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 on the issue of imported food safety. Last year, consumer confidence in the food they purchase at restaurants and grocery stores declined by 16 percent, according to an annual survey of the Food Marketing Institute.\(^1\) 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 today the Food and Drug Administration’s ability to protect the food supply is being questioned by consumers and Congress alike.

Each year 76 million Americans get sick, 325,000 are hospitalized, and 5,000 die from foodborne hazards in the United States, according to the Centers for Disease Control and Prevention (CDC). And with responsibility for 80 percent of food supply, FDA is a critical element of reducing this public health burden. Since September 2006, a number of nationwide outbreaks and recalls exposed glaring holes in the safety net guarding U.S. consumers from contaminated food. Spinach contaminated with a deadly strain of \textit{E. coli}; peanut butter with \textit{Salmonella}; pet

\(^1\) Food Marketing Institute, \textit{U.S. Grocery Shopper Trends 2007}. p. 66.

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.

**Americans Are at Risk From Imported Foods**

In recent weeks, both the Bush Administration and the food industry itself have admitted that the systems in place today are not sufficient to ensure the safety of imported foods. Yet the average American eats about 260 pounds of imported foods, accounting for about 13 percent of our annual diet.³ U.S. imports for 2006 reached a record value of $65.3 billion, roughly $6 billion higher than the year before.⁴ Overall, U.S. imports of agricultural and seafood products from all countries have increased by nearly 50 percent 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 percent in the same time period—an increase in value from $880 million in 1996 to over $4 billion in 2006.⁵

China is the sixth leading foreign supplier of agricultural products to the U.S. When seafood imports are considered, China rises to the third ranking supplier of all food products to this country—startling placement considering the spate of recent Chinese food safety scares. But China is not alone. U.S. agencies cannot depend on a large number of countries to ensure the safety of imports, because many countries have inadequate regulations and under-funded food safety agencies that do not have the ability to regulate food entering the global market.⁶

The announcement in June banning certain farmed seafood products from China was hardly surprising. Evidence of contamination from state testing had been reported in the media for some time.⁷ Moreover, the Food and Drug Administration (FDA) admitted at their June 28, 2007, press briefing that “investigators have found consistent problems with farmed fished

---

⁵ CRS Memorandum, *Food and Agricultural Imports from China,* June 6, 2007.
products produced in China and exported to the U.S.” \(^8\) In fact, products from Chinese importers have been placed under periodic alert for the last six years. \(^9\)

In May, FDA issued a consumer warning for pufferfish, mislabeled as monkfish, from China. \(^10\) After two people in Chicago were sickened by 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. In fact, 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. \(^11\) It appears that lethal pufferfish were illegally imported to the U.S. from China mislabeled as monkfish.

These events followed close after the most-widely discussed food safety catastrophe this year. Beginning in March 2007, pet food manufacturers recalled more than 100 brands of cat and dog food after 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. \(^12\)

While these problems with Chinese imports have been profiled most recently, China is certainly not the only example of FDA’s failure to guard against contaminated food imports.

---


\(^9\) Id. “The most - in recent years the longest alert was put on in 2001 which was an import alert for products from certain processors in China. So that’s - it – this goes back before 2001 because we were gathering data before that that led to that alert.”


Many human illnesses have been linked to imported produce. Americans enjoy 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 lead 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 this area were also linked to outbreaks in Georgia, Tennessee, and North Carolina that occurred earlier that fall.13

- 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.14

- 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.15

- 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.16 Illness associated with *Cyclospora* includes watery diarrhea and persistent fatigue, which can persist for a month or longer if untreated.17 *Cyclospora* is chlorine-resistant and can be transmitted through water or from infected handlers.

**A Broken Food Inspection System Doesn’t Do Enough**

to Ensure the Safety of Imported Foods

Twelve federal agencies share responsibility for regulating food, resulting in a chaotic and inefficient system. The two principal inspection agencies, FDA and USDA, each operate import programs purportedly responsible for ensuring the safety of 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. 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

18 National Research Council, Ensuring Safe Food From Production to Consumption, 26 (1998)
consideration. After appropriate notice-and-comment rulemaking, the foreign country is granted
importation status and is subject to annual re-certification documentation and review.20

This 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 percent of
meat and poultry shipments must be approved by FSIS before they are allowed into the
country.21 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
percent of products presented for importation were physically examined or sampled by USDA.22
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 percent (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

---

20 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

21 Since presenting this statement in previous testimony, CSPI was alerted by a USDA whistleblower that all
shipments may not in fact be inspected as reported.

22 Canada may account for as much as 43 percent of meat and poultry imports.
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 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.23

It is currently estimated that FDA only inspects 1 percent 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.24 Of these 9 million shipments, only 0.2 percent were analyzed in a laboratory as part of their inspection process.25

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.26 To increase inspections of FDA-regulated imports to 10 percent (still a strikingly low figure) would require an additional 1600 full-time inspectors. To double that figure to 20 percent import inspection would require 3200 full-time inspectors and $540 million, according to FDA estimates given to this Subcommittee in 2001.

**Food Industry Recognizes Need for Stronger Preventative Program**

Last week, the food industry issued “Four Pillars”, a reform proposal that calls for a multi-tiered approach to ensuring the safety of imported foods.27 Its formula—establishing mandatory and voluntary import quality assurance programs, improving oversight programs in the countries of origin, and providing FDA with better resources and clearer authority—signals areas of agreement on which solutions to our food safety problems can be built.

---

25 Id.
Change is hard, but it has been done before, and in many different countries. The United Kingdom reformed its food safety program to establish a single Food Standards Agency in 1999. That agency has proven effective in reducing the incidence of foodborne illness and building public confidence. Foodborne illnesses declined 18 percent within the first three years of the new agency, with a reduction from 37 percent to 6 percent in the occurrence of eggs and poultry infected with *Salmonella*. Public confidence in the safety of the food supply rose from 44 percent to 60 percent.\(^{28}\) The change came after food scares in the 1990s led all sides to recognize the need for change and that built momentum to reach a workable compromise. I believe we are at the same nexus of crisis and consensus in this country that Britain faced in the 1990’s and that the momentum for reform is building.

Congress also appears ready to adopt a modern regulatory oversight program and fund it adequately to fulfill its mission and in fact, just last week passed a Sense of Congress, stating this intent. And 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. But the need is great. In fact, the industry and consumers together have estimated that the food program at FDA needs additional funding of approximately $450 million for that agency to meet its program requirements.

In testimony submitted earlier this year for the Coalition, former Associate Commissioner of FDA Bill Hubbard stated that the agency had only 450 import inspectors in 2007, who are asked to screen almost 20 million imports of food, drugs, and other products, which average a “staggering” 44,000 shipments per inspector.\(^{29}\) Hubbard went on to state:

“I suggest to you, Mr. Chairman, that no ‘efficiencies’, ‘better management’ or ‘working smarter’—all solutions suggested for FDA—will significantly improve this picture. The agency needs to open a significant portion of these food containers, send samples to


\(^{29}\) In a July 25 meeting with the Office of Regulatory Affairs, CSPI was informed that FDA has only 301 food import inspectors assigned to inspect the 9 million lines of imported foods. (Source: Barrionuevo, A, “Food Imports Often Escape Scrutiny,” *N.Y. Times*, May 1, 2007.)
laboratories for analysis, and refuse entry to those foods deemed unsafe – and only
people can do that.”

The existing regulatory framework is simply insufficient to handle these challenges. Several bills propose modernizing import inspection.

The Food and Drug Import Safety Act of 2007, introduced by Representative John Dingell (D-MI), and the Imported Food Security Act of 2007, introduced by Senator Richard Durbin (D-IL), are the most recent in a spate of legislation being considered to address the import problem.31 Designed to bolster FDA resources—particularly in the areas of import inspection—the bills direct FDA to create and implement more rigorous import controls. The bills also create a new user fee program at FDA to resource import inspections and support 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 dangerous imports.32 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.

Modernizing the Law: The Safe Food Act

While these bills contain many excellent components, to restore consumer confidence Congress must build upon the growing consensus and enact comprehensive legislation like the Safe Food Act, introduced February 15, 2007, by Senator Durbin and Representative DeLauro.33 The Act would streamline food safety at the federal level by consolidating the FDA, USDA,

---


Center for Veterinary Medicine, EPA, and several other key food agencies to create a unified, science-based Food Safety Administration. Most importantly, 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.” The Administration would have the authority to audit the certified countries and would ensure continued compliance at least every five years. 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.” 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 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 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.

34 Id.
35 Id.
36 Id.
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.