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H.R. 3610, the Food and Drug Import Safety Act of 2007

KELLY CHEN AND ROSA DUNNEGAN-MALLAT*

Abstract

The Food and Drug Import Safety Act of 2007 (H.R. 3610) was introduced by Representative John Dingell, Chair of the House Committee on Energy and Commerce, and seeks to address limitations of the Food and Drug Administration (FDA) in ensuring the safety of imported foods. This article discusses the bill's proposals to bolster the FDA's regulatory authorities and highlights proposals currently implemented across the federal government and with foreign trading partners. Special attention is given to the Memorandum of Agreement on food safety between the FDA and China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). Contemporaneously with the introduction of the Act, the President authorized a Cabinet-Level Working Group on Import Safety. The Working Group published an Action Plan with recommendations and guidelines for interagency collaboration. Finally, the article discusses new FDA initiatives, including pilot programs designed to implement the agency's Food Protection Plan (FPP).

I. Introduction

The media has brought enormous attention to recent imports of tainted food to the United States. In a statement by William K. Hubbard before the House Subcommittee on Health, examples of such tainted food included “illegal pesticides on fruit from Latin America,” impure raw drug ingredients from China, “deadly pet food ingredients, toothpaste tainted with antifreeze, [and] seafood laced with illegal drugs.”¹ In response to these food-related threats, Congress has developed legislation to address the safety of food imports. Chief among the legislative proposals is the Food and Drug Import Safety Act of

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1. *The Food and Drug Import Safety Act of 2007: Hearing on H.R. 3610 Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 3 (2007) (statement of William K. Hubbard, Senior Advisor, The Coalition for a Stronger FDA), available at http://energycommerce.house.gov/cmtc_mtgs/110-he-hrg.092607.Hubbard-testimony.pdf [hereinafter Hubbard Statement].

2007.² This bill, known as H.R. 3610, was introduced by Representative John Dingell, Chair of the House Committee on Energy and Commerce.³ The Act seeks to address weaknesses of the Food and Drug Administration (FDA) to ensure the safety of imported foods.

Changes in the nature of imports, especially an increase in import volume, have overwhelmed FDA's ability to assure food safety. Hubbard testified before the U.S. House of Representatives Subcommittee on Health that imports regulated by FDA have increased from about two million in 1993 to nearly twenty million today.⁴ In addition, there has been a flood of "foods, drugs, medical devices, cosmetics, animal foods, and dietary supplements" into the United States from countries where food producers have little or no regulatory oversight.⁵ Another change Hubbard noted is that food from other countries is now increasingly raw materials used in production rather than items for immediate consumption.⁶ These raw materials include fundamental ingredients from India used for U.S. drugs and essential food products from China.⁷ Furthermore, Hubbard testified that the United States is faced with new risks, including food-borne diseases not previously identified by scientists, dangerous industrial compounds, and carcinogenic drugs in food imports.⁸

Part II of this paper highlights the inefficiencies of FDA in regulating food imports. Part III discusses tools FDA currently uses to monitor food imports. Part IV discusses the proposed Food and Drug Import Safety Act and the new authorities it will bestow on the FDA. Part V will briefly describe government initiatives focused on the safety of imported food with particular emphasis on the recent agreement between the United States and China on food safety. Part VI summarizes new FDA initiatives to improve the safety of food imports. Finally, Part VII discusses private sector initiatives on enhancing food product safety.

II. FDA Limitations in Regulating Food Imports

Hubbard identified two principal reasons for the limitations of FDA in regulating food imports. First, while FDA's responsibilities continue to grow in response to new regulatory challenges, its budget has not increased proportionately.⁹ The agency has received either the same amount of funds each year or budget decreases over the past decade, which has contributed to a decrease in food scientists and inspectors.¹⁰ Hubbard reported that although the volume of imports is now about twenty million shipments of FDA-regulated products annually, the number of import inspectors has not increased accord-

2. See H.R. 3610, 110th Cong. (2007).

3. Press Release, House Comm. on Energy and Commerce, Dingell Introduces H.R. 3610, the "Food and Drug Import Safety Act of 2007": Bill Addresses Growing Problem of Tainted Imports; Strengthens Consumer Protections (Sept. 20, 2007), available at http://energycommerce.house.gov/index.php?option=com_content&task=view&id=465&Itemid=1.

4. See Hubbard Statement, *supra* note 1, at 4.

5. *Id.*

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.* at 7.

10. *Id.*

ingly.¹¹ At present, FDA only employs approximately 450 food inspectors.¹² Although there are roughly 300 to 400 ports in the United States, less than one percent of annual shipments actually receive FDA inspection due to the shortage of food inspectors.¹³ The problem with inadequate inspection at inbound domestic ports is compounded by inadequate inspection of foreign food producers. In 2006, Hubbard testified, “only 125 examinations of foreign food manufacturers were conducted” by FDA, compared to 209 in 2001.¹⁴ Certain products received little or no inspection in 2006 (e.g., only two inspections of imports of dietary supplements and “zero animal food inspections . . . and . . . cosmetic imports”).¹⁵

The second reason Hubbard proposed for FDA’s limitations in regulating imports is the design of its system. He observed that FDA’s current system is reactive, in that it seeks to identify problems with food and drugs after their arrival in the United States.¹⁶ In contrast, a preventative system would seek to prevent the shipment of tainted products before they leave the source country.¹⁷ Moreover, the current system does not hold food producers and importers accountable but instead places accountability on FDA.¹⁸ FDA’s current system does not adequately incentivize foreign governments and foreign food producers to implement strict quality controls for production of safe food imports to the United States.¹⁹

In addition to an outdated system, FDA has relied on outdated methods of inspection. Inspection tools of the early and mid-twentieth century, such as “visual inspection, a well trained sense of smell, microscopic examination, and laboratory analysis,” are largely insufficient for today’s demands.²⁰ In order to ensure the safety of the public’s health due to the increasing number of imports into the United States, FDA needs modern methods of inspection to detect pathogens, heavy metals, and chemical agents.²¹ Hubbard testified that currently FDA must embark on a costly and lengthy routine of gathering a sample and sending it out for analysis, a process that often takes days before results are available.²²

III. Current FDA Tools To Protect Food Safety

To protect American consumers against adulterated imported food, FDA relies heavily on other methods of examination, prior notice, electronic screening, and import alerts. In 2002, Congress enacted the Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act), providing FDA with additional abilities to safeguard food sources in the United States.²³ Under the Bioterrorism Act and Final Rule issued on

11. *Id.* at 5.

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.* at 8.

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.* at 3-4

21. *Id.* at 6

22. *Id.*

23. *The Food and Drug Import Safety Act of 2007: Hearing on H.R. 3610 Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. (2007) (statement of Randall W. Lutter, Deputy Comm’r for

November 7, 2008 (effective May 6, 2009), importers are required to submit to FDA "prior notice of food, including animal feed, that is imported or offered for import into the United States."²⁴ This prior notice allows FDA, in coordination with Customs and Border Protection (CBP), to identify and inspect those imports that may potentially create a threat to the food supply before entry into the United States.²⁵ Presently, FDA reviews over 33,000 prior notices each business day.²⁶ The Bioterrorism Act also provides FDA with the authority to commission other federal officers to conduct inspections.²⁷ According to one FDA official, "[p]ursuant to [Section 314 of the Bioterrorism Act], FDA and CBP signed a Memorandum of Understanding [MOU] in December 2003 [authorizing] CBP officers to conduct examinations on FDA's behalf."²⁸ Under this MOU, FDA has commissioned nearly 10,000 CBP officers.²⁹ These commissioned officers are instrumental at ports where FDA is not staffed or where existing FDA staff need additional help in enforcing requirements under FDA's prior notice submissions.³⁰

In addition to receipt of prior notices, FDA uses electronic information from import entries submitted through CBP to determine whether a shipment will need to be physically examined, sampled, analyzed, or submitted for other review.³¹ FDA uses an electronic system, the Operational and Administrative System for Import Support (OASIS), to make import admissibility determinations.³²

Another tool FDA uses are import alerts, which notify FDA inspectors when to monitor a particular item or player in the food supply chain.³³ For example, FDA recently issued import alerts for vegetable protein and milk products tainted with melamine from China.³⁴ The import alerts allow FDA field staff to refuse entry of a product into the United States without FDA conducting any physical examinations of the refused item.³⁵

Policy, Assoc. Comm'r for Policy & Planning, Food and Drug Admin., Dept. of Health & Human Serv.), available at http://energycommerce.house.gov/cmte_mtgs/110-he-hrg.092607.Lutter-testimony.pdf [hereinafter Lutter Statement].

24. See Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 73 Fed. Reg. 66,293 (Nov. 7, 2008) (to be codified at 21 C.F.R. pt. 1).

25. *Id.*

26. See Lutter Statement, *supra* note 23, at 3.

27. See Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 314, 116 Stat. 594.

28. Lutter Statement, *supra* note 23, at 4.

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.* at 5.

33. *Id.*

34. See Import Alert #99-29, *Detention without Physical Examination of All Vegetable Protein Products from China for Animal or Human Food Use Due to the Presence of Melamine and/or Melamine Analogs* (2008), http://www.fda.gov/ora/fiars/ora_import_ia9929.html; See also Import Alert #99-30, *Detention without Physical Examination of All Milk Products, Milk Derived Ingredients and Finished Food Products Containing Milk from China Due to the Presence of Melamine and/or Melamine Analogs* (2008), http://www.fda.gov/ora/fiars/ora_import_ia9930.html.

35. See Import Alert #99-29, *Detention without Physical Examination of All Vegetable Protein Products from China for Animal or Human Food Use Due to the Presence of Melamine and/or Melamine Analogs* (2008), http://www.fda.gov/ora/fiars/ora_import_ia9929.html; See also Import Alert #99-30, *Detention without Physical Examination of All Milk Products, Milk Derived Ingredients and Finished Food Products Containing Milk from China Due to the Presence of Melamine and/or Melamine Analogs* (2008), http://www.fda.gov/ora/fiars/ora_import_ia9930.html.

In addition to import alerts, FDA also relies heavily on enforcement actions. For the seven-month period between November 2007 and May 2008, FDA refused entry of over 8,500 different and distinct product shipments “that appeared to be adulterated, misbranded, processed under unsanitary conditions, or unapproved new drugs.”³⁶ When FDA refuses entry of a product, the importer may appeal the decision by demonstrating that the refused products are not contaminated and/or are not in violation of food safety regulations.³⁷

Finally, the FDA official testified that FDA analyzes samples of imports in laboratories and completes regular evaluations on import filers to certify accurate data is provided to FDA.³⁸ He said that violations of regulations concerning imported food may result in civil or criminal prosecution.³⁹

IV. The Food and Drug Import Safety Act: New Tools For Food Safety

The proposed Food and Drug Import Safety Act is intended as a source of new authorities to enable FDA to better protect the public against threats from unsafe food imports. The Act includes provisions for improved testing techniques, user fees on food and drug imports, restricting food imports to specific ports, labeling requirements, penalties, recall authority, as well as inspections and certification of foreign food suppliers.

A. SECTION TWO

Section two of the proposed Act seeks to enhance FDA research on developing new testing procedures and “sampling methodologies [used] in inspections of food” imports.⁴⁰ This provision sets forth a goal of rapid testing that can discover intentionally adulterated food.⁴¹ Congress is reviewing suggestions from some parties, such as the Food Marketing Institute (FMI), recommending that the development of rapid screening tests “should take into account the seriousness of the threat posed by the pathogen or chemical; how frequently it occurs as a food contaminant; and the likelihood that a rapid test methodology would be successful.”⁴²

B. SECTIONS THREE AND FOUR

Another goal of the proposed Act is to increase FDA funds for import inspections and research by assessing a user fee on imported food and drugs. Under sections three and four of the Act, a user fee would be assessed on each line item imported, not to exceed fifty

36. INTERAGENCY WORKING GROUP ON IMPORT SAFETY, IMPORT SAFETY-ACTION PLAN UPDATE 3 (2008), <http://importsafety.gov/report/actionupdate/actionplanupdate.pdf> [hereinafter Action Plan Update].

37. See Lutter Statement, *supra* note 23, at 5-6.

38. *Id.* at 6.

39. *Id.*

40. See H.R. 3610, 110th Cong. § 2 (2007).

41. *Id.*

42. *The Food and Drug Import Safety Act of 2007: Hearing on H.R. 3610 Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 7 (2007) (testimony of Jill Hollingsworth, D.V.M., Group Vice President, Food Safety Programs, Food Marketing Institute), available at <http://energycommerce.house.gov/images/stories/Documents/Hearings/PDF/110-he-hrg.092607.Hollingsworth-testimony.pdf> [hereinafter Hollingsworth Testimony].

dollars per food line item or \$1,000 per drug line item.⁴³ These proposed user fees have received universal criticism. The American Association of Exporters and Importers (AAEI) announced its opposition to the user fees at a hearing before the Subcommittee on Health, Energy, and Commerce. The AAEI asserts that food and drugs already receive differing treatment because they are “highly regulated commodities.”⁴⁴ AAEI retail members contend the fees per line item assessed under the proposed Act will disproportionately affect small and medium businesses, particularly enterprises importing a range of products already regulated by the Food Drug and Cosmetics Act.⁴⁵ In some cases, it is possible the fee may be greater than the good’s value.⁴⁶

Another interested party, the FMI, recognizes that FDA and its “food safety programs are under-funded,” but it believes new user fees will increase food costs.⁴⁷ The FMI considers the fees to be a “conflict of interest by the Agency” inspecting the products in that the agency would essentially be “raising money for its own budget.”⁴⁸

In addition, the Grocery Manufacturers/Food Products Association (GMA/FPA) strongly opposes the user fee and asserts that the costs “to protect the public health” should not be funded with user fees, but rather through taxes.⁴⁹ Moreover, GMA/FPA hypothesizes that the proposed user fees might be an impetus for businesses to move production facilities from the United States abroad.⁵⁰ Under the proposed Act, a user fee would be imposed on each ingredient of a product each time it is imported.⁵¹ The implication is that companies with production facilities outside the United States would only be assessed the fee once (*e.g.*, once the final product was imported).⁵²

Finally, there is further concern that imposing a user fee would breach current U.S. trade commitments by establishing a preference for U.S. food products and ingredients.⁵³ Such unilateral action could cause foreign countries to impose analogous fees on food exports from the United States.⁵⁴

43. See H.R. 3610, 110th Cong. §§ 3-4 (2007).

44. *The Food and Drug Import Safety Act of 2007: Hearing on H.R. 3610 Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. (2007) 13 (statement of Hallock Northcott, President & CEO, Amer. Assoc. of Exporters & Importers), available at <http://energycommerce.house.gov/images/stories/Documents/Hearings/PDF/110-he-hrg.092607.Northcott-testimony.pdf> [hereinafter Northcott Statement].

45. *Id.* at 14.

46. *Id.*

47. Hollingsworth Testimony, *supra* note 42, at 8.

48. *Id.*

49. *The Food and Drug Import Safety Act of 2007: Hearing on H.R. 3610 Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. (2007) 5 (written testimony of Cal Dooley, President & CEO, Grocery Manufacturers/Food Products Association), available at <http://energycommerce.house.gov/images/stories/Documents/Hearings/PDF/110-he-hrg.092607.Dooley-testimony.pdf> [hereinafter Dooley Statement].

50. *Id.* at 6

51. *Id.*

52. *Id.*

53. *Id.*

54. *Id.* at 6-7.

C. SECTION FIVE

The proposed Act also seeks to restrict ports of entry for food imports under section five.⁵⁵ The bill would restrict the importation of food to cities where an FDA laboratory exists (currently thirteen) unless the Department of Health and Human Services (HHS) Secretary determines a food import will result in little to no risk of harm to the public.⁵⁶ There is conflict amongst consumer and industry groups about the utility of this provision. Consumers Union, the publisher of *Consumer Reports*, advocates that “[l]imiting the number of ports of entry for imported food is essential to preventing substandard food from slipping through the cracks in the inspection system.”⁵⁷ Consumers Union urges that, at a minimum, there should be a requirement that food imports enter a port having an FDA inspector on site.⁵⁸

In contrast, AAEI opposes restricting ports of entry for food imports. AAEI believes that “the added logistical costs for an importer . . . can be prohibitive particularly when . . . a product enters a given port, is transported to a second relatively convenient location for packaging or modification and then delivered to a third perhaps distant market for final distribution and consumption.”⁵⁹ Such added logistical costs can be devastating for competitive but low-margin products, such as pharmaceuticals and certain food products, which average between 1 and 4 percent in profits under normal market conditions.⁶⁰ Furthermore, AAEI attests that because of long-standing distribution patterns and production plant locations, there could be devastating consequences for many importers in these categories, including those of generic brands.⁶¹

Even though the proposal to restrict ports of entry is patterned after the U.S. Department of Agriculture (USDA) system, it may be impracticable for the wide array of products supervised by FDA.⁶² Dr. Jill Hollingsworth, in her testimony before the House Subcommittee on Health, pointed out that food importers are already contending with congested ports, and restricting ports further could increase food costs for many American consumers.⁶³ Moreover, reduced ports would increase delays and result in shrinkage and waste.⁶⁴ Specifically, she expressed concern about processing imports of perishable food products in the winter months when the U.S. growing season for these perishables has ended.⁶⁵ Finally, in the event that ports are reduced, food importers with distribution centers at or near the closed FDA ports will have considerable moving expense.⁶⁶ Finally, she pointed out that trade would be disrupted if ports of entry were restricted, as 90 percent of seafood deliveries enter through fourteen ports, of which, only four contain

55. See H.R. 3610, 110th Cong. § 5 (2007).

56. *Id.*; see also Dooley Statement, *supra* note 49, 7-8.

57. Letter from Jean Halloran, Dir. Food Policy Initiatives and Sally Greenberg, Sr. Product Safety, Consumers Union to Rep. John Dingell, U.S. House of Rep. (Aug. 10, 2007), available at http://www.consumersunion.org/pub/core_food_safety/004809.html [hereinafter Consumers Union Letter to Rep. John Dingell].

58. *Id.*

59. See Northcott Statement, *supra* note 44, at 17.

60. *Id.*

61. *Id.* at 12.

62. See Hollingsworth Testimony, *supra* note 42, at 9.

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.*

FDA laboratories.⁶⁷ As such, those ports without FDA laboratories would no longer be able to receive seafood shipments.⁶⁸

D. SECTION SIX

Section six of the proposed Act seeks to establish country of origin labeling requirements for food, drugs, and medical devices regulated by FDA.⁶⁹ The bill would require FDA to issue final regulations for country of origin labeling within 180 days of the bill's enactment.⁷⁰ There is concern that this is an overly aggressive timeframe and nearly impossible to achieve. It is difficult to determine what country is actually the country of origin due to the numerous source countries that may be involved for some food products.⁷¹ Moreover, the mere identification of origin does not correspond to increased safety of the original good.⁷² Opponents of the additional country of origin labeling requirement argue that this provision would provide little benefit, while placing an additional burden on food importers, as identification of origin is already mandated under the Tariff Act.⁷³

E. SECTION SEVEN

The proposed Act seeks to establish a Safe and Secure Food Importation Program under section seven. The program would begin not less than two years after the bill is enacted.⁷⁴ It would offer expedited passage of an importer's food products through the inspection process in exchange for adherence to certain food safety and security measures.⁷⁵ FMI favors this proposal and further advocates a recognized certification program, such as its Safe Quality Food risk assessment program, that requires observance of food safety regulations of both foreign and domestic countries.⁷⁶ AAEI agrees that any program should be based on risk management principles.⁷⁷ It also supports "voluntary programs for security and safety," such as the Customs Trade Partnership Against Terrorism (C-TPAT) and the Importer Self-Assessment (ISA) Program.⁷⁸ Both AAEI and CBP have found a high correlation between effective internal controls with compliance to federal regulations for those companies who are part of the ISA Program.⁷⁹ Currently, CBP is considering the inclusion of an import safety piece in its ISA Program.⁸⁰

67. *Id.* at 10

68. *Id.*

69. See H.R. 3610, 110th Cong. § 6 (2007).

70. *Id.* at § 6(c).

71. See Hollingsworth Testimony, *supra* note 42, at 11.

72. *Id.*

73. *Id.*

74. See H.R. 3610 § 7.

75. *Id.*

76. See Hollingsworth Testimony, *supra* note 42, at 7-8.

77. See Northcott Statement, *supra* note 44, at 19.

78. *Id.*

79. *Id.* at 21.

80. See Action Plan Update, *supra* note 36, at 2.

F. SECTION EIGHT

Under section eight of the bill, increased monetary penalties would be charged to importers or manufacturers who violate the Act.⁸¹ Penalties would increase to “\$100,000 in the case of any individual and \$500,000 in the case of any other person, not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding.”⁸² AAEEI members contend that increased fines are burdensome and will not enhance product safety.⁸³ AAEEI further argues that proposed penalties do not differentiate between “supply chain participants who had no reason to know [of violations] and those willing and knowingly participating companies.”⁸⁴ Instead, fines should be assessed under standards based on either negligence or intent.⁸⁵

G. SECTION NINE

The proposed Act seeks to maintain the current operation of FDA field laboratories.⁸⁶ Under section nine, the bill would prohibit FDA from closing any of its thirteen labs, consolidating any laboratory with another, closing any of the twenty district offices, or consolidating any of the district offices with each other without Congressional review of its reorganization plan.⁸⁷ There is general support of continued operation of FDA field laboratories. FMI advocates that resources of individual labs be identified and that certain labs be designated as a “center of excellence” for particular food safety tests or measures.⁸⁸

H. SECTION TEN

Section ten of the Act will provide FDA with recall authority if there is a reasonable probability that a food would “cause serious, adverse health consequences or death.”⁸⁹ Under the proposal, if a recall to cease distribution is issued, the affected person can request an informal hearing.⁹⁰ The food industry agrees that the current voluntary recall program works well. FMI suggests that no company has declined to remove contaminated product at FDA’s request or, in the alternative, that such company has taken independent action.⁹¹

In contrast, in a letter to Representative John Dingell expressing support for recall authority, consumers expressed their belief that FDA “mandatory food recall authority [is something] that is long overdue” and has been absent for both the USDA and FDA.⁹² In a national poll conducted by Consumers Union in 2004, 97 percent of those who responded stated that the government should have the authority to issue recalls for contami-

81. See H.R. 3610, 110th Cong. § 8(2)(ii) (2007).

82. *Id.*

83. See Northcott Statement, *supra* note 44, at 21.

84. *Id.*

85. *Id.*

86. See H.R. 3610 § 9.

87. *Id.*

88. See Hollingsworth Testimony, *supra* note 42, at 8.

89. See H.R. 3610, 110th Cong. § 10 (2007).

90. *Id.*

91. See Hollingsworth Testimony, *supra* note 42, at 6.

92. See Consumers Union Letter to Rep. John Dingell, *supra* note 57.

nated meat.⁹³ Presently, “FDA may not unilaterally order a recall even of a product that is life threatening.”⁹⁴ The Center for Science in the Public Interest (CSPI) also favors the mandatory recall and would like to add to the recall authority a notification requirement to affected consumers.⁹⁵ Importers express concern about the identification of recalled shipments because today’s rapid distribution system could burden an importer having to identify individual shipments, including those already distributed to merchants and consumers.⁹⁶

I. SECTION ELEVEN

Under section eleven of the Act, new certification standards would be established for FDA regulated products.⁹⁷ All food imports intended for consumption would be required to meet U.S. standards or be denied entry.⁹⁸ The Act further states that a foreign production facility for food imported to the United States must have either a “certification for such facility” or a “certification for such country” where the facility is located.⁹⁹ A facility certification may be obtained by demonstrating that the foreign facility uses “reliable analytical methods to ensure compliance with all [U.S. food] standards.”¹⁰⁰ Alternatively, a foreign country may obtain a certificate from FDA stating that the country has a program to monitor and “enforce[e] food safety standards [that are] at least as protective of food safety” as those in the U.S.¹⁰¹ Unlike the USDA, however, which conducts in-country examinations prior to confirming a country has carried out the food safety procedures it purports to have, the certification provision under the proposed Act lacks a periodic auditing requirement as part of the certification process.¹⁰²

In a statement by Cal Dooley, president and CEO of GMA/FPA, before the House Subcommittee on Health, he expressed concern that a certification requirement would unduly burden FDA, “violate [U.S.] trade agreements, and would invite reciprocal demands by [U.S.] trading partners.”¹⁰³ He also voiced concern that FDA does not have the necessary budget, with or without user fees, to conduct the certification of thousands of foreign facilities located throughout 150 countries.¹⁰⁴ Moreover, other groups have indicated that it may be difficult for some developing countries to meet the certification requirements, and they would likely need technical and monetary assistance from FDA and

93. *Id.*

94. *Id.*

95. The Food and Drug Import Safety Act of 2007: Hearing on H.R. 3610 Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 110th Cong. (2007) 10 (testimony of Caroline Smith DeWaal, J.D., Director of Food Safety, Center for Science in the Public Interest), available at <http://energy.commerce.house.gov/images/stories/Documents/Hearings/PDF/110-he-hrg.092607.DeWaal-testimony.pdf> [hereinafter DeWaal Testimony].

96. See Northcott Statement, *supra* note 44, at 21-22.

97. See H.R. 3610, 110th Cong. § 11 (2007).

98. *Id.*

99. *Id.* at (d)(1)(A)-(B).

100. *Id.* (2)(A).

101. *Id.* at (2)(B)(i).

102. See DeWaal Testimony, *supra* note 95, at 10.

103. See Dooley Statement, *supra* note 49, at 9.

104. *Id.*

the USDA.¹⁰⁵ FMI has suggested, though, that it may be possible to use existing in-country resources such as the USDA to participate in food facility inspections and certifications.¹⁰⁶

J. SECTION TWELVE

Section twelve of the Act initiates new testing of processed foods.¹⁰⁷ Within two years of the bill's enactment, regulations would require that processed foods be submitted for testing to detect any contaminants.¹⁰⁸ The food industry contends that it is impossible to test for all potential causes of food adulteration. Instead, it suggests that the preferred course of action is for every importer of record to implement a "foreign supplier quality assurance program," thus shifting the focus from detection to one of prevention.¹⁰⁹ It is generally agreed that prevention programs are superior to post-production testing in ensuring food safety.

K. SECTION FOURTEEN

Under section fourteen of the proposed Act, a label would be required for those meat, poultry, or seafood products with carbon monoxide stating that carbon monoxide has been used to preserve the color of the food product.¹¹⁰ The label would further warn that a consumer should not rely on color or the "use or freeze by" date to ascertain the product's freshness or safety.¹¹¹ The labeling requirement would go into effect thirty days after the Act's enactment.¹¹² The food industry, specifically the FMI, does not support carbon monoxide labeling because it states that both the "FDA and USDA have recognized that carbon monoxide is generally recognized as safe for its intended purpose."¹¹³

Finally, other proposals were offered during subcommittee testimony on the Food and Drug Import Safety Act. For example, the CSPI advocated that Congress enact legislation at least comparable to The Safe Food Act of 2007, H.R. 1148.¹¹⁴ This bill would combine several federal agencies that currently regulate food safety (e.g., FDA, the USDA, and the EPA) to create the Food Safety Administration.¹¹⁵ AAEE's Hallock Northcott testified that AAEE's members have encountered difficulty "dealing with multiple federal agencies whose regulatory jurisdiction . . . for certain imported goods overlap with other federal agencies."¹¹⁶

105. See Hollingsworth Statement, *supra* note 42, at 12.

106. *Id.*

107. See H.R. 3610, 110th Cong. § 12 (2007).

108. *Id.*

109. See Dooley Statement, *supra* note 49, at 8.

110. See H.R. 3610 § 14.

111. *Id.* at (a)(1).

112. *Id.*

113. See Hollingsworth Statement, *supra* note 42, at 13.

114. See DeWaal Testimony, *supra* note 95, at 10.

115. *Id.* at 10-11.

116. Northcott Statement, *supra* note 44, at 19.

V. Government Initiatives Focused on Food Safety

In addition to the proposed Food and Drug Import Safety Act, there are other government initiatives underway to improve the safety of imported food. In July 2007, President Bush granted authority for the creation of a Cabinet-level Working Group on Import Safety chaired by HHS Secretary Michael O. Leavitt.¹¹⁷ Included in the twelve federal agency-member Working Group are FDA, the USDA, and the Department of Commerce.¹¹⁸ Its responsibility is to review all necessary protocols and measures to ensure that all imported consumer products are safe.¹¹⁹ In September 2007, the Working Group released a report entitled, *Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety*.¹²⁰ The report advocates a program based on prevention, intervention, and immediate response.¹²¹ Members of the Working Group examined parties involved throughout the inspection process by visiting the various facilities and plants as well as discussed common import safety challenges.¹²² In November 2007, the Working Group presented President Bush with an action plan recommending short- and long-term proposals to improve the safety of imports.¹²³ The Action Plan emphasized the importance of giving government agencies new capabilities, such as authorizing FDA with the ability to require certification or guarantees that certain risky products are in compliance with U.S. regulations before they are allowed to enter the country.¹²⁴ The Action Plan also recommended that "asset forfeiture remedies for criminal offenses be made available under several of the laws implemented by the FDA, [the Consumer Product Safety Commission] CPSC, and USDA."¹²⁵ Finally, the Action Plan highlighted the importance of the International Trade Data System (ITDS). The ITDS is intended as a common point of entry by federal agencies to trade data provided by the importer in order to facilitate the import clearance process.¹²⁶ The Security and Accountability For Every Port (SAFE Port) Act mandates federal agency participation in the ITDS.¹²⁷

The initial success of President Bush's Working Group has been to foster collaboration across federal agencies to improve the safety of food imports. For example, Operation Guardian spans across multiple federal agencies and is the Department of Homeland Security's (DHS) main enforcement program focusing on enforcement of import safety.¹²⁸ DHS is also partnering with the National Center for Food Protection and Defense to research weaknesses in the import inspection process as well as improvements in import

117. Press Release, Dep't of Health & Human Servs., *New Agreement Will Enhance the Safety of Food and Feed Imported From the People's Republic of China* (Dec. 11, 2007), available at <http://www.hhs.gov/news/facts/foodfeed.html> [hereinafter *New Agreement Will Enhance the Safety of Food and Feed*].

118. See Lutter Statement, *supra* note 23, at 8.

119. *Id.*

120. *Id.* at 9.

121. *Id.*

122. *New Agreement Will Enhance the Safety of Food and Feed*, *supra* note 117.

123. *Id.*

124. See Action Plan Update, *supra* note 36, at 16.

125. *Id.*

126. *Id.* at 2-3

127. *Id.* at 13.

128. *Id.* at 3.

risk assessment.¹²⁹ In addition, FDA, in conjunction with the USDA and DHS, recently concluded an Inter-Agency Agreement “to determine the survivability of [anthrax] in processed liquid egg products.”¹³⁰ And, in April 2008, “CBP participated in the European Union Customs 2013 Seminar on *Preventing Imports of Dangerous Products*.”¹³¹ Furthermore, other federal agencies, including the U.S. Trade Representative (USTR), the USDA, FDA and the Department of Commerce (DOC) are collaborating in the Asian Pacific Economic Cooperation (APEC) Subcommittee on Standards and Conformance, which conducted a seminar on food safety systems in 2008, to ascertain solid progress was being made on product safety and to encourage trade in the APEC territories.¹³² Finally, in April of 2008, the Food Safety and Inspection Service (FSIS) put an Import Alert Tracking System (IATS) into effect to record data related to meat products refused for entry due to failure to meet specific import criteria or for illegality.¹³³ IATS allows the government to improve its response time on enforcement actions due to the ease and availability of access to data gathered on illegal entries.¹³⁴

The U.S. Department of Justice (DOJ) is also involved in discovering and adjudicating importers of unsafe food. In February 2008, the DOJ announced the indictment of two Chinese businesses and a U.S. company for their roles in manufacturing and importing wheat gluten tainted with melamine that was later used to make pet food.¹³⁵ In addition, the DOJ arrested two Chicago executives of Alfred L. Wolff, Inc. (ALW), a German food ingredients company, earlier in 2008, “on federal charges for allegedly conspiring to illegally import honey from China that was falsely identified as coming from other countries in order to avoid anti-dumping duties, and that was adulterated because it contained an antibiotic not approved for use in food producing animals, including bees.”¹³⁶ If found guilty, the individuals may face a maximum “five years in prison and a \$250,000 fine.”¹³⁷

A. INTERNATIONAL EFFORTS

Internationally, the United States is engaged in several forums to partner in initiatives for improving product safety, including the Security and Prosperity Partnership of North America (SPP), the U.S.-China Strategic Economic Dialogue (SED), and the Global Health Security Initiative.¹³⁸ Under the SPP Safe Food and Products Initiative, Canada, Mexico, and the U.S. exchange information, including risk assessment data, to improve food safety before entry to any of the three countries.¹³⁹ This initiative also seeks to

129. *Id.* at 9.

130. U.S. FOOD AND DRUG ADMIN., FDA FOOD PROTECTION PLAN SIX-MONTH PROGRESS SUMMARY (2008), <http://www.fda.gov/oc/initiatives/advance/food/progressreport.html> [hereinafter FDA Food Protection Plan Six-Month Progress Summary].

131. See Action Plan Update, *supra* note 36, at 9.

132. *Id.* at 8.

133. *Id.* at 15.

134. *Id.*

135. News Release, U.S. Dep’t of Justice, Chinese, American Business Owners Indicted for Importing Tainted Ingredient Used in Pet Food (Feb. 6, 2008), <http://www.usdoj.gov/usao/mow/news2008/xuzhou.ind.htm>.

136. Action Plan Update, *supra* note 36, at 14-15.

137. *Id.*

138. *Id.* at 1.

139. *Id.* at 5.

identify best practices used by importers in protecting their supply chains and determining product safety before export to North America.¹⁴⁰ In April 2008 at the North American Leaders' Summit, President Bush, Mexican President Calderon, and Canadian Prime Minister Harper agreed that the three countries needed to work together to ensure compatibility of product safety standards and to improve cross-border recall abilities.¹⁴¹

B. CHINA

The SED was established by President Bush and Chinese President Hu Jintao as a mechanism for addressing issues concerning both countries.¹⁴² Under the SED, FDA has begun partnering on new initiatives with its Chinese counterparts. On December 11, 2007, FDA and China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) executed a memorandum of agreement (MOA) for safety of foods imported from China.¹⁴³ To support the effort, HHS and FDA plan to establish offices in China to encourage information sharing.¹⁴⁴ This bilateral agreement will help ensure that products imported into the United States from China meet U.S. standards for quality and safety.

Under the terms of the MOA, the Chinese will establish two programs, both of which will be subject to FDA audit.¹⁴⁵ The first program will require Chinese exporters to register with AQSIQ and to agree to yearly inspections to ensure compliance with U.S. standards.¹⁴⁶ AQSIQ will inform FDA of those companies that fail the inspections, have been suspended by AQSIQ, or who have had their registered status taken and the reasons for such action.¹⁴⁷ Furthermore, under this program, AQSIQ will set up a tracing system whereby products will be tracked from production to exportation from China.¹⁴⁸

The second program entails a certification requirement. Once a company has satisfied FDA requirements, AQSIQ's Inspection Bureau will issue a certificate bearing an identification number that must be filed with FDA via a secure system developed by both countries in order to prevent counterfeit certificates from being issued¹⁴⁹ AQSIQ will also be required implement a testing program to statistically demonstrate to FDA that Chinese products shipped to the U.S. meet FDA requirements.¹⁵⁰ Furthermore, under the MOA, China and the U.S. must now provide notice to the other within two calendar days of when one party discovers a situation that may jeopardize product safety, a system that did not exist in the past.¹⁵¹ This would afford FDA an opportunity to timely investigate

140. *Id.*

141. *Id.*

142. *Id.* at 6.

143. *Id.*

144. *Id.* at 2.

145. Agreement between the Department of Health and Human Services of the United States of America and the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China on the Safety of Food and Feed (2007), <http://globalhealth.gov/news/agreements/ia121107b.html> [hereinafter MOA between FDA and AQSIQ].

146. *Id.* at § 2(A)(I)(a).

147. *Id.* at § 2(B)(8).

148. *Id.* at § 2(B)(10).

149. *Id.* at §2(C)(2).

150. *Id.* at §2(C)(6).

151. *Id.* at art. IV(1).

whether there is indeed a true threat to the public. AQSIQ will facilitate any FDA inspections of Chinese plants involved in the process of exporting food products to the U.S.¹⁵²

In addition, FDA and AQSIQ will establish a Working Group to monitor each party's progress as well as to establish any necessary future protocols to ensure food safety as the need may arise.¹⁵³ Execution of the terms under the China MOA for food and feed safety has already begun.¹⁵⁴ FDA has provided the Chinese government with registration materials, identified appropriate contact persons, and outlined an initial five-year work plan.¹⁵⁵ The first meeting in Beijing, held in March 2008, focused on FDA's relationship with the AQSIQ.¹⁵⁶ Both parties agreed to begin with a small subset of "designated covered products" before expanding to others.¹⁵⁷ Specifically, low-acid canned food products, plant or animal origin pet food or treats, raw ingredients for food or feed, and all "aquaculture farming products other than molluscan shellfish" will be tested first, and both parties may mutually agree to add other products to the list.¹⁵⁸ In addition, FDA is currently developing analogous requirements for MOA-covered animal feed products.¹⁵⁹ Finally, in November of 2008, FDA opened three field offices in Beijing, Guangzhou, and Shanghai, signaling both countries' efforts to enhance the safety of food products.¹⁶⁰

C. VIETNAM

In addition to the MOA with China, FDA is working with other countries to enhance the safety of imported food products into the U.S. FDA has already signed a memorandum of understanding (MOU) with Vietnam to take effect immediately, whereby both countries promised to cooperate on enhancing food and medical product safety between the two nations.¹⁶¹ Under the terms of the MOU, both governments agree to share information regarding each other's regulatory environments, to conduct workshops and training sessions, to develop best practices, and to review details on seafood safety.¹⁶²

D. INDIA

Recently, members of FDA visited Indian food authorities to discuss possibilities of an agreement, similar to the one with China, to improve food safety by creating regulatory transparency between the two countries.¹⁶³ India has already shown its earnestness in

152. *Id.* at § 2(B)(12).

153. *Id.* at art. VII(2).

154. See FDA Food Protection Plan Six-Month Progress Summary, *supra* note 131.

155. *Id.*

156. *Id.*

157. See MOA between FDA and AQSIQ, *supra* note 145.

158. *Id.* at § 1(B).

159. See FDA Food Protection Plan Six-Month Progress Summary, *supra* note 130.

160. News Release, U.S. Dep't of Health & Human Servs., HHS Announces Latest Efforts with China to Further Improve Cooperation on Food Safety (2008), <http://www.hhs.gov/news/press/2008pres/11/20081113d.html>.

161. News Release, U.S. Dep't of Health & Human Servs., United States and Viet Nam Sign Agreement on the Safety of Food, Medical Products (2008), <http://www.hhs.gov/news/press/2008pres/06/20080624a.html>.

162. *Id.*

163. *Id.*

ensuring food safety, as evidenced by the Spice Board of India's creation of a certification process asserting that Indian spice exports meet a certain standard.¹⁶⁴

E. LATIN AMERICA

In addition, there are also efforts to obtain the cooperation and participation of Latin American countries with U.S. food import safety standards. FDA is exploring an FDA presence in Latin America/Central America, and HHS Secretary Leavitt recently took part in a summit with El Salvador, Honduras, Nicaragua, Costa Rica, Guatemala, Dominican Republic and Panama.¹⁶⁵

F. OTHER COUNTRIES

In April 2008, FDA attended the Food Safety Quadrilateral meeting with Canada, New Zealand, and Australia to promote the FPP and ISAP.¹⁶⁶ The parties at the meeting are considering the implementation of a "rapid alert system" between the countries to share data concerning potential significant health risks found in food products before they are passed on for public consumption.¹⁶⁷

VI. New FDA Initiatives for Import Safety

In response to the Interagency Import Safety Action Plan finalized in November 2007, HHS and FDA are taking new steps to improve the safety of food imports.¹⁶⁸ Recently, FDA created a new position of Assistant Commissioner for Food Protection whose role is to monitor food safety as well as to advise FDA.¹⁶⁹ Moreover, on July 9, 2008, HHS Secretary Leavitt announced to industry leaders at the Import Safety Summit in Washington, D.C. two pilot programs to enhance the safety of FDA-regulated imports.¹⁷⁰ While U.S. authorities have historically relied on border intervention to prevent unsafe goods from entering the country, the new Action Plan calls for collaboration with U.S. trading partners to ensure quality control in production and distribution.¹⁷¹

The first initiative is a pilot project with regulatory officials in the European Union and Australia to conduct inspections of manufacturers of pharmaceutical drug ingredients and to allow FDA to utilize data gathered by other reliable examination systems.¹⁷² If the program proves successful, it could be expanded to include other manufacturers.¹⁷³

164. Action Plan Update, *supra* note 36, at 10.

165. *Id.* at 6.

166. See FDA Food Protection Plan Six-Month Progress Summary, *supra* note 130.

167. *Id.*

168. Press Release, Dep't of Health & Human Servs., HHS Announces New Int'l Programs to Enhance Drug and Food Safety: *Joint Inspections with European Union and Australian Regulators; Third-Party Certification Program Are Latest Steps Toward Implementing New Import Strategy* (July 9, 2008), <http://www.hhs.gov/news/press/2008pres/07/20080709a.html> [hereinafter HHS Announces New International Programs].

169. See Lutter Statement, *supra* note 23, at 7.

170. See HHS Announces New International Programs, *supra* note 168.

171. *Id.*

172. *Id.*

173. *Id.*

The second project is a voluntary third-party certification program for imported farm-raised shrimp.¹⁷⁴ Under this program, FDA is seeking to ascertain whether aquacultured shrimp raised in foreign jurisdictions are in compliance with FDA Seafood Hazard Analysis and Critical Control Point (HACCP) regulations.¹⁷⁵ FDA hopes that under this program, it will better understand its field needs as well as how to evaluate and to implement certification programs by gathering “technical and operational information.”¹⁷⁶

Moreover, FDA has concluded “a three-year plan to increase state inspections and [to] hire an additional 130” field staff.¹⁷⁷ In addition, FDA is exploring more efficient methods for identifying threats to food safety before they cross the U.S. border.¹⁷⁸ FDA has also contracted with New Mexico State University to develop a pilot program using “open-source intelligence” to improve screening of food products at the U.S. border.¹⁷⁹ FDA has completed its evaluation of the system, PREDICT (Predictive Risk-Based Evaluation of Dynamic Import Compliance Targeting) and is reviewing the final documentation.¹⁸⁰ Finally, FDA has also issued guidelines to assist the food and cosmetics industry in self-assessing its products to minimize possibilities of intentional product adulteration.¹⁸¹

VII. Private Sector Initiatives for Import Safety

The private sector is also joining FDA in monitoring the safety of imported food. For example, Wal-Mart announced earlier this year that it was requiring certain of its suppliers to be fully certified by the Global Food Safety Initiative by July 2009.¹⁸² This certification requires all goods to be examined by licensed food safety auditors.¹⁸³ Other private sector initiatives include the Grocery Manufacturers Association’s *Food Supply Chain Handbook* with examples of successful supplier management methodologies, the Natural Products Association’s *Good Manufacturing Practices* for those in the nutritional supplement trade, the U.S. Chamber of Commerce’s *No Trade in Fake Supply Chain Toolkit*, and the Natural Products Association’s partnership with U.S. Pharmacopoeia to create a screening program for imports of raw ingredients from China.¹⁸⁴

VIII. Summary

As potential harm from food imports increases in volume and variety, the U.S. is making a fundamental shift from reactively focusing on border intervention to preventatively verifying quality along a product’s lifecycle. Non-preventative measures in the proposed

174. *Id.*

175. See Voluntary Third-Party Certification Programs for Imported Aquacultured Shrimp; Notice of Pilot Program, 73 Fed.Reg. 39,705 (Jul. 10, 2008).

176. *Id.*

177. See FDA Food Protection Plan Six-Month Progress Summary, *supra* note 136.

178. *Id.*

179. *Id.*

180. *Id.*

181. *Id.*

182. See Action Plan Update, *supra* note 36, at 10.

183. *Id.*

184. *Id.* at 11.

Food and Drug Import Safety Act have been largely criticized. FDA, faced with constrained resources and mounting responsibilities, plans to ensure the safety of food imports by leveraging third-party certification programs and by providing technical assistance to facilitate the development of regulatory oversight among U.S. trading partners. By leading the global campaign for food safety, the United States is striving to safeguard consumers and help industry prosper.