



**Testimony of Caroline Smith DeWaal  
Director of Food Safety  
Center for Science in the Public Interest  
before the  
Senate Committee on Health, Education, Labor, and Pensions<sup>1</sup>**

**Washington, DC  
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Good morning Mr. Chairman, Ranking Member Enzi and Members of the Committee. My name is Caroline Smith DeWaal. I am the director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 950,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

CSPI works closely with the Make Our Food Safe Coalition that supports passage of food safety reform legislation in Congress. The coalition includes groups formed by and representing the victims of food borne illness, like Safe Tables Our Priority and the Center for Foodborne Illness Research and Prevention; broad-based consumer organizations, like Consumers Union and the National Consumers League; public health groups like the American Public Health Association and the Trust for America's Health; and it is coordinated by The Pew Charitable Trusts and the Consumer Federation of America.

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<sup>1</sup> The following members of the Safe Food Coalition and the MakeOurFoodSafe.org Campaign join in supporting this testimony: Center for Foodborne Illness Research and Prevention, Consumer Federation of America, Consumers Union, Food and Water Watch, National Consumers League, S.T.O.P. – Safe Tables Our Priority, and Trust for America's Health.

## **Now is the Time to Repair our Food Safety System.**

Thank you for asking me here today to discuss S. 510, the FDA Food Safety Modernization Act. The American public cannot wait any longer for solutions to address a seriously broken food safety system. Successive outbreaks caused by numerous healthy foods like spinach, lettuce, tomatoes, peppers, alfalfa sprouts, and even such treats as ice cream and cookie dough<sup>2</sup> have demonstrated that our hundred-year-old legal foundation and outdated strategies are inadequate to protect our citizens.

Reform of the food safety system is overdue. CDC estimates that foodborne diseases cause 76 million illnesses, 325,000 hospitalizations and 5,000 deaths annually. Economists believe that these illnesses pose a huge burden to society, with estimates for emergency room visits, hospitalizations, and lost work ranging from 40 billion to well over 100 billion dollars annually.<sup>3,4</sup> Even if these numbers were cut in half, they are still too high. These are illnesses and deaths that are largely preventable.

Foodborne illnesses are most severe for the elderly, the very young, pregnant women, and immunocompromised people, and some illnesses lead to chronic medical conditions. Unfortunately, some outbreaks cause consumers to stop buying healthy foods, a fact demonstrated by depressed spinach sales after the 2006 outbreak.<sup>5</sup> Consumer confidence in the safety of food has declined in recent years due to the steady parade of outbreaks.<sup>6</sup>

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<sup>2</sup> Details of these outbreaks are listed on the Center for Science in the Public Interest *Outbreaks & Recalls* website at [http://www.cspinet.org/foodsafety/outbreak\\_report.html](http://www.cspinet.org/foodsafety/outbreak_report.html).

<sup>3</sup> Trust for America's Health, *Fixing Food Safety: Supply from Farm-to-Fork*, Apr 30, 2008, at <http://healthyamericans.org/reports/foodsafety08/FoodSafety08.pdf>.

<sup>4</sup> Roberts, Tanya (2007) "The Economic Costs of Long-term Sequellae of Selected Foodborne Pathogens," Invited Speech, International Association of Food Protection, Orlando, Florida.

<sup>5</sup> Elizabeth Weise & Julie Schmit, *Spinach Recall: 5 Faces. 5 Agonizing Deaths. 1 Year Later.*, USA TODAY, Sept. 20, 2007, available at [http://www.usatoday.com/money/industries/food/2007-09-20-spinach-main\\_N.htm](http://www.usatoday.com/money/industries/food/2007-09-20-spinach-main_N.htm).

<sup>6</sup> Thompson West Research, *Consumers Worried About Product Safety*, Dec. 18, 2007, at <http://west.thomson.com/news/releases/productsafety.aspx>.

Outbreaks are the result of an antiquated legal system that ties the hands of FDA when seeking food safety information from plants and limits the effectiveness of the agency to enforce the laws. The FDA operates under a number of laws that are 50 to 100 years old: the Federal Food and Drug Act of 1906,<sup>7</sup> which focused on dangerous chemical preservatives; the Federal Food, Drug, and Cosmetic Act of 1938,<sup>8</sup> which addressed economic adulteration of food and provided authority to set food standards and inspect factories; and the Public Health Service Act of 1944, which gave the agency authority to prevent communicable diseases transmitted in food.<sup>9</sup> Food additive and pesticides laws gave FDA additional authorities in the 1950s.<sup>10</sup> None of these was designed to address microbial hazards or emerging technologies.

Within this legal structure, the agency has developed regulations to cope with the need for new oversight for modern hazards. In the 1990s, the agency adopted regulations that put seafood and juice industries under mandatory Hazard Analysis and Critical Control Point (HACCP) programs. After a long hiatus, the agency recently adopted a new regulation covering egg safety at the production level.<sup>11</sup> But the agency's approach of developing regulations food-by-food is proving brutally inefficient to protect the public. By the time one food is covered, the next problem has already emerged.

### **Consequences of Broken Food Safety System Fall on the Consumer**

Those who really pay the price for the antiquated legal and regulatory system are the consumers who must rely on it daily. Let me tell you about one consumer, a member of Safe Tables Our Priority. Michael Thomas was 50 years old when he became a victim of tainted

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<sup>7</sup> Federal Food and Drugs Act of 1906, Pub. L. 59-384 § 34 Stat. 768 (1906).

<sup>8</sup> Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 301.

<sup>9</sup> Public Health Service Act 42 U.S.C. § 264.

<sup>10</sup> E.g. Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 409, "The Delaney Clause".

<sup>11</sup> Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation; Final Rule. 74 Fed. Reg. 33,030 (July 9, 2009).

peanut butter. Michael loved peanut butter and had a spotless health history. A father of four and grandfather of 20, Michael was known for his love of peanut butter. It was so well known that his own father called to warn him when he heard media reports about a peanut butter recall. Unfortunately, Michael had already eaten some of the *Salmonella*-contaminated product—and the consequences were severe, leading to reactive arthritis.

Michael spent weeks in and out of emergency rooms, suffering from dehydration, stomach pains, and high blood pressure. His right eye hemorrhaged. He was treated for nervous system damage, and damage to his heart, eyes, intestines, shoulders, and arms. This previously healthy man spent over five months bedridden. And because he lacked insurance at the time, he spent thousands on medical bills and lost his house due to the financial toll of his illness.

But Michael was lucky enough to survive, only to be shocked and outraged when it happened all over again this year. Michael was a victim of the 2007 tainted peanut butter outbreak, but when he heard of the 2009 outbreak—which sickened hundreds and killed at least nine people—he couldn't believe it. In a 2009 letter describing his experience with foodborne illness, Michael says, "I did take some comfort in the belief after it happened to me that the system was fixed and would not happen to any more families...but here we are once again, literally right down the road from that very same plant I was poisoned from, with exactly the same situation, but even more widespread than it was before."

Just as Michael's 2007 experience was revisited in 2009, there is no question it will happen again—this year or next, from this product or another. Consumers will continue to be unwilling victims, until the system is fixed.

## The Public is Ready for Congress to Address Food Safety

The stories of outbreaks and recalls over the last few years are tragic, and they have had a huge impact on consumer confidence in the safety of the food supply. But there is good news too. This is an area where the public understands that government plays a vital role in protecting them and their families.

In a poll on Americans' Attitudes on Food Safety,<sup>12</sup> commissioned by The Pew Charitable Trusts and conducted by Hart Research/Public Opinion Strategies, nine out of 10 American voters support the federal government adopting new safety measures,<sup>13</sup> including the following individual measures:

- 92% support requiring **foreign countries** that export to the U.S. to certify that their food safety systems are as strong as ours;
- 94% support requiring **tracing systems** that enable the FDA to trace food back to its source
- 91% support annual or semi-annual government **inspections of facilities** that process food that is at a high risk of contamination, including 75 percent who strongly favor this.
- 92% support requiring food companies to **test for contamination and report** results to the government
- 90% support requiring **produce growers to meet standards** for water quality, manure use, and worker sanitation
- 89% support giving the FDA authority to issue **mandatory food recalls**

Since 2007, Congress has conducted 28 oversight and legislative hearings on food safety. These hearings often discussed the painstaking investigations by members of Congress and their staff of diverse outbreaks such as spinach tainted with *E. coli* O157:H7, peanut butter

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<sup>12</sup> These findings are derived from a nationwide survey of 1,005 registered voters, conducted June 29 through July 3, 2009, by Hart Research Associates (D) and Public Opinion Strategies (R) on behalf of the Pew Charitable Trusts and the Produce Safety Project. Respondents were reached by telephone through a random-digit dial method of sampling. The results of the poll are statistically representative of the opinions of voters across the country, and carry a margin of error of  $\pm 3.1$  percentage points for the full sample, and higher margins of error for subgroups of the sample.

<sup>13</sup> According to the polling firms, support crossed gender, age, economic, and even partisan lines—96% of Democrats, 88% of independents, and 83% of Republicans said they supported the need for food safety legislation.

contaminated with *Salmonella*, and pet food adulterated with melamine. In every case, the hearings revealed flaws both in the food manufacturers' processes and in the Food and Drug Administration's oversight. With evidence of both unintentional and intentional contamination leading to large-scale outbreaks, it is little wonder the Government Accountability Office has highlighted the inadequate state of our food regulatory system and placed food safety in its high risk category three years in a row.<sup>14</sup>

The evidence that FDA reform is needed has been made crystal clear in Congressional hearings, victims' stories, and voter polling. In addition, I think you will hear today that there is widespread consensus among a broad range of stakeholders that the time for passing this reform is now.

### **Safety Must Be Built Into the Food Supply System.**

The heart of any effective reform effort lies in prevention, not reaction. Congress should require every food processor regulated by FDA to have a food safety plan detailing that it has analyzed its operations, identified potential hazards, and is taking steps to minimize or prevent contamination. These hazard analysis and preventive control plans are already required for all meat and poultry plants,<sup>15</sup> and such plans should be a prerequisite for all food processors that want to sell food in the U.S.

Prevention is our first line of defense when it comes to food safety. The Senate legislation establishes the industry's fundamental responsibility for ensuring food safety and provides a foundation for government inspections. However, the history of these programs where they have been implemented by FDA, such as in the seafood area, demonstrates that Congress must also give FDA the authority and funding to enforce compliance through regular

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<sup>14</sup> Gov. Acct. Off., *High Risk Update: Revamping Federal Oversight of Food Safety*, Rep. No. GAO-09-271, Jan. 2009.

<sup>15</sup> Hazard Analysis and Critical Control Point (HACCP) Systems, 9 C.F.R. § 417 (2009).

inspections and access to company records.

Additionally, FDA needs the authority to set performance standards for the most hazardous pathogens and to require food processors to meet those standards. The standards are used to ensure that food is produced in a manner that limits the likelihood of contamination by pathogens, chemicals, or physical hazards. Most importantly, performance standards set a level-playing field for the industry. Companies know in advance what standards will be enforced for their industry and products.

With mandatory food-safety planning combined with performance standards, the government can focus on more effective government oversight through frequent inspections, with analysis of records and laboratory test results.

S. 510, the FDA Food Safety Modernization Act, contains these essential elements. But a few elements should be strengthened to ensure that FDA can prevent many future outbreaks and address the other hazards that can impact so many consumers.

### **Effective Federal Oversight Is Needed to Ensure Compliance.**

S. 510 is built on the framework of existing HACCP regulations adopted by the Food and Drug Administration. While this foundation mandates the actions that the industry itself is responsible for, it lacks similar specifics in describing the government's oversight and responsibilities. On behalf of the Make Our Food Safe Coalition, we would like to propose three changes that would strengthen S. 510:

#### **Recommendation 1: *Risk-Based Inspection and Inspection Frequency***

We believe it is critical to establish categories of risk to ensure that FDA will establish meaningful schedules of inspection. To be adequate, the statutory provisions on federal inspection should do three things:

- Establish a minimum of three risk categories;
- Set inspection frequencies based on these categories, with the minimum frequency of once every 6 to 12 months for high-risk facilities; and
- Prohibit FDA from using certification by a private entity as a factor in setting the frequency of federal inspection for a domestic facility.

**Recommendation 2:** *Testing and Reporting Requirements, Affirmative Reporting of Positive Test Results*

In order for a system based on preventive controls to be truly effective, food companies must be required to test for the types of contamination most common in their (or similar) products to determine whether their systems are actually working. We recommend that you strengthen the testing and reporting requirements of S. 510 by adopting requirements that:

- A facility conduct testing as a verification step in its preventive control plan; and
- Facilities report promptly to FDA any positive results from its testing program.

**Recommendation 3:** *Imports and Imported Produce*

Imports of FDA-regulated foods present many difficulties for the agency, simply because of the current number of suppliers and the volume of imports. We generally support the language in S. 510 on imports, which provides for certification of food facilities that import food products. The language should be strengthened by:

- Requiring government-to-government certification for high-risk foods;
- Clarifying that FDA has the principle responsibility for accrediting the import programs of foreign governments;
- Clarifying that private accrediting bodies must be under strict FDA oversight, and FDA should be notified of all actions they take regarding the agents they accredit; and
- Adding language requiring FDA to set up a system for determining whether standards for imported produce are at least equal to standards applicable to such commodities produced in the United States.

Finally, I would like to highlight that FDA and state inspectors are also hampered in conducting inspections by restricted access to plant records that could help identify problems



before they erupt into an outbreak. As the Committee may recall, FDA had to invoke the Bioterrorism Act to obtain records from Peanut Corporation of America of 12 tests that were positive for *Salmonella* in the year and a half leading up to the outbreak.<sup>16</sup> Food companies can refuse to disclose records to inspectors unless the FDA has a reasonable belief the food is adulterated, presents a risk of serious adverse health consequences or death, and the inspector presents a written demand.<sup>17</sup> We saw this same situation play out in the 2007 Peter Pan peanut butter outbreak where, had inspectors been given access to test records, they would have been alerted to the plant's test results for *Salmonella*.<sup>18</sup> To fix this, the law needs to be changed so that inspectors can access records that may allow them to prevent outbreaks. Meanwhile, the ability to access all food safety documentation during inspections is an essential tool to verify that control systems are present, maintained and operating properly.

### **S. 510, The FDA Food Safety Modernization Act**

Both the House-passed bill and the one under consideration in this Committee share many similarities: processors must re-register periodically, implement food safety plans, meet performance standards, and administer programs to verify the food they import complies with U.S. law. In addition, FDA must conduct risk-based inspections and can require high-risk imported food to be certified as complying with U.S. law. Lastly, FDA can order a recall of food likely to cause serious illness or death.

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<sup>16</sup> See, *The Salmonella Outbreak: The Continued Failure to Protect the Food Supply*: Hearing before the House Subcommittee on Oversight and Investigations, 111<sup>th</sup> Cong. (2009) (October 6, 2008 email from Stewart Parnell to Sammy Lightsey).

<sup>17</sup> 21 U.S.C. § 374(a)(1)(B); FDA, Regulatory Procedures Manual 2008, § 10-4-3.

<sup>18</sup> Two years before the outbreak, the plant manager refused an oral request from FDA inspectors to see company records of a positive *Salmonella* test telling them they would need a written request. Marion Burros, *Who's Watching What We Eat*, N.Y. Times, May 16, 2007, at <http://www.nytimes.com/2007/05/16/dining/16fda.html>.

There are numerous points of agreement when it comes to food safety reform packages being considered in Congress. We were very pleased to see the bipartisan consensus that emerged for H.R. 2749, which passed the House on July 30, 2009, with a vote of 283-142. We believe that food safety is truly a bi-partisan measure that can be passed this year. It is strongly supported by voters all over the country. And truly, as Mike Thomas's story reminds us, if we don't act now, the next outbreak may be even more serious.

### **Conclusion**

Now is the time for Congress to fundamentally reform our food safety system. The year is fast drawing to a close, but enactment by the end of this year should be the goal. Two years ago, Congress expressed its commitment to adopt a modern regulatory oversight program at FDA and fund it adequately to fulfill its mission.<sup>19</sup> Congress has increased the FDA food budget by 50 percent in that period, which lays the ground work for this legislation. Bipartisan legislation has already passed the House of Representatives.<sup>20</sup> And that spirit of compromise has also infected the groups you see before you who have formed make-shift alliances to help deliver the message that reform is urgently needed. It is rare to see the level of consensus reflected among such diverse consumer and industry organizations on the need to fix our national food safety system. The public debate has defined the issues and we have a consensus for action. Congress can, with simple changes, take action this year to make food safer for American consumers. I urge you to act. There is no reason to delay.

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<sup>19</sup> Food and Drug Administration Amendments Act of 2007, Pub. L. 110-85 § 1005, 121 Stat. 823, (2007).

<sup>20</sup> H.R. 2749, the Food Safety Enhancement Act, passed July 30, 2009, by a vote of 283-142.