companies that put their business interests before their duty to protect public health. USDA should have the authority to fine companies that had knowledge or information that should have led to a larger initial recall but negligently understated the necessary product amount.

Third, the voluntary recall system leaves consumers and even some states without critical information to know if the meat being sold locally might be linked to the recall. In order to protect business records, USDA only shares a plant's customer lists with the states that promise not to release the information to the public. This approach seems counter-intuitive, as consumers may urgently need to know if the meat in their refrigerator or freezer came from the implicated product. Some states have open record laws that prevent them from giving USDA the requisite assurances. Last summer, for example, Colorado public health officials were barred from obtaining ConAgra's distribution lists from USDA, even though the Denver plant distributed widely in the state.[1]

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[1] David Migoya, "Colorado unable to obtain list of where recalled meat sold," *Denver Post*, (Aug. 4, 2002).

This summer's recalls and outbreaks prove that changes are urgently needed in FSIS's recall policy

FSIS claims that it cannot release distribution information because it is protected under the Freedom of Information Act (FOIA) exceptions. However, this interpretation applies the FOIA "business records" exemption[2] too broadly. In fact, distribution lists have been released under FOIA[3] when it was determined that their disclosure would not cause "substantial competitive harm."[4] FSIS has not presented any evidence to demonstrate that telling consumers which establishments have received recalled product would create "substantial competitive harm" to the recalling company.[5] Since recalls are limited in their depth and scope, it is questionable whether the release of the names of specific recipients of specific product at a specific time would be of any use to competitors.

Moreover, the courts have emphasized that the "substantial competitive harm" must come from the "affirmative use of proprietary information by competitors," rather than "any injury to competitive position, as might flow from customer or employee disgruntlement."[6] Information regarding product hazards does not convey the type of competitive advantage that the exemption was

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[2] Specifically, exemption 4 of the FOIA protects "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. § 552(b)(4).

[3] See, e.g., *Greenberg v. FDA*, 803 F.2d 1213, (D.C. Cir. 1986); *Ivanhoe Citrus Assn. v. Handley*, 612 F. Supp. 1560, 1566 (D.D.C. 1985); *Braintree Elec. Light Dept. v. Dept. Of Energy*, 494 F. Supp. 287, 290 (D.D.C. 1980).

[4] *National Parks Ass'n. v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974). The leading standard for determining whether information that was compelled by the agency is "confidential" was set out in the *National Parks* decision: "To summarize, commercial or financial matter is 'confidential' for purposes of the exemption if disclosure of the information is likely to have either of the following effects: (1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained. *Id.*

[5] The agency withholding the information must present objective evidence from which a court can conclude that the submitting company is likely to suffer substantial competitive injury. Robert G. Vaughn, "Consumer Access to Product Safety Information and the Future of the Freedom of Information Act," *Admin. L. J.* 5:673 (Fall, 1991) [hereinafter *Vaughn*]. The burden under the Act is clearly on the agency that seeks to vindicate the company's interests. *Id.*

[6] *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1291, n.30 (D.C. Cir. 1983).

designed to protect.[7] In this instance, it seems likely that the companies are more interested in protecting themselves from disgruntled customers than from their competitors.

Some courts use a relaxed "confidentiality" standard for information voluntarily submitted to the government, protecting information that the submitter would not customarily release.[8] Even those courts would allow disclosure of customer lists because such information is made widely known. As some in industry have noted, distribution lists are not huge secrets because most people have a good idea of who is doing business with whom.[9] And, in theory, one could compile distribution lists from the plant numbers that are supposed to be on the packaging of meat and poultry products. But that would be infeasible, particularly at the time of a recall when public health is in jeopardy. Companies should not be allowed to use FOIA exemptions to shield themselves from the consequences of introducing potentially adulterated foods into the food supply by denying states and consumers critical information they need to act quickly to prevent illness.

Government communication is essential to an effective recall

At the consumer level, an effective recall is one that motivates people to do something they don't normally do: To question the safety of a product already in their refrigerator or cupboard. And recall messages must by necessity compete with many other consumer food-safety messages. At a time when consumers have more information coming at them from more places than ever before, not only reaching consumers, but getting their attention and arming them with adequate information to

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[7] *Vaughn*, *supra* note 5.

[8] See, e.g., *Critical Mass Energy Project v. Nuclear Regulatory Commission*, 975 F.2d 871 (D.C. Cir. 1992), *cert denied*, 507 U.S. 984 (1993) (holding that information remains "confidential" if it is of a kind that would not customarily be released to the public). *Cf., Comdico, Inc. v. Gen'l. Services Admin.*, 864 F. Supp. 510 (E.D. Va. 1994).

[9] Allison Beers, "USDA should share sensitive recall information, says NACMPI," *Food Chemical News*, (Nov. 6, 2000), pp. 3-4.

respond is very challenging.

Let me give you a case study to illustrate this challenge:

In 1994, Schwan's ice cream was identified as the cause of a major outbreak of *Salmonella* poisoning. According to the American Journal of Public Health, who reported this case study, this outbreak caused 224,000 illnesses in 41 states, making it one of the largest foodborne-illness outbreaks ever reported.

It was also relatively unique, because Schwan's had delivered the ice cream directly to consumers' homes, so customer lists were readily available. Schwan's sent letters to its customers and instructed its delivery personnel to collect the contaminated product. This gave researchers an opportunity to evaluate how consumers respond to recall information.

Researchers surveyed 179 households in Georgia that were Schwan's customers, representing over 600 consumers. 91% of the households heard the warning about the contaminated ice cream, but among these, 26% didn't initially believe that the ice cream was unsafe. In 31% of the households that both had the contaminated ice cream and had heard the warnings, someone subsequently ate the ice cream.[10]

With that in mind, it is critical that government agencies, not food companies, be the principle source of information about food safety, including information on food poisoning outbreaks and recalled products. A government announcement is treated more seriously by consumers and will garner more media attention than an announcement by a company. The 1998 Sara Lee recall was instructive:

In that outbreak, USDA relied on the company itself to make the recall announcement, which

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[10] Barbara E. Mahon et al., "Consequences in Georgia of a nationwide outbreak of Salmonella infections: What you don't know might hurt you, 89 *American Journal of Public Health*, (Jan. 1999), pp. 31-35.

it did on December 22, 1998. Unfortunately, there was a lot of breaking news that holiday season, and the recall got very little press attention. During the month that followed, people continued to eat the contaminated luncheon meats and hot dogs and became ill. The death toll continued to rise during the month following the company's recall announcement, indicating that the company's announcement was not halting the outbreak. Finally, on January 28, USDA issued a recall notice on the Bil Mar product, and the outbreak finally ended.[11]

A year after the Bil Mar recall, USDA announced a new recall policy, indicating that the agency would send out a public announcement whenever companies initiated a Class I recall.[12] This has resulted in many more recall announcements by FSIS, with the peak this year with over 110 separate recalls (see Appendix II). Unfortunately, this summer's problems show the need for further strengthening of the policy.

Delaying recalls can be deadly

Each day that a recall is delayed, more consumers are at risk of food poisoning. The General Accounting Office (GAO) has criticized FSIS for failing to systematically track companies' activities to ensure that recalls, particularly of foods that may cause serious adverse health consequences, are initiated and carried out without delay.[13] FSIS's guidance allows companies to give notice of recalls involving potentially life-threatening contaminants such as *Listeria monocytogenes* through U.S. mail.[14] To remedy this problem, the GAO recommended that FSIS provide specific guidance to

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[11] Peter Perl, "Outbreak," *Washington Post Magazine*, (Jan. 16, 2000).

[12] FSIS Directive 8080.1 Rev. 3, Recall of Meat and Poultry Products, (Jan. 19, 2000) [hereinafter *FSIS Directive*].

[13] Government Accounting Office, *Food Safety: Actions Needed by USDA and FDA to Ensure That Companies Promptly Carry Out Recalls*, (Aug. 2000), p. 19 [hereinafter cited as *GAO Report*].

[14] *GAO Report*, p. 16. See *FSIS Directive*.

companies on time frames for quickly initiating and carrying out food recalls that involve potentially serious adverse health risks, including procedures to expeditiously notify their distribution chains and alert the public.[15]

Moreover, GAO found that FSIS only performs selective checks to verify recall effectiveness.[16] Yet the Recall Policy Working Group acknowledged that FSIS's responsibility is "one of verifying that the establishment is fulfilling its obligation and, if the establishment is not doing so, of acting to ensure that the establishment does."[17] To resolve weaknesses in the FSIS recall program, the GAO recommended that the agency modify existing recall databases as necessary to include information on the timeliness of companies' recall activities to determine whether there was any delay in initiating and carrying out recalls.[18] We support this GAO suggestion as well.

Additionally, both the FSIS Recall Policy Working Group and the Association of Food and Drug Officials have recommended that FSIS require companies to maintain records that will enable them to trace every product from its entry into their facilities to its further distribution.[19] Such records are necessary to help determine the scope and depth of the recall. For example, the Recall Policy Working Group reported that product identification was hampered in the Beef America recall

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[15] *GAO Report*, pp. 19-20.

[16] *GAO Report*, p. 14.

[17] *Recall Policy Working Group* ("The Agency's activities should include verifying that the firm has identified the proper product, verifying that the firm is making the appropriate contacts through its distribution channels, and verifying the adequacy of the establishment's notification to consignees and the public.")

[18] *GAO Report*, p. 20 ("The information should, at a minimum, include the dates a company (1) finds out about the problem warranting a recall, (2) initiates the recall, (3) notifies the distribution chain, (4) notifies the public, and (5) completes the recall. In addition, the database should track the methods the company used to notify its distributors and the public, and the date(s) on which the agencies requested the company to initiate a recall.")

[19] *Recall Policy Working Group*; Association of Food and Drug Officials (AFDO), Comments on *Report of the Recall Policy Working Group*, (Oct. 5, 1998) (AFDO stated: "The manufacturer, the wholesaler, and the retailer need to have record keeping systems and coding which can readily identify where product has been shipped, and how much has been sold, in order for tracebacks to be effective.").

of 1997 because the consignees did not keep the records necessary to trace the product forward through the distribution system.[20]

The Working Group also recommended that the rulemaking require establishments to have a written plan that defines how they will conduct a recall.[21] The recall plan envisioned by the Working Group would be similar to the sanitation standard operating procedures and the Hazard Analysis and Critical Control Point (HACCP) plan and would "define[] how the establishment will respond should a situation that requires a recall arise."[22] To date, the agency has not initiated these rulemakings. We urge FSIS to promptly do so.

USDA should support statutory changes

These improvements in the existing FSIS voluntary recall system are only half-measures, however. And the meat industry promotes the myth that no changes are needed because no company has ever failed to comply with an FSIS recall request. In fact, a few years ago, a poultry processor refused to comply with a recall request after USDA discovered *Listeria monocytogenes* contamination in its products.[23] In the end, FSIS was forced to issue a press release warning the public that nearly 8,000 pounds of potentially adulterated chicken were in the food supply but could not be recalled.[24]

The reality is, under a voluntary recall authority, we may never know how many companies

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[20] *Recall Policy Working Group.*

[21] *Recall Policy Working Group.*

[22] *Recall Policy Working Group.*

[23] While the company subsequently asked its distributors not to ship the product, it never asked consumers or its distributors to return the product. T. Cosgrove, *House of Raeford Denies FSIS 'Refusal to Comply' Allegation*, The MeatingPlace Daily News Story (Oct. 12, 2000), available at *http://www.meatingplace.com/meatingplace/DailyNews/News.asp?ID=6216.*

[24] U.S. Department of Agriculture, Food Safety and Inspection Service, "USDA Warns Public of Barbecued Chicken with Possible *Listeria* Contamination," Press Release, (Oct. 6, 2000).

haven't complied with an FSIS request, because a recall is the result of a negotiation between a company and USDA. The government may have agreed to a less public market withdrawal rather than a recall on numerous occasions, and consumers would never know.

Clearly, FSIS needs the power to order contaminated food off the market and out of consumers' refrigerators. It is critical that USDA go to Congress and request mandatory recall authority. This is not a new or unique position for the Department. In fact, USDA is on record supporting mandatory recall authority and civil penalties, following the large Hudson Beef recall in 1997.

USDA should not continue to operate with century-old enforcement tools, especially as Congress has given numerous agencies regulating consumer products more modern tools. Here are several examples:

1. The Consumer Product Safety Act of 1972 requires manufacturers of consumer products such as toys to notify the government if their products pose a substantial product hazard. Companies can be fined for failure to comply with a Consumer Product Safety Commission recall order and the product can be banned from the market.
2. Manufacturers of infant formulas are compelled by a 1986 law to notify the government if they know, or should know, that their formula may be adulterated or misbranded. If the FDA determines that the formula presents a risk to human health, the FDA can dictate to the manufacturer the scope and extent of the recall and can audit the effectiveness of the recall through reporting and recordkeeping requirements.
3. The FDA also can order manufacturers to recall medical devices if there is a reasonable probability of serious adverse health consequences or death. The recall order takes effect immediately, with the opportunity for a hearing only after the order is issued. As with the

infant formula recalls, the FDA can impose stringent reporting requirements on the conduct of device recalls.

Mandatory recall and civil penalties are necessary enforcement tools if USDA is going to effectively operate as a public-health agency addressing food safety. After the 2002 recalls and associated outbreaks, we ask that USDA articulate its continued support for mandatory recall authority, and make clear that its principle mission is to protect public health, and not the business interests of the meat and poultry industry.

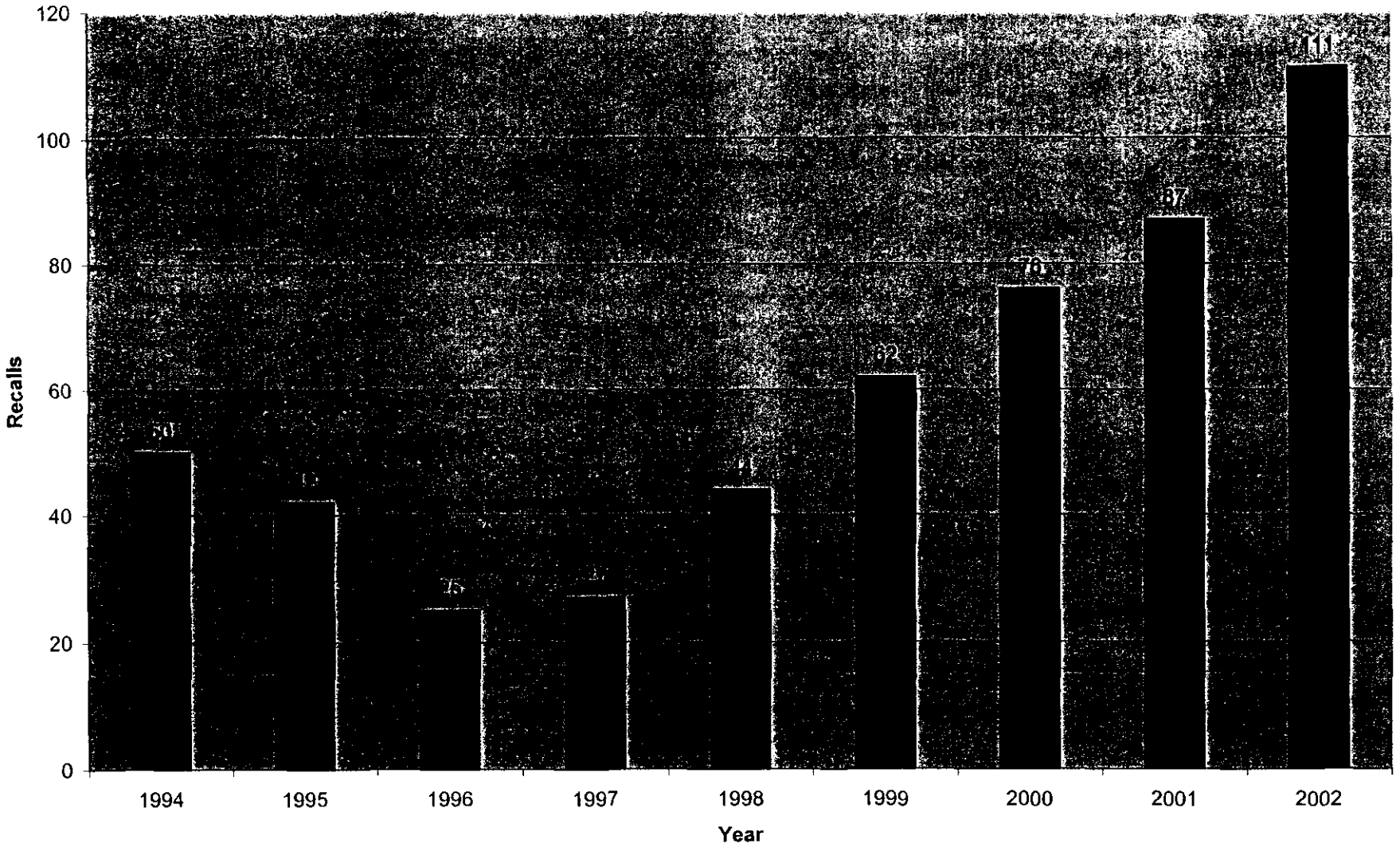
Appendix I

Expanded FSIS Recalls – Examples

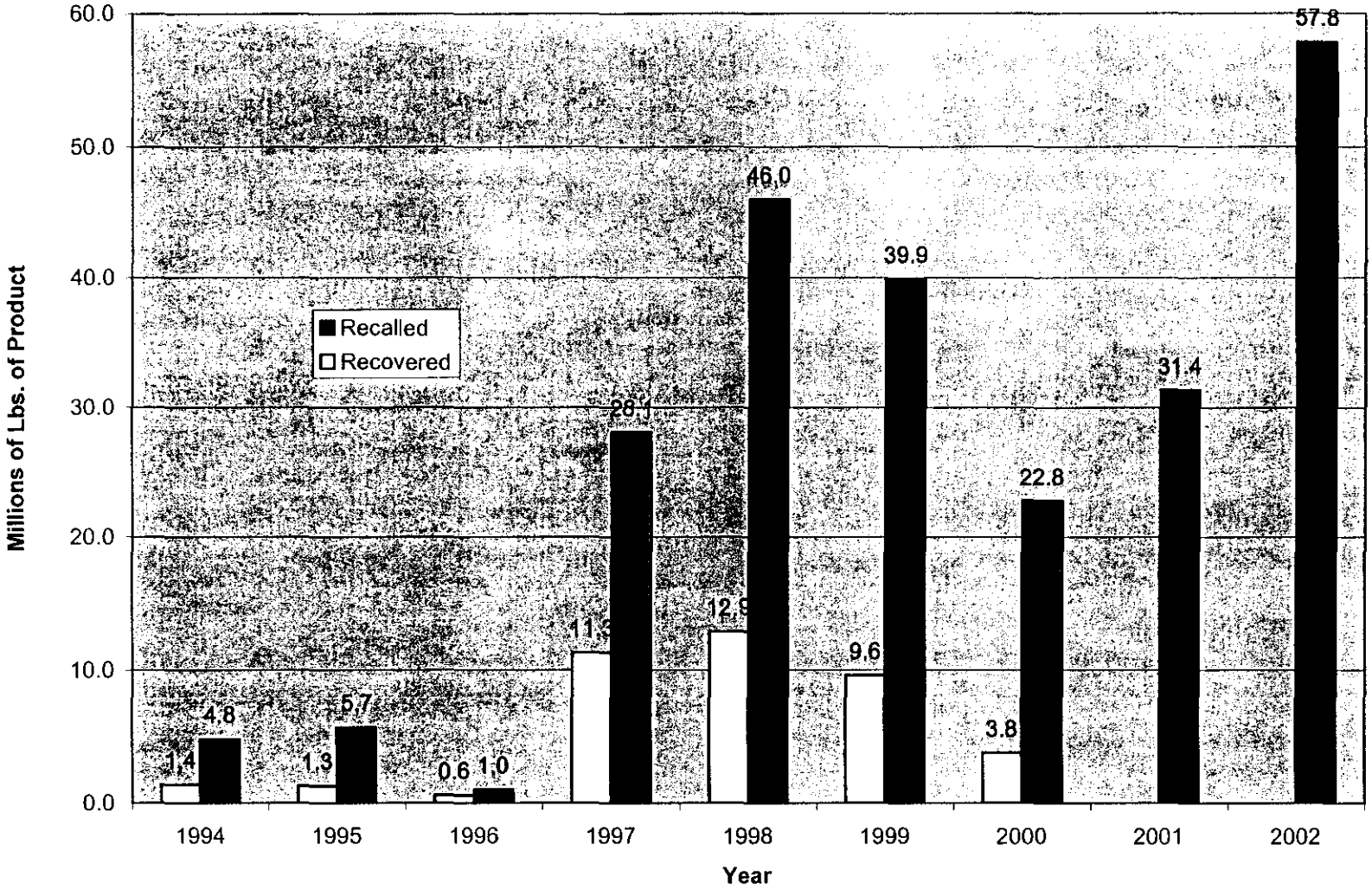
Company	Product	Reason for Recall (Recall Class)	Original Recall Date	Original Recall Amount	Expanded Recall Date	Expanded Recall Amount (including original amount)
Jack Lambersky Poultry Inc.	Fresh and frozen ready-to-eat turkey and chicken products	Products may be contaminated with *Listeria monocytogenes* (Class I)	11/2/02	200,000 pounds	11/20/02	4.2 million pounds
Pilgrim's Pride	Turkey and chicken products	Products may be contaminated with *Listeria monocytogenes* (Class I)	10/9/02	295,000 pounds	10/12/02	28 million pounds
Emmpak Foods, Inc.	Ground beef	Products may be contaminated with *E. coli* O157:H7 (Class I)	9/27/02	500,000 pounds	10/2/02	2.8 million pounds

Company	**Product**	**Reason for Recall (Recall Class)**	**Original Recall Date**	**Original Recall Amount**	**Expanded Recall Date**	**Expanded Recall Amount (*including* original amount)**
Broadway Ham Company	Crowley Ridge Brand B-B-Q seasoned cooked fresh ham	Products may be contaminated with *Listeria monocytogenes* (Class I)	8/28/02	2,200 pounds	8/30/02	8,725 pounds
ConAgra Beef Company	Beef products (ground beef and beef trimmings)	Products may be contaminated with *E. coli* O157:H7 (Class I)	6/30/02	354,200 pounds	7/18/02	19 million pounds
Hudson Beef	Ground beef	*E. coli* O157:H7 (Class I)	8/12/97	20,000 pounds	8/15/97 8/21/97	1.2 million pounds 25 million pounds

Total Number of FSIS Recalls By Year, 1994-2002



FSIS Recall and Recovery Data By Year, 1994-2002



FSIS Recalls By Pathogen and Year, 1994-2002