



**Going Beyond FDA's Food Protection Plan:
Modernizing U.S. Food Safety Law**

**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**

**Washington, DC
December 4, 2007**

My name is Caroline Smith DeWaal, and 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 900,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

Thank you for the opportunity to address this committee and comment on the Food and Drug Administration's (FDA) Food Protection Plan. Before getting to FDA's new plan, I would like to provide some background. In the 2002 Public Health Security and Bioterrorism Preparedness and Response Act ("Bioterrorism Act"), Congress passed new authorities designed to increase FDA's ability to prevent intentionally contaminated food from reaching U.S. consumers. These new authorities included mandatory registration of domestic and import food facilities, prior notice for import food shipments, enhanced recordkeeping and administrative detention. Despite mounting evidence at that time that FDA's legal authorities were inadequate to address the threat, Congress chose in 2002 to apply a targeted approach, adding these few additional authorities, instead of tackling the more difficult job of enhancing FDA's overall mission to ensure food safety and food protection. Unfortunately, that approach failed to prevent the many food outbreaks and recalls of the last year, including one involving a toxic substance intentionally applied to a food ingredient regulated by FDA.

Since September 2006, nationwide outbreaks of foodborne illnesses and subsequent recalls have exposed glaring holes in the safety net guarding U.S. consumers from contaminated

food. Spinach contaminated with a deadly strain of *E. coli*; peanut butter with *Salmonella*; canned chili with *Clostridium botulinum*; pet food with toxic chemicals – these were not isolated events. FDA-regulated foods are responsible for many outbreaks each year as documented in CSPI’s Outbreak Alert database.¹ But each of these tragedies in 2006-2007 demonstrated a distinct gap in FDA’s system for regulating the food supply that underscores the need for farm-to-table reform.

Today FDA’s ability to protect the food supply is being questioned by consumers and Congress alike. Overall consumer confidence in FDA has plummeted. A Harris Poll has documented that those who thought FDA was doing an “excellent” or “good” job went from 61 percent in 2000 to 36 percent in 2006. In addition, over the last year, consumers’ overall confidence in the safety of foods has fallen dramatically. The Food Marketing Institute reported a 16 percent decline in consumer confidence in the safety of food they purchase at grocery stores, according to its annual survey. *USA Today* reported in July that 83 percent of shoppers were concerned about food from China, and 61 percent about food from Mexico.² And based on many supermarket conversations, these concerns have affected purchasing behavior as well.

This loss of consumer confidence has palpable effects on food suppliers as well. After the spinach scare of 2006, spinach farmers reported losing \$350 million, and had still not recovered when a second leafy green outbreak occurred in August of this year.³ But these outbreaks were entirely predictable – and preventable – if FDA had the resources to look beyond the next crisis and the authorities to compel the food industry to take steps to prevent problems before they occur.

CSPI applauds FDA for putting forward its Food Protection Plan and for finally signaling to Congress the need to give FDA additional authorities. But Congress should recognize that this plan outlines only a few incremental steps that are not sufficient to prevent the food safety problems consumers experienced just last year. Reforming our outdated food safety laws could have tremendous public health benefits, as each year 76 million Americans experience foodborne

¹ CENTER FOR SCIENCE IN THE PUBLIC INTEREST, *Outbreak Alert! Database*, 2007 at <http://www.cspinet.org/foodsafety/outbreak/pathogen.php>.

² Elizabeth Weise, *Buying Only U.S. Food is a Tall Order*, USA TODAY, July 10, 2007, available at http://www.usatoday.com/news/health/2007-07-10-american-goods_N.htm.

³ 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.

illnesses that hospitalize 325,000 and result in 5,000 deaths.⁴ It is time for Congress to institute real solutions – not stop-gap measures that will fall short in a few years time.

FDA’s Food Protection Plan calls for several authorities that CSPI has long advocated, like mandatory recalls, and proposes changes to address shortcomings in the implementation of the Bioterrorism Act’s food facility registration program. But its shortcomings are numerous:

- It is not enough to ask for new authority to mandate recalls but fail to ask for authority to require traceability standards and impose civil penalties so that recalls are effective.
- It is not enough to require strict food security plans but fail to require food safety plans that would protect the public from the inadvertent contamination of food that annually sickens and kills so many Americans.
- It is not enough to identify a need for the full life-cycle approach to food safety but fail to ask for authority to implement programs on the farm or in the country of origin.

In sum, the Food Protection Plan underscores the need for reform, but Congress must take stronger action if it is to ensure the safety of the food supply and protect Americans from preventable illnesses and deaths.

100-Year-Old Food Safety Laws Create Confusion and Inefficiency

Today, our federal food safety system functions under two distinct statutory frameworks: one in operation at the U.S. Department of Agriculture (USDA) and another at FDA. USDA has responsibility for the safety of meat, poultry and certain egg products, covering about 20 percent of the food supply. Its statute provides for carcass-by-carcass inspection in all meat and poultry slaughter plants and daily inspection in meat and poultry processing plants using government-funded inspectors. The Federal Food, Drug and Cosmetic Act and the Public Health Service Act give FDA responsibility for regulating the safety of the remaining 80 percent of the food supply, but the statutes are reactive, giving the agency authority to act principally when food is found to be “adulterated” or “misbranded”. Plants that produce products regulated by both agencies see a stark disparity between the programs, as when a frozen pepperoni pizza processing line regulated by USDA is subject to daily inspections, while a frozen cheese pizza line in the same plant is inspected by FDA about once every 10 years.

⁴ Paul S. Mead, et al., *Food-Related Illness and Death in the United States*, 5 Emerging Infection Diseases 607, Sept.-Oct. 1999.

The disparity carries over into the programs that are responsible for ensuring the safety of imported foods – a key concern driving delivery of FDA’s Food Protection Plan. While USDA has a fairly intensive program for ensuring the safety of imported meat and poultry products, FDA’s program is anything but comprehensive. Unlike USDA, FDA does not evaluate national programs to determine equivalence or visit foreign countries to verify compliance with food safety procedures.⁵ Instead the agency relies on border inspections, but has the capacity to inspect only one percent of food at the U.S. border. Although imports of FDA-regulated foods have more than doubled in the last 7 years—from 4 million shipments in 2000 to approximately 9 million shipments in 2006—the rate of inspections has remained woefully low.⁶ Of these 9 million shipments, only 0.2 percent were analyzed in a laboratory as part of its inspection process.⁷

As with domestic food safety programs, import programs sometimes overlap, but resources are not shared. For example, USDA and FDA inspect food imports at 18 ports, but they do not share inspection resources at these locations. In fact, according to the Government Accountability Office, some USDA-approved import inspection facilities store FDA-regulated products, and although USDA maintains a daily presence at these facilities, FDA products can languish at the port waiting for FDA inspectors.⁸ When it comes to authority and resources, FDA remains the neglected stepchild of our food safety system.

Emerging Hazards and Intentional Threats to the Food Supply

One of the most-widely discussed food safety catastrophes this year began in March when pet food manufacturers recalled more than 100 brands of cat and dog food after receiving complaints of cats and dogs developing sudden kidney failure from eating pet food. For weeks after, new brands were pulled from shelves as processors tracked the tainted ingredient – wheat gluten.

⁵ FDA’s Import Program System Information website does not delineate an audit system for imported product and directs users to cross-reference the U.S. Customs Office for additional requirements. FDA OFFICE OF REG. AFFAIRS, IMPORT PROGRAM SYSTEM INFORMATION, (Sept. 21, 2004), at http://www.fda.gov/ora/import/ora_import_system.html.

⁶ Alexei Barrionuevo, *Food Imports Often Escape Scrutiny*, N.Y. TIMES, May 1, 2007, at <http://www.nytimes.com/2007/05/01/business/01food.html>.

⁷ *Id.*

⁸ GEN. ACCT. OFF. REP. NO. GAO-07-449T, *Federal Oversight of Food Safety: High-Risk Designation Can Bring Needed Attention to Fragmented System*, (Statement of David M. Walker, Comptroller General of the United States) (Feb. 8, 2007).

FDA investigations revealed that the pet foods that sickened so many pets were contaminated with melamine and cyanuric acid, two industrial chemicals. These toxins were found in wheat gluten imported from China and used in many pet food and animal feed products manufactured in the U.S. Chinese wheat gluten producers are believed to have intentionally contaminated the product with melamine to give the appearance of increased protein content. According to an investigation by *The New York Times*, cutting grain products with melamine to fool protein tests is common practice among producers in China, yet the contaminated wheat gluten passed across our borders without being found or stopped by FDA.⁹

Tracing the pet food back through its supply chain, FDA eventually identified the Chinese company that shipped the adulterated wheat gluten into the U.S. According to reports, however, the company was little more than two rooms adjoining a warehouse in China.¹⁰ Clearly the registration of importers, even coupled with prior notice, was not sufficient to prevent the importation of this purposefully contaminated product. FDA needs much stronger authorities.

In 2004, Tommy G. Thompson, the former Secretary of Health and Human Services, expressed deep concern, saying that he was “shocked” that terrorists had not struck the nation’s food supply “because it is so easy to do,” and that he “worried every single night” about food safety.¹¹ We share his concern, and hope that Congress treats the pet food contamination incident earlier this year as a “wake up call”. It could have been much worse if instead of melamine, a more potent chemical was applied to a food ingredient widely used in the human food supply. The U.S. should adopt modern systems that prevent or promote early discovery of such problems, rather than relying on FDA’s limited ability to respond to food safety emergencies.

Shortfalls in Resources and Authorities at FDA

Imports are not the only food safety challenge facing FDA. Outbreaks linked to fresh spinach and lettuce and processed peanut butter and canned chili in 2006 and 2007 are just the latest symptom of an agency that is overwhelmed by responsibility, but lacking the staff and

⁹ David Barboza & Alexei Barrionuevo, *Filler in Animal Feed Is Open Secret in China*, N.Y. TIMES, April 30, 2007, at <http://www.nytimes.com/2007/04/30/business/worldbusiness/30food.html>.

¹⁰ David Barboza, *Clues to Pet Food Recall Traced to Chinese City*, INT’L HERALD TRIBUNE, April 11, 2007, at <http://www.iht.com/articles/2007/04/11/asia/gluten.php>.

¹¹ *Tommy Thompson Resigns From HHS*, THE WASH. POST, Dec. 3, 2004.

resources to function effectively. Current FDA funding shortfalls have reached a critical level and budget cuts have left the agency with fewer inspectors, even as the workload continues to increase. Since 1972, domestic inspections conducted by FDA declined 81 percent.¹² Just since 2003, the number of FDA field staff dropped by 12 percent, and between 2003 and 2006, there was a 47 percent drop in federal inspections.¹³ These declines in inspectors and inspections can be traced to an ongoing funding shortfall in the food safety program estimated in the hundreds of millions of dollars.¹⁴

The Peter Pan peanut butter outbreak and recall shows the consequences of this gap in inspection capacity and the inadequacy of FDA's Food Protection Plan. Last winter, the Centers for Disease Control and Prevention determined that *Salmonella*-contaminated peanut butter was responsible for causing illness in over 600 people in 47 states. This outbreak could likely have been prevented with a more robust inspection program at FDA.

In 2005, FDA inspected the ConAgra facility where the peanut butter was produced because of complaints about conditions at the plant. The inspectors learned from plant managers that the company had destroyed some product due to "microbial problems" in 2004, but the managers did not disclose the problem was *Salmonella* contamination.¹⁵ When FDA's oral request for documents from the plant went unanswered, FDA did not follow up until 2007 when the agency conducted inspections of the plant during the outbreak investigation.¹⁶ This is unacceptable both to Congress and to consumers.

The legal structure of the current system tilts federal food safety resources toward USDA. While USDA regulates the 20 percent of the food supply known to cause 27 percent of attributed outbreaks, its food safety appropriations are *double* that given to FDA.¹⁷ This is due primarily to the legal requirements that the meat and poultry products regulated by USDA must be approved

¹² HOUSE COMM. ON GOV'T REFORM, *Fact Sheet: Weaknesses in FDA's Food Safety System*, (October 30, 2006), 2, available at <http://oversight.house.gov/documents/20061101115143-67937.pdf>.

¹³ Andrew Bridges & Seth Borenstein, *AP Investigation: Food Safety Inspections Lanquish*, Associated Press, February 29, 2007, available at <http://abcnews.go.com/Health/wireStory?id=2905819>.

¹⁴ Last year, one FDA budget official estimated a funding shortfall in the food safety program of \$135 million, which he described as equivalent to a 24 percent budget cut. HOUSE COMM. ON GOV'T REFORM, *supra* at 2.

¹⁵ The plant manager stated the FDA would have to submit a written request if it wanted more information on the incident. See, Joseph S. Enoch, *FDA Failed to Follow Up on 2004 Peanut Butter Contamination*, ConsumerAffairs.com, Oct. 19, 2007, at http://www.consumeraffairs.com/news04/2007/10/peanut_butter_recall17.html.

¹⁶ 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>.

¹⁷ CENTER FOR SCIENCE IN THE PUBLIC INTEREST, *Outbreak Alert!*, Dec. 2006, 2, at http://www.cspinet.org/foodsafety/outbreak_alert.pdf.

before sale, while foods regulated by FDA do not require pre-market approval.¹⁸ USDA employs more than 7,600¹⁹ inspectors who are stationed in 6,282 establishments to carry out its inspection mandate.²⁰ FDA, meanwhile, has 1,842 inspectors who are spread over 136,000 domestic food processors and warehouses.²¹

Unfortunately, the Food Protection Plan does not address these problems, and could in fact add new ones. The requirement that foods only come under process control programs if they have been linked to “repeated, serious adverse health consequences or death” could potentially block needed action on foods like peanut butter and spinach, where outbreaks are rare. By putting the burden on FDA rather than the food industry, this standard could stop FDA from taking necessary action to address problems by requiring preventive control systems.

In summary, FDA’s Food Protection Plan falls short of the transformative reforms that are needed to remedy the shortfalls in resources and antiquated authorities at FDA. Congress should implement comprehensive reform of FDA’s statutory mandate in order to better protect the American public.²²

CSPI’s Principles for a Modernizing FDA’s Food Safety Mandate

The timing is excellent to put fundamental reform of FDA’s food program on the agenda of Congress over the next 12 months. A Sense of Congress included in the recently enacted Food and Drug Administration Amendments Act states Congress’s readiness to adopt a modern regulatory oversight program and fund it adequately to fulfill its mission. Additionally, the emergence of coalitions of traditionally estranged consumer and industry organizations, like the Coalition for a Stronger FDA and the FDA Alliance, gives Congress a unique opportunity to appeal to many constituencies as it rebuilds the agency.

¹⁸ The differences between USDA and FDA regulatory authorities are detailed in “Overseeing the U.S. Food Supply: Steps Should be Taken to Reduce Overlapping Inspections and Activities,” GEN ACCT OFF REP. NO. GAO-05-549T (May 17, 2005).

¹⁹ USDA, *Farm Bill Forum Comment Summary and Background: Food Safety*, (undated) at http://www.usda.gov/documents/FOOD_SAFETY.doc

²⁰ USDA, *FY2008 Budget Summary and Annual Performance Plan*, 59, available at <http://www.obpa.usda.gov/budsum/fy08budsum.pdf>.

²¹ FDA, Food Protection Plan, (Nov. 2007) 6.

²² While food safety problems have garnered the most attention, many other parts of the agency’s responsibilities are not getting adequate attention – issues such as obesity, the safety of dietary supplements, and appropriate oversight of new technologies. In cases like the Castleberry botulism recall, inspectors are literally taken off other tasks to meet emergency needs.

While the Food Protection Plan clearly signals the Administration’s willingness to make changes in order to restore consumer confidence, Congress must enact more comprehensive reform than those contained in the Food Protection Plan. CSPI’s recently released white paper, “Building a Modern Food Safety System: For FDA Regulated Foods,” lays out the principles of comprehensive food safety reform. To meet the need for prevention, intervention and response, Congress should require food safety process control programs for all food processors that meet performance standards established by FDA. Regular risk-based inspections by FDA would ensure that food facilities are following good safety practices and meeting the safety standards set by the FDA. Under CSPI’s principles, the registration program for importers would be joined to a certification process to ensure foreign producers are meeting the same standards as their U.S. competitors. A strong research component is also necessary, as is a requirement that FDA build a strong on-farm safety program. Finally, CSPI urges Congress to give FDA five new enforcement authorities: (1) mandatory recall, (2) effective and mandatory traceability, (3) detention authority, (4) civil and criminal penalties, and (5) whistleblower protection.

The legislative authority sought by FDA is too narrowly targeted to encompass the principles that are critically important to comprehensive food safety reform. The heart of any effective reform effort lies in prevention, not response. Congress should require every food plant regulated by FDA to have food safety plans, like HACCP²³, that demonstrate the companies are aware of potential hazards and are taking steps to avoid them. This is already a requirement for all meat and poultry plants, and it should be a prerequisite for all food processors that want to sell food in the U.S. This provides the basis for establishing the industry’s fundamental responsibility for ensuring food safety.

The gaps in the FDA’s Food Protection Plan are both numerous and dangerous: it puts the burden on FDA to determine risk before requiring process control programs; it does not provide adequate inspection authority; it fails to require certifications of foreign facilities; it exempts farms; and it does not provide for traceability. The plan would do little to address the problems with spinach, lettuce, peanut butter, or even melamine-tainted wheat gluten. It simply does not go far enough to address the very real concerns with the food supply that U.S. consumers have faced over the last 18 months.

²³ Hazard Analysis and Critical Control Points.

U.S. food safety laws are more than a century old and were not designed to deal with modern issues such as escalating imports, bioterrorism, or tainted produce. The heightened awareness of terrorism over recent years has demonstrated the need for enhanced national security, and the recent outbreaks serve as a reminder that much more must be done to protect the food supply. Congress needs to enact a food safety program that puts public health at the forefront of food safety in America. On behalf of the 900,000 consumers represented by CSPI, I urge Congress to go beyond the incremental changes proposed in the Food Protection Plan and adopt comprehensive reforms to modernize food safety laws in the U.S.