

**Statement of Caroline Smith DeWaal
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**At the House Committee on Government Reform
Subcommittee on Civil Service and Agency Organization
“A System Rued: Inspecting Food.”**

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My name is Caroline Smith DeWaal, and I am director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 850,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants. We accept no government or industry funding.

This past November, imported produce was implicated in one of the nation’s most devastating outbreaks of foodborne illness. This provided more proof that the system to protect consumers from unsafe food is falling far short of its goal. Green onions imported from Mexico were the cause of this fatal Hepatitis A outbreak in Pennsylvania. What started out as a regular trip to a chain restaurant resulted in crippling illnesses for hundreds of individuals. At least 555 people fell ill and 3 people died from consuming the tainted produce. The outbreak sickened not only hundreds of Pennsylvania residents, but also restaurant employees and residents of six other states.¹ Beginning in August 2003, green onions imported from *the same farm* in Mexico had caused outbreaks in three other states.² These earlier illnesses provided a crucial warning that was ignored until it was too late.

¹ Dato V et al, *Hepatitis A Outbreak Associated with Green Onions at a Restaurant- Monaca, Pennsylvania, 2003*. Morbidity Mortality Weekly Report, November 28, 2003 /52(47);1155-1157

² Boodman S, *Raw Menace: Major Hepatitis A Outbreak Tied to Green Onions*. The Washington Post, Tuesday November 25, 2003.

The Food and Drug Administration (FDA) is responsible for ensuring the safety of many imported foods, such as the onions implicated in this Hepatitis outbreak. At a hearing of the House Appropriation Committee's Subcommittee on Agriculture on March 11, 2004, Lester Crawford, acting commissioner for the FDA, stated: "The FDA is overwhelmed by imports, which have increased fivefold since 1994." Due to FDA's lack of resources, a mere one percent of imported food is inspected. Crawford went on to state, "It's difficult for us, and we are missing the mark, but we pledge to do better."

Since 1999, CSPI has been compiling outbreak data from a variety of sources, organizing it by food group, and publishing it in a booklet called *Outbreak Alert!* In CSPI's *Outbreak Alert! 2004* database, which summarizes 3,529 outbreaks, FDA-regulated foods, like seafood, produce, and eggs, were the largest contributor to foodborne illness outbreaks.³ That is, 67% of all outbreaks in the database were caused by foods regulated by the FDA; the remaining 26% were caused by foods regulated by the USDA (meat and poultry products); and 7% were caused by foods regulated in part by both agencies. However, when examining the corresponding proportion of the federal budget allocated to these agencies, the paradox is apparent. The FY 2004 budget summaries show the U.S. Department of Agriculture (USDA) is allocated \$899 million to keep the food supply safe, more than twice as much food-related funding as the FDA, at \$413 million.

In 1997, the huge resource imbalance between FDA and USDA led CSPI and other consumer organizations to call on Congress to create a single independent food-safety agency, so that the government could apply resources more equitably to all the foods that pose the greatest risk to the public. The National Academy of Sciences (NAS) published a report in 1998 that called for the consolidation of food-safety responsibility under a single statute, with a

³*Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net.* Center for Science in the Public Interest. Updated and Revised March, 2004. CSPI, Washington, D.C.

single budget and a single leader. This report, entitled *Ensuring Safe Food From Production to Consumption*, concluded that the “current fragmented regulatory structure is not well equipped to meet the current challenges.”⁴ CSPI has documented many gaps and weaknesses that support the NAS’s conclusion:

Under the current structure, food-safety problems that start on the farm often fall through the cracks of agency jurisdiction. No federal agency today is responsible for overseeing food safety at the production level. While the Animal and Plant Health Inspection Service (APHIS) can quarantine farms and ranches due to disease outbreaks affecting the animals or plants, as they did recently to control BSE, the agency has no authority when it comes to human infections that originate in live animals or plants. At FDA, lettuce and other fresh vegetables and fruits are essentially unregulated for safety. While FDA published guidelines for farmers, these guidelines are legally unenforceable.⁵ The use of animal manure on food crops is also not controlled, even though USDA, FDA, and EPA have jurisdiction over various farm practices. These are just some of the problems that fall through the cracks of the current system.

Under the current structure, multiple agencies fail to address glaring public health problems. Eggs are regulated both by FDA and USDA, but neither agency has developed an effective containment strategy to prevent the spread of *Salmonella* Enteritidis (SE) in shell eggs.

⁴Institute of Medicine, National Research Council, *Ensuring Safe Food From Production to Consumption*. (Washington, DC: National Academy Press, 1998), p. 12 [hereinafter cited as *Ensuring Safe Food*].

⁵US Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Guidance for Industry. Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*. (Washington, DC: US Food and Drug Administration, October, 1998).

It took an agreement among three cabinet level officials to announce the Egg Safety Action Plan in 1999, but since then, little has changed. No agency has published regulations to require on-farm controls that could largely eliminated the *Salmonella* that infects eggs, sickening hundreds of thousands of consumers each year, and causing over 300 deaths. Today, nearly twenty years since SE inside eggs was first identified as a public-health concern by the CDC, consumers still await an effective strategy to eradicate SE in shell eggs.

Under the current structure, the same food-processing plant may get two entirely different food-safety inspections. The classic example is a processing plant that produces both pepperoni and cheese frozen pizzas. The pepperoni line will get daily visits from a USDA inspector to check on conditions in the plant as workers slice the pepperoni and apply it to the pizza.⁶ The cheese line will be subject to FDA inspection on average once every five to ten years.⁷ The minimal difference in hazard between the processing of cheese and pepperoni pizzas is not enough to justify the vast disparity in government inspection.

Under the current structure, some food-processing plants may get no federal food-safety inspections. Due to resource constraints, FDA has turned huge portions of its regulatory responsibility over to the states. The best example of this is in the area of shellfish production, where FDA relies totally on state inspectors. But FDA is now using state inspectors to conduct

⁶ Michael R. Taylor, "Preparing America's Food Safety System for the Twenty-First Century -- Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?" *Food and Drug Law Journal*, Vol. 52, No. 1 (1997), p. 18 [hereinafter cited as *Preparing for the Twenty-First Century*].

⁷ US Department of Agriculture, US Department of Health and Human Services, US Environmental Protection Agency, *Food Safety From Farm to Table: A National Food Safety Initiative. A Report to the President.*

many different food inspections. A June 2000 Inspector General investigation documented that states conduct a growing percentage of the food-firm inspections under a variety of agreements with FDA. Over a three-year period, states conducted 60% of the food firm inspections that FDA recorded in its database. Increasingly, states are inspecting high-risk food firms.⁸

Under the current structure, quality inspections sometimes occur more frequently than safety inspections. There are many shell-egg plants that receive regular inspections from U.S. government inspectors, but the inspections are for quality, not for safety. All plants shipping eggs between states are visited by the Agricultural Marketing Service (AMS) each quarter and many plants also participate in a voluntary grading program where they receive continuous inspection by AMS.⁹ Under the voluntary AMS program, government inspectors help ensure that each egg has a yolk of the proper diameter, but nothing in the program checks for the presence of SE.¹⁰ Nor does FDA, the agency charged with food-safety oversight of shell eggs, check for SE during its infrequent inspections.¹¹

May 1997, p. 37 [hereinafter cited as *Food Safety from Farm to Table*], *Preparing for the Twenty-First Century*, p. 18.

⁸ Department of Health and Human Services, Office of the Inspector General, *FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability*. June 2000.

⁹ 7 C.F.R. § 59.28; Poultry Division, AMS, USDA, “Quality Eggs for Volume Buyers.” Brochure No. AMS-627, August, 1996.

¹⁰ *Ibid.*

¹¹ Elizabeth Dahl and Caroline Smith DeWaal, *Scrambled Eggs: How a Broken Food Safety System Let Contaminated Eggs Become a National Food Poisoning Epidemic*. (Washington, DC: Center for Science in the Public Interest, 1997), p. 11 [hereinafter cited as *Scrambled Eggs*].

Under the current structure, HACCP is a different system at FDA and at USDA. The Hazard Analysis and Critical Control Points (HACCP) systems for seafood, meat, and poultry share almost as many differences as similarities. For example, both frequent inspection and laboratory verification of product samples are essential to give the government appropriate oversight over plants utilizing HACCP. Otherwise, the HACCP program is little more than an industry honor system. While USDA requires both on-site inspection by government inspectors and two levels of laboratory verification of meat and poultry products, FDA requires neither for seafood products. FDA inspects seafood plants once every one to five years and made laboratory testing for HACCP verification optional for seafood processors.¹² Because of these weaknesses, FDA's seafood program has been a dismal failure, with fewer than 50% of seafood firms using comprehensive HACCP plans, and seafood continues to be a major contributor to foodborne illness outbreaks.¹³

Multiple agencies may prolong the time it takes to bring the benefits of new technologies to the consumer. Everyone is optimistic that new technologies will help solve many of the food-safety problems that exist today. However, several agencies are involved with the approval of new technologies, especially for meat and poultry products. We have seen examples where technologies designed by government scientists at one agency then spent years being considered for approval at another.¹⁴ For several other technologies, like trisodium

¹² Caroline Smith DeWaal, "Delivering on HACCP's Promise to Improve Food Safety: A Comparison of Three HACCP Regulations." *Food and Drug Law Journal*, Vol. 52, No. 3 (1997), pp. 331-335.

¹³ "FDA's Evaluation of the Seafood HACCP Program For Fiscal Years 2000/200." available at <http://www.cfsan.fda.gov/~comm/seaeval2.html#evaluation>.

¹⁴ Telephone conversation with John DeLoach, MS BioScience, Inc., Dundee, IL, April 1998.

phosphate for poultry and irradiation for poultry and red meat, FDA approval was the last step that precedes a rulemaking process at USDA. Both approvals are necessary before products can be used in meat and poultry plants. This bifurcated process can take years to complete.¹⁵

Because of a complicated system of reviews by multiple agencies, new technologies can completely escape government review for food safety. For genetically modified foods, approval responsibilities for new plant varieties is done by three different federal agencies. USDA's APHIS has a mandatory review process to protect against plant diseases and pests that might emerge from genetically modified seed stock. The Environmental Protection Agency (EPA) has a mandatory review process for genetically modified seeds with pesticidal qualities. FDA, meanwhile, utilizes a voluntary review process to address food-safety problems that might emerge from genetically modified foods. Under this system, FDA relies on an industry honor system that allows the biotech companies to decide whether and when they should consult with FDA prior to putting a product on the market.

Coordination with the state agencies that handle food safety is a nightmare. State laboratories that analyze food samples for chemical or microbial contamination have complained about the lack of uniform testing methods and about inconsistent reporting requirements for the federal agencies, including USDA, FDA, CDC, and EPA. This means that state labs may have to run multiple tests on a single food simply to meet the requirements of the various federal agencies. In addition, they waste valuable staff time transmitting the same

¹⁵ Rosanna Mentzer Morrison, Jean Buzby, and C. T. Jordan Lin, "Irradiating Ground Beef to Enhance Food Safety." *Food Review*, Vol. 20, No. 1 (1997), p. 34; US Department of Health and Human Services, Food and Drug Administration, "Irradiation in the Production, Processing, and Handling of Food; Final Rules." *Federal Register*, Vol. 62, No. 232 (1997), pp. 64102-64121; Memo from Robert Sindt, Burditt & Radzius, to Caroline

information to different agencies, which each have their own customized system for reporting lab results. The lack of common data requirements for foods discourages many states from sharing their laboratory data with the federal agencies.¹⁶

In addition, the federal government has not established standard laboratory certification standards for state laboratories that test food for contamination. This means that in many outbreak and recall situations, a state lab test result will have to be repeated by a federal agency. This can result in a several-day delay in recalling food or informing the public, with a continuing risk to public health.

Under the current structure, imported products are treated differently at FDA and USDA. Imported meat and poultry products are subject to a two-stage approval process by USDA. First, the exporting country's meat or poultry inspection safety system must be approved by USDA; then, the individual plant must be inspected by USDA before it can ship meat to the U.S. Even then, the meat is subject to random verification checks at the border. FDA meanwhile only has the authority to inspect food at the border and, even then, only has the staff to check one to two percent of import shipments.¹⁷ FDA can't send inspectors to foreign

Smith DeWaal, April 1, 1998; Meeting with Robert Sindt, Burditt & Radzius, James Elfstrum, Rhodia, and Jerry Carosella, Consultant, Regulatory Microbiology, Washington, D.C., April 3, 1998.

¹⁶“National Integrated Food Safety System. An Update on Work Group Activities: Laboratory Operations and Coordination,” session at the 103rd Annual Educational Conference of the Association of Food and Drug Officials, June 5-9, 1999, San Antonio, TX; Association of Food and Drug Officials 1999 Resolution Number 99-09 Concerning National Standards for Computer-based Laboratory, Inspection and Surveillance Data Standards, June 7, 1999.

¹⁷Lester Crawford, Acting Commissioner of the FDA, Testimony before the House Appropriation Committee's Subcommittee on Agriculture on March 11, 2004. Also, US General Accounting Office, “Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable,” (Washington, DC: US General Accounting Office, April 1998), p. 5 [hereinafter cited as *Safety of Imported Foods*].

countries except by invitation, even when they are checking the source of food involved in an outbreak in the U.S.

In a global marketplace, our system is falling behind the safety systems in use in other countries. Numerous countries have already created unified food safety agencies to cover the entire food supply. The effort was driven in Europe by the BSE crisis. Unified agencies now exist in at least three European countries, England, Netherlands, and Germany. Other countries, like New Zealand, have moved to a single food agency to address gaps and weaknesses in the food safety programs. The Food Safety Authority of New Zealand, FSANZ, took over government programs largely designed to certify companies that wanted to export food to other countries. With the unified agency, they are now focusing additional resources on improving the safety and quality of domestic foods.

These gaps and inefficiencies demonstrate that until we address the problems inherent in the food-safety regulatory structure, we will not be able to achieve a risk-based food-safety system. CSPI stands in good company in its call for fundamental reorganization. Over the last twenty years, many expert panels from the White House and Congress to the National Academy of Sciences and the General Accounting Office have all reached similar conclusions. More recently, a major industry trade association, the Food Marketing Institute (FMI), and Consumers Union, the publisher of *Consumer Reports* magazine, have called for a single food-safety agency.

It is clearly not news to anyone that statutes designed when the Model T was being driven are not suited to address modern issues, like mad cow disease, genetically modified

foods, or even common foodborne bacteria. But make no mistake, if a terrorist were to strike the U.S. food supply, consumer confidence in the government's fractured food safety programs would plummet as fast as confidence in airport security did following September 11, 2001. Even Dr. John Bailar, the chairman of the NAS committee calling for a more unified food safety structure, said that "When bioterrorism is added to the mix, the case for prompt and sweeping change becomes compelling. While additional tinkering with the details of our food safety system might be helpful, the consolidation of responsibilities, authorities, and resources for food safety into a single high-level agency is critical."¹⁸ Today, a unified agency operating under a modern food safety statute is truly an issue of national security.

¹⁸ Bailar III, John C, "Ensuring Safe Food: An Organizational Perspective." Layne S, et al., *Fire Power in the Lab*,. National Academy of Sciences, 2001, p. 141.