



U.S. REGULATORY REGIME FOR IMPORTED FOOD SAFETY COMES UNDER SCRUTINY

The safety of the nation's food supply is a critical issue that has recently received a great deal of scrutiny from the media, the United States government, and the nation's consumers. Recent food-borne illness outbreaks have thrust the issue of food safety into the national spotlight and caused a sharp decline in consumer confidence.¹ In April 2009, the Food & Drug Administration ("FDA") issued a warning to consumers to avoid eating alfalfa sprouts due to an ongoing outbreak of salmonella that sickened people in six states. The alfalfa sprout case is only the latest in a string of hazardous outbreaks. In August 2008, for example, an E. coli outbreak sickened 314 people and killed one in Oklahoma. The exact source of the contamination has not been identified.² In the spring and summer of 2008, 1,442 people became ill with salmonella from fresh jalapeño peppers and/or raw Serrano peppers. The salmonella outbreak affected 43 states and the District of Columbia, and hospitalized at least 286 people.³ These and many other outbreaks not only illustrate the extreme importance

of food safety; they have also exposed the need to reform the processes by which food is regulated in the United States.

Although the contamination that resulted in a number of the recent outbreaks was found in food grown or processed in the United States, there is increasing concern over imported food. Last year, imported foods made up an estimated 10 to 13 percent of the U.S. diet,⁴ and in the past decade, food shipments to U.S. ports have more than doubled.⁵ As international commerce in food has increased, so have the outbreaks attributed to imported food products. These include outbreaks caused by Guatemalan raspberries contaminated by Cyclospora in 1996, Mexican strawberries and green onions contaminated by Hepatitis A in 1997 and 2003, respectively, and Mexican cantaloupes contaminated by Salmonellosis in 1997, 2000, 2001, and 2002.⁶ Critics of the U.S. food import system fault the country's "weakened inspection regime"⁷ for the increase in outbreaks attributed to

imported food, and many urge Congress to modernize U.S. food safety laws immediately.⁸

OVERVIEW OF THE CURRENT REGULATORY REGIME

Responsibility for food safety is split among an astonishing 12 federal departments and agencies. These 12 entities collectively administer at least 30 laws related to food safety.⁹ Two of them, the United States Department of Agriculture (“USDA”) and the FDA, an agency within the Department of Health & Human Services (“HHS”), have primary responsibility for inspecting imported food. The majority of all imported food inspections, about 80 percent, are the FDA’s regulatory responsibility, while the other 20 percent fall under the USDA’s authority. While both entities play a vital role in protecting the American consumer, the two entities’ import and inspection systems are quite different.

USDA’S REGULATORY PROCESS

The USDA’s Food Safety and Inspection Service (“FSIS”) is responsible for ensuring that imported meat, poultry, and egg products are safe and accurately labeled.¹⁰ FSIS operates under an “equivalency” program, meaning that a foreign country wishing to export to the U.S. must have an equivalent (though not identical) inspection system to the U.S. system. Thus, to determine eligibility of a particular country, the FSIS (1) evaluates the country’s laws, regulations, and other written information to determine whether its food safety and inspection program is equivalent to the U.S. system; and (2) visits the country to conduct on-site audits, ensuring, to the extent possible, that the country has implemented inspection programs properly. After the completion of both prongs of the review, a country is deemed eligible for import consideration.¹¹ As of July 2008, 33 countries were eligible for export to the United States.¹²

The FSIS’s oversight does not stop at eligibility; 100 percent of products under the USDA’s authority must be reinspected to enter the country. Meat and poultry are reinspected at

a U.S. port-of-entry, during which the products are visually inspected for general condition, proper labeling, proper certification and accurate count. Additionally, via random statistical sampling, some products undergo more stringent inspections such as microbiological analysis and food chemistry analysis. Unlike meat and poultry, egg products are inspected at the facility to which they are taken for further processing. All products that pass reinspection are allowed to enter the U.S.

Periodic review of an eligible country’s laws and regulations, annual in-country audits, and port-of-entry reinspections are used to determine whether a country has maintained its equivalency. If a country’s system fails to maintain equivalency, the FSIS can suspend that country’s eligibility.¹³ Suspension, however, is not permanent; a suspended country has the opportunity to improve its inspection standards to regain eligibility.

FDA’S REGULATORY PROCESS

The FDA has authority to inspect food products not covered by the USDA; that is, everything but meat, poultry, and egg products.¹⁴ As such, the FDA is responsible for inspecting the majority of all imported foods (about 80 percent), making its mission quite a prodigious one. Although imports of FDA-regulated foods more than doubled from 2000 to 2007,¹⁵ the rate of inspections has remained “woefully low.”¹⁶ It is estimated that the FDA inspects only 1 percent of the food products that arrive at the U.S. border.¹⁷

The FDA system is significantly different from the USDA inspection system. Critics of the FDA system consider it to be “shoddy,” “anything but comprehensive,” and “much less stringent and much less effective” than the USDA system.¹⁸ What sets the two systems apart is the fact that the FDA does not evaluate a foreign country’s inspection system for equivalency: that is, there is no review of the country’s laws and regulations, nor are there on-site audits. Rather, the FDA uses an inspection-based system, which can be divided into two stages: entry notification and determination of inspection.

During the entry notification stage of the FDA process, the exporting country gives the U.S. port of arrival notice of the incoming shipment. Without prior notification, the shipment will be refused at the U.S. border. Upon receipt of notification, the FDA accesses an internal automated system to make an admissibility decision about the particular shipment.¹⁹ The internal system, OASIS, clears 85 percent of all shipments without inspection. Shipments that are cleared for import without inspection are permitted to pass through U.S. Customs, into the U.S.

Physical samples are taken from shipments that reach the inspection stage and are analyzed at an FDA District Laboratory. If the FDA finds that the sample is in violation of the Food, Drug, and Cosmetic Act, it provides the exporting country notice of hearing. The hearing allows the exporting country to provide a defense regarding the shipment's admissibility. If, after the hearing, the FDA still finds that the shipment is inadmissible, Customs will destroy or export the shipment.²⁰

Critics claim that the FDA's inspection system is troubling for a number of reasons. Without USDA-type equivalence agreements with exporting countries, American consumers rely on the FDA to inspect incoming food. As mentioned above, however, rates of inspection are extremely low. Also, according to critics, the FDA is incapable of adequate inspections because it is underfunded, understaffed, and operates under antiquated policies that disproportionately focus on monitoring food after it has been produced "instead of trying to prevent and detect problems throughout the entire production process."²¹ Moreover, according to the Robert Wood Johnson Foundation's March 2009 report on food safety, problems also stem from the fact that authority over food safety is fragmented. "No one person in the federal government has the oversight and is held accountable for carrying out comprehensive, preventive strategies for reducing foodborne illnesses,"²² says the report.

LEGISLATIVE AND REGULATORY REFORM IS ON THE WAY

The state of the U.S. food import system has not gone unnoticed by Congress. In the 110th Congress, more than 80 pieces of legislation related to food safety were introduced, and a number of these specifically focused on imported food. Thus far, in the 111th Congress, five bills have been introduced that attempt to reform the food import system, four in the House of Representatives, and one in the Senate.²³ One of the House bills passed the House on July 29, 2009, and the Senate is expected to take action on this bill in the fall.

The House-passed bill, H.R. 2749, is an aggregated version of some of the earlier bills, and like one of the earlier bills, was introduced by John Dingell.²⁴ Referred to the Committee on Energy and Commerce, the bill was reported out less than two weeks later on June 17, 2009. It passed the House by a bipartisan vote of 283 to 142. The bill requires domestic and foreign food facilities and importers to register with the FDA and pay a \$500 registration fee. With respect to importers, the bill grants the FDA increased regulatory powers, specifically granting it the authority to establish a dedicated foreign inspectorate, to conduct regular inspections of all registered facilities and importers, to make warrantless searches of business records, to establish a national food tracing system, and to "quarantine" a specific geographic area to prevent the movement of unsafe food products. H.R. 2749 contains an equivalency certification requirement, as well as strict country-of-origin labeling and disclosure requirements. The bill does permit the FDA to create a fast-track import process that would allow importers meeting the requirements to receive expedited processing.

After the bill's passage, President Obama issued a statement commending the House for its action on the issue. The President stated that H.R. 2749 "represents a major step forward in modernizing our food safety system and protecting Americans from foodborne illness."

The Senate has its own bill pending. The FDA Food Safety Modernization Act, S. 510, was introduced by Sen. Richard Durbin (D-IL), Sen. Judd Gregg (R-NH), Sen. Richard Burr (R-NC), Sen. Edward Kennedy (D-MA), and Sen. Saxby Chambliss (R-GA).²⁵ The bill would require U.S. importers to verify the safe practices of foreign suppliers and the safety of imported food. Additionally, it would permit the FDA to require certification for high-risk foods and deny entry to a food that lacks certification or that is from a foreign facility that has refused U.S. inspectors. In March 2009, this bill was referred to the Senate Committee on Health, Education, Labor, and Pensions.

Outside of the legislative process, there have been other attempts at reform. For example, in late 2007, the U.S. government made an effort to improve the imported food safety system by signing a bilateral Memorandum of Agreement on food and feed safety with the General Administration of Quality Suspension, Inspection and Quarantine (“AQSIQ”) of the People’s Republic of China. The agreement states that Chinese companies that produce goods for American consumers must meet U.S. standards for quality and safety through a three-pronged strategy of registration, certification, and quality assurance to verify compliance.²⁶ The agreement focuses on four high-risk products: low-acid canned products, pet food, ingredients of food and feed, and all aquaculture farm products. The Chinese government has also agreed to allow FDA inspectors greater access to Chinese production facilities.²⁷

In mid-2007, President Bush issued Executive Order 13439 establishing the Interagency Working Group on Import Safety.²⁸ The Working Group, chaired by former HHS Secretary Michael O. Leavitt, composed of senior officials from 12 federal departments and agencies.²⁹ The goal of the Working Group was to strengthen the U.S. import safety system to meet the challenges of the expanding global economy and to improve consumer confidence in imported food products.³⁰

After consulting with the private sector, reviewing and assessing current import safety procedures and methods, and surveying the practices of the federal government, the Working Group concluded that a “risk-based” approach that focuses on prevention would most effectively improve import safety.³¹ This conclusion shifts the emphasis from an outdated “snapshot” approach to import safety, in which decisions are made at the border, to a prevention-focused “video” model that “identifies and targets critical points in the import life cycle where the risk of the product is the greatest, and then verifies the safety of products at those important points.”³²

Using this paradigm, the Working Group created an Action Plan that presented 14 broad recommendations and 50 specific action steps under the organizing principles of “prevention, intervention and response.”³³ In addition, in July 2008, the Working Group issued a report outlining the substantial progress made on import safety. According to the press release, “there have been strong enforcement actions, signed agreements with key trading partners, bilateral and multilateral discussions, critical information shared on safety and best practices, and a process begun to improve safety practices both inside and outside of government.”³⁴ The goals of the Working Group, however, are far from accomplished. To continue the spirit of the mission, in March 2009, President Obama created a new Food Safety Working Group to be chaired by the Secretaries of the Departments of HHS and Agriculture.

CONCLUSION

It is clear that food safety is an area of active Congressional and Presidential interest. On July 29, 2009, the House passed a bill that would dramatically increase oversight and enforcement of food safety, including the safety of the imported food supply. Meanwhile, under the Obama administration, the FDA has increased inspections of food processing facilities and requests for information from food companies. These initiatives show that many people are extremely concerned with food safety and how best to ensure that the American people have a safe food supply. While these efforts are important steps, the U.S. food safety system is more than a century old and was not designed to deal with the modern global economy. Given that legislative and regulatory actions seem inevitable, food importers, producers, and processors should begin to think about whether their current practices measure up.

Jones Day will continue to monitor pending legislation and provide updates on any further legislative or executive action taken on this subject.

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ENDNOTES

1. "Consumer Confidence in Food Safety Drops," *mndaily.com.*, March 1, 2009.
2. http://www.cspinet.org/foodsafety/outbreak__report.html.
3. <http://www.cdc.gov/salmonella/saintpaul/>.
4. *Id.*
5. "Why Import So Much Food?" *Jim Hightower*, May 15, 2007.
6. Nucci, M.L., Dellava, J.E., Cuite, C.L., & Hallman, W.K. (2008). *The U.S. Food Import System: Issues, Processes and Proposals* (hereinafter known as "The Rutgers Working Paper").
7. "Food Imports Often Escape Scrutiny," *The New York Times*, May 1, 2007.
8. The Government Accountability Office has called for a "fundamental re-examination of the federal food safety system." Walker, D.M. (2007). *Federal Oversight of Food Safety: High-Risk Designation Can Bring Needed Attention to Fragmented System*, Testimony before the Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, Committee on Appropriations, House of Representative. See <http://www.gao.gov/new.items/d07449t.pdf>.
9. For instance, the Environmental Protection Agency regulates the use of pesticides and maximum allowable residue levels on food commodities and animal feed; the National Marine Fisheries Services in the Department of Commerce conducts voluntary inspections of seafood safety and quality; and the Department of Homeland Security is responsible for coordinating the agencies' food security activities.
10. The FSIS derives this authority from the Federal Meat Inspection Act (1906), the Poultry Products Inspection Act (1957), and the Egg Products Inspection Act (1970).
11. Smith DeWaal, C.S. (2007). *Import inspection failures and what must be done*. Testimony of Caroline Smith DeWaal, Director of Food Safety, Center for Science in the Public Interest. See http://www.cspinet.org/new/pdf/house__import__testimony.pdf.
12. The 33 eligible countries are: Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, Costa Rica, Croatia, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Honduras, Hungary, Iceland, Ireland, Israel, Italy, Japan, Mexico, Netherlands, New Zealand, Nicaragua, North Ireland, Poland, Romania, San Marino, Spain, Sweden, and Uruguay. See http://www.fsis.usda.gov/pdf/Countries_Products_Eligible_for_Export.pdf.
13. For example, in July 2008, the FSIS suspended Great Britain from exporting raw and processed poultry to the United States. Great Britain continues to be eligible to export raw and processed pork. See http://www.fsis.usda.gov/pdf/Countries_Products_Eligible_for_Export.pdf.
14. The FDA's regulatory authority is derived from Section 801 of The 1938 Food, Drug, and Cosmetic Act.
15. In 2007, the U.S. imported about nine million shipments of food, compared to four million in 2000. See "Food Imports Often Escape Scrutiny," *The New York Times*, May 1, 2007.
16. Smith DeWaal, C.S. (2007). *Import inspection failures and what must be done*.
17. Nucci, M.L., Dellava, J.E., Cuite, C.L., & Hallman, W.K. (2008). The Rutgers Working Paper.
18. Smith DeWaal, C.S. (2007). *Import inspection failures and what must be done*.
19. See http://www.fda.gov/ora/import/oasis/home__page.html.
20. FDA Import Procedures. See <http://www.foodsafety.gov/~lrd/import.html>.
21. Robert Wood Johnson Foundation. (2009). *Keeping America's Food Safe: A Blueprint for Fixing the Food Safety System at the U.S. Department of Health and Human Services*. See <http://healthyamericans.org/assets/files/2009FoodSafetyReport.pdf>.

22. *Id.*
23. In early 2009, three food safety bills were introduced in the House: the FDA Globalization Act, H.R. 759, introduced by Rep. John Dingell (D-MI); the Food Safety Modernization Act, H.R. 875, introduced by Rep. Rosa DeLauro (D-CT); and the Safe FEAST Act (Safe Food Enforcement, Assessment, Standards and Targeting Act), H.R. 1332, introduced by Rep. Jim Costa (D-CA) and Rep. Adam Putnam (R-FL). Among other things, all three of these bills sought to increase regulatory authority over food importers and processors, add an USDA-like equivalency requirement for imported food, and increase testing and inspection.
24. "Food Safety Enhancement Act of 2009" (H.R. 2749, 111th Cong. 1st Sess.), introduced by Rep. John Dingell on June 8, 2009.
25. "FDA Food Safety Modernization Act of 2009" (S. 510, 111th Cong. 1st Sess.), introduced by Sen. Richard Durbin, Judd Gregg, Richard Burr, Edward Kennedy, and Saxby Chambliss on March 3, 2009). Sections 301-309.
26. Nucci, M.L., Dellava, J.E., Cuite, C.L., & Hallman, W.K.. (2008). *The U.S. Food Import System: Issues, Processes and Proposals [Addendum: Imported Food Safety]*.
27. *Id.*
28. Executive Order 13439, effective July 20, 2007.
29. In addition to the HHS Secretary, the Working Group included the Secretaries of the Department of State, the Department of Treasury, the Department of Agriculture, the Department of Commerce, the Department of Transportation and the Department of Homeland Security, the Attorney General, the Director of the Office of Management and Budget, the United States Trade Representative, the Administrator of the Environmental Protection Agency, and the Chairman of the Consumer Product Safety Commission. The Food & Drug Administration, Customs and Border Protection, and the Food Safety and Inspection Service participated in the Working Group as well.
30. See <http://www.foodshield.org/docs/powerpoints/Webinar100507.pdf>.
31. Interagency Working Group on Import Safety. (September 2007). *Protecting Americans Every Step of the Way: A strategic framework for continual improvement in import safety*. See <http://www.importsafety.gov/report/report.pdf>.
32. *Id.*
33. Interagency Working Group on Import Safety. (November 2007). *Action Plan for Import Safety: A roadmap for continual improvement*. See <http://www.importsafety.gov/report/actionplan.pdf>.
34. <http://www.hhs.gov/news/press/2008pres/07/20080701a.html>.

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