Imports from China Exploit Chaos in the U.S. Food Safety System

Comments of Caroline Smith DeWaal
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before the
United States Senate Commerce Committee

Washington, DC
July 18, 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.

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 last September, we had three significant nationwide outbreaks and recalls that amply demonstrate 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; 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. 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.

A recent USA TODAY/Gallup Poll showed that products from China are becoming highly suspect to U.S. consumers, with 83 percent voicing concern about Chinese products, versus 61 percent concerned with food from Mexico and 39 percent concerned with food produced here in the U.S. While many American consumers are making an effort to buy American, half of those shoppers say it is difficult to determine where items were produced.

Avoiding Chinese products is difficult, if not impossible. 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.

U.S. consumers are not alone in their concerns over Chinese products. In my work with the Safe Food International project and as a food law expert consulted by the Chinese government in 2005 and 2006, I heard from Chinese consumers and other independent sources that they have grave concerns about the safety of Chinese food sold domestically. These concerns range from excess use of pesticides, to high hormone levels in pork for human consumption, to intentional contamination of foods. Most striking was the bakery poisoning incident in Nanjing, China where 38 people (mostly schoolchildren) died and more than 200

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4 Id. Similar polls from the Food Marketing Institute show a decline in consumer confidence in the safety of supermarket food from 82 percent in 2006 to 66 percent in May, 2007, a nearly 20 percent decrease. Food Marketing Institute, *U.S. Grocery Shopper Trends* 2007. A 2006 Harris Poll conducted by the Coalition for a Stronger FDA found that almost 60 percent of respondents feel FDA is doing a “Fair/Poor job”. Coalition for a Stronger FDA.
others were hospitalized when breakfast bakery products were intentionally contaminated with rat poison by a rival baker.7

In 2005, the World Health Organization reported to the Chinese government that they faced an “enormous task of changing thinking and attitudes of those engaged in food enterprises to accept that it is their primary responsibility to provide consumers with safe food.”8 In light of the current situation, it is fair to say that responsibility has not yet been met.

Seafood Imports from China May Be Unsafe for American Consumers

Last month’s announcement 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.9 Moreover, FDA admitted at their June 28, 2007 press briefing that “investigators have found consistent problems with farmed fished products produced in China and exported to the U.S.”10 In fact, products from Chinese importers have been placed under periodic alert for the last six years.11

In May, FDA issued a consumer warning for pufferfish, mislabeled as monkfish, from China.12 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 tetrodoxin, one of the most hazardous toxins found in food. In fact, poisoning by tetrodoxin 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

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7 International Society for Infectious Diseases, Pro-Med Mail, published September 14, 2002.
11 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.”
consumption.\textsuperscript{13} 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 \textit{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.\textsuperscript{14}

Melamine in imported rice protein concentrate was also 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 and thousands of chickens also fed contaminated feed may have already entered the human food supply. The breadth of the pet food and animal feed scandal is a troubling signal of FDA’s inherent inability to stop contaminated ingredients from entering the food and feed chain.\textsuperscript{15}

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. Many human illnesses have been linked to imported produce. Americans enjoy a variety of fresh


\textsuperscript{15} New reports suggest that the wheat gluten and rice protein concentrate were in fact mislabeled wheat flour. Weiss, Rick. “FDA Finds Chinese Food Producers Shut Down,” \textit{Washington Post}, May 11, 2007.
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.16

- 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.17

- 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.18

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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.\(^{19}\) Illness associated with *Cyclospora* includes watery diarrhea and persistent fatigue, which can persist for a month or longer if untreated.\(^{20}\) *Cyclospora* is chlorine-resistant and can be transmitted through water or from infected handlers.

**FDA’s Front Line Import Procedures Fail Consumers**

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.\(^{21}\) The distinctions between the two import systems are not limited to actual inspection performance; however, the structure of import procedures is also vastly different.

FDA only inspects one 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 frequently. Although imports of FDA-regulated foods have more than tripled in the last decade—from less than 2.5 million shipments in 1996 to more than 10 million shipments in 2006—the rate of inspections has remained woefully low.\(^{22}\) Yet only 0.2 percent of the shipments received in 2006 were analyzed in a laboratory as part of their inspection process.\(^{23}\)


\(^{22}\) CRS Memorandum, *Food and Agricultural Imports from China*, June 6, 2007.

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 percent (still a strikingly low figure) would require an additional 1600 full-time inspectors and at least $270 million. To double that figure to 20 percent import inspection would require 3200 full-time inspectors and $540 million, according to FDA estimates given to the House Agriculture Appropriations Subcommittee in 2001.

FDA’s counterpart at USDA, the Food Safety and Inspection Service (FSIS), is responsible for ensuring that imported meat, poultry, and egg products are safe, wholesome, and accurately labeled. FSIS’ import procedures—though their covered products represent only 20 percent of the overall American diet—are significantly more robust than FDA’s. FDA does not evaluate national programs to determine equivalence or visit foreign countries to verify compliance with food safety procedures, while FSIS does both. Notably, FDA’s Import Program System Information website does not even delineate an audit system for imported product, but rather directs users to U.S. Customs for inspection and enforcement procedure information.

Under USDA’s more stringent protocol and 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
consideration. After appropriate notice-and-comment rulemaking, the foreign country is granted importation status and is subject to annual re-certification documentation and review.24

This application process, however, does not guarantee that all products from a certified country will enter the U.S. After certification, foreign product 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. 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—facilitates the 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 inspected by USDA. In 2006, a total of 3.88 billion pounds of meat, poultry, and egg products were presented, and 598 million pounds were reinspected.25 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 the USDA system is more robust than FDA’s, both contain potentially critical shortcomings. 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

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24 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.


25 Physical inspection after visual inspection is called reinspection.
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.  

Traceability and Certification: Two Ways to Protect Consumers

In the short term, many consumers want to be able to quickly identify foods and ingredients being sourced from China, and country-of-origin labeling would be simple way to accomplish this. The legislation already passed Congress as part of the 2002 Farm Bill, but significant portions—including the mandatory labeling provisions—have been pushed back to September 2008. At CSPI, we support many forms of traceability, including animal identification, farm-of-origin labeling for both domestic and imported products, better ingredient labeling (including sourcing information), and other information that would better facilitate traceback and recall efforts and would create greater accountability for food safety problems.

Labeling is not a substitute for better oversight and inspection. I would urge this Committee to consider the critical need for increased funding at FDA, and to modernize the antiquated legal tools that the agency uses to monitor the safety of imports. Things will not improve until Congress is willing to adopt a modern regulatory oversight program at FDA and fund it adequately to fulfill its mission. The Coalition for a Stronger FDA (which includes all stakeholders of that agency) recently submitted estimates to the House Energy and Commerce Committee indicating the food program at FDA needs additional funding of approximately $450 million for that agency to meet its program requirements. In testimony recently submitted 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. 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

laboratories for analysis, and refuse entry to those foods deemed unsafe – and only people can do that.”

Legislative Attempts to Fix a Broken System

Building a modern food safety system has been under discussion in Congress for almost a decade. In a 1998 report of the National Academy of Sciences, the Academy found that “[a]t least a dozen federal agencies implementing more than 35 statutes make up the federal part of the food safety system.” In a post-September 11th 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 recent bills propose modernizing import inspection. Common to each of them is the concept that countries or companies that want to import food to the U.S. should be certified as having appropriate food safety systems to protect American consumers.

The Imported Food Security Act of 2007 (S. 1776), introduced last week by Senator Richard Durbin (D-IL), is the most recent in a spate of legislation being considered to address the import problem. 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 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 (S. 1274), 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. The Act would help regulate the industry by establishing mandatory processing and ingredient standards (both domestically and internationally) and

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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.

Yet another, more comprehensive approach is the Safe Food Act (H.R. 1148), introduced February 15, 2007, also by Senator Durbin and Representative DeLauro. 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.” 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

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32 Id.
33 Id.
34 Id.
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 of 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 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 and recalls serve as a reminder that much more must be done to protect the food supply. The recent series of problems with domestic and imported foods and ingredients are serious, and have resulted in significant declines in consumer confidence. These are not problems that can be fixed with minor changes or modest budget increases. It is time for Congress to step in with comprehensive reform and effective budget solutions to create a federal program that puts public health at the forefront of food safety in America.