



Import Inspection Failures and What Must Be Done

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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 900,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

The Centers for Disease Control and Prevention (CDC) estimates that 76 million Americans get sick, 325,000 are hospitalized, and 5,000 die from foodborne hazards each year in the United States. Since September, we have had three significant nationwide outbreaks and recalls that amply demonstrate holes in the web of protection from contaminated food. Spinach contaminated with a deadly strain of *E. coli*; peanut butter with *Salmonella*; pet food with toxic chemicals – each of these tragedies has demonstrated a different problem with our system of regulating the food supply. It is time for Congress to take action to better ensure food safety and to protect Americans from these preventable illnesses and deaths.

Each year the average American eats about 260 pounds of imported foods, accounting for about 13 percent of our annual diet.¹ U.S. imports for 2006 reached a record value of \$65.3 billion, roughly \$6 billion higher than the year before.² Twelve federal agencies share responsibility for inspecting food imports, resulting in a chaotic and inefficient system. The two principal agencies, FDA and USDA, each control import programs purportedly responsible for ensuring the safety of those imported foods, but the programs are not comparable, not adequate, and, in many ways, not reliable. Further, 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 a recent GAO report, 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.³ The distinctions between the two import systems are not limited to actual inspection performance, however; the structure of import procedures is also vastly different.

USDA's Food Safety and Inspection Service (FSIS) is responsible for ensuring that imported meat, poultry, and egg products are safe, wholesome, and accurately labeled. According to FSIS's mandate, foreign countries wishing to export to the U.S. must undergo two levels of review to determine eligibility to import. USDA must first perform an evaluation of the foreign country's food system, reviewing the laws and regulations of that country as they pertain to five risk areas: sanitation controls, animal disease controls, slaughter and processing controls, residue controls, and enforcement controls.

If that evaluation shows the country's system to be equivalent to the U.S., a USDA technical team then conducts an in-country assessment, which involves an on-site review of the five risk areas as well as other aspects of the food system, including plant facilities and equipment, laboratories, training programs, and in-plant inspection operations. According to FSIS, these on-site audits are used to verify that a country has in fact implemented the programs described in the document review, and if not, to clarify and resolve any differences. It is only after the completion of both prongs of the review that a country is deemed eligible for import

¹ Bridges, A, "Imported food rarely inspected," *Washington Post*, April 16, 2007.

² U.S. Agricultural Trade Update, *Electronic Outlook Report from the Economic Research Service*, Feb. 15, 2007.

³ GAO, *Federal Oversight of Food Safety: High-Risk Designation Can Bring Needed Attention to Fragmented System*, Statement of David M. Walker (GAO-07-449T)(Washington, D.C.: Feb. 8, 2007).

consideration. After appropriate notice-and-comment rulemaking, the foreign country is granted importation status and is subject to annual re-certification documentation and review.⁴

This application process does not guarantee that all products from a certified country will enter the U.S., however. After certification, foreign products must pass through U.S. Customs, where appropriate documentation and bonds are required. Upon arrival at a U.S. port, 100% of meat and poultry shipments must be approved by FSIS before they are allowed into the country. Every lot is visually inspected for general condition, proper labeling, proper certification, and accurate count. In addition, the Automated Import Information System (AIIS)—implemented in 2002—conducts random statistical sampling of the lots and assigns other types of inspection based on an algorithm of risk and volume. These more stringent inspections could include sampling of the product for microbiological analysis, physical examination for visible defects, sampling for drug and chemical residues, and food chemistry analysis.

According to the FSIS Quarterly Enforcement Report from FY 2006, an average of 15% of products presented for importation were physically examined or sampled by USDA.⁵ In 2006, a total of 3.88 billion pounds of meat, poultry, and egg products were presented, and 598 million pounds were reinspected (physical inspection after visual inspection is called reinspection). Of those, 12 million were rejected. In the first quarter of FY 2007 (Oct- Dec 2006), over 935 million pounds were presented, 11.8% (110 million pounds) reinspected, and 2.7 million pounds rejected.

While USDA has a fairly intensive program for ensuring the safety of imported meat and poultry products, the FDA program is anything but comprehensive. FDA's procedures are much less stringent and much less effective. FDA does not evaluate national programs to determine equivalence or visit foreign countries to verify compliance with food safety procedures. FDA's

⁴ Special circumstances may result in a country's import status being suspended. FSIS offers three examples of special circumstances: (1) if an emergency sanitary measure is implemented by FSIS to address a hazard that is so severe that no product can enter the marketplace from a foreign establishment until the control is in place; (2) if an exporting country does not provide satisfactory documentation of an equivalent sanitary measure; (3) if a system audit reveals that an exporting country is not implementing a public health sanitary measure in the manner that FSIS initially determined to be equivalent.

Permanent withdrawal of eligibility, like initial approval of eligibility, can only be accomplished by rulemaking. FSIS may, however, take action to ensure that products from a particular country are not admitted into the United States if they are adulterated or misbranded based on specific findings during on-site audits, because of port-of-entry reinspection failures, or other means.

USDA Food Safety and Inspection Service, *Equivalence Process*, referenced July 13, 2007 at http://www.fsis.usda.gov/regulations_&_policies/equivalence_process/index.asp.

⁵ Canada may account for as much as 43% of meat and poultry imports.

Import Program System Information website does not delineate an audit system for imported product, but rather directs users to U.S. Customs for inspection and enforcement procedure information.

The shoddy state of U.S. inspection procedures has not gone unnoticed, even within the ranks of those tasked with creating and implementing the policies. In 2004, Tommy G. Thompson, the former secretary of health and human services, expressed deep concern about the nation's food supply, 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.⁶

It is currently estimated that FDA only inspects 1% of food at the U.S. border, so it is frankly surprising that catastrophes like the recent pet food contamination haven’t happened more often. 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.⁷ Of these 9 million shipments, only 0.2% were analyzed in a laboratory as part of their inspection process.⁸

Although products enter the U.S. through 361 ports, at the peak of its funding, FDA had inspectors on-site at only 90 of these ports. Today the agency likely covers half that number. To increase inspections of FDA-regulated imports to 10% (still a strikingly low figure) would require an additional 1600 full-time inspectors. To double that figure to 20% import inspection would require 3200 full-time inspectors and \$540 million, according to FDA estimates given to the House Agriculture Appropriations Subcommittee in 2001.

The gaps in protection from this system are indeed alarming, particularly as imports in some commodities grow. Overall, U.S. imports of agricultural and seafood products from all countries have increased by nearly 50% over the last decade, and certain countries and commodities are showing exponentially greater increases. U.S. imports of Chinese agricultural and seafood products, for example, have increased almost 350% in the same time period—an increase in value from \$880 million in 1996 to over \$4 billion in 2006.⁹ China is the sixth leading foreign supplier of agricultural products to the U.S. when seafood imports are not

⁶ “Tommy Thompson Resigns From HHS,” *The Washington Post*, December 3, 2004.

⁷ “Food Imports Often Escape Scrutiny,” *The New York Times*, May 1, 2007.

⁸ *Ibid.*

⁹ CRS Memorandum, *Food and Agricultural Imports from China*, June 6, 2007.

considered. Adding seafood, however, raises China to the third ranking supplier of all food products to this country.

Late last month, FDA announced import detention of five fish species routinely imported from China due to the presence of illegal and potentially dangerous antibiotics.¹⁰ Farm-raised catfish, shrimp, eel, basa, and dace were contaminated with the antimicrobials nitrofurans, malachite green, gentian violet, and fluoroquinolones, presumably in an effort to combat increasing levels of illness among aquatic populations. In humans, however, these substances may be carcinogenic, and can create antibiotic resistance in a critically important class of antibiotics.

In May, FDA issued a consumer warning for pufferfish, mislabeled as monkfish, from China.¹¹ After two people in Chicago were sickened after eating fish soup made with the purported monkfish, laboratory testing confirmed that the fish contained life-threatening levels of tetrodotoxin, one of the most hazardous toxins found in food. According to FDA's *Bad Bug Book*, poisoning by tetrodotoxin is one of the most violent intoxications from marine species. Pufferfish can contain levels of tetrodotoxin sufficient to produce rapid and violent death, as quickly as 20 minutes after consumption.¹² It appears that lethal pufferfish were illegally imported to the U.S. from China mislabeled as monkfish.

FDA cannot rely on other countries to ensure the safety of imports, because in many parts of the world, under-funded food safety agencies do not have the ability to regulate food entering the global market.¹³

A Failure of Import Inspections in the Pet Food Scandal

For the thousands of people whose cherished pets became ill or died during the recent recall of contaminated pet food, FDA's lapse in protecting our food supply was a tragedy. In March 2007, pet food manufacturers recalled more than 100 brands of cat and dog food after

¹⁰ U.S. Food and Drug Administration Press Release, *FDA Detains Imports of Farm-Raised Chinese Seafood*, June 28, 2007.

¹¹ U.S. Food and Drug Administration Press Release, *FDA Warning on Mislabeled Monkfish*, May 24, 2007.

¹² U.S. Food and Drug Administration *Bad Bug Book*, referenced June 11, 2007, <<http://www.cfsan.fda.gov/~mow/chap39.html>>.

¹³ World Health Organization, *Healthy Food Markets*, (2006).

receiving complaints about cats and dogs that developed kidney failure from eating pet food. For weeks after, new brands were pulled from shelves as processors tracked the tainted wheat gluten.

FDA investigations revealed that the pet food that sickened so many pets was 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 thought 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 apparently common practice among producers in China, yet the contaminated wheat gluten passed across our borders without being found or stopped by the FDA.¹⁴

Melamine was also found in imported rice protein concentrate that was identified as an ingredient in hog and chicken feed. After melamine was found in the urine of hogs fed with this feed, the hogs were quarantined. However, some hogs may have already entered the human food supply. Thousands of chickens fed contaminated feed have also already entered the food supply. The breadth of the pet food and animal feed scandal is a troubling signal of FDA's innate weaknesses.

Melamine-tainted feed is the latest example of gaps in FDA's oversight of imports. Many more human illnesses have been linked to imports as well, particularly from imported produce. Americans seek a variety of fresh fruits and vegetables year-round, and supplying this demand is done by importing produce from around the world. In fact, one-quarter of our fruit, both fresh and frozen, is imported. But lack of adequate border controls has led to numerous large and occasionally deadly outbreaks linked to imported food. Here are some examples:

- In Fall 2003, a major Hepatitis A outbreak linked to raw green onions used in restaurant salsa sickened 555 people in Pennsylvania, killing three of them. Preliminary traceback by FDA indicated that green onions supplied to the restaurant were grown in Mexico under conditions where contamination with human waste was likely. Green onions from

¹⁴ Barboza D and Barrionuevo A. "Filler in Animal Feed Is Open Secret in China." *NY Times*, April 30, 2007.

this area were also linked to outbreaks in Georgia, Tennessee, and North Carolina that occurred earlier that fall.¹⁵

- Three multistate outbreaks of *Salmonella* serotype Poona infections associated with eating cantaloupe imported from Mexico occurred in the spring of consecutive years during 2000-2002. FDA conducted traceback investigations and determined that the cantaloupes were from farms in Mexico. FDA conducted on-farm investigations in Mexico and found many possible sources of contamination, including sewage-contaminated irrigation water; processing (cleaning and cooling) with *Salmonella*-contaminated water; poor hygienic practices of handlers; pests in packing facilities; and inadequate cleaning and sanitizing of equipment that came in contact with the cantaloupe.¹⁶
- In 1997, over 256 cases of Hepatitis A were associated with the consumption of frozen strawberries. The strawberries were harvested in Mexico and processed and frozen in southern California before they were distributed by U.S. Department of Agriculture (USDA) to school lunch programs in several states, including Michigan, Wisconsin, Louisiana, Maine and Arizona.¹⁷
- In 1996 and 1997, thousands of people became ill in both the U.S. and Canada from a parasite, *Cyclospora*, on raspberries grown in Guatemala.¹⁸ Illness associated with *Cyclospora* includes watery diarrhea and persistent fatigue, which can persist for a month or longer if untreated.¹⁹ *Cyclospora* is chlorine-resistant and can be transmitted through water or from infected handlers.

Modernizing the Law: The Safe Food Act

Following September 11, 2001, Congress enacted the Bioterrorism Act of 2002 but left the most frequent traveler across U.S. borders — imported food — under the supervision of a

¹⁵ V Dato *et al.*, (2003) “Hepatitis A Outbreak Associated with Green Onions at a Restaurant—Monaca, Pennsylvania, 2003,” *MMWR*, 52(47): 1155-1157.

¹⁶ SM Anderson *et al.*, (2002) “Multistate Outbreaks of Salmonella serotype Poona Infections Association with Eating Cantaloupe from Mexico—United States and Canada, 2000-2002,” November 22, 2002, *MMWR*, 51(46);1044-1047.

¹⁷ Centers for Disease Control (1997), “Hepatitis A Associated with Consumption of Frozen Strawberries—Michigan, March 1997,” *MMWR*. 46(13): 288-295.

¹⁸ J Hoffman *et al* (1996). “Update: Outbreaks of *Cyclospora cayetanensis* Infection – United States and Canada, 1996,” July 19, 1996, *MMWR* 45(28): 611-612.

¹⁹ CDC Division of Parasitic Diseases (2004). “*Fact Sheet: Cyclospora Infection—Information for Healthcare Providers*,” April 19, 2004, March 5, 2007.
<http://www.cdc.gov/ncidod/dpd/parasites/cyclospora/healthcare_cyclospora.htm>.

bifurcated federal system of food regulation. According to the National Academy of Sciences, “[a]t least a dozen federal agencies implementing more than 35 statutes make up the federal part of the food safety system.”²⁰ In a post-September 11 world, with risks of bioterrorism and ongoing natural hazards such as *E. coli* O157:H7, the U.S. food safety system has become an issue of national security. The existing regulatory framework is simply insufficient to handle these challenges. Several bills propose modernizing import inspection.

The Imported Food Security Act of 2007, introduced by Senator Richard Durbin (D-IL), is the most recent in a spate of legislation being considered to address the import problem.²¹ Designed to bolster FDA resources—particularly in the areas of import inspection—the bill directs FDA to create and implement more rigorous import controls. The bill also creates a new user fee program at FDA and directs the agency to devote part of the user fee revenue to research efforts on promising testing technologies that would rapidly detect the presence of food contaminants.

The Human and Pet Food Safety Act, introduced May 2, 2007 by Senator Durbin (D-IL) and Representative Rosa DeLauro (D-CT), is another strong legislative attempt to stem the tide of alarming imports.²² The Act would help regulate the industry by establishing mandatory processing and ingredient standards (both domestically and internationally) and requiring more inspections of pet food processing plants. Further, the Act would create an early warning system to help identify possible contaminants earlier and penalize companies that don't report possible contamination. In an important step, the Act would also ensure that any future recalls are conducted quickly by giving the Food and Drug Administration the power to order mandatory recalls of tainted food.

²⁰ Institute of Medicine, National Research Council, *Ensuring Safe Food from Production to Consumption*. (Washington, DC: National Academy Press, 1998)

²¹ United States Senate, 110th Congress, 1st Session. S.1776, *The Imported Food Security Act of 2007*. [introduced in the Senate 12 July 2007]. 110th Congress.

²² United States Senate, 110th Congress, 1st Session. S. 1274, *The Human and Pet Food Safety Act of 2007*. [introduced in the Senate 2 May 2007]. 110th Congress. Accessed <http://thomas.loc.gov/cgi-bin/query/D?c110:1:./temp/~c110amOnGS::>

Yet another, more comprehensive, approach is the Safe Food Act, introduced February 15, 2007, also by Senator Durbin and Representative DeLauro.²³ The Act would streamline food safety at the federal level by consolidating the FDA, USDA, Center for Veterinary Medicine (CVM), EPA, and several other key food agencies to create a unified, science-based Food Safety Administration. In addition, the bill would modernize the outdated inspection system and give clear authority for on-farm programs. It relies on preventative control systems implemented by the industry and performance standards monitored and enforced by the government.

The Safe Food Act gives the Food Safety Administration the authority to evaluate and certify a country's food safety program to ensure that it is "at least equivalent to the food safety program in the United States."²⁴ The Administration would have the authority to audit the certified countries and would ensure continued compliance at least every five years.²⁵ The proposed law also requires routine inspections of foreign food imports to ensure that the food is safe and properly labeled. Under the Safe Food Act, foods would no longer have an "open visa" to enter the U.S. without inspection or regulation.

The Safe Food Act further mandates the establishment of a national system for "tracing food and food producing animals from point of origin to retail sale."²⁶ The Act would allow companies to issue voluntary recalls should their product be deemed unsafe, but also grants authority for the Food Safety Administration to issue a mandatory recall if the company fails to do so. This will ensure quick removal of contaminated products from the market and increase consumer confidence in the food supply.

The Safe Food Act creates a single food agency with the necessary authority to fulfill its mission to put safe food on America's tables, a recommendation made by the National Academy of Sciences in 1998. The new agency could detain imported food and recall tainted food from the market. It provides the necessary authority to penalize persons or organizations for violating

²³ United States. Congress. House of Representatives. 110th Congress, 1st Session. *H.R. 1148, The Safe Food Act of 2007*. [introduced in the House of Representatives 16 February 2007]. 110th Congress. Congressional Bills, GPO Access. <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h1148ih.txt.pdf>

²⁴Id.

²⁵ Id.

²⁶ Id.

food safety laws, allowing both civil and criminal penalties, and also provides whistleblower protection for individuals who disclose food safety violations.

The Act would work to prevent foodborne illness and bioterrorism without grand schemes or an inflated budget. Instead, it ensures a strong national program, outbreak surveillance, and effective, honest public communication. The food industry remains the first line of defense, but the Act recognizes that effective industry programs require government monitoring and oversight.

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 September 11, 2001 terrorist attacks 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. The Safe Food Act draws from these recommendations and creates a program that puts public health at the forefront of food safety in America. We urge Congress to take action this year to modernize food safety laws in the U.S. and to fully fund federal food safety programs.