

INSPECTING THE HANDS THAT FEED US: REQUIRING U.S. QUALITY FOR ALL IMPORTED FOODS

INTRODUCTION

Over the past twenty years, serious outbreaks of foodborne illnesses in the United States have been linked to imported foods.¹ In late 2003, contaminated Mexican green onions served in a Pennsylvania restaurant resulted in over 550 illnesses and three deaths across seven states.² In 1997, Guatemalan raspberries caused an outbreak of *Cyclospora* that resulted in 1,012 illnesses throughout seventeen states, Washington, D.C. and Canada.³ That same year, Mexican frozen strawberries were implicated in an outbreak of Hepatitis A that caused 270 illnesses in five states.⁴ These and other outbreaks were caused by foods under the jurisdiction of the Food and Drug Administration (FDA), highlighting the need for legislative reform of its authority regarding import controls.

Americans are becoming increasingly reliant on foods produced internationally, evidenced by the recent steep rise of the import shares⁵ of various products. Between 1980 and 2000, the import share of fruits in the United States rose dramatically, climbing from six to twenty-two percent. The import shares of fish and shellfish, and of fresh and frozen vegetables, reached sixty-eight and fourteen percent, respectively.⁶ In 1995, eighty-

1. U.S. GOV'T ACCOUNTABILITY OFFICE (GAO), REP. NO. GAO/RCED-98-103, FEDERAL EFFORTS TO ENSURE THE SAFETY OF IMPORTED FOODS ARE INCONSISTENT AND UNRELIABLE 47 (1998), available at <http://www.gao.gov/archive/1998/rc98103.pdf> [hereinafter GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT] (Appendix 1, Selected Outbreaks of Foodborne Illnesses Linked to Imported Foods, 1983–1997).

2. Caroline Smith DeWaal, *Rising Imports, Bioterrorism, and the Food Supply*, 59 FOOD & DRUG L.J. 433, 433 (2004). See also Center for Science in the Public Interest (CSPI), *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net* 10 (2005) [hereinafter *Outbreak Alert! 2005*] (“At least thirteen of the cases were restaurant employees, and seventy-five were residents of six other states who dined at the restaurant. . . . Green onions imported from the same farm in Mexico had caused outbreaks in three states prior to the detection of this larger, deadly outbreak.”).

3. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 47 (compiling data from the Centers for Disease Control and Prevention (CDC)).

4. *Id.* Perhaps the most crippling outbreak between 1983 and 1997 occurred in 1989, when Mexican cantaloupes caused 25,000 illnesses in thirty states.

5. “Import share” refers to the “ratio of imported volume to total volume consumed as food.” Alberto Jerardo, *The Import Share of U.S.-Consumed Food Continues to Rise*, ELECTRONIC OUTLOOK REPORT FROM THE ECONOMIC RESEARCH SERVICE 2 (U.S. Department of Agriculture (USDA)) (2002), <http://usda.mannlib.cornell.edu/reports/erssor/trade/fau-bb/text/2002/fau66-01.pdf> [hereinafter USDA ELECTRONIC OUTLOOK REPORT].

6. *Id.* at 3.

five percent of broccoli used for processing in the United States was imported.⁷ These statistics represent a 22.1 percent increase in the total consumption of internationally-produced fish and shellfish since 1980, and an 833 percent increase for broccoli.⁸ In July 2007 the *Washington Post* reported that “about 13 percent of the average American’s diet is imported food, and imports of FDA-regulated food have more than doubled since 2000, to 9 million shipments in 2006.”⁹ As a result, our food supply has become more vulnerable to contamination, either accidentally (raising food safety concerns) or intentionally (raising food security concerns).¹⁰ This Note discusses import controls solely as they relate to food safety concerns.¹¹

7. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 13 (citing the USDA Economic Research Service).

8. *Id.* From a safety monitoring perspective, this is not necessarily a positive trend. See Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 96 (2001) (“The growing share of the U.S. food supply made up of imported foods is a source of concern among some members of Congress and public health groups.”).

9. Renae Merle & Michael Abramowitz, *FDA Faulted In Safety Lapses: White House Orders Study of Imports*, WASH. POST, July 18, 2007, at D1.

10. See Mark B. McClellan, *Remarks of the Commissioner of Food and Drugs*, 58 FOOD & DRUG L.J. 191 (2003). See also World Health Organization (WHO), Food Safety Department, FOOD SAFETY ISSUES: TERRORIST THREATS TO FOOD, GUIDANCE FOR ESTABLISHING AND STRENGTHENING PREVENTION AND RESPONSE SYSTEMS 6 (2002) (observing that “food is . . . vulnerable to international contamination by debilitating or lethal agents” and that “the global market[] makes prevention difficult, if not impossible”).

Food safety concerns have also become greater in recent years. See *The Safety of Food Imports: Fraud and Deception in the Food Import Process—Part III and Improving the Safety of Food Imports—Part IV Before the Perm. Subcomm. on Investigations of the Comm. on Governmental Affairs, 105th Cong. (1998)* (testimony of William B. Schultz, Deputy Commission for Policy, FDA), available at <http://www.hhs.gov/asl/testify/t980924c.html> [hereinafter Schultz Testimony] (“[M]ore and more food imports consist of finished, value added foods (e.g., cooked, ready-to-eat, quick frozen shrimp as opposed to raw shrimp for cooking/processing in this country). As products receive additional processing, the potential for the product becoming contaminated and a potential public health hazard increases.”).

11. For an introduction to the FDA’s role in addressing food security concerns, see Joseph A. Levitt, *CFSAN’s Program Priorities: From Food Safety to Food Security*, 58 FOOD & DRUG L.J. 19 (2003). Though outside the specific focus of this Note, food security concerns are not to be taken lightly: in 1984, “a cult group poisoned some salad bars in some Oregon restaurants with *Salmonella* bacteria, and about 750 people became ill.” GAO, REP. NO. GAO-03-342, FOOD-PROCESSING SECURITY: VOLUNTARY EFFORTS ARE UNDER WAY, BUT FEDERAL AGENCIES CANNOT FULLY ASSESS THEIR IMPLEMENTATION 1 (2003), available at <http://www.gao.gov/new.items/d03342.pdf> [hereinafter GAO VOLUNTARY EFFORTS REPORT]. The purpose of the contamination was “to prevent people from voting in a local election.” GAO, REP. NO. GAO-02-47T, FOOD SAFETY AND SECURITY: FUNDAMENTAL CHANGES NEEDED TO ENSURE SAFE FOOD 15 (Oct. 10, 2001), available at <http://www.gao.gov/new.items/d0247t.pdf> [hereinafter GAO FUNDAMENTAL CHANGES REPORT]. More recently, in 2002, thirty-eight people were killed when a Chinese baker spiked a competitor’s flour with rat poison; in 2003, over 100 people fell ill when 200 pounds of meat at a Michigan grocery store were intentionally poisoned. DeWaal, *supra* note 2, at 434. The terrorist attacks of September 11,

The federal food safety system vests responsibility for imported foods and food products¹² with two agencies: the Food Safety and Inspection Service (FSIS), which operates under the umbrella of the U.S. Department of Agriculture (USDA), and the FDA.¹³ The FSIS has jurisdiction over meat, poultry and some egg products while the FDA has jurisdiction over all other foods. As a result, the FDA generally maintains responsibility for eighty percent of our nation's food supply.¹⁴ Both agencies, however, legally must warrant that shipments under their jurisdiction comply with U.S. standards for safety and wholesomeness.¹⁵

Specifically, the USDA must ensure that imported foods “meet U.S. standards for safety and wholesomeness, and comply with U.S. labeling and packaging requirements” while the Federal Food, Drug, and Cosmetic Act (FFDCA), the FDA's governing legislation, “requires imported products to comply with U.S. standards for purity, wholesomeness, safety, and hygiene.”¹⁶ The FSIS, as part of the USDA, uses its legislatively-granted “equivalency authority” to mandate foreign compliance with those standards.¹⁷ The FDA, on the other hand, lacks this necessary statutory

2001, have caused a heightened awareness of the potential dangers of the intentional contamination of the food supply as a vehicle for terrorist attacks. *See infra* note 114.

12. Hereinafter, the term “food” is used to apply to both food and food products.

13. GAO, REP. NO. GAO/RCED-91-19A, FOOD SAFETY AND QUALITY: WHO DOES WHAT IN THE FEDERAL GOVERNMENT 3–4 (1990), *available at* <http://archive.gao.gov/d21t9/142970.pdf> [hereinafter GAO WHO DOES WHAT REPORT]. The FSIS is a subdivision of the USDA and the FDA is an agency under the auspices of the U.S. Department of Health and Human Services. *Id.*

Domestic food safety “is governed by a highly complex system that is based on more than thirty laws and administered by twelve agencies. In addition, there are over fifty interagency agreements to govern the combined food safety oversight responsibilities of the various agencies.” GAO, REP. NO. GAO-04-588T, FEDERAL FOOD SAFETY AND SECURITY SYSTEM: FUNDAMENTAL RESTRUCTURING IS NEEDED TO ADDRESS FRAGMENTATION AND OVERLAP 2 (2004), *available at* <http://www.gao.gov/new.items/d04588t.pdf> [hereinafter GAO FUNDAMENTAL RESTRUCTURING REPORT].

Even domestically, however, the FDA and the USDA “have most of the regulatory responsibilities for ensuring the safety of the nation's food supply and account for most federal food safety spending.” *Id.* at 2–3.

14. GAO WHO DOES WHAT REPORT, *supra* note 13, at 3–4.

15. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 21–22.

16. *Id.*

17. Specifically,

all poultry, or parts or products of poultry, capable of use as human food offered for importation into the United States shall . . . be subject to inspection, sanitary, quality, species verification, and residue standards that achieve a level of sanitary protection equivalent to that achieved under United States standards; and [shall] have been processed in facilities and under conditions that achieve a level of sanitary protection equivalent to that achieved under United States standards.

21 U.S.C. § 466(d) (2006). *See also* 21 U.S.C. §§ 620(f) and 1046(a)(2) (2006) (codifying the parallel equivalency requirements for imported meat and egg products, respectively). Interestingly, at least one court has held that “the same” standards means “identical” as opposed to “at least equal to,” thereby

authority.¹⁸ In a study of 5,000 outbreaks of foodborne illnesses involving 152,097 individual cases that occurred between 1990 and 2004, FDA-regulated foods were associated with twice as many outbreaks as those regulated by the USDA.¹⁹ Left unresolved, this problem will only worsen as the number of imports continues to rise.

“Equivalency authority” refers to the requirement that foreign food production systems operate under standards equivalent to those enforced domestically before a country may export its food to the United States.²⁰ The FSIS has the ability to do this; the FDA does not.²¹ As a result, in 2006, only thirty-two countries were authorized to export meat and poultry to the U.S.;²² shipments of these products from anywhere else are automatically re-exported to the source country.²³

Conversely, all other foods can legally be imported from anywhere. For example, more than eighty percent of seafood consumed by Americans is imported from approximately 160 nations.²⁴ In 2006, seafood shipments

prohibiting importation of meat and poultry from countries with *superior* food safety systems. *See* Mississippi Poultry Ass’n, Inc. v. Madigan, 31 F.3d 293 (5th Cir. 1994) (justifying its seemingly misplaced holding by pointing to a failure on the part of the Secretary of Agriculture to present evidence of a food safety system superior to that of the U.S., thus rendering irrelevant the “identical” versus “at least equal to” distinction).

18. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 22.

19. *See* CSPI, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net* 5 (Dec. 2006) [hereinafter *Outbreak Alert!* 2006]. These results are eerily similar to those found one year earlier: of 4,486 outbreaks occurring between 1990 and 2003, involving 138,622 individual cases, “FDA-regulated foods were linked to 2,954 outbreaks with 83,076 cases, while USDA-regulated foods were linked to 1,229 outbreaks with 38,577 cases.” *Outbreak Alert!* 2005, *supra* note 2, at 4. Additionally, the two “single-food vehicles” linked to the most outbreaks were seafood and produce, both of which are regulated by the FDA. *Id.*

20. *Outbreak Alert!* 2005, *supra* note 2, at 4.

21. The result is a “disjointed American food-safety system,” through which a consumer dining out on steak and shrimp may be unaware that:

[t]he steak came from a cow that was examined by a government inspector before and after it was slaughtered. The shrimp most likely were not inspected. The steak probably came from an American producer. The shrimp likely came from overseas, perhaps from one of several Asian countries that have been criticized for sloppy practices in raising seafood.

Renaë Merle, *Two Very Different Paths From Farm to Table: Bifurcated Safety System Means Some Foods Get Less Scrutiny*, WASH. POST, Aug. 4, 2007, at D1.

22. Food Safety and Inspection Service (FSIS), FOREIGN COUNTRIES AND PLANTS CERTIFIED TO EXPORT MEAT AND POULTRY TO THE UNITED STATES, http://www.fsis.usda.gov/regulations_&_policies/Eligible_Foreign_Establishments/index.asp (last visited Sept. 3, 2007). The FSIS notes that Mexico is only approved to export poultry products slaughtered in the U.S. under Federal inspection or in another eligible exporting country. Additionally, Canada is the only nation authorized to export egg products to the U.S. *Id.*

23. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 22.

24. GAO, REP. NO. GAO-04-246, FDA’S IMPORTED SEAFOOD SAFETY PROGRAM SHOWS SOME PROGRESS, BUT FURTHER IMPROVEMENTS ARE NEEDED 1 (2004), *available at* <http://www.gao.gov/new.items/d04246.pdf> [hereinafter GAO IMPORTED SEAFOOD PROGRAM REPORT] (analyzing data compiled by the CDC between 1993–1997 and published in Mar. 2000). The GAO notes that,

from China alone were valued at \$1.9 billion, a monetary increase of 193 percent since 2001.²⁵ Seafood provides a critical example of an FDA-regulated food that causes a significant number of foodborne illnesses. The Centers for Disease Control and Prevention (CDC) estimates that between 1993 and 1997 “contaminated seafood . . . accounted for about 15 percent of the documented foodborne illness outbreaks in the United States – a greater percentage than either meat or poultry, even though meat and poultry [which are not regulated by the FDA] are consumed at eight and six times the rate of seafood, respectively.”²⁶ In fact, seafood and produce (also regulated by the FDA) topped the list of all foods responsible for illnesses.²⁷

This Note offers a twofold proposal: first, that legislation granting the FDA equivalency authority matching that of the FSIS is necessary to ensure the safety of imported food in the U.S. and to adequately protect Americans’ health; and second, that the FDA requires additional resources, primarily in the form of increased funding and oversight, to effectively implement and enforce that new authority. Part I outlines the current procedures used when a food shipment is received at the U.S. border by the Department of Customs and Border Protection (Customs) under the FSIS and FDA regulatory schemes.

Part II explains how the lack of equivalency authority renders the FDA unable to ensure the safety of imported foods because of insufficient resources. Consequences of this insufficiency include: a vast majority of shipments escape inspection; ineffective methods are employed at the border with respect to inspected shipments; the FDA’s reliance on self-reported data creates loopholes through which unscrupulous importers frequently slip; and ineffective containment procedures combined with unclear communication with Customs officials results in FDA-rejected shipments mistakenly entering domestic commerce.²⁸ Comparisons are made throughout this Note to the FSIS’s ability to better guard against similar hazards concerning the importation of meat and poultry products through the application and enforcement of its equivalency authority.

“[a]ccording to the National Marine Fisheries Service, National Oceanic and Atmospheric Administration, the percentage of imported seafood is based on live weight.” *Id.* at n.1.

25. Andrew Martin, *F.D.A. Curbs Sale of Five Seafoods Farmed in China*, N.Y. TIMES, June 29, 2007, at A1.

26. GAO IMPORTED SEAFOOD PROGRAM REPORT, *supra* note 24, at 1.

27. Seafood was linked to 984 outbreaks involving 9,969 illnesses while produce was linked to 639 outbreaks involving 31,496 illnesses. *Outbreak Alert! 2006*, *supra* note 19, at 5–6.

28. *See infra* notes 90–112 and accompanying text.

Part III first outlines two initiatives that would give the FDA more authority and control over imported foods: the Public Health Security and Bioterrorism Preparedness and Response Act of 2002²⁹ (Bioterrorism Act of 2002) and, specifically regarding seafood, the Hazard Analysis and Critical Control Point (HACCP) system,³⁰ fully implemented in 1997. This Part then explains why these two initiatives are not fungible substitutes for equivalency authority.

Part IV demonstrates that widespread support exists for the proposition that the FDA needs equivalency authority in addition to increased resources to effectively perform its duties. The Government Accountability Office (GAO) has released numerous reports with this recommendation,³¹ as has the Center for Science in the Public Interest (CSPI),³² and bills to this effect have been repeatedly introduced in both the House of Representatives and the Senate.³³ Additionally, FDA officials have commented on the need for equivalency authority.³⁴ Furthermore, the international community, speaking through the Codex Alimentarius Commission (Codex), has adopted guidelines for establishing equivalence agreements.³⁵ Codex, created jointly by the United Nations Food and

29. Pub. L. No. 107-188, 116 Stat. 594 (2002) [hereinafter Bioterrorism Act of 2002].

30. See 21 C.F.R. §§ 123 & 1240 (1997) (final rule requiring application of HACCP principles to domestic and imported seafood).

31. See generally GAO FUNDAMENTAL RESTRUCTURING REPORT, *supra* note 13. See also GAO IMPORTED SEAFOOD PROGRAM REPORT, *supra* note 24; GAO, REP. NO. GAO/T-RCED-98-271, FOOD SAFETY: WEAK AND INCONSISTENTLY APPLIED CONTROLS ALLOW UNSAFE IMPORTED FOOD TO ENTER U.S. COMMERCE (1998), available at <http://www.gao.gov/archive/1998/rc98271t.pdf> [hereinafter GAO UNSAFE IMPORTED FOOD REPORT]; GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1.

32. See *Outbreak Alert!* 2005, *supra* note 2, at 15.

33. See, e.g., Safe and Secure Food Act of 2005, S. 1534 109th Cong. § 301(b); Imported Food Safety Act of 2001, H.R. 3075 107th Cong. § 3(a) (proposing to amend FFDC to require “prior approval” of Secretary for imported foods).

34. “FDA . . . agree[s] . . . that it is imperative that Congress enact legislation giving FDA authority to require that, as a condition to exporting to the United States, foreign governments adopt adequate measures in their own countries to ensure that food exported to the U.S. is safe.” Press Statement from Dr. Michael Friedman, Lead Deputy Commissioner of the FDA, on GAO Food Safety Report (May 11, 1998), <http://www.fda.gov/bbs/topics/NEWS/NEW00639.html> (responding to the GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1). See also FDA, Center for Food Safety and Applied Nutrition (CFSAN), Affirmative Agenda for International Activities (Dec. 1999), <http://www.cfsan.fda.gov/~comm/intlact.html#IV> (establishing, inter alia, the following “International Priorities” for 2000–2002: strengthening the FDA’s participation in the Codex Alimentarius Commission, see *infra* note 35; establishing guidance on equivalence criteria for foods; conducting foreign equivalence evaluations; assessing the food safety and food production systems of other countries; and enhancing the safety of imported foods at their source).

In recent years, the FDA has backed away slightly from its endorsement of mandatory equivalency authority, instead suggesting discretionary authority to enter into voluntary equivalence agreements with willing nations.

35. See, e.g., CODEX, GUIDELINE NO. CAC/GC 34-1999, GUIDELINES FOR THE DEVELOPMENT

Agriculture Organization (FAO) and the World Health Organization (WHO) in 1963, develops global food safety standards.³⁶

This Note concludes by arguing that increased resources and mandatory equivalency authority, granted either through an amendment to the FFDCA or through separate legislation, is the most effective and efficient way for the FDA to adequately minimize the risk of foodborne illnesses posed by imported foods under its jurisdiction. While both individuals and groups have asserted strenuously that the FDA lacks necessary resources,³⁷ this Note contends that merely throwing money at the problem is an unsatisfactory solution. It is only by coupling increased funding with authority to address unsanitary growing and preparatory conditions at the source—namely, exporting facilities—that the FDA will be able to use expanded resources efficiently to guarantee the quality of food imports.

I

When a shipment of food under either the FSIS's or the FDA's jurisdiction arrives at the U.S. border, Customs officials first notify the proper agency.³⁸ Next, Customs conditionally releases the shipment to the importer, provided that the correct paperwork is in order.³⁹ Thereafter, the protocols followed by the FSIS and the FDA deviate considerably from one another, largely as a result of the FDA's inability to mandate equivalence.⁴⁰

OF EQUIVALENCE AGREEMENTS REGARDING FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (1999), available at http://www.codexalimentarius.net/download/standards/362/CXG_034e.pdf.

36. Codex Alimentarius, <http://www.codexalimentarius.net> (last visited Sept. 3, 2007). See also Jørgen Schlundt, Wim van Eck & Mary Vallanjon, *Editorial: WHO and FAO Have a Recipe for Safer Food*, BULLETIN OF THE WORLD HEALTH ORGANIZATION 315 (2003), <http://www.who.int/bulletin/volumes/81/5/Schlundt0503.pdf>.

37. According to the *New York Times*, detractors of the FDA contend that the agency “is woefully underfinanced and understaffed.” Alexei Barrionuevo, *Globalization in Every Loaf: Ingredients Come From All Over, but Are They Safe?*, N.Y. TIMES, June 16, 2007, at B1.

38. GAO UNSAFE IMPORTED FOOD REPORT, *supra* note 31, at 1.

39. *Id.* at 3. According to the GAO, this paperwork includes, inter alia, bonds posted with Customs by importers to allow movement of the shipment from port. *Id.* Additionally, the FSIS requires a health certificate with each shipment attesting to the product's safety. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 21.

Both the FSIS and the FDA have the power to authorize the immediate release of the shipment into U.S. commerce or to decide that the shipment must be inspected. *Id.* at 1.

40. The FDA and the FSIS have penalties that are imposed for violations of the various inspection regulations. A common criticism of the FDA is that the penalties currently in place are ineffective deterrents of subversive and negligent behavior. A discussion of the penalty issue is outside the scope of this Note; however, for an overview of the arguments involved, see GAO UNSAFE

A. Shipments Under the FSIS's Jurisdiction

The FSIS categorizes its border patrol duties as “reinspection.”⁴¹ According to FSIS officials, the initial “inspection” of every shipment occurs when the FSIS conducts the requisite equivalency investigation and approves the facilities from which shipments are sent.⁴²

Once through Customs, all FSIS shipments must be delivered to FSIS-controlled warehouses to await reinspection.⁴³ At FSIS-approved import inspection stations, inspectors visually check every shipment to determine that the documentation and labeling are correct and that the shipments have not been damaged.⁴⁴ In fiscal year 2003, the FSIS subjected about ten percent of imported food shipments to more extensive reinspection.⁴⁵

On shipments failing reinspection, the FSIS stamps “U.S. Refused Entry.”⁴⁶ Customs and the importer are notified, and the shipment is either returned to the country of origin, destroyed, or in some cases turned into animal food, within forty-five days.⁴⁷ The FSIS allows removal of the shipment from its warehouse only if the importer provides documentation demonstrating that arrangements for disposal have been made.⁴⁸ Because all reinspected goods are stamped with the USDA’s official inspection mark, any unstamped shipment readily identifies it as one not yet having been subjected to reinspection.⁴⁹ Shipments passing reinspection are

IMPORTED FOOD REPORT, *supra* note 31, at 9–10. *See also* GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 41–42.

41. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 17.

42. *Id.* at 17–18.

43. GAO UNSAFE IMPORTED FOOD REPORT, *supra* note 31, at 1.

44. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 17.

45. FSIS Reinspection Data, http://www.fsis.usda.gov/oa/Congress/Import_Equivalence/Appendix_6.pdf (last visited Sept. 3, 2007).

Reinspection is dictated by the FSIS’s computer database, the Automated Import Information System (AIIS). USDA, FSIS Import Reinspection, http://www.fsis.usda.gov/regulations_&_policies/fsis_import_reinspection/index.asp (last visited Sept. 3, 2007) [hereinafter FSIS Import Reinspection Policies]. Shipments are selected for reinspection both randomly and based on an importer’s history. *Id.* AIIS may assign various inspection methods, “including net weight checks of retail packages; examination of the container’s condition; examination for product defects; incubation of canned goods; and laboratory analyses for product composition, microbiological contamination, residues, and species. Additionally, FSIS randomly samples products at ports for drug and chemical residues.” *Id.*

46. USDA, Import Procedures for Meat, Poultry & Egg Products, http://www.fsis.usda.gov/Fact_Sheets/FSIS_Import_Procedures/index.asp (last visited Sept. 3, 2007) [hereinafter FSIS Import Procedure Fact Sheet].

47. *Id.* The FSIS must approve any “diversion” request for the conversion of rejected shipments to animal food.

48. GAO UNSAFE IMPORTED FOOD REPORT, *supra* note 31, at 3.

49. FSIS Import Procedure Fact Sheet, *supra* note 46. However, shipments from Canada bear a Canadian stamp. *Id.*

released by the FSIS and the importer may thereafter distribute the goods in domestic markets.

*B. Shipments Under the FDA's Jurisdiction*⁵⁰

The FDA electronically screens all shipments upon their arrival at the U.S. border. However, a vast majority of those shipments are then simply released by the FDA into domestic markets without inspection.⁵¹ For example, less than one percent of FDA shipments were physically inspected in 2001.⁵² Furthermore, a House of Representatives subcommittee recently found that FDA employees in San Francisco have an average of thirty seconds to decide whether any of the hundreds of shipments reviewed each day require more extensive investigation.⁵³

In contrast to FSIS procedures, shipments under the FDA's jurisdiction remain under the importer's control throughout the entire inspection process.⁵⁴ Once a sample of the shipment has been collected, Customs releases the shipment to the importer for transport to, and storage in, the importer's warehouse, pending the FDA's final decision regarding the shipment's compliance.⁵⁵ The FDA claims it lacks statutory authority to establish and mandate the use of FDA-controlled warehouses for shipment storage.⁵⁶

The FDA does not have a counterpart to the FSIS's "U.S. Refused Entry" stamp.⁵⁷ When a test sample fails inspection, the FDA sends a

50. The data for this section were gathered directly from the FDA, *infra* note 55, published in 1996 and currently under review by the FDA in light of the Bioterrorism Act of 2002. The effects of this legislation on FDA import procedures are discussed in Part III of the text.

51. GAO UNSAFE IMPORTED FOOD REPORT, *supra* note 31, at 3.

52. John D. Dingell, Ranking Member, House Committee on Energy and Commerce, Remarks Before the Consumer Federation of America 25th Annual National Food Policy Conference: Food Safety and the Bioterrorism Legislation (Apr. 23, 2002), <http://energycommerce.house.gov/press/107rm4.shtml> [hereinafter Dingell Conference Remarks].

53. Merle & Abramowitz, *supra* note 9, at D1.

54. GAO UNSAFE IMPORTED FOOD REPORT, *supra* note 31, at 3.

55. FDA/CFSAN, FDA IMPORT PROCEDURES (1996), <http://www.cfsan.fda.gov/~lrd/import.html> [hereinafter FDA IMPORT PROCEDURES]. For shipments it decides to analyze, the FDA sends a "Notice of Sampling" to both Customs and the importer. A sample is then taken of the shipment and sent to an FDA District Laboratory for testing. *Id.*

In some cases, usually involving perishable goods, the "FDA will select samples for testing and allow the shipments to continue in domestic transit—on the condition that the shipment be returned if FDA finds the shipment to be adulterated and refuses entry." GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 39.

56. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 18 n.11.

57. GAO UNSAFE IMPORTED FOOD REPORT, *supra* note 31, at 7. "According to FDA officials, FDA does not stamp refused shipments because it lacks the statutory authority to do so." GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 40.

Notice of Detention and Hearing to Customs and the importer.⁵⁸ Unlike the procedures followed by the FSIS, the importer then has ten working days to produce testimony affirming the admissibility of the shipment.⁵⁹ If the FDA rejects such testimony, a Notice of Refusal is issued.⁶⁰ The importer is then given another opportunity to move the shipment into domestic markets by proffering evidence from a “reliable laboratory” showing shipment compliance.⁶¹ Importers may choose their own laboratories for this purpose⁶² and may choose which products are used as test samples.⁶³ At any of these steps, the FDA may approve the release of the shipment if satisfied that the shipment is safe for consumption. If the FDA still refuses entry, it relies on the importer to return the shipment to Customs within ninety days for re-export or destruction.⁶⁴

II

As bad as you may believe FDA controls are at the border, the reality is . . . much worse As a result, imported food that is intentionally or unintentionally adulterated is much more likely to end up on America’s dinner table than it is to be detected and held at the border. This is true largely because FDA doesn’t have enough inspectors at ports of entry, but FDA’s own practices and lack of authority make matters worse.⁶⁵

A. *Lack of Equivalency Authority Renders the FDA Unable to Allocate Sufficient Resources to Ensuring Imported Food Safety*

The FDA only receives thirty-eight percent of the federal food safety budget⁶⁶ even though it is responsible for overseeing eighty percent of the

58. FDA IMPORT PROCEDURES, *supra* note 55.

59. *Id.*

60. *Id.*

61. *Id.*

62. GAO UNSAFE IMPORTED FOOD REPORT, *supra* note 31, at 3. *See also* Marian Burros, *F.D.A. Inspections Lax, Congress Is Told*, N.Y. TIMES, July 18, 2007, at C3 (reporting findings by an oversight subcommittee of the House of Representatives that the FDA “allowed importers to take possession of suspect goods and arrange for their testing by private laboratories that are not approved by the F.D.A.”).

63. GAO UNSAFE IMPORTED FOOD REPORT, *supra* note 31, at 2.

64. *Id.* at 7.

65. Dingell Conference Remarks, *supra* note 52.

66. *Outbreak Alert! 2005*, *supra* note 2, at 2. *See also* USDA, *FY 2005 Budget Summary* 65, available at <http://www.usda.gov/agency/obpa/Budget-Summary/2005/FY05budsum.pdf>; FDA Office

nation's food supply.⁶⁷ Budget summaries for fiscal year 2004 show \$899 million allocated to the USDA's food inspection program, but only \$413 million allocated to the FDA for similar purposes.⁶⁸ In 2003, the FDA reported that "more than six million food shipments arrive in the U.S. each year," and that figure rises annually.⁶⁹

This is a logical extrapolation from recent trends. The number of imported food shipments under the FDA's jurisdiction more than doubled between 1992 and 1997, rising from 1.1 million to 2.7 million.⁷⁰ To put these increases in perspective, consider that approximately 950,000 items were offered for import into the U.S. in 1985.⁷¹ This places a premium on the efficient and focused use of resources. However, the lack of equivalency authority forces the FDA to spread its limited resources too thinly. While equivalency authority allows the FSIS to shift much of the burden of ensuring the safety of imported foods under its jurisdiction to exporting nations, the FDA must shoulder the complete inspection responsibility at the U.S. border.⁷²

1. The FSIS's Equivalency Authority Shifts the Burden of Ensuring Imported Food Safety to Foreign Nations and Allows for Efficient Use of Border Resources

Any country wishing to export meat or poultry to the United States must apply to the USDA for eligibility.⁷³ The FSIS can deny any

of Financial Management, *FY 2006 Budget Summary and Budget in Brief* 124, available at <http://www.fda.gov/oc/oms/ofm/budget/2006/PDFs/consolidatedbudget.pdf>.

The FDA received a one-time special appropriation of \$151 million to facilitate its implementation of the provisions of the Bioterrorism Act of 2002. See McClellan, *supra* note 10, at 202. According to McClellan, some of that money was used to "hire more than 800 new employees, 655 of whom are earmarked for food safety activities in the field." *Id.*

67. GAO, REP. NO. GAO-05-549T, OVERSEEING THE U.S. FOOD SUPPLY: STEPS SHOULD BE TAKEN TO REDUCE OVERLAPPING INSPECTIONS AND RELATED ACTIVITIES, 8 (May 2005), available at <http://www.gao.gov/new.items/d05549t.pdf> [hereinafter GAO OVERLAPPING INSPECTIONS REPORT].

68. DeWaal, *supra* note 2, at 433.

69. FDA CFSAN, Ensuring the Safety and Security of the Nation's Food Supply (July 23, 2003), <http://www.cfsan.fda.gov/~dms/sssrepg.html>.

70. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 25.

71. Schultz Testimony, *supra* note 10.

72. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 24.

73. FSIS Import Procedure Fact Sheet, *supra* note 46. Eligibility determination is a two-step process involving document review and an on-site audit. A satisfactory document review is a prerequisite for an on-site audit. The document review evaluates the candidate nation's regulations and laws. The USDA focuses on controls for five risk areas: residue; slaughter and processing; enforcement; animal disease; and sanitation. *Id.*

If the document review reveals an equivalent system, USDA inspectors visit the site to examine its production facilities, laboratories and training programs. *Id.* If the nation's system passes inspection, a

eligibility application and is not required to solicit one from a foreign country. Once a country is eligible, it bears continued responsibility for certifying each individual export shipment, as well as for providing annual re-certification paperwork.⁷⁴ Additionally, the FSIS reserves the right to suspend a country from the list if its food safety system falls below equivalency.⁷⁵ For example, in 1998 Paraguay was suspended “because its inspection system was not adequate to prevent contamination on repeated shipments.”⁷⁶

The use of equivalency authority allows the FSIS to shift a significant portion of the burden of ensuring U.S. quality standards for all food exports to the would-be exporting country.⁷⁷ Therefore, at the border the FSIS is primarily concerned with detecting superficial defects in shipments, such as improper labeling or transport damage.⁷⁸ As a result, the FSIS is able to concentrate its resources on annual facility re-certification reviews rather than ad hoc border patrol inspections.⁷⁹

2. The FDA Bears the Entire Burden of Ensuring the Safety of Imported Foods Under its Jurisdiction and Lack of Equivalency Authority Forces the FDA to Rely on Ineffective Border Controls

Mandatory equivalency authority would allow the FDA to require, inter alia, sanitation and production information about foreign facilities and enforce standards akin to those required by the FSIS. According to the United Nations FAO, “testing products at the port of entry involves a concentration of inspection resources on the imported product itself and is an attempt to compensate for a lack of knowledge about the processing, hygiene, and sanitation practices of the producer.”⁸⁰ Shipments of FDA-regulated food arrive at the border virtually unknown.⁸¹ The FDA has no information regarding the conditions under which the food was grown, produced, handled or shipped.⁸² Therefore, the FDA must rely solely on its

proposed rule to add the country to the eligibility list is published in the Federal Register, followed by standard agency rulemaking procedures, including a public notice and comment period. *Id.*

74. *Id.*

75. *Id.*

76. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 48.

77. See FSIS Import Procedure Fact Sheet, *supra* note 46 (providing that the burden for submitting annual re-certification paperwork rests with the exporting nation).

78. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 17.

79. *Id.* at 24.

80. *Id.* at 24–25.

81. The Bioterrorism Act of 2002 requires that FDA be given advance notice of shipments.

82. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 24.

border inspections to ascertain these facts to the degree necessary for ensuring that the food is safe for American consumption.⁸³ Success, measured as allowing only safe imported foods to enter domestic markets and detaining contaminated or otherwise unsafe shipments at the border, depends upon inspecting a representative sample of shipments.⁸⁴

The percentage of shipments inspected by the FDA has fallen as the number of imports has risen. “Since 2003, the number of [FDA] inspectors has decreased while imports of food alone have almost doubled.”⁸⁵ The current inspection methods are also ineffective even when employed,⁸⁶ underscoring the need for legislative reform.

B. Consequences of the FDA’s Insufficient Allocation of Resources Due to Lack of Equivalency Authority

Relying wholly on port-of-entry inspections to ensure the safety of imported foods⁸⁷ has several serious and dangerous consequences for the American consumer. First, an overwhelming majority of shipments simply pass across the border without inspection.⁸⁸ As the number of imported shipments has risen, the FDA’s inspection percentage has fallen, dropping from eight percent in 1992 to less than one percent in 2001.⁸⁹ However, even these numbers may be misleadingly optimistic. In 1997, the FDA inspected 46,295 shipments, or 1.7 percent of the total imports for that year, yet only 16,048 shipments, representing 0.6 percent of the total shipments for 1997, were subjected to laboratory testing.⁹⁰

The FDA lacks the resources to employ enough personnel to properly supervise and oversee the rising number of imports. In 2001, 150 inspectors were responsible for overseeing imports at 307 ports of entry.⁹¹

83. *Id.*

84. *Id.*

85. See Burros, *supra* note 62, at C3.

86. See text Part II.B. See also Burros, *supra* note 62, at C3 (“Unlike the Department of Agriculture—which . . . limits imports to 10 ports—the F.D.A. has no control over imports. Even though it has inspectors at only 90 of the more than 300 American ports, the food it inspects can come into any of them.”).

87. See text Part II.A.2. The FDA must do this because it lacks equivalency authority. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 22.

88. See *supra* notes 50–53 and accompanying text.

89. Dingell Conference Remarks, *supra* note 52.

90. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 25–26.

91. Dingell Conference Remarks, *supra* note 52. Even FDA officials commented on the disconnect between the amount of shipments arriving at the border and the resources available to hire inspection personnel:

In 1992, [the FDA] received approximately 1.1 million . . . items of imported foods and had 631 . . . Full Time Equivalent employees (FTEs) to look at those items. By 1997, our line

This is not a new problem for the FDA; between 1992 and 1997, “the average number of annual food shipments each [FDA] inspector was responsible for increased from about 3,350 to about 10,500.”⁹² In that same time period, inspectors for the FSIS experienced a more manageable increase; the “number of import entries per FSIS inspector rose from about 1,236 in calendar year 1992 to about 1,645 in 1997.”⁹³ Only 1,750 food inspectors were responsible for all the ports and domestic food-production plants in 2007.⁹⁴ By contrast, the USDA employs about 9,000 inspectors.⁹⁵ A shipment that arrives at a port without an FDA inspector passes into domestic commerce unchecked.⁹⁶

Equivalency authority would allow FDA inspectors to spend less time on each shipment, thereby allowing them to inspect more shipments each year and thus ameliorating the pressure to conduct exhaustive inspections by providing a presumptive assurance of safety and quality.

Second, the methods available for conducting port-of-entry inspections are ineffective. Contaminants that may be introduced into food at the foreign production and handling stages are often undetectable by visual or laboratory tests at the port of entry. Thus, pre-emptive inspections of the production facilities are necessary to effectively guard against these hazards.⁹⁷ Even if laboratory tests were sufficient to detect most problems, American consumers would still be at risk: for example, the percentage of seafood imports sent for laboratory analysis has recently declined, from .88 percent in 2003 to .59 percent in 2006.⁹⁸

Third, the FDA’s reliance on importers’ self-reported data creates incentives and opportunities for importers to circumvent the FDA’s

items more than doubled to approximately 2.7 million but budget limitations caused us to cut our . . . FTEs to 565[, of which] only 314 are . . . “operational,” with 112 actual investigators and 202 analyzing samples in the laboratories.

Schultz Testimony, *supra* note 10. The practical effect of these numbers meant that, “in 1992 [the FDA was] able to physically inspect 8 percent of all imported foods. [In 1997], the [FDA] physically inspect[ed] only 1.6 percent of imported food.” *Id.*

92. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 25.

93. *Id.* at 26.

94. According to William Hubbard, a former FDA Associate Commissioner, this means that most domestic food-production plants are visited by an inspector once every five to ten years. *See* Alexei Barrionuevo, *Food Imports Often Escape Scrutiny*, N.Y. TIMES, May 1, 2007, at C1.

95. *Id.*

96. Dingell Conference Remarks, *supra* note 52.

97. *See* GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 24 (reporting a CDC finding that “both visual inspections and laboratory tests are inadequate to detect *Cyclospora*”). Conversely, superficial defects, such as improper labeling or violations of transport temperature guidelines, can usually be discovered through reasonable border and laboratory inspection methods. *Id.*

98. *See* Martin, *supra* note 25, at A1 (reporting the findings of Food and Water Watch, a nonprofit group based in Washington, D.C.).

efforts. Importers electronically enter data regarding incoming shipments on the FDA's computer system.⁹⁹ The FDA determines which shipments are inspected using these data, and the "paperless filers" are required to periodically submit paper documents for comparison.¹⁰⁰ Though the FDA may remove importers from paperless status if their discrepancies between the paper and electronic data exceed ten percent, FDA records show that this corrective action is rarely, if ever, used.¹⁰¹ Importers have been discovered using this practice to their advantage by, for instance, tagging a shipment that would otherwise automatically be detained with the product code of one permitted to cross the border without inspection.¹⁰²

Fourth, conditional release¹⁰³ and the FDA's delegation to importers of both the selection of tested samples and the laboratories at which the tests are performed, leads to "substitution."¹⁰⁴ Importers can substitute safe products for unsafe ones during transport to a laboratory or when re-submitting data to the FDA to show compliance of a previously-rejected shipment.¹⁰⁵ Additionally, the FDA gives importers ninety days—twice

99. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 33. The FDA's computer system is called Operational and Administrative System for Import Support (OASIS). *Id.* at 16, 33.

100. *Id.* at 33.

101. *Id.*

102. The following is an example of the misconduct that was uncovered in a 1998 GAO survey:

[A]n FDA inspector at one port of entry said that, while most errors are accidental, he has encountered problems with importers who appeared to deliberately avoid FDA's inspections by using the wrong product code for swordfish, which is automatically held until the importer provides laboratory test results demonstrating that the product complies with U.S. standards.

By entering a code for another type of fish, the importers hope that the on-screen review will not detect a discrepancy and the shipment will not be selected for inspection.

GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 34. Alarming, FDA inspectors reported to GAO that, even when they encounter incorrect data "that appear[s] to be deliberate misrepresentations, they work with the importer to correct the entry problems and, in most cases, do not investigate the suspect filers further. They said that they view their role as teachers, not investigators." *Id.*

103. *See* text Part I.B.

104. *See infra* notes 108–09 and accompanying text.

105. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 38. One example of substitution reported by the GAO included the following:

On a shipment of frozen shrimp, Customs alleged that the importer removed a portion of the shipment that had thawed during transport before making the shipment available for FDA's inspection. If the thawed shrimp had not been removed, FDA would have refused entry for the entire shipment because the thawing indicated that the proper temperature controls were not maintained during transport, and thus the entire shipment may be contaminated.

Id. at 40. Customs discovered that importers in San Francisco, California, were engaged in "banking," or "sharing the same acceptable product when they had to present a shipment for inspection." GAO UNSAFE IMPORTED FOOD REPORT, *supra* note 31, at 5.

the time allowed by the FSIS—to return to Customs any shipments that are refused entry, affording importers more time to substitute.¹⁰⁶

Fifth, shipments rejected by the FDA occasionally enter domestic commerce as a result of ineffective containment procedures¹⁰⁷ and communication breakdowns between the FDA and Customs.¹⁰⁸ The FDA's initial decision to refuse entry sometimes does not occur until the FDA receives the laboratory results, which may be several days, or even a few weeks, after the shipment was initially imported and conditionally released into the importer's custody.¹⁰⁹ Often, this is too late since the importer may have already sold the goods or may simply refuse to heed the FDA's request for re-export.¹¹⁰ In 2001, the GAO reminded Congress of its earlier finding that "in a [Customs surveillance] operation called 'Bad Apple,' about 40 percent of the imported foods FDA checked and found in violation of U.S. standards were never redelivered to Customs for disposition. These foods were not destroyed or reexported as required and presumably were released into U.S. commerce."¹¹¹ Furthermore, Customs is not always aware of the FDA's decision to refuse entry of a particular shipment.¹¹² The FDA claims it lacks statutory authority to mirror the FSIS's practice of stamping "U.S. Refused Entry" on rejected shipments, which would help address this concern as well as help prevent substitution.¹¹³

The weaknesses in the FDA's current import procedures highlight the need to re-examine how the FDA regulates imported foods under its jurisdiction. Granting the FDA equivalency authority would be the most efficient and effective method of ensuring that imported foods meet U.S. standards for quality and safety.

III

Both the Bioterrorism Act of 2002 and the HACCP system address important concerns facing the food industry. However, both regulatory schemes, individually and collectively, fail to provide the more generally

106. *Id.* at 7. Succinctly, "importers will distribute into domestic commerce shipments refused entry and substitute for re-export a shipment that arrives at a later date." *Id.*

107. *See id.* at 4.

108. *See id.* at 7–9.

109. *Id.* at 4.

110. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 40. Penalties for such action are ineffective deterrents. *See supra* note 40.

111. GAO FUNDAMENTAL CHANGES REPORT, *supra* note 11, at 7.

112. *See supra* notes 105–11 and accompanying text.

113. GAO UNSAFE IMPORTED FOOD REPORT, *supra* note 31, at 7.

reliable and comprehensive protection of mandatory equivalency authority.

A. *The Bioterrorism Act of 2002*

The Bioterrorism Act of 2002 was passed in response to the terrorist attacks of September 11, 2001.¹¹⁴ Under the Act, the FDA requires advance notice of imported foods under its jurisdiction.¹¹⁵ Additionally, “entities such as the manufacturers, processors, and receivers of imported foods” must keep records that allow the FDA to identify the “immediate previous source and . . . subsequent recipients of food.”¹¹⁶ Although the latter requirement is generally directed at allowing the FDA to trace ownership of imported food in the event of intentional contamination, any heightened recordkeeping requirements also boost food safety oversight.

The Bioterrorism Act of 2002 is a security (rather than a safety) measure; therefore, the most comprehensive solution to concerns of both food safety and food security¹¹⁷ would be to amend the FFDCa to give the FDA mandatory equivalency authority *in addition to* the regulatory powers granted by the Bioterrorism Act of 2002. Alone, the latter fails to address many of the potential hazards that jeopardize food safety, such as the sanitation conditions of foreign food production facilities.

B. *The HACCP System*

The Hazard Analysis and Critical Control Point (HACCP) system is a science-based initiative geared toward improving and monitoring food safety originally developed by the FDA in the 1970s for astronauts as a way of preventing foodborne illnesses in space.¹¹⁸ Today, HACCP has

114. FDA, *The Bioterrorism Act of 2002*, <http://www.fda.gov/oc/bioterrorism/bioact.html> (“The events of Sept. 11, 2001, reinforced the need to enhance the security of the United States. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which President Bush signed into law June 12, 2002.”) [hereinafter *FDA Informational Page on the Bioterrorism Act of 2002*].

115. GAO OVERLAPPING INSPECTIONS REPORT, *supra* note 67, at 4. See also Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 381(m) (2006), amended by Bioterrorism Act of 2002, *supra* note 29.

116. GAO OVERLAPPING INSPECTIONS REPORT, *supra* note 67, at 4.

117. This Note addresses food *safety* concerns; namely, accidental contamination, often the result of unsanitary production facilities. The portions of the Bioterrorism Act of 2002 focusing on the food industry, however, focus on food *security* concerns; namely, a possible terrorist attack in the form of intentional poisoning of the U.S. food supply.

118. FDA Backgrounder, *HACCP: A State-of-the-Art Approach to Food Safety* (2001), <http://www.cfsan.fda.gov/~lrd/bghaccp.html> [hereinafter *HACCP: A State-of-the-Art Approach to Food Safety*].

been adopted as the international standard for food safety by Codex.¹¹⁹ The FDA currently requires foreign plants exporting seafood to the U.S. to comply with the HACCP principles.¹²⁰

1. Overview of the HACCP Requirements

HACCP guidelines require all seafood processors and importers to institute the seven HACCP principles.¹²¹ First, each processor¹²² must identify likely food safety hazards.¹²³ If potential hazards are identified, the processor must develop a HACCP plan that, in addition to stating the potential hazards, administratively incorporates the remaining six safety principles: (1) critical control points (CCP) which control hazards occurring both within and without the workplace; (2) critical limits (safe operating restrictions) for the CCP; (3) monitoring procedures; (4) corrective action plans (if the processor has any); (5) verification procedures that ensure at least annual revision of the plan and review of current implementation status; and (6) a recordkeeping system documenting the processor's monitoring, corrective actions and certain verification procedures.¹²⁴

2. HACCP is not a Fungible Substitute for Equivalency Authority

HACCP is a far cry from being a solution to the problem of unsafe imported foods under the FDA's jurisdiction reaching the American marketplace. As of 2004, the GAO continued to maintain that the "FDA's system for ensuring the safety of imported seafood does not sufficiently protect consumers. . . . [T]he agency inspected about 100 of roughly 13,000 foreign firms in 2002 and tested slightly over 1 percent of imported seafood products."¹²⁵ Though the system approaches food safety from a

119. *Id.* See also *supra* note 36 and accompanying text. The Codex Alimentarius Commission is discussed in more detail in Part IV of the text.

120. Press Handout, *The Provisions of the Regulation: The Seafood HACCP Regulations* (Dec. 5, 1995), <http://www.cfsan.fda.gov/~dms/haccppro.html> [hereinafter *FDA HACCP Press Handout*].

121. *Id.*

122. "Processors" are all seafood-related entities in the food and drug industry, all importers, and all foreign processors that export to the U.S. The term does not include fishing vessels, common carriers, or retailers.

123. *Id.* If none is identified, the processor satisfies HACCP requirements as long as (a) the analysis is correct and (b) the processor reassesses when necessitated by a change in the work environment. *Id.*

124. *Id.* Additionally, a "senior firm official" must sign and date the plan, and reaffirm his or her signature at least annually and upon any modification of the plan. *Id.*

125. GAO FUNDAMENTAL RESTRUCTURING REPORT, *supra* note 13, at 7.

preventative perspective, rather than the reactive approach of relying on border inspections,¹²⁶ it does so with a limited scope, in that it does not apply to all foods. And, while the current HACCP protocol would be put to its maximum utility if used in addition to, rather than instead of, equivalency authority,¹²⁷ a true solution must be broad based, covering all foods under the FDA's jurisdiction. That the FSIS chose to institute HACCP for meat and poultry on top of its equivalency authority supports the proposition that HACCP is most effectively used in conjunction with mandatory equivalency authority.¹²⁸

The FDA requires that seafood importers meet one of two conditions before being permitted to bring seafood into the U.S., the *second* of which is demonstrated HACCP compliance.¹²⁹ The *first* condition, illustrating the agency's preference for equivalency, is to acquire shipments from countries with which the FDA has entered into voluntary equivalency agreements.¹³⁰

The discussion in Part II.A.1 of this Note observed that the FSIS is able to efficiently deploy its resources because much of the burden for ensuring foreign producers' compliance with U.S. safety and wholesomeness requirements is shifted to those foreign producers. Similarly, equivalency authority would allow the FDA to shift the burden for ensuring compliance with HACCP to foreign producers. Making an initial equivalency determination, followed by periodic check-ups, would certainly be less taxing on the FDA's scarce resources than bearing the entire burden of ensuring continuing HACCP compliance from all importers.¹³¹ Additionally, mandatory equivalency authority would prevent the following error, uncovered in a 2002 survey conducted by the GAO: "in about 4 percent of the inspection forms, FDA investigators erroneously indicated that the exporting country had an equivalence agreement in place for seafood" and did not, therefore, inquire as to HACCP compliance.¹³² Moreover, in the absence of equivalence

126. See *FDA HACCP Press Handout*, *supra* note 114; *HACCP: A State-of-the-Art Approach to Food Safety*, *supra* note 118.

127. See generally GAO IMPORTED SEAFOOD PROGRAM REPORT, *supra* note 24.

128. See Levitt, *supra* note 11, at 20.

129. GAO IMPORTED SEAFOOD PROGRAM REPORT, *supra* note 24, at 2.

130. *Id.*

131. GAO IMPORTED SEAFOOD PROGRAM REPORT, *supra* note 24, at 6. As of January 2004, the GAO "continue[d] to believe that equivalence agreements are one of the most cost-effective methods for ensuring the safety of imported seafood." *Id.*

132. *Id.* at 16. These mistakes are all the more curious considering that, at the time, the FDA had not entered into such an equivalence agreement with any foreign country. *Id.*

agreements, the FDA relies on importers' self-reported data to determine HACCP compliance,¹³³ which raises previously enumerated concerns.

IV

Both the GAO and the CSPI have argued forcefully that the FDA needs increased resources and mandatory equivalency authority to effectively meet its safety and wholesomeness mandate.¹³⁴ Members of Congress have also recognized the need for legislative reform, as evidenced by numerous proposed bills.¹³⁵ FDA officials have pressed for equivalency authority.¹³⁶ However, while the need for equivalency authority is a repeated theme, parties have suggested different means of achieving the desired goal of safer imported food.¹³⁷

133. *Id.* at 3.

134. *See supra* notes 31–32 and accompanying text.

135. *See supra* note 33 and accompanying text. None of the proposed legislation advanced beyond committee level. *See also, e.g.*, Imported Products Safety Improvement and Disease Prevention Act of 2000, S. 2692, 106th Cong. (2000) (introduced in Senate); Imported Food Safety Improvement Act, S. 1123, 106th Cong. (1999) (introduced in Senate); Imported Food Safety Improvement Act of 1999, S. 1126, 106th Cong. (1999) (introduced in Senate); Imported Food Safety Improvement Act of 1999, H.R. 2055, 106th Cong. (1999) (introduced in House); Imported Food Safety Act of 1999, H.R. 830, 106th Cong. (1999) (introduced in House); Imported Food Safety Act of 1998, H.R. 4080, 105th Cong. (1998) (introduced in House); Safety of Imported Food Act of 1998, S. 1707, 105th Cong. (1998) (introduced in Senate); Safety of Imported Food Act of 1997, 105th Cong. (1997) (introduced in House); Food Safety Assurance Act of 1989, H.R. 3292, 101st Cong. (1989) (introduced in House).

136. *See supra* note 34 and accompanying text.

137. For example, the GAO recently suggested that control over U.S. food be consolidated under one agency, headed by a food czar. *See generally* GAO OVERLAPPING INSPECTIONS REPORT, *supra* note 67; GAO, REP. NO. GAO-05-213, OVERSIGHT OF FOOD SAFETY ACTIVITIES: FEDERAL AGENCIES SHOULD PURSUE OPPORTUNITIES TO REDUCE OVERLAP AND BETTER LEVERAGE RESOURCES (Mar. 2005), available at <http://www.gao.gov/new.items/d05213.pdf>; GAO, REP. NO. GAO-05-212 FOOD SAFETY: EXPERIENCES OF SEVEN COUNTRIES IN CONSOLIDATING THEIR FOOD SAFETY SYSTEMS (Feb. 2005), available at <http://www.gao.gov/new.items/d05212.pdf>. Members of Congress have submitted similar proposals. *See, e.g.*, Safe Food Act of 2005, S. 729, 109th Cong. (2005); Safe Food Act of 2005, H.R. 1507, 109th Cong. (2005). *See also* *Outbreak Alert!* 2006, *supra* note 19. For perhaps the most well-known treatment of the food safety issue recommending agency consolidation, see INSTITUTE OF MED. & NAT'L RESEARCH COUNCIL, ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION (Nat'l Acad. Press 1998).

Such a course of action, however, would require an incredible amount of government restructuring and likely result in years of confusion and uncertainty. *See* Merrill & Francer, *supra* note 8, at 114 (“Any proposal to consolidate the federal food safety bureaucracy must take into account the statutory and institutional histories of the existing agencies, as well as the impact of such change at the federal level on domestic local governments and emerging international regimes.”). *See also id.* at 115–18 (providing a table of the “Major Proposals for Reorganizing the Federal Food Safety Regulators Since 1949”). Strengthening the FDA’s authority under the current division of responsibilities is both practical and feasible.

Concededly, there is substantial overlap in the current regulatory schemes. However, that problem lies outside the focus of this Note. For an overview and critique of the overlapping responsibilities of

The need for mandatory equivalency authority granted through legislative reform is made more vital by the FDA's recent position that current demands on its resources preclude it from pursuing voluntary equivalence agreements.¹³⁸ If the FDA no longer believes it can allocate the resources necessary to negotiate these agreements, mandatory equivalency authority granted through an amendment to the FFDCFA or separate legislation is the surest way of requiring U.S. quality for all imported foods. Of course, increased resources are also required to facilitate the implementation and enforcement of equivalency authority, but the new statutory mandate would ensure that the money is put toward that specific end.

The discussion of food safety and equivalency authority is not unique to the United States. The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures¹³⁹ (WTO SPS Agreement) imposes an obligation on member nations to "enter into consultations with the aim of achieving equivalence agreements upon the request of other WTO member nations."¹⁴⁰ The U.S. is a signatory to the WTO SPS Agreement.¹⁴¹ Additionally, Codex urges countries to work together to achieve "the appropriate level of sanitary protection of the importing country, consistent with the principle of equivalence as provided for in the [WTO SPS Agreement]."¹⁴² Codex primarily develops food guidelines and standards and implements the Joint FAO/WHO Food

the various agencies charged with food safety, see GAO OVERLAPPING INSPECTIONS REPORT, *supra* note 67. See also GAO FUNDAMENTAL RESTRUCTURING REPORT, *supra* note 13.

138. GAO IMPORTED SEAFOOD PROGRAM REPORT, *supra* note 24, at 47 (maintaining that, due to "FDA priorities associated with implementation of the provisions of the Bioterrorism Act [of 2002] . . . FDA is not currently positioned to assign high priority to negotiating equivalence or similar types of agreements with the numerous countries that are currently exporting seafood to the United States").

139. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement), Art. 4 (1994), http://www.wto.org/English/tratop_e/sps_e/spsagr_e.htm.

140. GAO IMPORTED SEAFOOD PROGRAM REPORT, *supra* note 24, at 12.

141. *Id.*

142. CODEX, GUIDELINE NO. CAC/GL 53-2003, GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS 1 (2003), available at http://www.codexalimentarius.net/download/standards/10047/CXG_053e.pdf. Codex recognizes that:

Application of the principle of equivalence has mutual benefits for both exporting and importing countries. While protecting the health of consumers, it serves to facilitate trade, and minimize the costs of regulation to governments, industry, producers, and consumers by allowing the exporting country to employ the most convenient means in its circumstances to achieve the appropriate level of protection of the importing country.

Id.

Standards Programme.¹⁴³ To that end, Codex publishes guidelines for developing equivalency agreements.¹⁴⁴

CONCLUSION

The CDC estimates that approximately 76 million cases of foodborne illness occur in the United States each year, resulting in 325,000 hospitalizations and 5,000 deaths annually.¹⁴⁵ In 2000, the Economic Research Service (ERS) of the USDA approximated the cost from five of the most common foodborne bacterial pathogens to be \$6.9 billion.¹⁴⁶ For example, a 1994 *Salmonella enteritidis* outbreak traced to a national brand of ice cream infected 224,000 people nationwide and cost an estimated \$18.1 million.¹⁴⁷ According to the U.S. International Trade Commission, food imports more than doubled in the last decade, totaling \$79.9 billion in 2006.¹⁴⁸ As the import share of foods consumed in the United States continues to rise, the risk of illness from imported foods becomes greater.¹⁴⁹

Currently, the procedures employed by the FDA to monitor imported foods under its jurisdiction, a category broadly encompassing almost all foods,¹⁵⁰ are inadequate. Lack of equivalency authority forces the FDA to concentrate its scarce inspection resources at the U.S. border, which

143. Codex, FAO/WHO Food Standards, <http://www.codexalimentarius.net> (last visited Jan. 10, 2007). The Programme focuses on the following areas: “protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.” *Id.*

144. *See supra* note 35.

145. CDC, Disease Listing, Foodborne Illness, General Information 5 http://www.cdc.gov/ncidod/dbmd/diseaseinfo/files/foodborne_illness_FAQ.pdf (last visited Sept. 18, 2007).

146. USDA ERS: Economics of Foodborne Disease, <http://www.ers.usda.gov/briefing/FoodborneDisease/> (last visited Jan. 15, 2007). The bacterial foodborne pathogens factored into the cost estimate are: “*Escherichia coli* O157 and other STECs (and associated hemolytic uremic syndrome), *Campylobacter* (and associated Guillain-Barré syndrome), *Listeria monocytogenes*, and *Salmonella*.” *Id.*

“The cost estimate includes medical costs, productivity losses from missed work, and an estimate of the value of premature death that takes into account the age distribution of those taken ill.” *Id.* For a detailed description of the factors that constitute the estimate, see USDA ERS Foodborne Illness Cost Calculator, <http://www.ers.usda.gov/data/foodborneillness/> (last visited Sept. 18, 2007).

147. GAO VOLUNTARY EFFORTS REPORT, *supra* note 11, at 2. This estimate included “\$6.9 million for medical care and \$11.2 million in time lost from work.” *Id.*

148. Barrionuevo, *supra* note 37, at B1.

149. *See* Schultz Testimony, *supra* note 10 (While the U.S. food supply is one of the safest in the world, “every year tens of millions of Americans become sick and thousands die from illnesses caused by both domestic and imported food. The increasing quantities of food that are imported into the United States has raised some significant questions about [the FDA’s] ability to protect consumers from potential hazards.”).

150. Except meat, poultry and some egg products. *See supra* note 14 and accompanying text.

provides insufficient protection against possible foreign contamination. “Because such port-of-entry inspection and testing has been widely discredited as an effective means for ensuring safety, [the] FDA cannot realistically ensure that unsafe foods are kept out of U.S. commerce.”¹⁵¹ Lack of funds renders the FDA unable to adequately staff ports with inspectors; additional authority must be coupled with a budget reflective of the FDA’s responsibilities.¹⁵² The FDA needs the power to require U.S. quality for imported foods under its jurisdiction and the resources to wield and enforce that power.¹⁵³ Mandatory equivalency authority, together with appropriately increased funding, ensures inspection of the hands that feed us, which is more effective than attempting to catch at the border unclean foods prepared in unknown conditions.

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151. GAO INCONSISTENT AND UNRELIABLE EFFORTS REPORT, *supra* note 1, at 26.

152. Rep. Bart Stupak (D-Mich.), Chairman of the House Energy and Commerce Committee’s Oversight and Investigations Subcommittee, commented that, “[e]ntry reviewers, investigators and compliance officers simply cannot keep up with the flood of imported food.” Merle & Abramowitz, *supra* note 9, at D1 (also describing the FDA’s food-safety program as “woefully understaffed”).

153. Part of the problem, according to William Hubbard, a former FDA official, is that “the FDA’s responsibilities have grown faster than the agency has. . . . When the FDA was established, it oversaw the import of such staples as flour and molasses, in which problems were usually easy to spot. . . . The FDA foods were not considered dangerous.” Merle, *supra*, note 21, at D1.

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