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Good Importer Practices: Can the FDA Afford to Rely on the Importer for Food Safety?

*Christy O'Berry**

I. INTRODUCTION

The Food and Drug Administration (FDA) is responsible for protecting the public health by inspecting and maintaining the United States' food supply.¹ The FDA is responsible for inspecting approximately eighty percent of the U.S. food supply, including both domestic and imported food, whereas the United States Department of Agriculture (USDA) is responsible for the remaining twenty percent of the food supply.²

Recent outbreaks of E. coli in spinach, salmonella in peanut butter, and melamine contamination in pet food prompted the FDA to formulate the *Food Protection Plan* to address the oversight of food safety³ and led to the *Draft Guidance for Industry on Good Importer Practices* (GIP).⁴ Upon finalization, the

* Juris Doctor Candidate, Loyola University Chicago School of Law, Class of 2010. Ms. O'Berry is a staff member of *Annals of Health Law*.

¹ FDA, FDA'S MISSION STATEMENT, <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Mar. 29, 2009).

² U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-435T, FEDERAL OVERSIGHT OF FOOD SAFETY: FDA'S FOOD PROTECTION PLAN PROPOSES POSITIVE FIRST STEPS, BUT CAPACITY TO CARRY THEM OUT IS CRITICAL 1, 4 (2008) [hereinafter FOOD PROTECTION PLAN] (testimony of Lisa Shames, Director Natural Resources and Environment); see Eric M. Goldstein, *Inspecting the Hands that Feed Us: Requiring U.S. Quality for all Imported Foods*, 7 Wash. U. Global Stud. L. Rev. 137, 139 (2008).

³ FOOD PROTECTION PLAN, *supra* note 2, at 1.

⁴ Notice for Draft Guidance for Industry on Good Importer Practices, 74 Fed. Reg. 1692, 1692 (proposed Jan. 13, 2009).

GIP will not create legally enforceable rights or responsibilities but rather, will establish the current position of the United States on food safety.⁵ With promulgation of the GIP, the FDA will rely on importers, and the food safety and inspection laws of other countries to meet the standards set forth in the GIP. An importer “initiates or causes the entry or attempted entry of foreign-sourced products into the U.S. or the reimportation of U.S.-made products (American Goods Returned) for commercial purposes or distribution.”⁶ The FDA lacks many of the resources, such as personnel and funding to inspect all importers, which may be to blame for its inability to inspect all imported foods and to order mandatory recalls when contaminated food is discovered.⁷ This article examines the effectiveness of the GIP.

II. BACKGROUND

A. *The FDA*

The mission statement of the FDA is, in part, to protect the safety of the U.S. food supply through enforcement of the Federal Food, Drug, and Cosmetic Act (FD&C), which includes both imported and domestic food lines.⁸ The enforcement division of the FDA, the Office of Regulatory Affairs (ORA), has the mission to “safeguard the public health and to ensure honesty and fair dealing between the regulated industry and consumers,”⁹ as well as to conduct inspections on foreign imports.¹⁰ Imported foods must meet the same standards as domestic

⁵ FDA, FDA-2009-D-0675, DRAFT GUIDANCE FOR INDUSTRY ON GOOD IMPORTER PRACTICES 3 (2009) [hereinafter FDA, DRAFT GUIDANCE].

⁶ *Id.*

⁷ See Noam N. Levey, *Food Safety Reform Sits on Back Burner: Obama Appears to Back a Long-Sought Overhaul of the FDA, but More Urgent Issues May Push it Aside*, L.A. TIMES, Dec. 26, 2008, at A17.

⁸ OFF. OF REG. AFF., FDA IMPORT PROGRAM SYSTEM INFORMATION, http://www.fda.gov/ora/import/ora_import_system.html (last visited Mar. 29, 2009).

⁹ FDA, IMPORTS AND INSPECTIONS: INTERNATIONAL REGULATORY ACTIVITIES, <http://www.fda.gov/oia/impinsp.htm> (last visited Mar. 29, 2009).

¹⁰ *Id.*

food.¹¹ Practically, this means that they must be safe to eat and produced under sanitary conditions.¹²

However, inadequate financial resources, inadequate personnel, new responsibilities imposed by Congress, and increased food safety demands have prevented the FDA from fulfilling its mission.¹³ The FDA accounted for only twenty-four percent of the federal food safety budget but is responsible for approximately eighty percent of the nation's food supply.¹⁴ Additionally, the FDA lacks the authority it needs to appropriately regulate the food industry.¹⁵ For instance, the FDA lacks the authority to implement mandatory recalls and the ability to set binding standards for the safe production of fruits and vegetables.¹⁶

B. Food Borne Illnesses

The Centers for Disease Control and Prevention (CDC) “estimates that approximately 76 million cases of food borne illness occur in the United States each year, resulting in 325,000 hospitalizations and 5,000 deaths annually.”¹⁷ Domestic and imported food has been linked to these outbreaks of food borne illnesses.¹⁸ In fact, some of the most serious outbreaks over the past twenty years have been associated with imported foods that are under the jurisdiction of the FDA.¹⁹ For instance, in July 2008, salmonella-tainted jalapeños imported from Mexico sickened more than 1,200 people in forty-three states, the District of Columbia, and Canada.²⁰ In 2007, melamine, an ingredient used to make plastics and tanning leather, was found as an additive in pet food imported from China

¹¹ OFF. OF REG. AFF., *supra* note 8.

¹² *Id.*

¹³ FOOD PROTECTION PLAN, *supra* note 2; see Richard Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 432 (2008).

¹⁴ FOOD PROTECTION PLAN, *supra* note 2, at 4.

¹⁵ Levey, *supra* note 7.

¹⁶ *Id.*

¹⁷ Goldstein, *supra* note 2, at 158.

¹⁸ U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-1047, FOOD SAFETY: IMPROVEMENTS NEEDED IN FDA OVERSIGHT OF FRESH PRODUCE 1 (2008).

¹⁹ Goldstein, *supra* note 2, at 137.

²⁰ Annys Shin, *Salmonella-Tainted Jalapeño Found in Texas*, WASH. POST, July 22, 2008, at A1.

and caused thousands of animal fatalities in the United States.²¹ Melamine was also added to milk powder in China, killing at least three children and causing illness to over 1,300 more.²² As the United States becomes more reliant on imported foods, the food supply will become more vulnerable to contamination.²³

C. Inspections

With respect to imported food, the FDA relies on inspections at ports of entry to prevent contaminated food from entering the U.S. food supply.²⁴ The FDA electronically screens all shipments when they arrive at the U.S. border using data supplied by the shipper's themselves.²⁵ Since only about one percent of imported food is tested at the U.S. border,²⁶ most shippers are aware that it is unlikely that the food they are importing will be inspected.²⁷ Therefore, adulterated or contaminated food is more likely to enter the U.S.' food supply.²⁸

Furthermore, many of the contaminants that enter the food at the processor's facility are undetectable at port of entry inspections even if the food is laboratory tested.²⁹ To address this issue, the FDA is attempting to implement a system of preemptive testing, in which the FDA will test the foreign food producer's facility for contaminants that may be introduced at the facility.³⁰ For example, the FDA has an inspection office in China.³¹ However, the office in China is staffed with only eight inspectors and will have little impact on a country

²¹ Lee Spears & Helen Yuan, *China Widens Probe into Milk Scandal as Recalls Rise (Update 2)*, BLOOMBERG.COM, <http://www.bloomberg.com/apps/news?pid=20601080&sid=a01qefqeLN1o&refer=asia#> (last visited Mar. 29, 2009).

²² *Id.*

²³ Goldstein, *supra* note 2, at 137, 138.

²⁴ David Plunkett & Caroline Smith DeWaal, *Who is Responsible for the Safety of Food in a Global Market? Government Certification v. Importer Accountability as Models for Assuring the Safety of Internationally Traded Foods*, 63 Food & Drug L.J. 657, 657 (2008).

²⁵ Goldstein, *supra* note 2, at 145, 150.

²⁶ Plunkett & DeWaal, *supra* note 24, at 657-658.

²⁷ *See* Goldstein, *supra* note 2, at 151.

²⁸ *Id.* at 146.

²⁹ *Id.* at 150.

³⁰ *Id.*

³¹ Steve Brozak, *Caution – FDA Could be Hazardous to Your Health*, UPDATE, Jan./Feb. 2009, at 30, 31.

as large as China.³² The United States also plans to open offices in India, Europe, and Latin America so that they can conduct inspections in countries that have a growing number of imports into the United States.³³ Although the ideal situation would be to inspect all 189,000 foreign food facilities,³⁴ doing so would cost over three billion dollars when the FDA's proposed food safety budget is less than one billion dollars.³⁵

III. GOOD IMPORTER PRACTICE DRAFT GUIDELINES

The GIP is intended to help importers ensure their products meet U.S. health and safety requirements.³⁶ The GIP sets forth recommendations designed to mitigate safety hazards that might be present in a foreign-sourced product's life cycle and offers preventative controls that facilities can implement.³⁷ The product's life cycle consists of growing, manufacturing, processing, and transportation.³⁸

The principles of the GIP are set out under four guidelines: (1) "Establishing a Product Safety Management Program;" (2) "Knowing the Product and Applicable U.S. Requirements;" (3) "Verifying Product and Firm Compliance with U.S. Requirements throughout the Supply Chain;" and (4) "Taking Corrective and Preventative Action When the Product or Firm is Not Compliant with U.S. Requirements."³⁹

The first principle suggests that importers should develop a clearly defined organizational structure to implement the recommendations in the guidelines and to foster corporate accountability.⁴⁰ The second principle suggests that the

³² *Id.*

³³ *Id.*

³⁴ See Gardiner Harris, *Report Faults F.D.A. Action for Safe Food*, N.Y. TIMES, June 12, 2008, at A22.

³⁵ *Id.*

³⁶ FDA, DRAFT GUIDANCE, *supra* note 5, at 2.

³⁷ *Id.* at 4.

³⁸ *Id.* at 2.

³⁹ *Id.* at 6.

⁴⁰ *Id.*

importers should have a good understanding of where the product originates, its intended use, and any vulnerabilities and risks associated with the product.⁴¹ In addition, the importer should be aware of which import regulations or requirements apply to the product throughout its life cycle and the product's compliance history.⁴² The third principle states that once importers know the regulatory requirements that apply to their product and the producer, the importer should ensure that they meet these requirements.⁴³ Importers must take several steps to ensure product compliance before, during, and after entry into the United States.⁴⁴ Finally, the fourth principle suggests that in order to minimize the potential of importing a hazardous product, the importer should develop a plan that implements corrective and preventative action if a non-compliant product is discovered.⁴⁵

IV. EFFECT OF THE GOOD IMPORTER PRACTICE GUIDELINES

The GIP puts the burden of inspecting the food supply on the importer and relies on the regulatory scheme of the country where the importer is located.⁴⁶ However, relying on the regulatory scheme of other countries and the importer to police the food supply is unlikely to have a positive effect, especially in countries where the adequacy of government oversight and regulatory structure has been questionable.⁴⁷ For instance, China, the second largest source of imported goods into the United States, has been the subject of numerous food health and safety concerns.⁴⁸ The imports of concern include toothpaste, pet foods, seafood, and more recently, milk products.⁴⁹

⁴¹ *Id.* at 7.

⁴² FDA, DRAFT GUIDANCE, *supra* note 5, at 7.

⁴³ *Id.* at 9.

⁴⁴ *Id.* at 9-10.

⁴⁵ *Id.* at 14.

⁴⁶ *See Id.*

⁴⁷ WAYNE M. MORRISON, CONG. RESEARCH SERV., HEALTH AND SAFETY CONCERNS OVER U.S. IMPORTS OF CHINESE PRODUCTS: AN OVERVIEW, CRS REPORT RS22713, 1 (Aug. 28, 2007).

⁴⁸ *Id.* at 2.

⁴⁹ *Id.* at 1; *see* THE OFF. OF REG. AFF., FDA IMPORT ALERT 99-30 (Jan. 15, 2009), http://www.fda.gov/ora/fiars/ora_import_ia9930.html.

Agreements between the United States and China to boost protection of the public health would be difficult due to China's vast geography and rudimentary system of national oversight and inspection; thus, it would be unwise to rely on the Chinese importer for food safety.⁵⁰ This issue is further compounded by the Chinese central government's lack of control over some remote provinces⁵¹ and its inability to create and enforce food safety regulations.⁵² With similar bureaucratic problems found in other importing countries, the result of reliance on the importer through the GIP is unlikely to improve food safety.⁵³

Even though these guidelines do not have any legally enforceable rights, they may prove more effective than anticipated because U.S. product liability law holds parties in the food supply chain accountable for the defects found in their products.⁵⁴ However, recovery for damages from the importers of contaminated products is not guaranteed.⁵⁵

V. CONCLUSION

In light of the economic downturn, the FDA is unlikely to see any necessary reforms and will have to rely on the GIP to encourage accountability with foreign importers and other countries to assure food safety for imported products.⁵⁶ Furthermore, with the passage of more unfunded congressional mandates, Congress will be putting the U.S. food supply at risk due to the FDA's financial inability to meet its expanding responsibilities.⁵⁷ Along with the FDA's expanding financial woes, public fears and distrust with the FDA's inability to quickly identify the source of food contamination have intensified.⁵⁸ The FDA's

⁵⁰ See Brozak, *supra* note 31, at 31.

⁵¹ *Id.*

⁵² Michael Lelyveld, *China's Bureaucracy Stymies Food Safety*, RADIO FREE ASIA, Nov. 4, 2008, http://www.rfa.org/english/energy_watch/food-safety-11042008154540.html.

⁵³ See *Id.*

⁵⁴ Plunkett & DeWaal, *supra* note 24, at 660.

⁵⁵ *Id.* at 661.

⁵⁶ See Levey, *supra* note 7.

⁵⁷ Hutt, *supra* note 13, at 432.

⁵⁸ Levey, *supra* note 7.

inability to find the source of food contamination is linked to their lack of technology that would allow them to analyze historical data and assess the risks to the food supply.⁵⁹ Considering these basic infrastructure problems surrounding the FDA, it is an illusion to believe that reliance on the importer is going to improve the safety of imported food.

⁵⁹ *Id.*