Rising Imports, Bioterrorism, and the Food Supply

Caroline Smith DeWaal
Rising Imports, Bioterrorism, and the Food Supply

CAROLINE SMITH DEWAAL, J.D.*

In November 2003, imported produce was implicated in one of the United States’ most devastating outbreaks of foodborne illness. The outbreak was nearly as large as the 1993 Jack in the Box outbreak, and killed almost as many people. This time, instead of fast food hamburgers, 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 Pittsburg-area Chi-Chi’s restaurant resulted in crippling illnesses for hundreds of individuals and further proof that the U.S. system to protect consumers from unsafe food is falling far short of its goal. At least 555 people fell ill and three people died from consuming the tainted produce.1 The outbreak sickened not only hundreds of Pennsylvania residents, but also restaurant employees and residents of six other states. Beginning in August 2003, green onions imported from the same farm in Mexico had caused outbreaks in three other states.2 While these earlier illnesses provided a crucial warning, it was ignored until it was too late to prevent the Pennsylvania outbreak.

The Hepatitis A outbreak also provided a reminder that while meat and poultry products frequently are suspected in a food poisoning outbreak, more often outbreaks are linked to produce, seafood, and other foods that are subject to minimal regulation under current law. This bias carries over into the federal statutes and funding of food safety programs. The U.S. Department of Agriculture (USDA) is responsible for regulating meat and poultry products and enjoys the lion’s share of the federal food safety budget in order to conduct daily inspections at meat and poultry processing plants. The Food and Drug Administration (FDA) in the Department of Health and Human Services (DHHS) regulates all other food (with the exception of certain egg products), but without the same commitment of resources. The fiscal year (FY) 2004 budget summaries show the USDA is allocated more than twice as much food-safety funding as FDA; $899 million to the USDA’s food inspection program versus $413 million to FDA’s.3

Since 1999, the Center for Science in the Public Interest (CSPI) has been compiling outbreak data from a variety of sources and publishing it in a booklet called Outbreak Alert! CSPI’s Outbreak Alert! 2004 database, which summarizes 3,500 outbreaks, demonstrates the problems inherent in the bifurcated U.S. system of food regulation. FDA-regulated foods (e.g., seafood, produce, eggs and dairy) together were linked to about two-thirds of all outbreaks where both the food and the hazard were identified, but FDA’s food program receives only one-third of the federal budget.4

* Ms. Smith DeWaal is Director of Food Safety at the Center for Science in the Public Interest (CSPI), Washington, D.C. and co-author of Is Our Food Safe? A Consumer Guide to Protecting Your Health and the Environment (Three Rivers Press 2002). Stephen Watkins contributed to this article.

When the budget allocations are considered together with the outbreak data, the paradox is apparent. The solution, however, is not simply to give FDA more money. In fact, the problem is much more complex and the solution will require both innovation and motivation in order to be achieved. The food safety laws that govern both the USDA and FDA are nearly 100 years old. These statutes need to be combined and rewritten to provide a new basis for food regulation, one that fully incorporates both the risk and the science of today’s food industry.

When the Pure Food and Drug Act and the Meat Inspection Act originally were passed in 1906, the food industry largely was local. Today, the food on America’s tables comes from all over the world. Innovations in transportation and refrigeration have revolutionized the food industry, leading to more centralized food production nationally and greater reliance on imports, both of which pose risks.

Studies of food poisoning outbreaks clearly illustrate that a single contamination point in a production chain can cause a food safety problem that results in thousands of illnesses. For example, in 1994, Schwann’s Ice Cream contaminated with Salmonella sickened over 200,000 people, according to estimates, in forty-one states; the contamination point was a single tanker truck. An unusual outbreak linked to breakfast cereal in 1998 was linked to over 200 confirmed cases in twenty-three states; the contamination point was a single room in a production plant where vitamins were sprayed onto the cooked cereal. And numerous outbreaks involving fresh produce, including the most recent Pennsylvania outbreak traced to raw green onions, demonstrate that a single farm anywhere in the world can be a contamination point.

Centralized food production and increasing imports also increase the risks of bioterrorism. Examples of outbreaks caused by intentional contamination illustrate the ease with which food can be used as a terrorist target. In 1984, members of the Rajneeshee cult injected Salmonella into items in a salad bar in Oregon, causing 751 illnesses. Their purpose was to influence an election. In 1996, a disgruntled employee intentionally contaminated pastries in a Texas hospital, causing twelve cases of Shigella dysenteria. More recently, in 2002, a Chinese baker spiked the flour of a competitor with rat poison, killing thirty-eight people. This was followed by a 2003 episode when 200 pounds of meat at a Michigan grocery store were poisoned intentionally with an insecticide, sickening over 100 people. On a larger scale, events like these could be devastating to national and world markets.

Worldwide, food is an obvious target for both intentional contamination and food scares. During the 2003 World Cup race in New Zealand, The Dominion Post, the newspaper of that nation’s capital, ran the front-page headline, “Cyanide Threat to Food, Warning: Watch What You Eat.” Letters addressed to the British and Australian High Commissions and the U.S. Embassy in Wellington, purportedly from a group calling

---

6 Personal conversation between Caroline Smith DeWaal, CSPI, and Centers for Disease Control and Prevention (CDC) personnel during the outbreak investigation (1998).
itself “September 11,” said they were “fighting for the rights of free Islamic people” and warned that 25kg of cyanide had been stockpiled for use in the event of an invasion of Iraq. A national security alert set off a flurry of discussion about the effects of such a threat—the economic damage it might do to the multimillion-dollar America’s Cup restaurant and hotel business, destabilization of Arab relations, and, were the cyanide spread through the food supply, the number of deaths it could cause.\textsuperscript{11}

The international globalization of the food industry makes New Zealand’s problem emblematic of what every nation faces. The extent to which New Zealand authorities—or authorities in Mexico, the Philippines, the United States, etc.—are prepared to detect and prevent such threats has an effect on all nations. Porous U.S. borders allow over ninety-eight percent of the estimated five million shipments of food (excluding meat and poultry) to be imported free of inspection.

When disasters strike—deliberate or accidental—the public quickly loses confidence in the ability of government agencies to offer protection. In the United States, consumer confidence has been shaken following large outbreaks, massive meat recalls, and even when genetically-altered StarLink animal-feed corn was found in the human food supply (a problem detected by a public interest group rather than through a formal governmental surveillance program).\textsuperscript{12}

\section*{Calls for Reform}

Since the early 1990s, the Government Accountability Office (GAO—formerly the General Accounting Office) has documented the weaknesses in the food safety infrastructure and repeatedly called for the creation of a single food safety agency.\textsuperscript{13} In 1997, CSPI and other consumer organizations called on President Clinton to create a single independent food-safety agency so that the government could apply resources to create a risk-based inspection and regulatory system.\textsuperscript{14} In 1998, the National Academy of Sciences (NAS) published a report that called for the consolidation of food-safety responsibility under a single statute, with a single budget, and a single leader. This report, entitled \textit{Ensuring Safe Food From Production to Consumption}, concluded that the “current fragmented regulatory structure is not well equipped to meet the current challenges.”\textsuperscript{15}

Recent events have made these calls for reform even more urgent. After September 11, 2001, it became clear that the problems evident in the food safety regulatory system would become acute if food was used in an attack against the United States. 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 11th. Dr. John Bailar, chairman of the 1998 NAS committee, writing three years later, said that

\begin{itemize}
  \item \textsuperscript{15} INST. OF MEDICINE, NAT’L RESEARCH COUNCIL, \textit{ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION} 12 (Nat’l Acad. Press 1998) [hereinafter ENSURING SAFE FOOD].
\end{itemize}
The 1998 NAS committee developed its recommendation based on the hazards that are already with us, paying almost no attention to bioterrorism. 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.16

Today, a unified agency operating under a modern food safety statute is truly an issue of national security. In 2001, in one of his first appearances before Congress after the September 11th attack on the World Trade Center, DHHS Secretary Tommy Thompson said, “Am I satisfied with the [food] inspections we are doing? No, I am more fearful about this than anything else.”17 A year later, Secretary Thompson reiterated his concerns when he told Congress, “This is one area in which we must be more vigilant, because disease-causing agents can easily be spread through the food supply.”18

It is rare to hear such an honest appraisal from a public official in Washington, D.C., but September 11th certainly illustrated the need for an assessment of our vulnerabilities. Whether contamination is intentional or unintentional, improving government programs will protect consumers and ensure consumer confidence in the food supply. Unfortunately, since Secretary Thompson’s 2001 testimony, the situation at FDA has not improved significantly. Although Congress increased the funding for FDA’s food safety program in 2001 by nearly $100 million, the money was just a drop in the bucket.

While FDA is responsible for ensuring the safety of many imported foods, such as the onions implicated in the Hepatitis A outbreak, the agency’s ability to regulate effectively is being challenged continually by increasing numbers of imports. At a hearing of the House Appropriation Committee’s Subcommittee on Agriculture in March 2004, Acting FDA Commissioner Lester Crawford stated, “The FDA is overwhelmed by imports, which have increased five-fold since 1994.” Due to FDA’s lack of resources, just over one percent of imported food is inspected and FDA has inspectors stationed at only ninety of the 360 ports of entry.19 Crawford went on to state, “It is difficult for us, and we are missing the mark, but we pledge to do better.”20

Following September 11th, Congress created a single homeland security agency to manage terrorist threats,21 but when it comes to food safety, numerous agencies are still involved. According to the NAS, approximately twelve agencies enforce thirty-five laws.22 Further, states play a huge role in conducting food plant inspections for FDA, and federal reliance on the states has been growing.

So how could bioterrorism affect our food supply? According to the World Health Organization (WHO), the threats to food span from the farm all the way to the table—from agricultural production and harvesting, through processing, transport, and distri-

---

19 Personal conversation between Caroline Smith DeWaal, CSPI, and Lou Carson, Deputy Director of the Food Safety Initiative, FDA (Oct. 2003).
20 Statement of Lester M. Crawford, D.V.M., Ph.D., Acting Commissioner of Food and Drugs, Hearing of the House Appropriations Committee’s Subcommittee on Agriculture (Mar. 11, 2003).
22 ENSURING SAFE FOOD, supra note 15, at 3, 7.
The WHO says, “Many foods are produced at centralized facilities and distributed over large geographical areas, often globally. Contamination at such facilities can affect large number of people, and exposure may be widespread before the outbreak is detected.”\footnote{24} These facts have been amply demonstrated by recent outbreaks.

The WHO recommends prompt identification and rapid removal of contaminated products. Under the current U.S. system, however, the Centers for Disease Control and Prevention (CDC) cannot identify whether the USDA or FDA has the jurisdiction to address an ongoing outbreak until investigators identify the specific food source. This inefficient system may result in significant delays, while the agencies work out the jurisdictional issues.

The U.S. system is further hampered by the fact that neither agency has effective food tracking systems or even mandatory recall authority. According to the WHO, “Tracing systems and market recalls are thus critical in responding to food contamination, whether deliberate or inadvertent.”\footnote{25} In the United States, each agency relies on a system of voluntary company recalls. The USDA has even taken the position that they cannot give information on the distribution of contaminated meat products to state public health officials unless the officials sign a nondisclosure agreement. This policy means that the states are barred from giving consumers information about where and when recalled meat was sold. If the food supply were used in a terrorist attack, the USDA’s policy likely would contribute to a higher rate of deaths and illnesses, as it would interfere with the ability of consumers to obtain the knowledge necessary to protect themselves.

Improving the safety of the food supply from both intentional and unintentional contamination will require improvements in many existing systems. According to the WHO, “An effective emergency response … should include links to law enforcement and intelligence agencies, food recall systems, risk assessment specialists and the food industry as well as the more traditional sectors of healthcare providers, laboratories and emergency services.”\footnote{26} Improvements in the food safety infrastructure to respond to terrorist concerns will have many immediate benefits, such as improved outbreak response and investigation. For example, with better public health monitoring and faster tests, the three outbreaks that preceded the massive Chi-Chi’s outbreak in Pennsylvania could have acted as an effective warning; with faster identification and effective recall of the tainted food, the massive outbreak could have been prevented and three lives saved.

The effectiveness of the food safety infrastructure is subject to frequent tests even in the absence of bioterrorism, but often fails in its ability to keep tainted food from reaching the public. The recent finding of BSE in a single cow in Washington State illustrates many gaps and weaknesses. For example, BSE tests did not work quickly enough to prevent the cow from entering the human and animal food supply; recall systems were inadequate to fully inform consumers about where the meat was sold; and traceback systems worked only because the cow originated in Canada. If the cow had been born in the United States, much of the information about where it lived would be lacking.

The good news was that U.S. consumer confidence in the meat supply remained largely unchanged, although beef producers lost a large number of export markets.\footnote{27} If the government finds additional infected cows—or if terrorists target a large amount of food—consumer confidence would not remain static.

\footnote{24} Id. at 15.
\footnote{25} Id.
\footnote{26} Id. at 26.
Within the United States, it is vital that the entire infrastructure be reviewed, including federal, state, and local governments, to ensure that effective systems are in place. Following is a brief overview of the essential functions identified by the WHO, and a brief description of where the regulatory authority for these functions currently resides.

- Food inspection—largely a federal function for meat and poultry, but not for other foods.
- Food control laboratories—these function at the federal, state, and local levels.
- Food technology expertise—largely a function of federal research and private companies.
- Food contaminant monitoring—uncoordinated systems are used at the federal, state, local, and private levels.
- Recall and tracing systems—these are inadequate at the federal level.
- Industry alert systems—largely private.
- Agricultural alert system—largely handled by the USDA.
- Food safety risk assessments—primarily a federal function, handled by both the USDA and FDA, sometimes jointly.

Some might ask what the government can do to prevent a targeted attack on the food supply. The role of government is vital though admittedly limited. It consists of monitoring and auditing industry systems, largely through inspection and testing programs; reducing access to chemical and biological agents and radionuclear materials; and inspections of imports in the country-of-origin and at the ports of entry. Effective programs that accomplish these objectives not only will help make the food supply safer overall, they will serve as a deterrent to using food as a way to threaten public safety. If food is seen as a difficult target, it is less likely to be used.

While Congress has adopted some patchwork improvements with the Public Health Security and Bioterrorism Response Act of 2001,28 implementation of even these modest changes has been uneven. Registration with the government for both domestic and importing food companies became mandatory in December 2003, but as of May, only about half of the domestic firms FDA expected to register have done so.29 Meanwhile, due to intense opposition by the food industry, FDA weakened the prior notice requirement for food imports from 12-36 hours in the proposed regulation, down to 2-8 hours in the interim rule.30 A recent FDA notice suggests that the import notice requirement could be shortened even further for food coming on trucks and by rail.31 Even with these watered-down requirements, however, compliance statistics show that FDA is receiving incomplete prior notices for the majority of imported food shipments arriving in the United States.32

What is becoming increasingly obvious is that food is an international commodity and hugely-complicated national regulatory systems are just one element in a much

---

28 H.R. 3448, signed into law on June 12, 2002, as Pub. L. No. 107-188.
29 See FDA, Center for Food Safety and Applied Nutrition (CFSAN), Registration of Food Facilities, Compliance Information: Registration (May 28, 2004), available at http://www.cfsan.fda.gov/~furlis/firegsum.html (last visited Aug. 24, 2004). As of May 19, 2004, FDA had received 202,024 registrations, of which 105,193 are foreign and 96,831 domestic. The agency has estimated that 420,000 companies must register; of these, about 216,000 are domestic and 205,000 are foreign.
larger and more complex international system. As the United States works to modernize its food safety system, it must ensure that other countries apply equally effective systems with the same stringency.

Many countries already are moving toward creating unified food safety agencies, including Britain, New Zealand, The Netherlands, and Germany. The United States should be helping to drive these efforts, but, so far, it is continuing to rely on antiquated statutes to address modern issues such as bioterrorism, mad cow disease, and genetically-modified foods. The problems with the current system are obvious to both insiders and observers alike; addressing these problems will require a willingness to change on the part of many stakeholders, including consumers, the food industry, and the government.