



Review

The science of recalls

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Abstract

Morbidity due to foodborne illnesses in the US has decreased over the last ten years. During the same time period recalls affecting the meat and poultry industry have increased from 38 in 1993 to a peak of 128 in 2002. Recalls due to *L. monocytogenes* (*LM*) and *E. coli* O157:H7 have accounted for the majority of recalls in recent years, while incidence rates for these pathogens have decreased. Incidence of *Salmonella* and *E. coli* O157:H7 cases since 1996 have decreased 17% and 42% respectively while product positives in ready to eat foods for *LM* has decreased from 3% in 1995 to 0.75% in 2003. In response to the increasing number of recalls, members of the meat and poultry industry have developed recall plans to effectively manage a recall crisis. A detailed recall plan which is tested through mock scenarios is essential to reducing the economic and negative consumer confidence impact of recalls.

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1. Introduction

In recent years, the number of food recalls in the US has increased due in part to a renewed focus on food safety and security by the US government. The Food

Safety Initiative, started by President Bill Clinton as a response to *E. coli* O157:H7 in ground beef was continued and strengthened by President George W. Bush. Elevated security measures in response to anticipated acts of terrorism on the food supply, new and highly sensitive pathogen tests, and reliance on epidemiological investigations have all contributed to this trend (NFPA, 1999; UF, 2004). Most major meat processors in the United States have now been involved in a recall at some

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point in their history, and spend considerable funds to prevent, as well as to prepare and respond quickly to, future occurrences. With guidance from the USDA and industry groups, the meat and poultry industry has responded with intensive food safety and security programs, which have greatly improved the safety of our nation's food supply over the years, yet the number of recalls on an annual basis continues to rise. Does the increased number of USDA recalls reflect the safety of the US meat and poultry supply, and how has the public's health been affected?

2. Regulation of recalls by the US government

The FDA and USDA/FSIS are the agencies primarily responsible for the protection and safety of the US food supply. Under federal guidelines, the FSIS branch of the USDA is responsible for recalls involving meat and poultry, while the FDA handles most other foods, including seafood and produce. FSIS defines a recall as 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 under the provisions of the Federal Meat Inspection Act or the Poultry Products Inspection Act (USDA, 2004b). Under current regulations, FSIS may only request that a company recall product. FSIS does not have the authority to order the recall, although FSIS, in conjunction with local and state departments of health and agriculture, does have the authority to seize and detain product from commerce and/or shut down processing operations if a firm chooses to not cooperate. USDA may also choose to remove their inspector from a plant as a means of preventing food from legally entering commerce. During recent Congressional Sessions, legislation has been proposed which would give authority to USDA/FSIS to order recalls. In addition to proposed legislation, an October 2004 Government Accountability Office (GAO) report on Food Recall Programs recommended not only to grant the agencies the authority to order recalls, but also to establish recall requirements and the ability to impose monetary fines if a company does not cooperate in a timely manner (GAO, 2004; UF, 2004). As of the date this report was written, no proposals to finalize this legislation have proceeded.

3. Initiation of recall

Recalls are usually a voluntary action carried out in the interest of public health by responsible members of the meat and poultry industry. Initiation of a recall is commonly due to the detection of: microbial agents, undeclared allergens, chemical contamination, foreign

materials such as glass, metal, and plastic, undercooking of product and misinformation on the product label (Table 1). A firm's decision to conduct a recall may come from an internal investigation of two key triggers. First, the company should conduct thorough investigations of all product liability claims whether thought to be fraudulent or real. Close monitoring and record keeping of such events can help the firm identify a problem area which can prevent or lead to the initiation of a recall (Hartford, 1997). Second, a firm's ability to construct and continuously monitor an effective HACCP plan allows for detection and correction of critical errors in the production of the food product. Stringent record keeping and review of the HACCP data can alert a processor to a problem area which may result in the initiation of a recall. Conducting an in depth investigation and review of HACCP documentation will streamline the response once a problem has been detected and help determine the amount of product to be recalled.

Recently, USDA/FSIS in conjunction with the CDC have used epidemiological data to implicate a meat or poultry product in an outbreak when the food has been associated with illness but yet to test positive for the identified agent (NFPA, 1999). In an effort to detect large multi-state outbreaks due to a common food source, the CDC developed Pulse Net, a network of linked public health laboratories who perform pulse-field gel electrophoresis, "DNA Fingerprinting," on five foodborne disease causing bacteria. Pulse Net was established in 1996 and includes seven regional federal public health laboratories, 43 state laboratories and five county laboratories (CDC, 2003). In 1999, Pulse Net Canada joined the network with seven public health laboratories (CDC, 2003). The network which allows for rapid multi-state comparisons in a CDC managed database of DNA Fingerprints monitors for *E.coli* O157:H7, *Salmonella* (non-typhoidal), *Shigella*, *Campylobacter*, and *Listeria monocytogenes* (LM). The network of laboratories performs genetic fingerprinting on bacterial samples isolated from human cases, as well as suspected food items, and enters the results into the network, which then allows health agencies to compare local isolates to others across the country. In the current regulatory climate, with increased pressure to ensure the safety of

Table 1
USDA recalls by cause 2000–2003

Cause/year	2000	2001	2002	2003
<i>Listeria</i>	35 (46%)	26 (28%)	42 (33%)	16 (23%)
<i>E. Coli</i> O157:H7	20 (27%)	25 (27%)	35 (27%)	11 (15%)
<i>Salmonella</i>	4 (5%)	2 (2%)	4 (3%)	2 (3%)
Allergens	5 (7%)	11 (12%)	20 (16%)	14 (20%)
Other	11 (15%)	28 (31%)	27 (21%)	28 (39%)

Other category contains recalls due to; foreign materials, mislabeling, undercooking and chemical contamination.

the food supply, large scale recalls have been initiated due to requests by USDA/FSIS relying on Pulse Net epidemiological data alone. This trend is a departure from traditional epidemiological investigation, which relies on a thorough investigation, microbial confirmation in the product and matching of genetic fingerprints between product and a human case.

The government classifies recalls into three general risk groups. Class 1 recalls involve the highest risk for severe health effects and the potential for death due to ingestion of the contaminated food and represents the majority of USDA recalls on a yearly basis (USDA, 2004b) (Table 2). Common causes for Class 1 USDA recalls include *LM*, *E. coli* O157:H7, undeclared allergens, *Salmonella*, and foreign materials (USDA, 2004b). Class 2 recalls represent a remote potential for an adverse health effect which is temporary or medically reversible. Agents in this class include minor allergens and incorrect ingredient labeling (USDA, 2004b). Class 3 recalls involve foods in which ingestion is not likely to cause any harm or illness (USDA, 2004b). A review of USDA recalls from year 2000 to 2003 shows *LM* as the leading bacterial cause for recall, followed by *E. coli* O157:H7 (Table 1). *LM* and *E. coli* O157:H7 recalls gradually increased from 2000 to 2002, and both experienced a drop to 16 (23%) and 11 (15%), respectively, in 2003 (Table 1). While bacterial causes are on the decline, USDA recalls due to allergens have increased from five (7%) in 2000 to 14 (20%) in 2003 (Table 1). Recalls due to foreign materials, mislabeling of ingredients, and undercooking of meat and poultry products have also increased from 11 (15%) in 2000 to 28 (39%), accounting for the majority of USDA recalls in 2003 (Table 1).

4. Recall preparation and response

The manner in which a firm prepares and responds to a USDA recall, can ultimately determine if and when the establishment will recover from the economic impact and loss of consumer confidence. In an effort to prevent recalls, meat and poultry firms have aggressively addressed the industries' food safety needs. Furthermore, members within the industries readily share new food safety technologies as they develop in an effort to ensure the quality of meat and poultry products. The industries' development of new food safety technologies in conjunc-

tion with the employment of GMPs and HACCP are key to the prevention of a USDA recall.

Advanced preparation in the form of a recall team is essential to effective crisis management. Members of the recall team should represent distinct departments of the company such as quality assurance, operations/production, accounting, shipping/distribution, and corporate counsel (NFPA, 1999; UF, 2004). Many firms also include non-corporate members to assist with government agencies and media/public relations. A designated team leader should have contact information and the ability to gather all members minimally by phone in a very short amount of time. The recall team's core responsibilities include both prevention and response measures to a crisis. Initially, a review of product production, HACCP plans and records, traceability of product within the facility and as it is shipped to distributors is required. The information collected will allow the recall team to assess and update procedures to prevent or facilitate quick control in the event of a recall (NFPA, 1999; UF, 2004). The recall team should be able to communicate effectively through their team leader with the company's corporate hierarchy, as well as with federal agencies involved in the recall (NFPA, 1999; UF, 2004). Regular meetings between members should continue until the recall is completely closed and be followed up with a post-crisis meeting to determine the effectiveness of their recall plan.

A well-developed recall plan is crucial to a timely response in a crisis. A detailed plan can eliminate confusion and prevent duplicated efforts by various team members by providing a framework for action (Hartford, 1997; NFPA, 1999). Key components of a recall plan include all contact information for members of the recall team: the corporate hierarchy, clients/distributors and federal, state and local regulatory agencies. A log should be maintained of all actions initiated in response to the recall, this documentation will aid in possible litigation, which may arise as a result of the crisis (UF, 2004). A decision tree will provide the team with predetermined logical answers or actions in response to issues that may arise during a recall. This will prevent ill-advised decisions made hastily in the face of a crisis. The plan must detail a system for quickly locating important documents, the amount of product involved, and the location of the product or where it was distributed (UF, 2004). USDA/FSIS require specific documentation when a firm makes the decision to recall a product. Development of a checklist or preprinted packets to be filled out can ease this process and ensure all requirements are met (NFPA, 1999; UF, 2004). Lastly, the company should present itself to the public and media as a unified front, from entry-level employees to the president, one person should be the sole spokesperson for the company, with all questions and requests directed by this person. To

Table 2
USDA recalls by classification 2000–2003

Class/year	2000	2001	2002	2003
Class 1	64 (85%)	69 (75%)	89 (75%)	47 (66%)
Class 2	8 (11%)	10 (11%)	13 (11%)	14 (20%)
Class 3	3 (4%)	13 (14%)	16 (14%)	10 (14%)

validate that the plan is effective, mock recalls should be conducted to test the framework. The mock recall should attempt to mimic a true scenario as closely as possible. This assessment will provide insight as to how current the contact data is and the quickness in which the team can be assembled to begin assessing the situation.

5. Recalls and their affect on public health

Recent FSIS and CDC data demonstrate a significant decrease in morbidity due to foodborne illness since 1996 (USDA, 2004a). Over this time period, the incidence of common foodborne pathogens, such as *Salmonella* and *E. coli* O157:H7 have decreased 17% and 42%, respectively. *Salmonella*, once a major factor in the food processing industry, now accounts for less than five percent of USDA recalls (Table 1). As the trend of decreased morbidity due to foodborne illness continues,

USDA recalls have increased steadily over the past ten years (Fig. 1). The number of USDA recalls in the United States jumped from 38 in 1993 to 71 in 2003 with a peak of 128 recalls in 2002 (Fig. 1). *LM* accounted for the majority 42 (33%) of 2002 USDA recalls, yet CDC (Fig. 2) data shows the number of annual cases of *Listeriosis* have remained relatively constant over the last five years (Fig. 2). In addition to the low incidence rate in the general population, FSIS data shows that ready-to-eat foods positive for *LM* have decreased from 3% in 1995 to 0.75% in 2003. *E. coli* O157:H7 cases have decreased 42% since 1996, as the second leading cause of a recall due to pathogen contamination behind *LM* (USDA, 2004a). Incidence of *E. coli* O157:H7 decreased 36% from 2002 to 2003, according to FSIS, but the numbers of recalls due to this pathogen have remained constant, with an average of 23 recalls per year since 2000 (Table 1 and Fig. 3).

Many factors, such as increased sensitivity of pathogen tests and heightened surveillance through USDA/

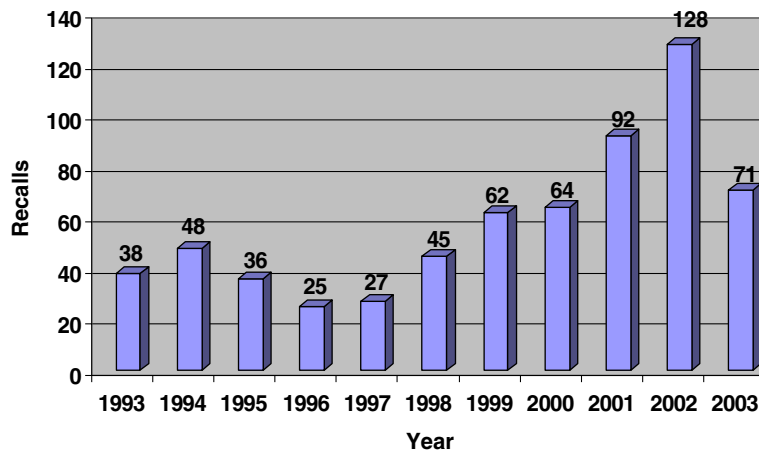


Fig. 1. USDA recalls per year 1993–2003. Source: FSIS (2005).

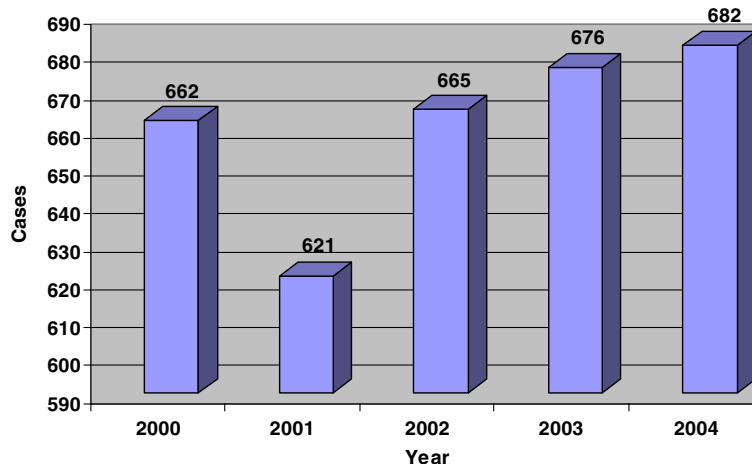


Fig. 2. Annual *Listeria* cases US 2000–2004. Source: CDC (2005).

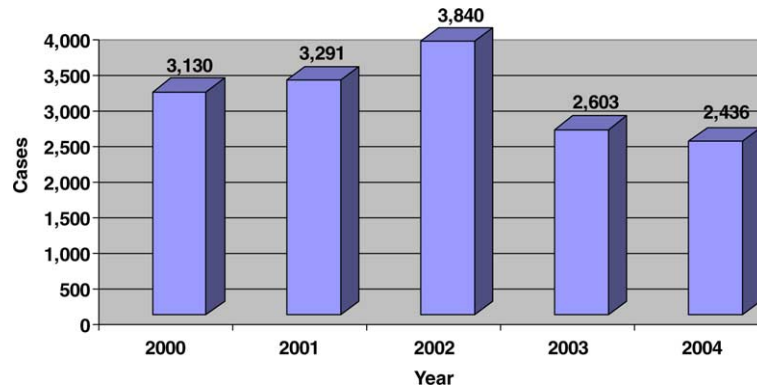


Fig. 3. Number of *E. coli* O157:H7 cases in the US 2000–2004. Source: CDC (2005).

FSIS product sampling and the expansion of Pulse Net, contribute to the rising numbers of recalls in the meat and poultry industry (NFPA, 1999; UF, 2004). In 2002, the USDA recalled 36 million pounds of meat and poultry products compared to 6 million pounds in 1988 (GAO, 2004). While foods are recalled by the millions of pounds, the recovery rate for these products is approximately 30% (GAO, 2004). Fresh meats present a difficult scenario due to their short shelf life. Product recalls are usually announced well after use by dates and have most likely been consumed by the public. This scenario, coupled with documented low recovery rates of recalled product, questions the effectiveness of the current recall system employed by the USDA.

6. A retrospective look at past recall

A respective look at past USDA recalls reveals a few shortcomings of the current regulatory climate. The current top five meat and poultry recalls occurred between 1997 and 2002 and involved over 140 million pounds of product. Deficiencies of the current recall system include, miscommunication between federal agencies, the lack of authority to order recalls, requesting recalls based on presumptive data and, recently, the use of epidemiological data alone to request a recall. A closer look at a past USDA recall will demonstrate some of the deficiencies of the current system.

In 1998, Colorado Boxed Beef operating in Florida announced a recall of 359,000 pounds of ground beef possibly contaminated with *E. coli* O157:H7. FSIS requested that the firm recall the product based on a presumptive positive on a routine sample obtained by the Florida Department of Agriculture. The presumptive positive result was not confirmed by a more accurate 48-h test. In addition to the lack of confirmation on the meat sample, the recall was announced thirteen days after the latest use by date. Ultimately, one pound was recovered and no illnesses were ever associated with this product. The lack of confirmed scientific evi-

dence and the date that the product recall was announced offered minimal to no benefit to the public's health.

7. The effect of recalls on the meat and poultry industry

Meat and poultry recalls have a direct economic and public perception effect on the industry. Research has shown that when meat recalls are announced there is a direct negative effect on demand for the products and a move toward non-meat products (Marsh, Schroeder, & Mintert, 2004). Costs associated with the prevention, response and litigation that may arise as a result of the escalating number of recalls initiated annually have increased the cost of industry products. The growing number of recalls has changed the public perception of the meat and poultry supply in the United States. Media coverage of a few large outbreaks in recent years due to pathogen contamination has generated public concern regarding the industries' ability to provide safe and wholesome food products. Studies indicate that the public perceives the recalls as an indicator of the industries' lax attitude toward quality control and food safety (Marsh et al., 2004; Skees, Aleta, & Kimberley, 2001).

In a response to the growing number of recalls, many members of the meat and poultry industries now carry recall insurance. In the early 90s, insurance companies began to offer policies to cover the costs of recalls. Today, such policies can save a company from bankruptcy due to a crisis. As a result of the rising economic impact, litigation and verdicts of large recalls due to foodborne illnesses, the industry, from processors to retailers, are looking for new ways to share or indemnify themselves against product liability. Processors are exploring the possibility of sharing liability with equipment manufacturers, if a contamination issue arises as a result of a defective or poorly designed processing machine. Recall insurance can have a positive effect on the industry by promoting well-developed food safety programs, which

will reduce premium costs on the company (Skees et al., 2001).

8. Conclusion

The rising numbers of USDA recalls is not indicative of the safety or quality of the United States meat and poultry supply. Recent FSIS data shows significant decreases of the most common foodborne illness over the past few years. The industry has embraced new technologies and programs which have impacted morbidity and mortality rates for foodborne pathogens in the United States. Nonetheless, even the best managed company employing the latest programs and technology cannot guarantee food that is 100% free of pathogens.

Detailed preparation in the event of a recall is essential to a company's survival, from an economic and public relations perspective. The recall plan should be tested and updated annually to ensure that the information contained within is current and the plan is effective. The negative publicity generated by a USDA recall does affect the overall demand for meat products. Studies have demonstrated that when a meat or poultry recall is announced there is a temporary shift towards non-meat products (3). A well-executed plan can project to the public the company's concern for public health, thus minimizing long-term negative effect on the brand or product.

Members of the meat and poultry industry and the USDA/FSIS will continue to respond to old and new challenges that arise as the demand for fresh and processed products continues to grow. As today's common foodborne agents decline, new emerging pathogens will evolve to drive new food safety technology and programs. Cooperation and guidance between the meat and poultry industries and federal regulatory agencies

will be imperative in successfully facing tomorrow's challenges.

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