



# Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods

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## Summary

The 111<sup>th</sup> Congress is considering legislation to revise the U.S. food safety system, focusing primarily on those laws and programs administered by the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS). The House has passed a comprehensive bill, H.R. 2749, and the Senate Committee on Health, Education, Labor, and Pensions has planned a markup of its comprehensive proposal, S. 510. The ultimate goal of both bills is to reduce the burden of foodborne illness, which is a considerable and persistent public health problem in the United States. However, an understanding of the true burden of illness caused by foodborne hazards, the risks associated with various types of foods, and the types of regulatory and other approaches that can effectively address these problems has been elusive.

Public health officials monitor and investigate foodborne illnesses in a number of ways. For example, active surveillance is used to track trends in the incidence of several common bacterial and parasitic foodborne illnesses. Outbreaks of foodborne illness are tracked to help improve approaches to investigation and to identify the foods that cause illnesses, among other things. Genetic “fingerprinting” is used to identify infections from a common source, including large multistate outbreaks, and can also help identify the foods that cause illnesses. These systems are administered jointly by various federal agencies, in partnership with state health officials. Collectively, these tools and others can shed light on the burden of foodborne illness in the United States, and ways to decrease it. However, these systems also have two significant shortcomings. First, because they monitor a limited number of known food safety threats, and because foodborne illnesses are substantially underreported, these systems do not, individually or collectively, capture the magnitude of foodborne illness that occurs each year. Second, these systems often detect or track the contaminant that causes illness, rather than the type of food that was contaminated, although it is the latter that government officials actually regulate.

Consumers and the media often focus on recalls—particularly those that are extensive and/or that involve widely consumed products—as indicators of the safety of the U.S. food supply. In many but certainly not all cases, products subject to a recall may have sickened or killed people or other animals. It is not always clear, however, how useful recall data are as a measure of the burden of foodborne illness or the effectiveness of federal food safety programs. For example, does a relatively high number of recalls signify a failure of the system to keep unsafe products from being consumed? Or is it actually an indication that the safety net is working by finding and getting tainted products off the market? Conversely, is a relatively low number of recalls an indication of the system’s effectiveness, or simply of not reporting or finding all defective food products? Because of these questions, caution should be exercised in using recall data as the basis for concluding that certain changes are needed in the nation’s food safety systems.

This report describes several systems to monitor foodborne illnesses, discussing their strengths and the gaps that remain in understanding the burden of foodborne illness in the United States. Next, this report presents recent data on more serious recalls of FDA-regulated foods, also discussing the strengths and gaps associated with the information. Finally, this report describes three recent foodborne outbreaks that led to nationwide recalls of FDA-regulated foods: (1) *Salmonella* in peanut products, (2) melamine in pet foods and dairy products, and (3) *E. coli* in spinach. Following each description are discussions of associated policy issues, and, if applicable, how these issues are addressed in food safety legislation pending before the 111<sup>th</sup> Congress. Descriptions of selected authorities in the Federal Food, Drug, and Cosmetic Act (FFDCA), FDA’s principal food safety law, are provided in the **Appendix**.

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## Introduction

The Government Accountability Office (GAO) has identified as many as 15 federal agencies that collectively administer at least 30 laws related to food safety.<sup>1</sup> The Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) and the Food Safety and Inspection Service (FSIS) within the U.S. Department of Agriculture (USDA) together comprise the majority of both the total funding and the total staffing of the federal government's food regulatory system. FDA has lead responsibility for ensuring the safety of all human and animal foods except those from the major meat and poultry species, catfish, and some egg products. These latter types of foods are within the purview of FSIS. According to GAO, FDA-regulated foods account for 80% of at-home U.S. food spending.<sup>2</sup> In addition to federal activities, states may play a substantial role in food facility inspections, outbreak investigations, and other food safety activities, particularly with respect to FDA-regulated foods.

The 111<sup>th</sup> Congress is considering legislation to revise the U.S. food safety system, focusing primarily on those laws and programs administered by FDA. Both the House and Senate have introduced comprehensive bills that address a number of perceived problems with the current food safety system. The House passed H.R. 2749, the Food Safety Enhancement Act of 2009, on July 30, 2009. The Senate Committee on Health, Education, Labor, and Pensions has planned a markup of S. 510, the FDA Food Safety Modernization Act. The bills cover much of the same material, although they differ somewhat in their specific approaches. Among other things, both bills would expand registration requirements for food facilities and require facilities to implement food safety plans based on assessments of risk. Also, both bills would require FDA to conduct periodic safety inspections, expand the agency's access to industry records, and allow the agency to mandate that companies conduct recalls of unsafe products. Both bills would also set new standards for produce safety and place more scrutiny on imported foods.

The FDA faces considerable challenges in assuring the safety of the foods for which it is responsible. The complexity of the food distribution system is steadily increasing. Processed foods, in particular, may contain dozens of ingredients with domestic and imported origins. Similarly, a contaminated ingredient may find its way into dozens of seemingly unrelated products, including foods for both humans and animals. The ultimate goal of the House and Senate food safety bills is to reduce foodborne illness, which is a considerable and persistent public health problem in the United States. However, a comprehensive understanding of the burden of illness caused by foodborne hazards, the risks posed by different types of foods, and the types of safeguards that can effectively address these problems has been elusive.

This report describes several systems to monitor foodborne illnesses and define the burden of this public health problem in the United States. Next, this report presents recent data on more serious recalls of FDA-regulated foods. Finally, this report describes three recent foodborne outbreaks that led to nationwide recalls of FDA-regulated foods: (1) *Salmonella* in peanut products, (2) melamine in pet foods and dairy products, and (3) *E. coli* in spinach. Following each description

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<sup>1</sup> U.S. Government Accountability Office, *High-Risk Series: An Update*, GAO-09-271, January 2009, pp. 71-72, <http://www.gao.gov/new.items/d09271.pdf>, and related food safety reports and testimony.

<sup>2</sup> For more information on the roles of FDA, FSIS, and other federal agencies in the nation's food safety efforts, see CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Geoffrey S. Becker (in particular Tables 1 and 2). See also CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, coordinated by Judith A. Johnson.

are discussions of associated policy issues, and, if applicable, how these issues are addressed in the food safety legislation pending before the 111<sup>th</sup> Congress. Descriptions of selected authorities in the Federal Food, Drug, and Cosmetic Act (FFDCA), FDA's principal food safety law, are provided in the **Appendix**. Like the bills under consideration, the main focus of this report is on the FDA and its authorities and approaches to assure food safety. Comprehensive discussion of the pending bills is beyond the scope of this report, but is available in CRS Report R40443, *Food Safety: Selected Issues and Bills in the 111<sup>th</sup> Congress*, by Geoffrey S. Becker.

## The Burden of Foodborne Illness

### Overview and Estimates

Health officials monitor and investigate foodborne illness in a number of ways. For example, surveillance is used to track trends in the incidence of several common bacterial and parasitic foodborne illnesses. Tracking of outbreaks of foodborne illness helps improve approaches to investigation, among other things. Genetic “fingerprinting” is used to identify infections from a common source, including large multistate outbreaks.

Collectively, these tools shed light on the burden of foodborne illness in the United States, and ways to decrease it. However, these tools also have two significant shortcomings. First, because they monitor a limited number of known food safety threats, and because foodborne illnesses are substantially underreported, these systems do not, individually or collectively, capture the magnitude of foodborne illness that occurs each year. Second, they often detect the contaminant that causes illness, rather than the type of food that was contaminated, although it is the latter that government officials actually regulate. These concepts are discussed below, followed by descriptions of three key federal foodborne illness monitoring systems: FoodNet active surveillance of individual cases of foodborne illness; surveillance of foodborne disease outbreaks; and PulseNet genetic “fingerprinting” of certain foodborne pathogens. Key definitions are provided in a text box, below.

Because the existing foodborne illness surveillance systems do not identify all cases of foodborne illness, health officials can only estimate the true burden of illness in the population. In 1999, the Centers for Disease Control and Prevention (CDC) published such an estimate for the United States, saying that on average, about 76 million people become sick, 325,000 are hospitalized, and 5,000 die each year from foodborne illnesses caused by one or more of a number of microbial pathogens and other contaminants.<sup>3</sup> The authors noted that most foodborne illnesses are not reported to authorities, and are therefore not reflected in foodborne illness surveillance data.<sup>4</sup> They also reported that:

... many pathogens transmitted through food are also spread through water or from person to person, thus obscuring the role of foodborne transmission. Finally, some proportion of

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<sup>3</sup> Paul S. Mead et al., “Food-Related Illness and Death in the United States,” *Emerging Infectious Diseases*, vol. 5, pp. 607-625, 1999 (hereafter Mead article), <http://www.cdc.gov/ncidod/EID/vol5no5/mead.htm>. These estimates were derived from a variety of sources. See also, CDC, “Foodborne Illness: Frequently Asked Questions,” <http://www.cdc.gov/foodsafety/>.

<sup>4</sup> In the United States, states may mandate that laboratories, health care providers, and others report cases of illness to state authorities. Reporting by states to the Centers for Disease Control and Prevention (CDC) is voluntary.

foodborne illness is caused by pathogens or agents that have not yet been identified and thus cannot be diagnosed. The importance of this final factor cannot be overstated. Many of the pathogens of greatest concern today (e.g., *Campylobacter jejuni*, [E. coli] O157:H7, *Listeria monocytogenes*, [and] *Cyclospora cayentanensis*) were not recognized as causes of foodborne illness just 20 years ago.<sup>5</sup>

CDC's estimate was derived from a variety of data sources, dating from 1997 and earlier. The agency is in the process of revising the estimate.

### Definitions: Foodborne Illness Investigation

**Active Surveillance:** Active surveillance means that CDC and state health officials follow up with physicians, laboratories, and others to assure completeness of reporting. Active surveillance is labor- and time-intensive.

**Attribution:** Determining, through investigation, the type of food vehicle responsible for transmitting an etiologic agent that has caused a foodborne illness.

**Cause:** Referring to the cause of a foodborne illness or outbreak may be confusing, as it could refer either to the etiology or to the vehicle. Also, a food production or handling practice could be implicated in an outbreak investigation, and could also be referred to as a "cause."

**Etiology:** The pathogen (bacteria, viruses, parasites or fungi), toxin, or other contaminant that causes illnesses in humans or other animals. These contaminants may be referred to as *etiologic agents*.

**Genetic "fingerprinting":** Refers to several approaches to describe the specific make-up of a bacterial pathogen, such as its genetic material, cell wall components, or other features, in order to distinguish related strains from other strains. For example, the PulseNet system uses pulsed-field gel electrophoresis (PFGE) to break apart and separate bands of bacterial DNA. Identical banding patterns usually mean that the strains are genetically related, and that they arose from common origins and/or were transmitted through a common vehicle. This approach allows health officials to, for example, quickly distinguish among many thousands of strains of *Salmonella* that cause illness each year, to see if one of them is responsible for illnesses identified across jurisdictions.

**Outbreak:** A foodborne disease outbreak is not defined in law or in regulation. In public health practice, a foodborne disease outbreak is defined as "the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food." As a practical matter, particularly for less serious hazards, outbreak investigations are rarely launched when only two people are affected, although there are exceptions, such as for botulism.

**Passive Surveillance:** Unlike active surveillance, passive surveillance does not involve efforts to validate the completeness of reporting. As a result, under-reporting is usually more of a concern than with active surveillance.

**Vehicle:** The type of food that carries or transmits an etiologic agent.

**Source:** Adapted by CRS from CDC, "Surveillance for Foodborne-Disease Outbreaks: United States, 1998–2002," *MMWR*, vol. 55 (Surveillance Summary 10), pp. 1-34, November 10, 2006; and CDC, "Overview of CDC Food Safety Activities and Programs," <http://www.cdc.gov/foodsafety/fsactivities.htm>.

As noted earlier, foodborne illness surveillance generally identifies illnesses by their *etiology* i.e., the pathogen or other contaminant responsible for illness, such as *Salmonella* or the toxin that causes botulism. It is more difficult to identify the *vehicle*, i.e., the type of food that bears the contaminant. For example, foodborne illness surveillance systems track cases of human *Salmonella* infection. It can be difficult to attribute these infections to one or more of a variety of possible vehicles, which may include poultry, eggs, produce, and dairy products, among others. When a vehicle is identified, it can then be difficult to identify the practice that caused the

<sup>5</sup> Mead article. See also CDC, "Foodborne Illness: Frequently Asked Questions," <http://www.cdc.gov/foodsafety/>.

contamination, such as an on-farm or processing practice, or cross-contamination in the home or food-service establishment. Because regulators are responsible for the safety of food vehicles and food production and handling practices, and not the etiologies *per se*, the gap between identification of an illness or outbreak and *attribution* to a food vehicle and/or practice remains a substantial challenge in reducing the burden of foodborne illness in the United States.

Following are presentations of three important monitoring systems for foodborne illness: FoodNet active surveillance of certain pathogens; passive surveillance of foodborne disease outbreaks; and PulseNet genetic “fingerprinting” of certain foodborne bacteria.<sup>6</sup> These and other monitoring systems together provide information about the nature of foodborne illnesses in the United States, and, increasingly, information about the means to prevent them.

## **FoodNet: Active Surveillance of Foodborne Illness**

Since 1996, the *FoodNet* system has been used to monitor the incidence of certain foodborne illnesses. FoodNet is a population-based active surveillance system chiefly administered by CDC in partnership with FDA, USDA, and 10 states.<sup>7</sup> FoodNet tracks the incidence of individual laboratory-confirmed infections caused by several bacteria and parasites, in sites in the 10 states. Because FoodNet tracks only laboratory-confirmed infections, it does not capture foodborne illnesses that do not involve a health care visit, testing with a positive result, and reporting of that result. **Figure 1** presents the “burden of illness” pyramid, showing that FoodNet data capture only the “tip of the iceberg.” Also, the bacteria and parasites monitored by the FoodNet system account for only a portion of the causes of foodborne illness each year.

For the reasons noted above, FoodNet does not provide information about the overall burden of foodborne illness in the United States. Also, FoodNet data do not capture information (if it is known) about the food vehicle(s) that caused reported illnesses.<sup>8</sup> However, because FoodNet monitors illnesses in the same population and in the same way from year to year, capturing most or all laboratory-confirmed cases through active surveillance, the system can be used to track trends in the incidence of foodborne illness. FoodNet data can indicate whether the problem of illnesses caused by a specific pathogen appears to be getting better or worse over time, which can provide general information about the effectiveness of food safety programs, among other things. Prior to the implementation of FoodNet, it was not possible to track the monitored foodborne illnesses in this way.

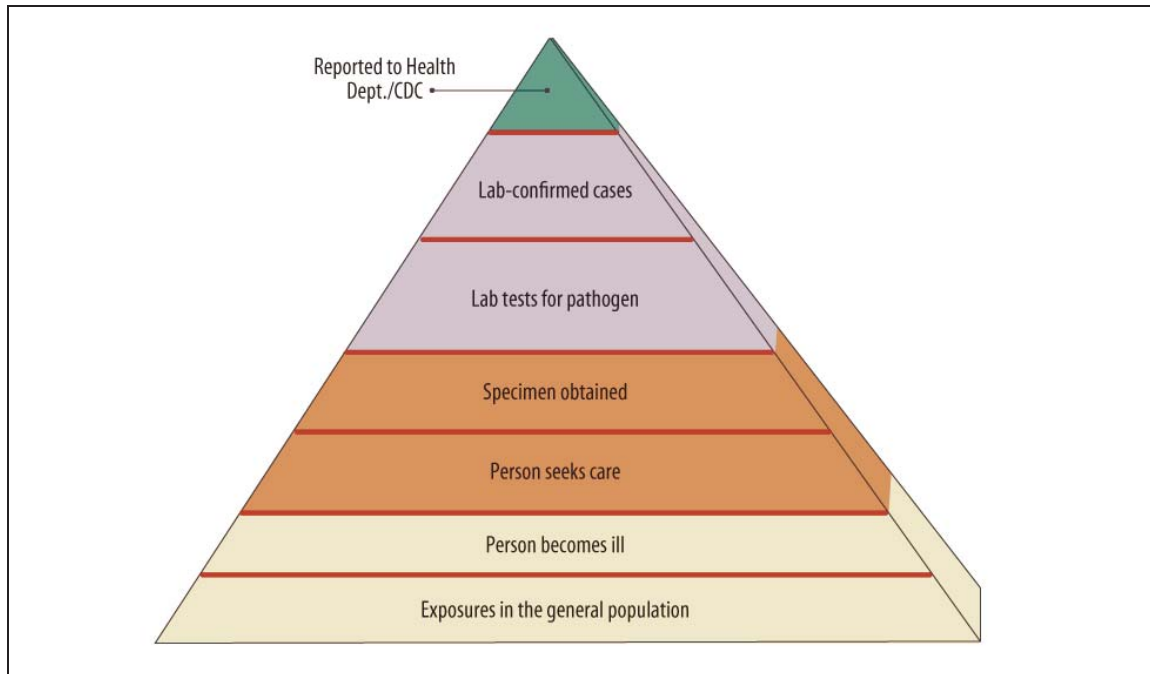
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<sup>6</sup> For information about foodborne illness monitoring programs in general, see CDC, “Overview of CDC Food Safety Activities and Programs,” <http://www.cdc.gov/foodsafety/fsactivities.htm>.

<sup>7</sup> CDC, “FoodNet—Foodborne Diseases Active Surveillance Network,” <http://www.cdc.gov/foodnet/>. The 10 FoodNet sites—the states of Connecticut, Georgia, Maryland, Minnesota, New Mexico, Tennessee, and Oregon, and certain counties in California, Colorado, and New York—are the sites for CDC’s Emerging Infections Program. They were selected to be generally representative of the U.S. population. FoodNet surveillance in these sites captures a range of regional and ethnic experiences with foodborne illness.

<sup>8</sup> However, additional studies based on FoodNet-identified cases of illness can establish attribution to food vehicles.

Figure I. Pyramid Showing Burden of Foodborne Illness

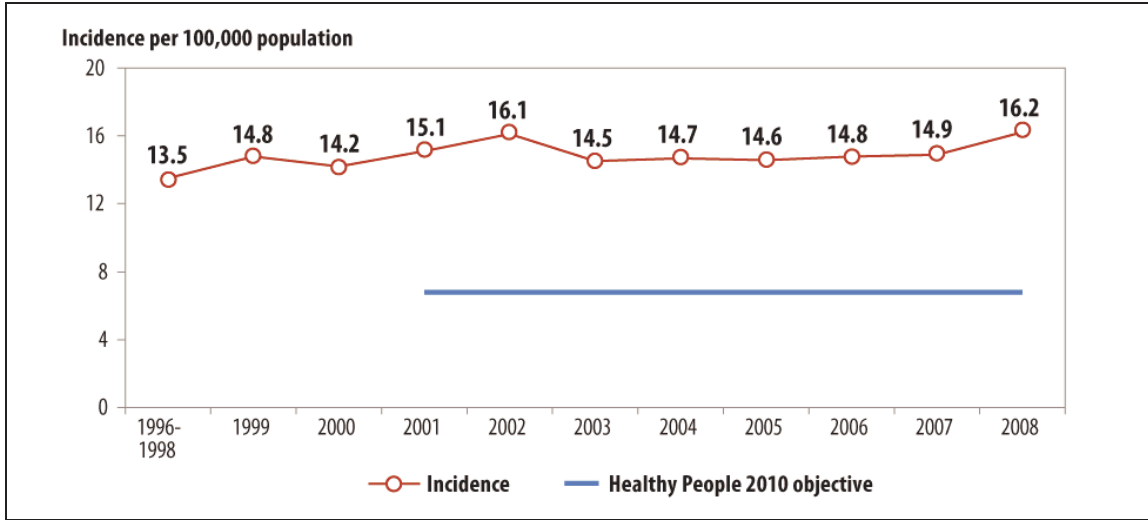


Source: Adapted by CRS from CDC, “FoodNet Surveillance—Burden of Illness Pyramid,” [http://www.cdc.gov/FoodNet/surveillance\\_pages/burden\\_pyramid.htm](http://www.cdc.gov/FoodNet/surveillance_pages/burden_pyramid.htm).

Based on FoodNet data, CDC reported that in 2008 the incidence of several of the illnesses under surveillance since 1996 had reached a plateau, instead of declining, and that national Healthy People 2010 (HP2010) health targets for these illnesses may not be met.<sup>9</sup> For example, **Figure 2** presents the FoodNet incidence of *Salmonella* infections from 1996 through 2008, and the HP2010 target. CDC noted that of all the FoodNet pathogens monitored in 2008, the incidence of *Salmonella* was farthest from the HP2010 target. CDC also commented on efforts at FSIS to reduce levels of *Salmonella* contamination in poultry, a common vehicle for *Salmonella* infection. But CDC also noted the growing recognition that several types of food vehicles regulated by FDA, such as peanut products and leafy greens, may also contribute considerably to the burden of illnesses caused by the FoodNet pathogens, including *Salmonella*.

<sup>9</sup> CDC, “Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food—10 States, 2008,” *MMWR*, vol. 58, no. 13 (April 10, 2009), pp. 333-337. “Healthy People 2010” is a set of national health objectives developed by governmental and nongovernmental scientists identifying the most significant preventable threats to health and establishing national goals to reduce them. Food safety is one of 28 focus areas. See <http://www.healthypeople.gov/>.

**Figure 2. Incidence of Human *Salmonella* Infections in the United States, 1996–2008**  
 From FoodNet Active Surveillance of Laboratory-Confirmed Cases



**Source:** Prepared by CRS from FoodNet annual reports, <http://www.cdc.gov/mmwr/>; and Healthy People 2010, Ch. 10, Food Safety, <http://www.healthypeople.gov/Document/HTML/Volume1/10Food.htm>.

**Notes:** According to CDC, the increased incidence (cases per 100,000 population) for *Salmonella* in 2008 was not statistically significant when compared with the rates for the previous three years. The 1996-1998 *Salmonella* incidence is a three-year average, as published by CDC. The Healthy People 2010 objective for *Salmonella* is to halve the incidence from the 1997 baseline of 13.7 cases per 100,000 to 6.8 cases per 100,000 by 2010.

## Passive Surveillance of Foodborne Disease Outbreaks

In addition to FoodNet, CDC also partners with FDA, USDA, and state and local health officials to coordinate national passive surveillance of foodborne disease outbreaks (FBDOs), which are groups of illnesses that result from a common exposure.<sup>10</sup> Outbreaks may involve as few as two or as many as thousands of people. Outbreak reporting differs from FoodNet reporting in several ways. First, FoodNet tracks individual cases of illness only for a handful of specific etiologies, such as *Salmonella*, and only when infections are laboratory-confirmed. In contrast, for some outbreaks the etiology is never identified; the recognition of an outbreak may hinge only on the finding of common symptoms among individuals with an obvious common exposure. For example, if a group of people experience acute vomiting after eating at the same function, and no etiology is identified, states authorities could report the incident to CDC as an outbreak, but FoodNet would not capture any of the cases.<sup>11</sup> Also, most foodborne illnesses are “sporadic”; i.e., they are not associated with outbreaks. Finally, as with individual cases of illness, many outbreaks, particularly those that are small, are not reported to authorities. Therefore, outbreak data provide limited information about the incidence or overall burden of foodborne illness.

A strength of outbreak data is that it may provide attribution information that is not captured by FoodNet. Investigating outbreaks may allow health officials to attribute them to specific types of foods and/or food handling practices, as well as to identify the types of techniques that are most

<sup>10</sup> CDC, “OutbreakNet Team Overview,” <http://www.cdc.gov/foodborneoutbreaks/>.

<sup>11</sup> Refer also to footnote 5, regarding the fact that some proportion of foodborne illness results from causes (etiologies) that have not yet been identified.

effective in responding to and controlling a FBDO. A food safety advocacy group maintains a database of foodborne outbreaks (involving two or more people) in the United States for which the outbreak was attributed to a specific food vehicle(s), compiled largely from CDC and state health department outbreak listings, reports by the CDC's Foodborne Outbreak Response and Surveillance Unit, and peer-reviewed journal articles.<sup>12</sup> The group identified a total of 5,778 outbreaks of illness linked to specific foods between 1990 and 2006, reporting hundreds of outbreaks each attributed to seafood, meat, poultry, produce, and eggs. It also noted the problem associated with attribution of outbreaks to multi-ingredient foods, namely, that it can be more difficult to identify the contaminated ingredient in these situations.

In summary, FBDO data capture passive reports of outbreaks based on symptoms of foodborne illness among groups of people. Reported outbreaks may or may not be accompanied by information about an identified etiology and/or an attributed food or food handling practice. Outbreaks vary considerably in size, from small ones linked to social gatherings, to large ones involving commercial products consumed by thousands of people across the country. FBDO data may be most useful when considered qualitatively (e.g., saying that produce continues to be a source of multiple large FBDOs each year), but may not support quantitative conclusions (e.g., saying that produce is a leading cause of foodborne illness, compared with other vehicles).<sup>13</sup>

## **PulseNet: Genetic “Fingerprinting”**

In the last two decades, technologies to link foodborne illnesses that have a common bacterial etiology have revolutionized the ability to identify large multistate outbreaks and mount an urgent response.<sup>14</sup> The PulseNet program, coordinated by CDC, links state and local health departments and federal agencies (including CDC, FDA, and FSIS) to a common database to determine whether bacteria that are associated with illnesses or found on foods are related. By its nature, PulseNet analyzes only laboratory-confirmed illnesses caused by several specific pathogens.

Although the PulseNet system can greatly improve the speed of detection of an outbreak, the tools used subsequently to attribute the responsible food vehicle(s) remain cumbersome. Epidemiologists often must still rely on time-consuming patient interviews. Especially for those foodborne infections with long incubation periods, patients' recollection of foods eaten may be imperfect. Also, if interviews suggest a suspicious subset of foods, the foods may no longer be available for testing. In addition, especially for FDA-regulated foods, information about common contaminants that may be present during production and in commerce, as well as how to test for them, is limited.<sup>15</sup> For these reasons, attribution of illnesses and outbreaks to a specific food vehicle remains a significant challenge.

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<sup>12</sup> Center for Science in the Public Interest, “Outbreak Alert! 2008,” December, 2008, [http://cspinet.org/new/pdf/outbreak\\_alert\\_2008\\_report\\_final.pdf](http://cspinet.org/new/pdf/outbreak_alert_2008_report_final.pdf). This report describes a subset of FBDOs that have been attributed to specific foods.

<sup>13</sup> Michael Lynch et al., “Surveillance for Foodborne-Disease Outbreaks—United States, 1998-2002,” *MMWR Surveillance Summaries*, vol. 55(SS10) (November 10, 2006), pp. 1-34.

<sup>14</sup> CDC PulseNet program, <http://www.cdc.gov/pulsenet/>.

<sup>15</sup> FSIS conducts routine *Salmonella* testing of meat and poultry products, and inputs genetic “fingerprints” from a subset of these samples into the PulseNet database. This is the most comprehensive public-sector sampling program for bacterial foodborne pathogens.

## FDA-Announced Food Recalls

With the exception of infant formula, FDA does not have the authority to order a recall of an unsafe or potentially unsafe food.<sup>16</sup> Rather, the agency relies on food companies to voluntarily recall adulterated, misbranded, or otherwise unsafe products, either on their own initiative or upon regulators' request. Some in the food industry assert that the industry rarely if ever fails to conduct a recall when necessary, although the U.S. Government Accountability Office (GAO) has identified some instances of non-cooperation.<sup>17</sup>

FDA has stated that a company recall is generally the most effective current means for protecting consumers, but the FDA's principal statute, the Federal Food, Drug, and Cosmetic Act (FFDCA), does provide the agency with other legal enforcement tools, such as the power to seize adulterated and misbranded products. Such tools can be employed if a recall is not undertaken or is found to be ineffective.

A recall is "a firm's removal or correction of a marketed product that the [FDA] considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure."<sup>18</sup> The FDA categorizes recalls into three classes, as follows:

- Class I recalls, the most serious, involve "situation[s] in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death."
- Class II recalls involve "situation[s] in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote."
- Class III recalls involve "situation[s] in which use of, or exposure to, a violative product is not likely to cause adverse health consequences."<sup>19</sup>

FDA compiles information about recalls primarily via two publicly accessible formats. The first is a regularly updated listing, in reverse chronological order, of each major recall or related action regarding products it regulates (i.e., drugs, biologics, medical devices, cosmetics, and most foods).<sup>20</sup> This listing consists primarily of Class I recalls. Each item on the list is hot-linked to a press release announcing the recall, with additional details on the type of product, the reason for the recall, its geographical extent, and other basic information. The agency currently offers an online archive for these recalls dating back to 2004, and the database is searchable. Second, FDA publishes weekly enforcement reports that generally contain the same information, also dating

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<sup>16</sup> Portions of this discussion are drawn from CRS Report RL34167, *The FDA's Authority to Recall Products*, by Vanessa K. Burrows, where additional information, including arguments for and against mandatory recall authority, may be found.

<sup>17</sup> U.S. Government Accountability Office, *Food Safety: Actions Needed by USDA and FDA to Ensure that Companies Promptly Carry Out Recalls*, GAO-RCED-00-195, August 2000, pp. 15-16 and 37-38, <http://www.gao.gov/>. The agency was called the General Accounting Office at the time of publication.

<sup>18</sup> 21 C.F.R. § 7.3(g). The definition of a recall "does not include a market withdrawal or a stock recovery," which are defined in the regulation.

<sup>19</sup> 21 C.F.R. § 7.3(m)(1) through (3).

<sup>20</sup> FDA, "Recalls, Market Withdrawals, and Safety Alerts," <http://www.fda.gov/safety/recalls/default.htm>.

back to 2004.<sup>21</sup> The information in these reports appears to be less current than that in the first source, but is said by FDA to be more complete in that it includes all Class I, II, and III recalls.

Recalls—particularly those involving large numbers of widely consumed products—cause consumers to question not only the safety records of the recalling companies but also the ability of health officials to protect the food supply. In many, but certainly not all, cases, products subject to a recall may have sickened or killed people or animals. It is not clear, however, how useful FDA recall data are as a measure of the burden of foodborne illness or the effectiveness of federal food safety programs. For example, does a relatively high number of recalls signify a failure of the system to keep unsafe products from being consumed, or does it indicate that the safety system is working by finding unsafe products and removing them from the market? Conversely, is a relatively low number of recalls an indication of the system’s effectiveness, or simply of not finding and/or reporting all unsafe food products? Because of these questions, care should be exercised in using recall data as the basis for evaluating the effectiveness of food safety efforts. With these caveats in mind, CRS presents, in **Table 1**, the total number of Class I and Class II recalls of FDA-regulated foods for each of FY2005 through FY2009, by type of product, as categorized by FDA. (The data do not include Class III recalls, which, according to the definition, are not likely to involve problems that could cause foodborne illness.)

These tabulations do not include the several hundred recalls, which occurred during the same time period, of various meat and poultry products regulated by FSIS. Like FDA, FSIS also does not have mandatory recall authority and thus relies on private firms to voluntarily withdraw products from commerce when problems arise. However, FSIS’s recall policies and its other enforcement authorities differ from those of FDA in some other ways.<sup>22</sup>

The data in **Table 1** show a spike in the number of products recalled in the first 11 months of FY2009. Most of this increase appears to be linked to two major food safety incidents in 2009. The first was a widespread outbreak of *Salmonella* linked to consumption of contaminated peanut ingredients from a single company’s plants. Peanut butter, peanut paste, and related ingredients from this company, Peanut Corporation of America (PCA), were used by hundreds of other companies in thousands of products that collectively constituted hundreds of the FY2009 recalls. In **Table 1**, increases in the following categories are likely to reflect PCA-related products that were recalled: bakery products, doughs, bakery mixes, icings; nuts and edible seeds; snack food items; chocolate and cocoa products; ice cream and related products; and candy without chocolate. See the subsequent section of this report, “*Salmonella* Outbreak from Peanut Products (2008–2009)”, for more information about this recall.

The second incident—*Salmonella* contamination of pistachio nuts that were also provided to many other companies by a single supplier—led to another 100 or more recalls. Although the number of peanut- and pistachio-related recalls appears to be particularly high, multiple recalls traced to a single common problem source are not surprising given the organization of the U.S. food system, where a single supplier may provide products or ingredients to hundreds of processors and distributors nationwide.

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<sup>21</sup> FDA, “Enforcement Reports,” <http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>.

<sup>22</sup> For more information on meat and poultry recall authority, see CRS Report RL34313, *The USDA’s Authority to Recall Meat and Poultry Products*, by Cynthia Brounger and Geoffrey S. Becker.

**Table I. Recalls of FDA-Regulated Foods by Product Type, FY2005-FY2009**

| Product Type                                        | FY2005     | FY2006     | FY2007     | FY2008     | FY2009      | Totals      | % of all Recalls<br>FY2005-FY2009 |
|-----------------------------------------------------|------------|------------|------------|------------|-------------|-------------|-----------------------------------|
| Bakery products, doughs, bakery mixes, icings       | 73         | 42         | 62         | 85         | 164         | 426         | 13.4%                             |
| Multiple food dinners, gravies, sauces, specialties | 137        | 16         | 38         | 44         | 92          | 327         | 10.3%                             |
| Fishery/seafood products                            | 76         | 56         | 41         | 59         | 37          | 269         | 8.5%                              |
| Nuts and edible seeds                               | 15         | 5          | 24         | 9          | 216         | 269         | 8.5%                              |
| Fruit and fruit products                            | 36         | 25         | 81         | 72         | 23          | 237         | 7.5%                              |
| Snack food items (flour, meal, vegetable base)      | 10         | 7          | 16         | 7          | 183         | 223         | 7.0%                              |
| Chocolate and cocoa products                        | 10         | 19         | 29         | 32         | 127         | 217         | 6.8%                              |
| Vitamins, minerals, proteins, unconventional diet   | 41         | 12         | 52         | 32         | 69          | 206         | 6.5%                              |
| Vegetables and vegetable products                   | 39         | 35         | 25         | 33         | 50          | 182         | 5.7%                              |
| Spices, flavors, salts                              | 33         | 3          | 3          | 11         | 61          | 111         | 3.5%                              |
| Ice cream and related products                      | 12         | 6          | 5          | 15         | 60          | 98          | 3.1%                              |
| Candy without chocolate, candy specialties, gum     | 11         | 7          | 4          | 5          | 69          | 96          | 3.0%                              |
| Prepared salad products                             | 0          | 21         | 8          | 40         | 3           | 72          | 2.3%                              |
| Dietary conventional foods and meal replacements    | 7          | 7          | 2          | 3          | 42          | 61          | 1.9%                              |
| Milk, butter, dried milk products                   | 1          | 4          | 3          | 3          | 46          | 57          | 1.8%                              |
| Cheese and cheese products                          | 5          | 9          | 7          | 11         | 15          | 47          | 1.5%                              |
| Soft drinks and waters                              | 4          | 2          | 13         | 10         | 3           | 32          | 1.0%                              |
| Cereal preparations, breakfast foods                | 1          | 1          | 3          | 10         | 13          | 28          | 0.9%                              |
| Coffee and tea                                      | 5          | 10         | 3          | 1          | 7           | 26          | 0.8%                              |
| Soups                                               | 4          | 5          | 2          | 7          | 8           | 26          | 0.8%                              |
| Dressings and condiments                            | 6          | 4          | 4          | 6          | 4           | 24          | 0.8%                              |
| Gelatin, rennet, pudding mixes, pie fillings        | 1          | 4          | 13         | 0          | 5           | 23          | 0.7%                              |
| Baby (infant and junior) food products              | 3          | 5          | 7          | 4          | 0           | 19          | 0.6%                              |
| Macaroni and noodle products                        | 12         | 3          | 1          | 0          | 1           | 17          | 0.5%                              |
| Vegetable protein products (simulated meats)        | 10         | 2          | 0          | 5          | 0           | 17          | 0.5%                              |
| Whole grains, milled grain products, starch         | 2          | 8          | 5          | 1          | 0           | 16          | 0.5%                              |
| Filled/imitation milk products                      | 1          | 0          | 6          | 1          | 4           | 12          | 0.4%                              |
| Meat, meat products, and poultry                    | 0          | 2          | 0          | 1          | 6           | 9           | 0.3%                              |
| Beverage bases                                      | 0          | 0          | 0          | 0          | 8           | 8           | 0.3%                              |
| Food sweeteners (nutritive)                         | 1          | 0          | 6          | 0          | 0           | 7           | 0.2%                              |
| Eggs and egg products                               | 1          | 2          | 0          | 1          | 2           | 6           | 0.2%                              |
| Other                                               | 0          | 1          | 0          | 2          | 1           | 4           | 0.1%                              |
| <b>TOTAL FOOD RECALLS</b>                           | <b>557</b> | <b>323</b> | <b>463</b> | <b>510</b> | <b>1319</b> | <b>3172</b> | <b>100.0%</b>                     |

**Source:** Prepared by CRS based on data provided by FDA via e-mail, August 31, 2009.

**Notes:** FY2009 is for 11 months (through August). Figures are counts of recall announcements, which can involve more than one recalled product. Includes Class I and Class II recalls. Does not include several hundred recalls that occurred during the same time period involving meat and poultry products regulated by FSIS.

Also of note in **Table 1** is that nine food product types, out of nearly 35 categories logged by the FDA, accounted for approximately 75% of all recalls during the FY2005-2009 period.<sup>23</sup> The leading category (as designated by FDA) was bakery products, doughs, bakery mixes, and icings, which accounted for 13.4% of all recalls. This was followed by the category of multiple food dinners, gravies, sauces, specialties, with 10.3% of all recalls during FY2005-2009. Snack foods and chocolate products, respectively, constituted 7% and 6.8% of all recalls. It may not be surprising that all four of these categories involve diverse product lines that combine many different ingredients. The other five categories among the nine leaders were fishery and seafood products, and nuts and edible seeds, each with 8.5% of the total recalls; fruit and fruit products, 7.5%; vitamins, minerals, proteins, and unconventional dietary items, 6.5%; and vegetables and vegetable products, 5.7%.

## **Selected FDA Food Recalls: Information and Implications**

Following are discussions of three recalls involving FDA-regulated foods. These recalls were selected by CRS for their scope, the interest they generated among the press and the public, and their illustration of several policy issues under debate in pending food safety legislation (H.R. 2749 and S. 510). Following a description of each recall are discussions of selected issues and brief mentions of the relationship to pending legislation, when applicable. Descriptions of selected current authorities in the FFDCRA are provided in the **Appendix**. This CRS report does not provide comprehensive information about the House and Senate food safety bills or the differences between their approaches to the policy issues discussed here. For more detailed information about provisions in pending legislation, see CRS Report R40443, *Food Safety: Selected Issues and Bills in the 111<sup>th</sup> Congress*, by Geoffrey S. Becker.

### ***Salmonella* Outbreak from Peanut Products (2008–2009)<sup>24</sup>**

#### **Overview**

One of the largest food recalls in U.S. history began on January 11, 2009 when King Nut Companies announced it was recalling peanut butter it distributed to food service institutions. The company said *Salmonella* had been found in a five-pound tub of the product, manufactured for the firm by Peanut Corporation of America (PCA). The first PCA recall of its own products was announced on January 13, 2009, and by the end of the month had been extended several times to include all PCA peanuts and peanut products (including meal, butter, paste, and granulated). Over the ensuing months, the number of PCA-related recalls grew to approximately 475, involving more than 200 companies and 3,900 individual human or animal food products.

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<sup>23</sup> Generally, this trend also applies if data for FY2009 are excluded.

<sup>24</sup> Unless otherwise noted, information for this section is derived from CDC, “Investigation Update: Outbreak of *Salmonella* Typhimurium Infections, 2008–2009” (final web update of the investigation), April 29, 2009, <http://www.cdc.gov/salmonella/typhimurium/update.html>; FDA, “Peanut Products Recall,” <http://www.fda.gov/Safety/Recalls/MajorProductRecalls/Peanut/default.htm>; and testimony of Stephen F. Sundlof, Director, FDA Center for Food Safety and Applied Nutrition, hearing of the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Foodborne Illness Outbreak Associated with Salmonella*, 111<sup>th</sup> Cong., 1<sup>st</sup> sess., February 11, 2009.

The recalls stemmed from public health investigations of a *Salmonella* outbreak that eventually would involve at least 714 confirmed cases of illness in 46 states. According to CDC, related illnesses were determined retrospectively to have begun as early as September 2008, and the outbreak may have contributed to nine deaths. (The CDC noted in its final update in April 2009, that the outbreak was “expected to continue at a low level for the next several months since consumers unaware that they have recalled products in their home continue to consume these products, many of which have a long shelf-life.”)

Two months had elapsed between the first recognized cluster of illnesses and the King Nut recall. The CDC on November 10, 2008 had first noticed what it said was a small and highly dispersed multistate cluster of *Salmonella* infections having the same PulseNet “fingerprint” among patients in multiple states. A related cluster of *Salmonella* infections from 17 states was identified by late November. The two investigations were merged in December 2008.

Early efforts to identify the causative food vehicle proved inconclusive; initially chicken was suspected as the source. Peanut butter became the focus after a national case-control study conducted by CDC and public health officials in multiple states in January 2009, which compared foods reported eaten by ill and well persons. Subsequently, the Minnesota Department of Agriculture Laboratory found the outbreak-associated *Salmonella* strain in an opened tub of King Nut peanut butter. At least two other states isolated the same strain in unopened tubs of King Nut peanut butter, which PCA had produced at its plant in Blakely, GA. By mid-January 2009, preliminary studies indicated an association between the *Salmonella* infections and consumption of pre-packaged Austin and Keebler brand peanut butter crackers. The crackers were produced by the Kellogg Company in North Carolina, using peanut paste from PCA.

FDA began an investigation of the Blakely PCA facility on January 9, 2009, which continued until January 27, 2009. This involved sampling and testing, as well as collection of documents deemed necessary to support product recall activities. Environmental sampling (i.e., sampling in the plant rather than the actual product) found two *Salmonella* strains other than the one involved in the outbreak. This investigation also found plant records revealing numerous instances in 2007 and 2008 in which the plant distributed products in commerce even though samples they had submitted to outside testing laboratories had been positive for *Salmonella*. According to FDA, other samples of the product had been resubmitted by the company to other laboratories to obtain a negative result for *Salmonella*.<sup>25</sup>

The PCA recall highlights a number of issues under debate in food safety legislative proposals. Following are examples of these issues.

## **Registration of Food Facilities**

Under current law, FDA requires domestic and foreign food facilities to register once, with no renewal requirement, although they must also report in a timely manner any relevant changes in their registration information.<sup>26</sup> Failure to register is prohibited, but as a practical matter the agency relies on each facility to take that initial step, as well as to report changes. Also, it does

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<sup>25</sup> The FDA “Form 483” inspectional observation reports, which contain these findings, were accessed on September 10, 2009, at <http://www.fda.gov/AboutFDA/CentersOffices/ORR/ORRElectronicReadingRoom/ucm109818.htm>.

<sup>26</sup> This requirement was enacted as a new Sec. 415 of the FFDCRA by P.L. 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

not appear that food from unregistered facilities would be considered adulterated or misbranded, and therefore prohibited from being introduced into interstate commerce. (FDA's authority to deem food adulterated or misbranded, and its relationship to "prohibited acts" and associated penalties, is explained in the **Appendix**.) Exactly how many facilities may fail to register is unknown. In the course of its investigation of PCA, FDA reportedly learned about 20 additional facilities making peanut products without the agency's knowledge.<sup>27</sup> (For example, investigators also found *Salmonella* at a PCA facility in Plainview, TX that opened in 2005. Texas public health officials had not previously inspected the plant because it had not been registered for a state manufacturer's license.)

Both H.R. 2749 and S. 510 contain provisions to expand federal facility registration requirements, in different ways. Among the key differences, H.R. 2749 would require annual registration renewal and would impose registration fees, while S. 510 would require biennial registration renewal and would not impose registration fees. Both bills would authorize processes by which FDA could suspend a facility's registration. Under H.R. 2749, food products from unregistered facilities (including due to suspension) would be deemed misbranded, so their introduction into interstate commerce would be prohibited. S. 510 would prohibit the importation, the offer to import, and the introduction into interstate commerce of food products from facilities whose registration had been suspended.

### **The "Attribution Gap"**

This incident illustrates that the PulseNet genetic fingerprinting system quickly identified a multi-state outbreak caused by a specific strain of *Salmonella*, but that it took about two months of subsequent epidemiologic investigation, including patient interviews, before food vehicles were identified. FDA noted during its investigation that it had not previously considered peanut products to be at high risk of bacterial contamination, but that such products would likely be considered for greater scrutiny in the future.<sup>28</sup>

Food safety officials often lack good information about the kinds of hazards and contaminants that may be present in different kinds of foods. This is particularly true for FDA-regulated foods. Epidemiologic investigation is often needed during outbreak investigation to focus in on suspected food vehicles for testing. This results both in a delay in identifying the contaminated food vehicle (if one is identified at all), and the risk of misattribution, in which investigators erroneously implicate a product based on epidemiologic findings that are later contradicted by laboratory findings.

Economic consequences for producers of the misidentified commodity can be substantial. In addition, a product type may be implicated by the consuming public more broadly than is necessary. (In the case of the peanut products recall, makers of retail peanut butter products reported marked declines in sales of their products, although the products were not found to be

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<sup>27</sup> See for example "FDA Hasn't Intensified Inspections at Peanut Facilities, Despite Illness," *The Washington Post*, April 2, 2009.

<sup>28</sup> According to FDA, "The term 'High Risk Foods' is used to denote foods that may present hazards, which FDA believes, may present a high potential to cause harm from their consumption. The firms that produce high risk foods have priority for inspectional purposes." FDA, Compliance Program Guide 7303.803, "Domestic Food Safety Program," Part II, p. 1, November 2008. <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm071496.htm>.

contaminated and were not included in the recalls.) As a result, those in the food industry are skeptical about the possible effects of expanding FDA's access to industry food testing results, especially if the parameters governing the agency's disclosure of such information are unclear or subject to agency discretion.

Both H.R. 2749 and S. 510 would require, in somewhat differing ways, that the HHS Secretary work to improve systems of foodborne illness surveillance and outbreak investigation.

## **Reporting of Food Safety Problems**

The FDA Amendments Act of 2007 (FDAAA, P.L. 110-85) added a new section to the FFDCa on reporting requirements, with associated penalties for failure to notify the FDA regarding food safety problems. With certain exceptions, the provision requires persons who register a food facility to report to the FDA within 24 hours after they have determined that an article of food is a "reportable food," defined as a food "for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals."<sup>29</sup> The requirements were to have been implemented within one year of enactment, or by September 27, 2008. FDA implemented the provision as the Reportable Food Registry in September 2009.<sup>30</sup> Hence, the requirement was not in effect during the PCA outbreak.

It has been argued that PCA would not have been legally required to inform the FDA of the results of testing that found *Salmonella* even if the Reportable Food Registry had been implemented at the time, because the statute leaves the determination of what is reportable up to the registrant.<sup>31</sup> It is unclear whether the company would have had an obligation to report what it called "presumptive" findings of *Salmonella* if it did not determine that there was a reasonable probability of serious adverse health consequences or death associated with the consumption of its products.

H.R. 2749 would amend the authority for the Reportable Food Registry to explicitly require companies to report test results on reportable food products and facilities to the HHS Secretary. In addition, the bill would require reporting by high-risk facilities of test results on finished products if these tests reveal contaminants posing a risk of severe adverse health consequences or death. The bill also would expand the scope of those who now must report foods (i.e., those who must register facilities) to also include farms where food is produced for sale or distribution in interstate commerce, restaurants and other retailers, and those who would be newly required under the bill to register as importers. S. 510 would not amend current law regarding the reporting requirements established by FDAAA.

## **Access to Records**

The FFDCa (as amended by P.L. 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002) authorizes FDA to require food facilities (but not farms or restaurants) to maintain certain records including immediate prior sources and immediate

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<sup>29</sup> FFDCa § 417; 21 U.S.C. 350f.

<sup>30</sup> FDA, "Reportable Food Registry," <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm>.

<sup>31</sup> See CRS Report R40450, *Penalties Under the Federal Food, Drug, and Cosmetic Act (FFDCa) That May Pertain to Adulterated Peanut Products*, by Vanessa K. Burrows and Brian T. Yeh, where this argument is explained on page 4.

subsequent recipients. FDA also must be able to inspect and copy records, upon written notice, when the Secretary of HHS has “a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.”<sup>32</sup> Some have argued that this authority, which does not appear to provide officials with the ability to access records under other conditions, enabled PCA to hide its problems from regulators. Even where existing authority could be exercised, needed records are not always in an electronic format and/or can be time-consuming and resource-intensive to access during a quickly unfolding investigation. Food safety experts and regulators generally agree that good records, and the ability to access them quickly, are important in traceback investigations in order to quickly determine the cause and source of a problem. But others assert that this must be balanced carefully with industry cost burdens and with commercial privacy concerns.

H.R. 2749 and S. 510 each include provisions, which differ somewhat, that would expand both the HHS Secretary’s access to a facility’s records and the ability to trace products in the event of a foodborne illness outbreak. In general, H.R. 2749 would appear to allow the Secretary to have routine access to records, no longer requiring that there be any food safety problem triggering such access. S. 510 would retain a trigger, but would lower the threshold for it from the current requirement in two ways; the Secretary would no longer need to believe a product to be adulterated, and would be able to access records for products believed to be affected in a similar manner to products believed to be causing serious health consequences. For example, similar products made by other companies, or products using the same ingredients, could be included in the access authority if the products of one company were linked to an outbreak of illness.

## **Frequency of Inspections**

The FFDCA appears to authorize, but not require, FDA to inspect food facilities; therefore, no inspection frequency is specified. The Blakely, GA, PCA plant had never been inspected by FDA, although the agency had a contract with the Georgia Department of Agriculture to conduct inspections. (See “Role of States and Other “Third Party” Inspectors”, below.) This is not surprising, given that FDA inspectors report visiting, out of a reported 136,000 domestic food facilities (of which 44,000 are manufacturers or processors), only about 6,000 of the higher-risk ones each year. Whether one or more routine visits by the FDA might have uncovered safety problems at the Blakely plant is unclear. At issue is the frequency and intensity of inspections that would be effective in deterring unsafe conditions and practices; which facilities, if any, should come under greater scrutiny; and what level of funding would be needed to meet the inspection frequency requirements of various proposals.

Both H.R. 2749 and S. 510 would amend FDA’s current authority regarding food facility inspections, in a number of ways that differ between the bills. Among other things, the bills address the frequency with which FDA would be required to inspect facilities. H.R. 2749 would require FDA to inspect high-risk facilities every 6 to 12 months, lower-risk facilities every 18 months to three years, and facilities that hold food at least every five years. S. 510 would require FDA to inspect high-risk facilities annually, and non-high-risk facilities at least every four years.

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<sup>32</sup> FFDCA, § 414; 21 U.S.C. § 350(c).

## **Role of States and Other “Third Party” Inspectors**

FDA’s resource limitations are one reason the agency relies on states to conduct many safety inspections, as was the case with PCA.<sup>33</sup> Georgia state inspectors had issued numerous citations for unsanitary conditions in the three years prior to the outbreak, but some observers argue that an FDA inspection would have been more rigorous and/or led to sanctions that might have kept unsafe peanut products off the market. The president and CEO of the Kellogg Company told a House panel in early 2009 that food companies commonly rely on third-party private auditors to conduct safety inspections and testing in plants from which they buy ingredients or finished food products. He added that his company utilizes 3,000 ingredients from 1,000 suppliers in its products, that PCA had provided Kellogg with a report of a high safety rating from a widely used industry auditor (AIB International), and that PCA also provided its corporate customers with certificates from private laboratories it had paid to test its products, saying that the products were free of *Salmonella*.<sup>34</sup>

Both H.R. 2749 and S. 510 contain provisions aimed at setting common standards for accrediting third-party auditors and ensuring that they are free of conflicts of interest. Both bills would authorize or require third-party certification of specified entities as a condition to meet certain other requirements in the bills, although the bills vary in how such programs would be implemented.

## **Hazard Prevention Plans**

Unlike USDA-inspected meat and poultry establishments, most FDA-regulated facilities are not required to write and follow plans that analyze potential hazards, implement controls to prevent them, and document compliance. (The agency does require such plans for seafood, low-acid canned foods, and juices, but the programs are not viewed to be as strict as the USDA program.) It has been argued that even when state inspectors visited the Blakely, GA, PCA plant, they were only inspecting conditions on a given day, seeing a “snapshot” that did not necessarily reflect routine conditions. Proponents of hazard prevention planning and documentation argue that regulators could get a better sense of routine conditions if there were records for review documenting a facility’s implementation of and ongoing adherence to a hazard prevention plan.

Although they differ in details, both H.R. 2749 and S. 510 would mandate that facilities develop such plans, provide for FDA to set minimum safety standards for the plans, and allow modifications to mitigate regulatory impacts on small businesses.

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<sup>33</sup> The lack of sufficient funding and staff to meet FDA’s responsibilities was the key theme of a late 2007 report by an FDA scientific advisory panel. See “Paying for Food Safety” in CRS Report R40443, *Food Safety: Selected Issues and Bills in the 111<sup>th</sup> Congress*, by Geoffrey S. Becker, for more information on food safety funding issues.

<sup>34</sup> Testimony and comments of A. D. David Mackay, President and Chief Executive Officer, Kellogg Company, hearing on *The Salmonella Outbreak: The Role of Industry in Protecting the Nation’s Food Supply*, before the House Energy and Commerce Subcommittee on Oversight and Investigations, March 19, 2009.

## **Melamine Contamination of Animal Feeds (2007) and Dairy Products (2008)<sup>35</sup>**

### **Overview**

On March 15, 2007, Menu Foods, a pet food manufacturer, alerted FDA that 13 cats and a dog had died during routine taste trials at the company, reportedly from kidney failure after eating certain cat and dog foods produced at its facilities in Emporia, KS, between December 3, 2006, and March 6, 2007. Consumers and veterinarians in subsequent months reported many more illnesses and deaths of pets potentially associated with a wide variety of pet food brands. As a result, starting on March 16, 2007, more than 150 brands of pet food were voluntarily recalled by a number of companies.

In an investigation, FDA laboratories found melamine and cyanuric acid (a related contaminant linked to the illnesses) in samples of pet food. Cornell University scientists also found melamine in the urine and kidneys of deceased cats that were part of the Menu Foods taste trials. Melamine-tainted ingredients subsequently were found in some hog, chicken, and fish feed. Also, FDA and USDA discovered that some animals that had been fed contaminated feed were processed into food for humans, although they asserted that this presented a very low risk to human health.

Melamine and related compounds have a number of industrial uses, including as an industrial binding agent, flame retardant, and in the manufacture of cooking utensils and plates. The compounds have no approved use as an ingredient in either animal or human food in the United States. If ingested, melamine can crystallize and cause kidney stones and, ultimately, kidney failure, which apparently occurred in the many dog and cat deaths.

FDA traced the melamine to products labeled as wheat gluten and rice protein concentrate imported from China. By February 2008, FDA announced that two Chinese nationals and their businesses, along with a U.S. company and its two top officials, were indicted on federal charges related to importing these products.

Nonetheless, melamine was again found in a number of Chinese-sourced human foods later the same year. On November 12, 2008, FDA issued an import alert for all milk products, milk-derived ingredients, and finished food products containing milk if they are from China. The alert stated that these products could be contaminated by melamine or cyanuric acid. FDA explained that in September 2008, it had become aware of reports that more than 53,000 infants in China had been sickened, including 13,000 who were hospitalized and four who had died, due to consumption of infant formula tainted with melamine.<sup>36</sup> Milk used in the formula was implicated as the source of the melamine, which was added to watered-down bulk milk at collection points in China to inflate the protein content. This “economic adulteration” also apparently was the reason melamine had found its way into pet foods and animal feed ingredients.<sup>37</sup>

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<sup>35</sup> Unless otherwise noted, information for this section is derived from information on the FDA website and material prepared previously by CRS, including CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, by Geoffrey S. Becker.

<sup>36</sup> The Chinese as of early 2009 revised these numbers upward, to an official count of seven infant deaths and 300,000 illnesses due to consumption of melamine-tainted milk products.

<sup>37</sup> The FFDCA states that a food shall be deemed adulterated if, among other things, “any substance has been added (continued...)”

The import alert for milk products was added to existing alerts for Chinese-sourced vegetable protein products and animal foods. Under the alerts, which remain in effect, these products cannot be imported from China unless they have been shown, through independent (third-party) laboratory testing, to be free of melamine or cyanuric acid.<sup>38</sup> An importing firm can request exemption from these requirements—which can greatly slow if not completely stop its imports—by demonstrating that it has adequate safety controls in place and that it has had five consecutive non-violative shipments.<sup>39</sup>

Chinese government sources also indicated that contaminated milk components, especially milk powder, were used in a variety of finished foods dispersed throughout the Chinese food supply chain. More than a dozen countries throughout Asia and Europe, along with Australia and the United States, soon reported that they had detected contamination of milk-derived ingredients and products with melamine or cyanuric acid. These products included candy and beverages found in the United States by the FDA. In other countries, melamine was detected in Chinese-sourced fluid and powdered milk, yogurt, frozen desserts, biscuits, cakes and cookies, soft candy products, chocolates, and beverages.

In a health information advisory issued on September 12, 2008, FDA had stated that there was no known threat of contamination in infant formulas “that have met the requirements to sell such products in the United States.” FDA said that it had been reassured by companies that manufacture infant formula for the U.S. market that they are not importing formula or sourcing milk-based materials from China.<sup>40</sup> Nonetheless, China was exporting dairy proteins and other products to the United States for some time, but at somewhat low levels, according to USDA trade data. China accounted for no more than 2% of all U.S. imports of casein (a dairy protein) from January 2007 through July 2008. According to a U.S. government study, two-thirds of all casein purchases in 2002 were used here for nondairy food products, primarily imitation cheese and coffee creamers.<sup>41</sup>

The melamine contamination incidents highlight a number of issues under debate in food safety legislative proposals. Following are examples of these issues.

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(...continued)

thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.” FFDCA § 402(b)(4); 21 U.S.C. § 342(b)(4). This so-called economic adulteration is intentional, although the intent is typically to defraud, not to cause harm. The melamine incident showed that harm is, however, a possible consequence.

<sup>38</sup> FDA Import Alert #99-30 (for milk products) and other alerts regarding melamine are available at FDA, “Import Alerts,” <http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm>, by searching for alerts involving products imported from China.

<sup>39</sup> FDA announced in early 2009 that it planned to begin testing aquaculture imports from China for melamine. Studies have shown that fish can retain high levels of melamine after receiving feed contaminated with it. Earlier, in December 2008, FSIS said that as a precautionary measure it had begun 12 weeks of sampling to test meat, poultry and dairy products for melamine. No problems were reported.

<sup>40</sup> On November 26, 2008, the Associated Press (AP) reported that the FDA had found traces of melamine in samples of U.S. infant formula. FDA officials reportedly told the AP that the trace amounts had occurred during manufacturing, not intentionally, and posed no health concerns. On November 28, 2008, FDA reported, “To date, FDA tests have found extremely low levels of melamine in one infant formula sample and extremely low levels of cyanuric acid in another. The levels were so low (well below 1 ppm) that they do not pose a health risk to infants.” <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm179005.htm>.

<sup>41</sup> U.S. International Trade Commission, *Conditions of Competition for Milk Protein Products in the U.S. Market* (Investigation No. 332—453), May 2004.

## **Confluence of the Food Supply for Humans and Other Animals**

The melamine incident illustrates the confluence of ingredients (whether legal or illegal) found in both animal and human foods. The initial U.S. investigation had focused on melamine-contaminated pet foods. It was soon found that the same ingredients were used to manufacture feeds for food animals. For example, it was reported that Tyson foods processed hogs for food that had been fed melamine-contaminated feed.<sup>42</sup> As has been reported, melamine in animal feed not only was transferred to and detected in human foods (for example, it was being detected in eggs in China), it also was being added directly to milk used for infant formula and other dairy products intended for human use.

The FFDCA defines “food” as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article,”<sup>43</sup> effectively charging the agency to regulate both human and animal foods with equal diligence. FDA’s authorities over animal food and feeds would not be diminished under the pending food safety bills.

## **Reporting of Food Safety Problems**

Some observers noted that the contaminated pet food incident involved a long delay between when the Menu Foods company first learned of the deaths among its taste-trial animals and when it notified FDA and product recipients of the problem.<sup>44</sup> The incident also showed the weakness in foodborne illness recognition and reporting by veterinarians and others caring for sick dogs and cats, for which there is no national system comparable to that for reporting of foodborne illnesses in humans.

It was in large part as a result of the melamine pet food incident that Congress, in the FDA Amendments Act of 2007 (FDAAA, P.L. 110-85), established the reporting requirements discussed earlier in this report. (See “Reporting of Food Safety Problems” in the earlier section regarding the peanut products recall.) As such, the requirements were not in effect during the pet food incident. However, had the requirements been in effect, the responsible companies might not have been required to report for a number of reasons, such as a firm’s interpretation of the reporting trigger “reasonable probability.”<sup>45</sup>

As discussed earlier, the reporting requirements established by FDAAA define a reportable food as a food “for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans *or animals*.” (Emphasis added.) Consequently, had the reporting provision been in force at the time, the Menu Foods company would not have been freed of the obligation to report solely because the problem involved pet food. The language for the reporting requirement is in keeping with the common definition of “food” in the FFDCA, noted earlier as food for “man or other animals,” and is consistent with the frequent confluence of the two food supplies.

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<sup>42</sup> See for example “U.S. Has Its Own Melamine Problem,” *The Seattle Post-Intelligencer*, November 26, 2008.

<sup>43</sup> FFDCA § 201(f); 21 USC § 321(f).

<sup>44</sup> See for example U.S. Congress, Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, *Hearing to Examine the Current Pet Food Recall*, 110<sup>th</sup> Cong., 1<sup>st</sup> sess., April 12, 2007, S.Hrg. 110-72 (Washington: GPO, 2007).

<sup>45</sup> Portions of this discussion are taken from CRS Report R40450, *Penalties Under the Federal Food, Drug, and Cosmetic Act (FFDCA) That May Pertain to Adulterated Peanut Products*, by Vanessa K. Burrows and Brian T. Yeh.

## **Authority to Recall Products**

The melamine incidents also focused attention on the FDA's authorities and procedures for recalling foods.<sup>46</sup> An August 2009 report by the HHS Office of Inspector General (OIG) found, for example, that the FDA's lack of statutory authority to order a recall (or to assess penalties for recall violations) was only one reason the agency encountered difficulty in ensuring that the contaminated pet food was quickly taken off the market. The OIG also uncovered other contributing factors, including the agency's failure to closely follow its own recall policies or to adequately determine the effectiveness of the recall, which the agency could have accomplished without new authorities. Among the OIG's recommendations were to establish mandatory industry recall requirements including a written strategy, prompt effectiveness checks, and periodic status reports.<sup>47</sup>

Both H.R. 2749 and S. 510 would grant FDA the authority to mandate recalls to address food safety problems. The bills propose somewhat different approaches regarding the triggers allowing or requiring a mandatory recall, the conditions and processes by which a recall mandate may be appealed, requirements regarding notification of recipients of affected products and of the public, and other particulars.

## **Oversight of Import Safety**

The melamine incidents also illustrate the challenges of ensuring the safety of imported foods and food ingredients, which have increased significantly over the past several decades to about 15% of the food consumed here. (For some products such as seafood the proportion is far higher.) In the case of wheat gluten, to which the melamine was added, the United States imports almost all of its supply. A frequently quoted statistic is that FDA only physically inspects or tests samples of approximately 1% of all food import "lines."<sup>48</sup> Even if FDA were given a clear mandate to inspect foreign facilities that export to the United States, there are an estimated 200,000 of them (and likely many more that are not registered), which the FDA now rarely enters.

H.R. 2749 and S. 510 would make a number of changes to FDA's authority regarding imported foods, including requiring U.S. importers of foreign foods to implement good importer practices, essentially a set of standards to ensure the products (and their sources) meet minimum safety requirements; requiring third party certification of certain higher-risk food imports; developing agreements with foreign countries whereby U.S. authorities determine that their safety systems are at least equivalent to the U.S. system, at least for certain designated products; and placing more FDA assets in foreign countries to conduct inspections or assist foreign regulators, particularly for those countries that are the largest source of imports.

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<sup>46</sup> Although FDA publishes guidance for industry on how to carry out a food product recall, the agency's current authority to mandate a food product recall is limited to infant formula. See CRS Report RL34167, *The FDA's Authority to Recall Products*, by Vanessa K. Burrows.

<sup>47</sup> HHS, OIG, *Review of the Food and Drug Administration's Monitoring of Pet Food Recalls*, August 12, 2009, <http://oig.hhs.gov/oas/reports/region1/10701503.asp>. See also Jennifer C. Smith, "Food Safety Groups: FDA Should Act Now on OIG Recommendations," *FDA Week*, August 28, 2009.

<sup>48</sup> A "line" is a portion of an import shipment that is listed separately on that import's entry document. An item in a shipment must have a separate line if its tariff description differs from other items in that shipment. Lines have no standard size, so the 1% is not a measurement of volume. For more information, including a source for this estimate, see CRS Report RL34198, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, by Geoffrey S. Becker.

## ***E. coli* O157:H7 Outbreak from Spinach (2006)<sup>49</sup>**

### **Overview**

In September 2006, CDC began receiving reports of clusters of patients with confirmed cases of *E. coli* O157:H7 infection, linked through the PulseNet system, which would soon be recognized as a single foodborne illness outbreak with more than 200 confirmed illnesses. Twenty-six states reported cases. Three persons died, and more than 100 were hospitalized, nearly a third of them with hemolytic-uremic syndrome (HUS), a life-threatening complication associated with *E. coli* O157:H7 infections.

Epidemiological investigation, based on food history surveys of persons with illness compared with control subjects, pointed to fresh spinach as a possible source of infection. Based on this epidemiological evidence, on September 14, 2006, FDA issued a nationwide alert advising consumers to avoid eating any brand of packaged fresh spinach. The progressing investigation revealed that the illnesses were most often associated with Dole brand baby spinach processed by a facility in San Juan Bautista, CA, owned by Natural Selection Foods (NSF) and doing business as Earthbound Farm. After discussions with FDA and California public health officials, NSF on September 15, 2006 initiated a national recall of all brands of all products they packed that contained spinach and that had “best if used by” dates between August 17 and October 1 of that year. On September 20, 2006, almost a week after FDA’s first consumer advisory was issued, investigators made the first laboratory identification of the outbreak *E. coli* strain in a bag of Dole baby spinach.

Although the outbreak strain of *E. coli* was subsequently found in a number of packaged spinach products, investigators were unable to find the pathogen in samples taken at the processor or to identify how the pathogen could have been introduced there. During product traceback activities using product codes from bags of the implicated spinach, investigators sampled four specific farm fields in Monterey and San Benito Counties, CA. Sampling revealed *E. coli* O157:H7 in each of the four fields, but only one of the fields and its surrounds had the outbreak strain of the pathogen. For this field, the outbreak strain was found in river water, cattle feces, and wild pig feces, the closest a mile from the spinach field. The field was part of a large ranch where the land was primarily used for cattle grazing, with only a small portion used for ready-to-eat crop production. Although investigators found evidence of wild pigs around both the cattle pastures and crop-growing regions of the ranch, no definitive determination was made regarding how the pathogen contaminated the spinach.

The *E. coli* O157:H7 outbreak due to contaminated fresh spinach highlights several issues under debate in food safety legislative proposals. Following are examples of these issues.

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<sup>49</sup> Unless otherwise noted, information for this section is derived from archived CRS Report RL33722, *Food Safety: Federal and State Response to the Spinach E. coli Outbreak*, by Donna V. Porter; CDC, “Multi-State Outbreak of *E. coli* O157:H7 Infections from Spinach,” <http://www.cdc.gov/ecoli/2006/september/>; FDA, “Spinach and *E. coli* Outbreak,” <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm179124.htm>; and a series of reports on the outbreak investigation by the California Department of Health Services and the FDA, <http://www.dhs.ca.gov/fdb/HTML/Food/EnvInvRpt.htm>.

## **Foodborne Illness Surveillance and Outbreak Investigation**

In 2006 testimony before a Senate committee, a CDC official observed:

The [spinach] event illustrates how a large and widespread outbreak can occur, appearing first as small clusters, and then rapidly increasing if a popular commercial product is contaminated. It also illustrates the importance of existing public health networks: the laboratories performing PulseNet “fingerprinting”; the epidemiologists interviewing patients and healthy people and collecting leftover spinach; the multi-disciplinary approach to the investigation; and the close communication and collaboration among local, state, and federal officials. This investigation illustrates what a robust public health system can do and lays down a benchmark for the future. Without question, a rapid and accurate analysis of and response to an outbreak will result in prevention of exposure to contaminated products and will stop further illness and death.<sup>50</sup>

As this statement and the discussion at the beginning of this memorandum suggest, foodborne illness surveillance and outbreak response have progressed significantly in the past decade, but many limitations remain.

Both H.R. 2749 and S. 510 would require, in somewhat different ways, that the HHS Secretary work to improve systems of foodborne illness surveillance and outbreak investigation, information sharing and coordination among public health officials, and incorporation of research findings into foodborne illness prevention and outbreak response activities.

## **Determining and Ranking Risk**

Almost all food safety experts agree on the need to concentrate finite resources on the highest-risk products, processes, and operations, and that the decisions on what these are must be based on authoritative information supported by sound science. However, achieving this goal can be difficult, particularly given the constantly evolving ways in which food is produced, distributed and consumed. For example, public attention through much of the 1990s focused on outbreaks of *E. coli* infections associated with the consumption of undercooked or otherwise mishandled hamburger meat, as the pathogen is sometimes found in animal intestines and feces. However, as public health officials acknowledge, outbreaks associated with the consumption of fresh produce have become more common in recent years. Spinach in particular had not been identified as a source of *E. coli* O157:H7 outbreaks before the 2006 incident, but other leafy greens were implicated in a number of outbreaks, several of them traced to California.<sup>51</sup> Consumers have responded to dietary advice that they consume more fresh produce, and are buying and consuming it in pre-washed and packaged forms that generally were not available 20 years ago. These types of products are most frequently mass-produced in centralized locations and then shipped to many distributors nationally. As a result, contamination on a single farm can result in illnesses across the country. Like the food system itself, assessments of food safety hazards, and how to address them, will have to evolve continually as well.

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<sup>50</sup> Statement of Lonnie J. King, CDC Senior Veterinarian, before the Senate Committee on Health, Education, Labor and Pensions, hearing on “Food Safety: Current Challenges and New Ideas to Safeguard Consumers,” November 15, 2006, hereafter Statement of Lonnie J. King, November 15, 2006.

<sup>51</sup> Ibid.

Determining the food safety risks associated with specific foods or practices underlies a number of provisions in H.R. 2749 and S. 510. For example, both bills would require the HHS Secretary to review relevant health, epidemiologic and other data every two years to identify the most significant foodborne contaminants, and apply such information (in somewhat different ways) when issuing standards, guidance, and/or regulations. Both bills imply that the Secretary would have to determine relative risks before issuing standards for safe produce, setting any required certifications for certain types of imported foods, or ranking which food facilities should be inspected the most frequently. In the case of inspection frequencies, for example, H.R. 2749 states that the Secretary, if altering inspection frequencies, must consider the type of food, the facility's compliance history, and other factors that are, essentially, determinants of risk.

### **On-Farm Food Safety Standards**

Many food safety advocates and public health officials and a number of produce industry leaders agree that produce-related outbreaks are a growing challenge. Many are calling for the development of more stringent FDA-issued and enforced standards for on-farm production where, it is believed, many of the pathogens causing these outbreaks can originate.

Nonetheless, not everyone is convinced that mandatory standards are necessary. A number of opponents support the generally voluntary approach taken by FDA through the issuance of nonbinding guidance documents for producers and others who handle fresh produce. They may also support recent produce industry efforts to self-impose standards through binding marketing arrangements, which they believe may generate more enthusiastic support and participation among producers than would the imposition of a government-enforced approach. Under the Agricultural Marketing Act of 1946,<sup>52</sup> USDA's Agricultural Marketing Service (AMS) has implemented a wide range of these voluntary testing and process verification programs. Funded by industry user fees, these services use independent, third-party audits and other standardized procedures to help producers certify that products meet buyer specifications. Although some of these programs can be, and are, designed to ensure the safety of certain food commodities from a public health standpoint, they are not regulatory by nature. Rather, they are intended to facilitate commercial agreements in the trade or to provide consumers with more information about their prospective purchases.<sup>53</sup> AMS recently proposed a marketing agreement for leafy green vegetables.<sup>54</sup>

Moreover, it is argued that producers should not be required to take on new responsibilities until more is known about exactly what types of interventions are needed and effective. Others have argued that while there may be gaps in the knowledge base, enough is known to address some of the more obvious practices, such as basic worker sanitation, the separation of animals and their waste from produce fields, use of clean water, and so forth. As noted above, the definitive cause of the contamination of spinach, leading to the nationwide outbreak, was never established. As a CDC official observed, "As this and other outbreaks indicate, research should focus on tracing the

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<sup>52</sup> 7 U.S.C. § 1621 note.

<sup>53</sup> These marketing arrangements are described in more detail in CRS Report RL34612, *Food Safety on the Farm: Federal Programs and Selected Proposals*, by Geoffrey S. Becker.

<sup>54</sup> USDA, Agricultural Marketing Service, "Leafy Green Vegetables Handled in the United States; Hearing on Proposed Marketing Agreement No. 970," *74 Federal Register* 45565-45574, September 3, 2009.

specific pathways that connect fields of leafy green vegetables with potential animal reservoirs of *E. coli* and other disease-causing microbes.<sup>55</sup>

H.R. 2749 and S. 510 would require, in somewhat different ways, that the HHS Secretary (i.e., FDA) develop safety standards for raw fruits and vegetables, primarily those for which the Secretary (FDA) has determined there is a need to reduce the risk of serious illness or death.<sup>56</sup>

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<sup>55</sup> Statement of Lonnie J. King, November 15, 2006.

<sup>56</sup> For more information on the specific proposals in each bill, see CRS Report RL34612, *Food Safety on the Farm: Federal Programs and Selected Proposals*, by Geoffrey S. Becker.

## Appendix. Key Definitions and Authorities in the FFDC Act Regarding Food<sup>57</sup>

**Adulteration:** The FFDC Act has multiple definitions of adulteration that differ, depending on whether they apply to food, drugs, or other products. With respect to the general safety of food, adulteration is defined in FFDC Act § 402(a) [21 USC § 342(a)], as follows:

A food shall be deemed to be adulterated—

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; [or]

(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 406; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a); or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 409; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512; or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.

Additional subsections of § 402 define several additional specific types of adulteration, or adulteration of specific types of foods. *FFDC Act § 301(a) - (c) provide that introducing adulterated food into commerce, adulterating food that is in commerce, or the receipt and delivery of adulterated food in commerce is prohibited.* See the definition of “Prohibited Acts,” below.

**Facility:** FFDC Act § 415(b) [21 USC § 350d(b)] defines a food facility as “any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or

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<sup>57</sup> A version of the FFDC Act is available on FDA’s website at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFFDCAct/default.htm>.

served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in section 123.3(k) of title 21, Code of Federal Regulations).”

The term “facility” is only defined for the purposes of FFDCA § 415 and not for the entirety of the FFDCA. FFDCA § 415(a)(1) states that “The Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary. To be registered—(A) for a domestic facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary; and (B) for a foreign facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary and shall include with the registration the name of the United States agent for the facility.”

**Food:** FFDCA § 201(f) [21 USC § 321(f)] defines food as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” *Unless a provision in law regarding food limits its applicability to one or the other, it would apply equally to both human foods, and to animal foods and feeds.*

**Misbranding:** FFDCA § 403 [21 USC § 343] defines a number of conditions under which a food would be deemed to be misbranded, beginning with a broad provision in paragraph (a) saying that a food is deemed misbranded if its label “is false or misleading in any particular, ... ” Similar to the definition of adulteration, numerous specific types of misbranding are also defined. *FFDCA § 301(a) - (c) provide that introducing misbranded food into commerce, misbranding food that is in commerce, or the receipt and delivery of misbranded food in commerce is prohibited. See the definition of “Prohibited Acts,” below.*

**Person:** FFDCA § 201(e) [21 USC § 321(e)] defines “person” to include an individual, partnership, corporation, and association.

**Prohibited Acts:** Acts that are stated to be prohibited are added to a list of “prohibited acts” in FFDCA § 301 [21 USC § 331]. As described earlier, along with many other listed prohibited acts in FFDCA § 301, *paragraphs (a) through (c) provide that introducing adulterated or misbranded food into commerce; adulterating or misbranding food that is in commerce; or the receipt and delivery of adulterated or misbranded food in commerce is prohibited.* Pursuant to FFDCA § 303 [21 USC § 333], in general, any person who violates a provision of FFDCA § 301 may be subject to civil or criminal penalties, including imprisonment, fines, or both. The criminal penalties provisions provided for in the FFDCA are adjusted by 18 U.S.C. §§ 3559 and 3571. Additional sanctions may apply for drugs or devices, and certain exceptions may be made, including for the misbranding of foods.

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