

FOREIGN SUPPLIER VERIFICATION PROGRAMS: A STEP FORWARD FOR IMPORTED FOOD SAFETY?

LIZZY RETTINGER*

Introduction	1
I. Background of the FDA & the Food Safety Modernization Act.....	3
II. The Foreign Supplier Verification Program.....	6
III. Comparison of the FSVP with the USDA's Regulatory Schemes	10
A. FSVP Scheme vs. USDA Slaughterhouse Inspection Program	11
B. FSVP Scheme vs. USDA Import Inspection Scheme	14
IV. Recommendations for Strengthening FSVPs.....	18
Conclusion	23

INTRODUCTION

Jensen Farms cantaloupes. Peanut Corporation of America peanut butter. Yuma region romaine lettuce. For anyone that has paid attention to food safety issues over the past ten years, these examples represent notorious failures in protecting American consumers. In 2009, an outbreak of Salmonella affected 714 people across forty-six states stemming from contaminated peanut butter.¹ The year 2011 saw the deadliest outbreak of Listeria in a decade with 147 reported cases, 143 hospitalizations, and thirty-three deaths stemming from cantaloupes grown at Jensen Farms in

*J.D. Candidate, American University Washington College of Law, Class of 2020. I would like to thank Professor Jeffrey Lubbers for his guidance and insightful recommendations throughout the writing process. I would also like to thank the staff of the *Administrative Law Review* for their hard work and the feedback I received in preparation of publication.

1. See generally *Multistate Outbreak of Salmonella Typhimurium Infections Linked to Peanut Butter, 2008–2009 (FINAL UPDATE)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (May 11, 2009), <https://www.cdc.gov/salmonella/2009/peanut-butter-2008-2009.html>; Andrew Martin & Gardiner Harris, *Outbreaks Put Worry on the Table*, N.Y. TIMES (May 10, 2009), <https://www.nytimes.com/2009/05/11/health/11food.html>.

Colorado.² In 2018, the largest *Escherichia coli* (*E. coli*) flare-up in over a decade infected 210 people across thirty-six states, with almost half requiring hospitalization.³ These are just a few examples of foodborne illnesses wreaking havoc on unsuspecting Americans. To address the life-or-death issue of foodborne illnesses, Congress passed the FDA Food Safety Modernization Act (FSMA), which President Obama signed into law on January 4, 2011.⁴ While it has been a slow process, the Food and Drug Administration (FDA) has promulgated several rules under this Act with the goal of adding more instruments to its toolbox in order to secure America's food supply and to guarantee its safety.⁵ Under the FSMA, the FDA promulgated the Foreign Supplier Verification Program (FSVP) rule, which focuses on the certification of food safety for food imported into the United States.⁶

Under the FSVP rule, private importers bear more responsibility for ensuring the safety of the food they import.⁷ While this regulation may be efficient, it is not the most effective way of guaranteeing the safety of our imported food. In Part I, this Comment will provide a brief history of the FDA and the background surrounding the passage of the FSMA. Part II will examine the FSVP rule and identify its problems and loopholes. Part III will analogize the FDA's regulatory scheme for the FSVP with more established regulatory schemes implemented and enforced by the United States

2. See generally *Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado (FINAL UPDATE)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 27, 2012, 10:30 AM), <https://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/index.html>; Christina Caron, *CDC: Cantaloupe Listeria Outbreak Deadliest in a Decade*, ABC NEWS (Sept. 28, 2011), <https://abcnews.go.com/Health/cdc-cantaloupe-listeria-outbreak-deadliest-decade/story?id=14622507>.

3. See generally *Multistate Outbreak of E. coli O157:H7 Infections Linked to Romaine Lettuce (Final Update)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (June 28, 2018, 3:30 PM), <https://www.cdc.gov/ecoli/2018/o157h7-04-18/index.html>; Julia Jacobs, *Officials Identify a Source in the Romaine Lettuce E. Coli Outbreak*, N.Y. TIMES (July 1, 2018), <https://www.nytimes.com/2018/07/01/us/romaine-lettuce-e-coli-nyt.html>.

4. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 21 U.S.C.).

5. See generally *Fact Sheets & Presentations*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247546.htm> [<http://wayback.archive-it.org/7993/20180907212828/>] (last updated Sept. 7, 2018) (listing and providing summaries of various final rules promulgated to safeguard America's food supply).

6. Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals Rule, 21 C.F.R. §§ 1.1(a), 1.501(a) (2012).

7. See Agostino S. Filippone, *New Powers Under Food Safety Modernization Act: FDA Proposes New Rules to Combat Foodborne Illness*, 25 LOY. CONSUMER L. REV. 307, 315 (2013) (claiming that the onus is now on importers to ensure the food they import meets relevant safety standards).

Department of Agriculture (USDA). Finally, Part IV will analyze loopholes in the FSVP rule and provide recommendations as to how to ensure the FDA retains oversight and enforcement authority, thereby making the FSVP rule more tenable and effective.

I. BACKGROUND OF THE FDA & THE FOOD SAFETY MODERNIZATION ACT

When Congress established what is now known as the FDA in the early 1800s, its primary purpose was to conduct chemical analysis of agricultural goods.⁸ In 1906, Congress passed the Pure Food and Drugs Act,⁹ providing American consumers with protections against misbranded and adulterated food for the first time.¹⁰ Congress also passed the Meat Inspection Act¹¹ on the same day, further signifying its commitment to protecting the American food supply. These laws came in response to shocking disclosures of unsanitary conditions in meat-processing facilities, use of poisonous dyes and preservatives in food, and misleading claims regarding dangerous medicines.¹²

Throughout the twentieth century, Congress passed additional legislation establishing the FDA in its current regulatory form.¹³ The passage of the Federal Food, Drug, and Cosmetic Act (FDCA) in 1938 represented a complete

8. See *id.* at 308–09; see also *The History of FDA's Fight for Consumer Protection and Public Health*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/History/default.htm> (last updated June 29, 2018) (explaining that the Food and Drug Administration (FDA) is the oldest comprehensive consumer protection agency in the United States, and while it was not known by its present name until 1930, the FDA's modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act).

9. Pure Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906).

10. See Filippone, *supra* note 7, at 309.

11. Meat Inspection Act, Pub. L. No. 59-242, 34 Stat. 1256, 1260 (1906) (codified as amended at 21 U.S.C. §§ 601–695 (2014)).

12. See Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 79 (2000) (asserting that the publication of Upton Sinclair's *The Jungle* contributed to President Theodore Roosevelt supporting and Congress passing both pieces of legislation); *Significant Dates in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/About> (last updated Dec. 19, 2014) [<https://wayback.archive-it.org/7993/20170722191634/>].

13. These laws include the Federal Food, Drug, and Cosmetic Act (1938), 21 U.S.C. § 301 (2012), which enhanced the FDA's powers and purpose; the Food and Drug Administration Act of 1988, *id.* § 393, which established the FDA as an agency within the Department of Health and Human Services and broadly spelled out the responsibilities of the Secretary and Commissioner for research, enforcement, education, and information; and the Food and Drug Administration Modernization Act, Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified as amended in scattered sections of 21 U.S.C.), which mandated the most wide-ranging reforms in agency practices since 1938.

overhaul of the public health system and came in response to the deaths of 107 people from a legally marketed toxic elixir.¹⁴ Under this statute, the FDA has the power to demand evidence of the safety of new drugs, issue standards for food, and conduct factory inspections.¹⁵ In 1949, the FDA published its first guidance for industry, a valuable regulatory tool that clarifies governing standards and promotes industry stakeholder compliance.¹⁶ A reorganization of federal programs in 1968 placed the FDA in the Public Health Service until the 1988 Food and Drug Administration Act established the FDA as an agency within the Department of Health and Human Services.¹⁷

Enacted in 2011, the FSMA enabled the FDA to better protect the American public by strengthening the food-safety system.¹⁸ While the FSMA passed Congress with bipartisan support, the road to implementation has been anything but smooth.¹⁹ As required by the Administrative Procedure Act (APA),²⁰ the FDA must publish newly proposed rules in the Federal Register, allow for a public notice-and-comment period, and review submitted comments before issuing a final rule.²¹ After reviewing the comments, the

14. *Laws Enforced by FDA*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/default.htm> (last updated Mar. 29, 2018).

15. *Id.*

16. FDA guidance documents represent the agency's current thinking on a topic and describe the agency's interpretation of its policy on a regulatory issue. *See Guidances*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234622.htm> (last updated May 24, 2018). While the documents are published in the Federal Register, they do not create or confer any rights, and are nonbinding on the FDA and the public. *Id.*

17. *See Significant Dates in U.S. Food and Drug Law History*, *supra* note 12.

18. *See* U.S. FOOD & DRUG ADMIN., FSMA FACTS: BACKGROUND ON THE FDA FOOD SAFETY MODERNIZATION ACT (FSMA) 1 (2011), <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM263773.pdf>; Neal Fortin, *The U.S. Food Safety Modernization Act: Implications in Transnational Governance of Food Safety, Food System Sustainability, and the Tension with Free Trade*, 25 DUKE ENVTL. L. & POL'Y F. 313, 320 (2015) (claiming the FSMA "may be the most significant addition to U.S. food law in history"); Jessica Hopton Youngberg, *U.S. Food Safety vs. An International Agreement: The FDA Food Safety Modernization Act in the Context of World Trade Organization's Sanitary and Phytosanitary Agreement*, 8 J. HEALTH & BIOMEDICAL L. 507, 511 (2013) (noting the FSMA empowered the FDA to transition from a reactionary to actively preventative system by giving the agency a variety of new tools).

19. *See, e.g.*, Fortin, *supra* note 18, at 319–20 (discussing the peanut foodborne illness outbreak in 2008 and 2009, which resulted in the deaths of nine Americans).

20. 5 U.S.C. §§ 551–559, 561–570a, 701–706 (2012).

21. *See* U.S. FOOD & DRUG ADMIN., FSMA FACTS: THE FOOD SAFETY LAW AND THE RULEMAKING PROCESS: PUTTING FSMA TO WORK 1 (2011), <https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM27713.pdf>. Congress may pass a law that directs an agency to act on a certain subject, but more often agencies conduct surveys of their areas of responsibility and determine priorities for rulemaking. *See A Guide to the Rulemaking Process*, OFFICE OF THE FEDERAL REGISTER, <https://www.federalregister.gov/uploads/2011/01/>

agency then publishes the final rule.²² However, this step is where the FDA ran into trouble as the agency missed several deadlines for publishing its final rules.²³ In 2012, the Center for Food Safety sued the FDA for failing to meet seven deadlines for promulgating food safety rules.²⁴ In *Center for Food Safety v. Hamburg*,²⁵ the U.S. District Court for the Northern District of California found that the FDA violated the FSMA and APA by “failing to promulgate the FMSA [sic] regulations by their statutory deadlines.”²⁶ While the case was pending on appeal, the parties settled. The settlement vacated the court’s order and entered into a consent decree that “set out a schedule for FDA action on pending FSMA regulations and processes should the FDA need additional time to develop and finalize regulations.”²⁷

To date, the FDA has promulgated several final rules under the FSMA.²⁸ However, industry stakeholders are still apprehensive.²⁹ In a survey conducted by Strategic Consulting, Inc. and *Food Safety Magazine*, a majority of respondents identified implementation as their biggest concern regarding the FSMA—specifically what it would cost and how to attain the resources required to meet deadlines.³⁰ Respondents also identified audits and enforcement as another area of concern, particularly noting the uncertainty around how inspections will be conducted and potential inconsistencies in inspections and enforcement as inspectors go through the “learning process.”³¹ Although there is still some hesitation and skepticism surrounding the FSMA, ensuring the safety of our food is unquestionably necessary.

According to the Centers for Disease Control and Prevention (CDC), roughly one in six Americans, or forty-eight million people, get sick from food-borne illnesses each year; of these people, 128,000 are hospitalized and three

the_rulemaking_process.pdf (last visited May 13, 2019). When issuing a regulation, an agency must follow an open public process per the Administrative Procedure Act (APA). See 5 U.S.C. § 553.

22. After the notice-and-comment period ends, the agency publishes the final rule in the Federal Register with an “Effective Date.” See *id.* § 553(d).

23. See Lindsey Lazopoulos Friedman & Wesley Van Camp, *Pitfalls of the Food Safety Modernization Act: Enhanced Regulation, Minimal Consumer Benefit, and Zero Tolerance Levels for Naturally-Occurring Trace Pathogens*, U. MIAMI INTER-AM. L. REV., Fall 2016, at 13, 25.

24. *Id.*

25. 954 F. Supp. 2d 965 (N.D. Cal. 2013).

26. *Id.* at 970.

27. See Friedman & Van Camp, *supra* note 23, at 25.

28. See *Fact Sheets & Presentations*, *supra* note 5.

29. See Bob Ferguson, *What Industry and FDA are Thinking about FSMA Implementation*, FOOD SAFETY MAG. (June/July 2017), <https://www.foodsafetymagazine.com/magazine-archive1/junejuly-2017/what-industry-and-fda-are-thinking-about-fsma-implementation/>.

30. *Id.*

31. *Id.*

thousand die.³² According to the USDA’s Economic Research Service, foodborne illnesses cost consumers about \$6.9 billion annually.³³ The goal of the FSMA was to transform the FDA from a reactive to a proactive agency, with a focus on enhancing the FDA’s capacity to prevent future outbreaks of foodborne illnesses, by improving the agency’s detection and response capabilities with regards to food-safety problems and ensuring the safety of imported food.³⁴ To achieve these goals, the FSMA has five primary focus areas: preventative controls, inspection and compliance processes, imported food-safety regulations, response plans, and enhanced partnerships.³⁵ Thus far, the FDA has promulgated several rules aimed at preventing foodborne illnesses.³⁶ To improve its inspection ability, the FDA promulgated the final rule on Accreditation of Third-Party Auditors.³⁷ With a stronger focus on the safety of imported food, the FDA promulgated the Final Rule on Foreign Supplier Verification Program³⁸ and the Voluntary Qualified Importer Program.³⁹ The FSMA also provided the FDA with more powerful tools to enforce regulations, particularly by empowering the agency to mandate product recalls.⁴⁰

II. THE FOREIGN SUPPLIER VERIFICATION PROGRAM

The need for improving the safety of imported food has become more important than ever, as approximately 20% of the U.S. food supply is imported from more than ninety countries.⁴¹ A significant percentage of fish

32. See *Estimates of Foodborne Illnesses in the United States*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html> (last updated Nov. 5, 2018).

33. U.S. DEP’T OF AGRIC., FOOD SAFETY AND INSPECTION SERVICE: PROTECTING PUBLIC HEALTH AND PREVENTING FOODBORNE ILLNESS 4 (2013), <https://www.fsis.usda.gov/wps/wcm/connect/7a35776b-4717-43b5-b0ceaec64489fbd/mission-book.pdf?MOD=AJPERES> [hereinafter FOOD SAFETY AND INSPECTION SERVICE].

34. See Filippone, *supra* note 7, at 313.

35. *Id.*; see also Youngberg, *supra* note 18, at 513–22.

36. See Final Rule for Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 55,908, 55,911 (Sept. 17, 2015); Final Rule on Sanitary Transportation of Human and Animal Food, 21 U.S.C. § 350e (2012); Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration, *id.* § 350i.

37. 21 U.S.C. § 384d.

38. *Id.* § 384a.

39. *Id.* § 384b.

40. FSMA, Pub. L. No. 111-353, 124 Stat. 3885, 3939–44. (2011) (codified as amended in scattered sections of 21 U.S.C.).

41. See Ramakrishnan Nara, *The Foreign Supplier Verification Program: Boon or Bane?*, FOOD SAFETY MAG. (June/July 2018), <https://www.foodsafetymagazine.com/magazine-archive1/junejuly-2018/the-foreign-supplier-verification-program-boon-or-bane/>; L. Hannah Gould et al., *Outbreaks of Disease Associated with Food Imported into the United States*, 23

and shellfish consumed in the United States is imported, along with a significant percentage of fresh produce.⁴² In 2015, the CDC, FDA, and several state public health officials collaborated to identify cucumbers imported from Mexico as the source of a Salmonella outbreak in which 907 people were infected, with 204 individuals requiring hospitalization, across forty states.⁴³ In 2016, 143 people were infected with Hepatitis A after drinking smoothies from Tropical Smoothie Café that contained strawberries imported from Egypt.⁴⁴ These are just two of many examples where imported food was identified as the origin of health outbreaks in the United States.

According to a CDC study, investigations of 195 outbreaks between 1996 and 2014 implicated imported food; these outbreaks resulted in 10,685 illnesses and 1,017 hospitalizations.⁴⁵ Although the number of outbreaks associated with imported food is relatively small, the study makes clear that both the absolute number and the proportion to the total number of outbreaks, has increased.⁴⁶ To maintain the safety and security of food consumed in the United States and accommodate increasingly diverse consumer tastes contributing to greater food importation, the FDA promulgated the Foreign Supplier Verification Program (FSVP) rule under the FSMA.⁴⁷

The purpose of the import provisions of the FSMA is to ensure that imported food meets the same safety standards as food produced domestically.⁴⁸ Under the FSVP, importers⁴⁹ must ensure that food is produced in a manner that provides the same level of health protection as required under the

EMERGING INFECTIOUS DISEASES 525, 525 (Mar. 2017), https://wwwnc.cdc.gov/eid/article/23/3/16-1462_article (stating that the steady increase in the proportion of food imported is a result of changing consumer demand for wider selection of food products and increased demand for produce items year round).

42. See Gould, *supra* note 41 (stating that approximately 97% of fish and shellfish, 50% of fresh fruits, and 20% of fresh vegetables are imported).

43. See *Multistate Outbreak of Salmonella Poona Infections Linked to Imported Cucumbers (Final Update)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 18, 2016), <https://www.cdc.gov/salmonella/poona-09-15/index.html>.

44. See *Multistate Outbreak of Hepatitis A Linked to Frozen Strawberries (Final Update)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 16, 2016), <https://www.cdc.gov/hepatitis/outbreaks/2016/hav-strawberries.htm>.

45. See Gould, *supra* note 41.

46. *Id.*

47. 21 C.F.R. § 1.500 (2012).

48. See *id.* § 1.502; see also Kristin Eads & Jennifer Zwagerman, *In Focus: Examining the New FDA Food Safety Modernization Act*, 33 *HAMLIN J. PUB. L. & POL'Y* 123, 149 (2011).

49. “Importer” is defined as the owner or consignee of the food item at the time it enters the United States, and if there is none, then the U.S. agent or representative of the foreign owner or consignee. See 21 C.F.R. § 1.500.

FDCA,⁵⁰ and is not adulterated⁵¹ or misbranded with respect to allergen labeling under the FDCA.⁵² The FSVP requires importers to conduct risk-based verifications of their foreign suppliers to confirm their compliance with the aforementioned food safety requirements.⁵³ With the FSVP, the FDA endeavored to strike a balance between flexibility and accountability by allowing importers to determine for themselves the appropriate verification measures they will take depending on the food they import.⁵⁴ While importers have some flexibility in shaping their respective FSVPs, each importer must still develop, maintain, and follow an FSVP for each food imported from each supplier.⁵⁵ If an importer lacks an FSVP for the product being imported, the product will be refused admission into the United States.⁵⁶

The first requirement of each importer's FSVP is to conduct a hazard analysis to identify and evaluate any known or reasonably foreseeable hazards associated with each food product to be imported.⁵⁷ This analysis must take into account a variety of different hazards⁵⁸ that are naturally occurring,

50. 21 U.S.C. § 301 (2012). The hazard analysis and risk-based preventative controls section outlines the requirements owners, operators, or agents in charge of facilities must satisfy, including: identifying reasonably foreseeable hazards associated with the facility and those that might be intentionally introduced; implementing preventative controls that assure identified hazards will be significantly reduced or prevented; monitoring the effectiveness of the implemented controls; establishing procedures for corrective actions; verifying the previous requirements; and keeping records of compliance. *Id.* § 350g.

51. A food product will be considered adulterated if it: (a) contains poisonous or unsanitary substances; (b) is missing any valuable constituent or has substances added to increase its bulk, reduce its quality or strength, or make it appear of greater value than it is; (c) contains unsafe color additives; (d) is not in compliance with sanitary transportation practices; or, (e) has previously been refused admission into the United States. *Id.* § 342.

52. A food product is considered misbranded with respect to major allergens if it is missing the inclusion of a major food allergen in the list of ingredients. *Id.* § 343(w).

53. See Eads & Zwagerman, *supra* note 48, at 150 (explaining that verification activities can include lot-by-lot certification, annual onsite inspections, review of foreign suppliers' preventative control plan, and periodic sampling and testing of shipments).

54. See Nara, *supra* note 41.

55. See *id.*; Fortin, *supra* note 18, at 324–25. Some types of imports are exempt from FSVP, including: certain types of juice and seafood products, food imported for research or evaluation, food imported for personal consumption, alcoholic beverages, and food that is transshipped or imported for further processing and export. See 21 C.F.R. § 1.501 (2012).

56. See Eads & Zwagerman, *supra* note 48, at 150.

57. 21 C.F.R. § 1.504(a) (2018) (explaining that the hazard analysis should be based on experience, illness data, scientific reports, and other information).

58. *Id.* § 1.504(b) (listing the following types of hazards that must be identified: biological and microbiological hazards like parasites and pathogens; chemical hazards like pesticide and drug residues; radiological hazards; natural toxins; decomposition; unapproved food or color additives and food allergens; and physical hazards such as stones, glass, or metal fragments);

unintentionally introduced, or intentionally introduced for economic gain.⁵⁹ After identifying potential hazards, importers must assess the probability that the hazards will occur in the absence of controls and the severity of the illness or injury that would result should the hazard occur.⁶⁰ All hazard analyses must be documented in writing, regardless of the outcome.⁶¹ An importer may utilize a third party to conduct this hazard analysis, but must still review and assess the information.⁶²

Second, importers must evaluate and document their foreign supplier's performance and the risk posed by importing the food.⁶³ When evaluating a supplier's performance, an importer must consider: the food-safety processes, procedures, and practices the supplier has in place; applicable U.S. regulations and the supplier's compliance with them;⁶⁴ the supplier's food-safety history; and any other factors as necessary.⁶⁵ These evaluations must be repeated every three years, or any time new information comes to light regarding a potential hazard or the supplier's performance.⁶⁶ However, if an importer receives adequate assurances that a subsequent entity in the distribution chain will oversee the fulfillment of food-safety requirements, reevaluation is not required.⁶⁷

Third, importers must determine appropriate supplier verification activities and approve suppliers.⁶⁸ The verification activities must assure that the identified hazards requiring a control have been prevented or significantly minimized.⁶⁹ Importers have the ability to tailor their verification activities based on the unique risks of the food they are importing and their supplier's characteristics.⁷⁰ In determining the appropriate verification activities, importers must use the evaluations conducted under the requirements discussed in the

see also U.S. FOOD & DRUG ADMIN., KEY REQUIREMENTS: FINAL RULE ON FOREIGN SUPPLIER VERIFICATION PROGRAMS 2 (2017), <https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472890.pdf> [hereinafter KEY REQUIREMENTS: FINAL RULE ON FSVP].

59. 21 C.F.R. § 1.504(b)(2).

60. *Id.* § 1.504(c).

61. *Id.* § 1.504(a); *see also* Nara, *supra* note 41, at 4.

62. *See* KEY REQUIREMENTS: FINAL RULE ON FSVP, *supra* note 58, at 2.

63. 21 C.F.R. § 1.505; *see also* KEY REQUIREMENTS: FINAL RULE ON FSVP, *supra* note 58, at 2.

64. Determining a supplier's compliance includes whether the supplier has been the subject of an FDA warning letter, import alert, or other compliance action. *See* 21 C.F.R. § 1.505(a)(iii)(B).

65. *Id.* § 1.505(a)(iii)(C).

66. *Id.* § 1.505(c); *see also* KEY REQUIREMENTS: FINAL RULE ON FSVP, *supra* note 58, at 2.

67. *See* Nara, *supra* note 41, at 4.

68. 21 C.F.R. § 1.506(a); *see also* KEY REQUIREMENTS: FINAL RULE ON FSVP, *supra* note 58, at 1.

69. 21 C.F.R. § 1.506(c).

70. *See* KEY REQUIREMENTS: FINAL RULE ON FSVP, *supra* note 58, at 3.

previous paragraph.⁷¹ The FDA recognizes certain activities as appropriate for foreign supplier verification, including: onsite audits,⁷² sampling and testing of food, and review of the supplier's relevant food-safety records.⁷³ Importers may rely on a third party to conduct these verification activities, but the importer is still ultimately responsible for the safety of the food.⁷⁴

Finally, if an importer learns that a supplier failed to meet the applicable food-safety standards, it must take prompt action to correct the issue.⁷⁵ The appropriate corrective measure will depend on the circumstances, but one example is discontinuing use of the foreign supplier.⁷⁶ If a foreign supplier's noncompliance is identified by a means other than through the enforcement of the importer's FSVP, the importer must promptly examine whether the FSVP is adequate or needs to be modified.⁷⁷

III. COMPARISON OF THE FSVP WITH THE USDA'S REGULATORY SCHEMES

The responsibility for ensuring food safety in the United States is distributed between fifteen different agencies but mostly falls on the FDA and the Food Safety Inspection Service (FSIS) within the USDA.⁷⁸ As mentioned in Part I of this Comment, the FDA derives its current regulatory authority from a slew of legislation passed starting in the early 1900s.⁷⁹ The USDA also derives its regulatory authority from a variety of laws, including the Federal Meat Inspection Act (FMIA),⁸⁰ the Poultry Products Inspection Act (PPIA),⁸¹ and the Eggs Product Inspection Act (EPIA).⁸² As the public health agency within the USDA, FSIS is responsible for enforcement, as well as ensuring that meat, poultry, and processed eggs are "safe, wholesome, and

71. 21 C.F.R. § 1.506(d); *see also* Nara, *supra* note 41, at 3.

72. Onsite audits must be conducted by a qualified auditor. *See* 21 C.F.R. § 1.506(e)(i).

73. 21 C.F.R. § 1.506(d)(ii).

74. Importers may not rely on the foreign supplier itself or its employees to conduct verification activities, except for the sampling and testing of food. *See id.* § 1.506(e)(2)(ii). Further, there must not be any financial conflicts of interest that influence the results of the verification activities. *See id.* § 1.506(e)(4).

75. 21 C.F.R. § 1.508(a).

76. *Id.*

77. *Id.* § 1.508(b).

78. *See* Friedman & Van Camp, *supra* note 23, at 17.

79. *See supra* I. Background of the FDA & the Food Safety Modernization Act; *see also* Michael T. Roberts, *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*, 59 FOOD & DRUG L.J. 563, 566 (2004).

80. Federal Meat Inspection Act, Pub. L. No. 59-242, 34 Stat. 1256 (1906).

81. Poultry Products Inspection Act, Pub. L. No. 85-172, 71 Stat. 441 (1957).

82. Eggs Product Inspection Act, Pub. L. No. 91-597, 84 Stat. 1635 (1970).

accurately labeled.”⁸³ To do this, FSIS performs food-safety inspections at over six thousand establishments nationwide, maximizes domestic and international compliance with food-safety policies, enhances public education and outreach regarding food-safety policies, and strengthens collaboration among stakeholders as well as public- and private-sector partners.⁸⁴

While both the FDA and FSIS are responsible for regulating segments of the food industry, they regulate different products. Although a division of regulatory authority may sound simple in theory, it is complicated in practice.⁸⁵ This section compares the FSVP inspection scheme with two regulatory schemes enforced by the USDA: the inspection of slaughterhouses and the inspection of imports to the United States.

A. FSVP Scheme vs. USDA Slaughterhouse Inspection Program

Under the FMIA, the Secretary of Agriculture has the authority to place federal inspectors in establishments that process or in any way handle meat products.⁸⁶ These facilities provide inspectors with access to all parts of the premises at any time.⁸⁷ In the years following the passage of the FMIA, government officials performed inspections using sight, touch, and smell to identify any diseases or defects in the meat.⁸⁸ If an inspector deemed a meat product unfit for consumption, she could order the product’s removal and revoke the facility’s inspection privileges if the processor failed to remove it.⁸⁹ However, in 1996, the FSIS adopted the Hazard Analysis Critical Control Point (HACCP) system,⁹⁰ in part to rectify the traditional inspection

83. FOOD SAFETY AND INSPECTION SERVICE, *supra* note 33, at 1.

84. *Id.* at 3.

85. See Wil S. Hylton, *A Bug in the System: Why Last Night’s Chicken Made You Sick*, NEW YORKER (Jan. 26, 2015), <https://www.newyorker.com/magazine/2015/02/02/bug-system> (providing examples of this complexity, such as: fish are regulated by the FDA, except for catfish, which are regulated by the USDA; frozen cheese pizza is regulated by the FDA, but frozen pepperoni pizza is regulated by the USDA; the skin of a link of sausage is regulated by the FDA, but the meat inside is regulated by the USDA).

86. See Eileen S. Pape, *A Flawed Inspection System: Improvements to Current USDA Inspection Practices Needed to Ensure Safer Beef Products*, 48 HOUS. L. REV. 421, 432 (2011).

87. See 21 U.S.C. § 606(a) (2012).

88. See Pape, *supra* note 86, at 434.

89. See Katherine A. Straw, *Ground Beef Inspections and E. Coli O157:H7: Placing the Needs of the American Beef Industry Above Concerns for the Public Safety*, 37 WASH. U. J.L. & POL’Y 355, 358–59 (2011).

90. See Hazard Analysis Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38,806, 38,814 (July 25, 1996) (codified in scattered sections of 9 C.F.R.); Pape, *supra* note 86, at 435–36 (identifying the four HACCP requirements: (1) facilities must develop and implement written sanitation standard operating procedures; (2) facilities must test for microbial pathogens to verify their procedures adequately prevent or remove contamination; (3) facilities that

method's inability to detect microbial contamination.⁹¹ The goal of the HACCP system is to establish a preventative approach by requiring controls on conditions that could pose a contamination threat throughout the entire inspection process, rather than keeping the reactive model of looking for defects after contamination has already occurred.⁹²

The HACCP system is currently used by FSIS personnel. This has changed the inspection regime from one in which a government inspector is responsible for safety assessments to an honor system that places the primary responsibility on production facility employees.⁹³ The FSVP rule endorses the same approach, as importers and their foreign suppliers are responsible for identifying and controlling any hazards in the food they import.⁹⁴ A major criticism of the FSIS's HACCP system is that FSIS inspectors are now merely reviewing paperwork, while production facilities can manipulate the system to further limit the interference of FSIS inspectors.⁹⁵ The inspection process under FSVP is identical, in that inspections are based on a review of records and do not involve any observations of actual food production.⁹⁶

Additionally, under the HACCP system, facilities are not required to provide inspectors with complete access to their records; instead, they are only

produce raw ground meat products must meet “pathogen reduction performance standards” for Salmonella; and (4) all facilities must develop and implement a system of preventative controls to improve the safety of their products).

91. See Pape, *supra* note 86, at 434, 436–37 (identifying the seven HACCP principles: (1) hazard analysis of each process within the facility to identify all food safety hazards; (2) identification of every step in the process where control can “prevent, eliminate, or otherwise reduce a potential food safety hazard to acceptable levels;” (3) establishing critical limits for each critical control point (CCP); (4) establishing monitoring requirements for CCPs; (5) taking corrective action when a process parameter for a CCP goes beyond its boundaries; (6) record-keeping, including documentation of the entire HACCP system that remains accessible; and (7) ability to systematically verify the HACCP system).

92. *Id.* at 438.

93. See *id.* at 439; Straw, *supra* note 89, at 362–63.

94. See KEY REQUIREMENTS: FINAL RULE ON FSVP, *supra* note 58, at 1.

95. See Pape, *supra* note 86, at 439; Straw, *supra* note 89, at 364, 373. But see *Ensuring Meat Safety: The HACCP System*, FRONTLINE, <https://www.pbs.org/wgbh/pages/frontline/shows/meat/evaluating/ensuring.html> (last visited May 13, 2019). In an interview with Elsa Murano, former USDA Undersecretary of Food Safety, she stated that the HACCP system gives inspectors more control over inspections and does not delegate authority to plants, but rather assigns them responsibility. *Id.* In his interview, Patrick Boyle, former CEO of the American Meat Institute, stated “[a]nyone who thinks that HACCP is tantamount to self-regulation does not understand HACCP as a process control technology, and does not understand the inspection system that exists in the United States.” *Id.*

96. *What Do Importers Need to Know About FSVP: A Conversation with Sharon Mayl*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm560689.htm> (last updated Aug. 20, 2018) [hereinafter *What Do Importers Need to Know About FSVP*].

obligated to share documentation relating to their HACCP programs.⁹⁷ Similarly, the FDA relies solely on the information contained in the documents provided by the importer upon entry to the United States.⁹⁸ Because neither the FSIS nor FDA have enough staff to conduct in-person examinations, it is almost impossible to confirm the veracity of the provided documents.⁹⁹ A major problem with this process is that when an audit focuses solely on reviewing records, it may verify that the documentation is correct without actually verifying that the facility has met the HACCP standard.¹⁰⁰ The FSVP rule has been in full effect for over a year and while there is not much information available yet, there have been reports of “extensive falsification” of HACCP documentation submitted for FSIS inspections.¹⁰¹ Furthermore, these documents are not available under the Freedom of Information Act; thus, the public has no option but to take facilities at their word.¹⁰²

Under both regulatory schemes, the company processing or importing the food product has the ability to establish its own plan based on what it has identified as the unique risks of its product.¹⁰³ This is problematic because in the past, companies have appeared to be more concerned with profit than public safety.¹⁰⁴ This means that relying on for-profit companies to ensure

97. See Straw, *supra* note 89, at 373.

98. See generally *What Do Importers Need to Know About FSVP*, *supra* note 96.

99. See Straw, *supra* note 89, at 364 (asserting that while the beef industry has continued to grow, the number of FSIS inspectors has decreased).

100. See Lesley K. McAllister, *Third-Party Programs to Assess Regulatory Compliance*, Report Prepared for the Administrative Conference of the United States 1, 43 (Oct. 22, 2012).

101. See Straw, *supra* note 89, at 374.

102. *Id.*; see also *General FOIA Information*, U.S. SMALL BUS. ADMIN., <https://www.sba.gov/about-sba/sba-performance/open-government/foia/general-foia-information> (last visited May 13, 2019) (explaining that only government agency records are available under the Freedom of Information Act; information from private citizens or companies is not subject to it).

103. See KEY REQUIREMENTS: FINAL RULE ON FSVP, *supra* note 58, at 1; Pape, *supra* note 86, at 439.

104. See, e.g., Kevin McCoy, *Peanut Exec in Salmonella Case Gets 28 Years*, USA TODAY (Sept. 21, 2015, 1:49 AM), <https://www.usatoday.com/story/money/business/2015/09/21/peanut-executive-salmonella-sentencing/72549166/> (discussing the conviction of a Peanut Corporation of America executive who was found guilty of introducing adulterated food into commerce with intent to defraud or mislead, after prosecutors alleged he knew that products were contaminated and sold them anyway); Khushbu Shah, *Former Blue Bell Employees Say Texas Factory was Unsafe and Unsanitary*, EATER (Sept. 14, 2015, 1:00 PM), <https://www.eater.com/2015/9/14/9323179/former-blue-bell-employees-say-texas-factory-was-unsafe> (referring to FDA records regarding the 2015 Blue Bell Ice Cream Listeria outbreak, indicating that the company knew random samples of its ice cream tested positive for the bacteria, but failed to change its practices to eliminate it); Stephanie Strom, *Dole Knew About Listeria Problem at Salad Plant, F.D.A. Report Says*, N.Y. TIMES (Apr. 29, 2016), <https://www.nytimes.com/2016/04/30/business/dole-knew-about-listeria-problem-fda-report-says.html> (referring to an FDA

food safety is not always an effective strategy. Furthermore, if the FSIS finds that a company violated agency regulations, its options for enforcing compliance are limited. For example, the FSIS does not have the authority to suspend a facility's inspection privileges for noncompliance with HACCP requirements.¹⁰⁵ If the FSIS wants to suspend inspection privileges, it can only do so with judicial intervention, though this level of sanction is rarely utilized due to a number of administrative hurdles.¹⁰⁶ On the other hand, the FSVP provides some stronger compliance tools, including refusal of an imported product or a civil or criminal action in federal court.¹⁰⁷

Both the FSVP inspection scheme and the FSIS inspection scheme for slaughterhouses have substantial loopholes stemming from the shift in responsibility for ensuring food safety from a government agency to private companies.¹⁰⁸ If public safety is in the hands of private businesses, whose primary objective is to make money, how safe can our food truly be? This is of particular concern when there is a lack of government oversight ensuring that these companies comply with the appropriate food-safety regulations. Simply reviewing paperwork is not sufficient supervision, particularly when the company being assessed and the company submitting documentation are one and the same.

B. FSVP Scheme vs. USDA Import Inspection Scheme

The FSIS also has authority to inspect imported meat, poultry, and egg products under the FMIA, the PPIA, and the EPIA.¹⁰⁹ All imports under the purview of the USDA must come from eligible countries and

report demonstrating that products in the plant tested positive for *Listeria* nine times before FDA inspectors showed up to conduct their own test).

105. See Pape, *supra* note 86, at 442.

106. See Straw, *supra* note 89, at 367.

107. See 21 C.F.R. § 1.514; see also U.S. FOOD & DRUG ADMIN., FOREIGN SUPPLIER VERIFICATION PROGRAM FOR IMPORTERS OF FOOD FOR HUMANS AND ANIMALS: GUIDANCE FOR INDUSTRY *DRAFT GUIDANCE* 10 (2018), <https://www.fda.gov/media/118241/download>.

108. See Pape, *supra* note 86, at 439 (asserting that a key consequence of the HACCP system is the shifting of food-safety tasks away from federal inspectors to meatpacking employees, made worse because the facility's records do not need to be shared with inspectors or the public); see also KEY REQUIREMENTS: FINAL RULE ON FSVP, *supra* note 58 (explaining that importers are responsible for conducting verification activities and employing corrective actions themselves, rather than having these activities carried out by a government agency).

109. See U.S. DEP'T OF AGRIC., FSIS GUIDANCE FOR IMPORTING MEAT, POULTRY, AND EGG PRODUCTS INTO THE UNITED STATES, DRAFT 1 (2017), <https://www.fsis.usda.gov/wps/wcm/connect/415278f6-9c67-4641-bf92-8aafb90e2ac0/Guidance-for-Importing-Meat-Poultry-Egg-Products-into-US.pdf?MOD=AJPERES>.

establishments or plants certified to export to the United States.¹¹⁰ If a country wishes to become eligible to export to the United States, it must go through the equivalence determination process.¹¹¹ To do this, the foreign government's Central Competent Authority (CCA) responsible for inspecting meat, poultry, and egg products must make a formal written request.¹¹² For a country to be considered equivalent, the products it exports must meet all safety standards applicable to food produced in the United States.¹¹³ However, foreign food regulatory systems do not need to be identical to those in the United States; if the country applies equivalent sanitary processes that result in the same level of protection against hazards, the country will be approved.¹¹⁴ For an establishment to become eligible to export to the United States, the foreign government's CCA must confirm to the FSIS that it meets requirements equivalent to those of the FSIS.¹¹⁵ Once a country is deemed equivalent, the FSIS relies on the foreign government to conduct inspection activities.¹¹⁶ However, the FSIS can reinspect any product when it is presented for importation.¹¹⁷ Further, the FSIS can conduct periodic audits to ensure the foreign country's food-safety regulatory system remains equivalent.¹¹⁸

All qualifying import shipments must be presented to the FSIS for inspection.¹¹⁹ Inspections occur after an importer has submitted an import inspection application to the FSIS and occur at the official import inspection establishment designated in the application.¹²⁰ Any shipment that enters commerce without going through the FSIS import inspection violates the

110. 21 U.S.C. §§ 620, 466, 1046; *see* FSIS GUIDANCE FOR IMPORTING MEAT, POULTRY, AND EGG PRODUCTS INTO THE UNITED STATES, DRAFT, *supra* note 109, at 1.

111. FSIS GUIDANCE FOR IMPORTING MEAT, POULTRY, AND EGG PRODUCTS INTO THE UNITED STATES, DRAFT, *supra* note 109, at 1.

112. *Equivalence Process Overview*, U.S. DEP'T OF AGRIC., <https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/equivalence/equivalence-process-overview> (last updated July 26, 2016).

113. *Id.*

114. *Id.* (stating evaluations of the foreign country's regulatory system can include document reviews, on-site audits, and port of entry reinspection at the time of importation).

115. FSIS GUIDANCE FOR IMPORTING MEAT, POULTRY, AND EGG PRODUCTS INTO THE UNITED STATES, DRAFT, *supra* note 109, at 1.

116. *Id.*

117. *Id.*

118. *Id.* (stating audits can include "assessment[s] of selected exporting establishments").

119. *Id.* (explaining that shipments are available for FSIS inspection after being cleared by the U.S. Customs and Border Control and the USDA Animal and Plant Health Inspection Service).

120. FSIS GUIDANCE FOR IMPORTING MEAT, POULTRY, AND EGG PRODUCTS INTO THE UNITED STATES, DRAFT, *supra* note 109, at 2–3.

FMIA, PPIA, or EPIA.¹²¹ Products are considered “in-commerce” when they are off-loaded at a location other than the official designated inspection establishment; these products are considered to be a Failure to Present and thus ineligible for FSIS inspection.¹²² When this occurs, the FSIS has several options for handling the issue.¹²³

The FDA has a process similar to the FSIS for determining the comparability and equivalence of foreign food-safety systems. The FSVP permits modified requirements for imports of certain food from foreign suppliers from countries with a food-safety system that has been officially recognized by the FDA as being comparable or equivalent to the U.S. food system.¹²⁴ Importers must document that their supplier is in a country with a comparable or equivalent food system, the food being imported is within the official recognition or equivalency determination, and the supplier is in good standing with the food-safety authority of its country.¹²⁵ A system is considered comparable when the FDA determines it provides a set of protections similar to those in the United States.¹²⁶ The FDA’s equivalence process determination uses an “in-depth scientific and regulatory analysis” and includes two main components: a technical evaluation of the foreign country’s food-safety control system and administrative procedures to finalize the determination when appropriate.¹²⁷

Unlike imports under the USDA, imports governed by the FDA are not required to come exclusively from comparable or equivalent countries.¹²⁸ Additionally, there is concern that “comparable” governments may not be inspecting suppliers’ facilities on a regular basis, and are therefore failing to meet the FDA standards for inspections of domestic facilities.¹²⁹ Under the

121. *Id.* at 4.

122. *Id.*

123. *Id.* (explaining that a Failure to Present (FTP) product in its original shipping container may be destroyed or returned to its country of origin; any FTP product removed from its original container will be the subject of regulatory control action to ensure appropriate disposition).

124. KEY REQUIREMENTS: FINAL RULE ON FSVP, *supra* note 58, at 4.

125. 21 C.F.R. § 1.513(b); U.S. FOOD & DRUG ADMIN., FOREIGN SUPPLIER VERIFICATION PROGRAMS FOR IMPORTERS OF FOOD FOR HUMANS AND ANIMALS: WHAT YOU NEED TO KNOW ABOUT THE FDA REGULATION: GUIDANCE FOR INDUSTRY SMALL ENTITY COMPLIANCE GUIDE 14 (2018), <https://www.fda.gov/media/110327/download>.

126. *See International Cooperation*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/InternationalInteragencyCoordination/InternationalCooperation/default.htm> [<https://wayback.archive-it.org/7993/20171101113401/>] (last updated Oct. 13, 2017).

127. *Id.*

128. *Id.*

129. *See* CONSUMER FED’N OF AM., Comment Letter on Docket Number FDA-2016-N-4662 (May 16, 2017), <https://consumerfed.org/wp-content/uploads/2017/05/5-16-17->

FSVP, importers are technically required to only import from approved foreign suppliers.¹³⁰ However, importers can temporarily import from unapproved suppliers if the products are subject to “adequate verification activities” before importation.¹³¹ This ambiguity in the law potentially provides importers with an opportunity to bypass one of the law’s main requirements.

At the port of entry, the FSIS has the authority to reinspect shipments using a variety of methods, including physical examination of the product for visible defects, inspection of the container’s condition, and collection of samples to analyze for pathogens and residue.¹³² If FSIS schedules a laboratory inspection of a product for specific adulterants, the shipment must be held pending acceptable results.¹³³ Any time a shipment fails reinspection, it is recorded in the Public Health Information System, which will thereafter automatically generate an intensified rate of reinspection; products that pass reinspection are permitted to enter U.S. commerce and are treated as domestic articles.¹³⁴ FSIS has several options regarding the products that are refused entry, including rectification, exportation, and disposal.¹³⁵

While the FSIS has the authority to conduct inspections of a product itself when it is presented for importation, FDA imports under the FSVP rule do not have that option. As previously mentioned, inspections under the FSVP consist solely of reviewing the importer’s documentation.¹³⁶ If an importer does not have the correct FSVP documentation at the time of importation, the import can be refused admission.¹³⁷ The rule requires importers to provide the name, email address, and unique facility identifier for each line entry of food

FDA-Systems-Recognition-Hearing_Comments.pdf. The Consumer Federation of America also recommended that the FDA “reserve recognition of ‘comparable or equivalent food safety systems’ to those instances where foreign governments satisfy a rigorous and open process that is responsive to public concerns.” *Id.*

130. See Nara, *supra* note 41 (explaining that the requirement is based on an “evaluation of the risk posed” by imported food and a supplier’s prior performance).

131. *Id.*

132. See FSIS GUIDANCE FOR IMPORTING MEAT, POULTRY, AND EGG PRODUCTS INTO THE UNITED STATES, DRAFT, *supra* note 109, at 11; see also FOOD SAFETY AND INSPECTION SERVICE, *supra* note 33, at 11 (stating that FSIS inspects three billion pounds of imported meat, poultry, and processed egg products annually).

133. See FSIS GUIDANCE FOR IMPORTING MEAT, POULTRY, AND EGG PRODUCTS INTO THE UNITED STATES, DRAFT, *supra* note 109, at 12.

134. *Id.*

135. *Id.* at 13 (suggesting that the FSIS can address these violating products by returning them to the originating country, imposing a timeline for importers to correct product misbranding, converting products into animal food with FDA approval, or simply incinerating the products).

136. See *What Do Importers Need to Know About FSVP*, *supra* note 96.

137. 21 C.F.R. § 1.514(a) (2012).

product being offered for importation.¹³⁸ However, unlike the product inspections carried out by the FSIS, the document inspections under the FSVP do nothing to truly verify the safety of the imported food.¹³⁹ While this sort of inspection may confirm compliance with the record-keeping requirements under FSVP, it seemingly fails to assess the true hazards of the products.¹⁴⁰

IV. RECOMMENDATIONS FOR STRENGTHENING FSVPs

Congress has notoriously underfunded the FDA for years,¹⁴¹ and President Trump's Executive Order on Reducing Regulation and Controlling Regulatory Costs¹⁴² could potentially inhibit the FDA's ability to regulate and safeguard America's food supply.¹⁴³ This is evidenced by the fact that the 2019 regulatory priorities for the Department of Health and Human Services, under which the FDA operates, focus almost solely on medical issues.¹⁴⁴ The FSVP rule is an attempt to ameliorate this problem by forcing importers to bear more responsibility for ensuring the safety of imported food products. The rule's purpose is to provide the FDA with new tools that prevent unsafe

138. See Nara, *supra* note 41.

139. See *What Do Importers Need to Know About FSVP*, *supra* note 96 (responding that, unlike traditional facility inspections, FSVP inspections are based solely on review of records rather than observations of food production).

140. See McAllister, *supra* note 100, at 43 (clarifying that even if an importer presents documentation showing his supplier meets governing standards, the FSVP's audit does nothing further to verify the information).

141. See Ron Nixon, *Funding Gap Hinders Law for Ensuring Food Safety*, N.Y. TIMES (Apr. 7, 2015), <https://www.nytimes.com/2015/04/08/us/food-safety-laws-funding-is-far-below-estimated-requirement.html>; *FDA Funding*, CONSUMER HEALTHCARE PRODS. ASS'N, <https://www.chpa.org/increasefdafunding.aspx> (last visited May 13, 2019) (stating that the FDA has jurisdiction over \$1 of every \$5 spent on food, drugs, and cosmetics in the United States).

142. Exec. Order No. 13,771, 82 Fed. Reg. 9339 (Jan. 30, 2017).

143. See *Deregulation and Food Safety Fact Sheet*, CONSUMER FED'N OF AM. (Sept. 29, 2017), https://consumerfed.org/in_the_media/deregulation-food-safety/ (stating that the "[r]egulations to prevent food safety threats cost less than reacting after people get sick"); see also *Introduction to the Fall 2018 Regulatory Plan*, U.S. OFF. OF INFO. & REG. AFF., <https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/201810/VPStatement.pdf> (last visited May 13, 2019) (noting that federal agencies collectively issued 176 deregulatory actions during the Trump Administration's first two years for a total regulatory cost reduction of \$33 billion).

144. The outline of priorities only addresses food-related issues by stating that the FDA will "[take] action to facilitate food innovations that can give consumers more choices and enable better nutrition." See *Statement of Regulatory Priorities for Fiscal Year 2019*, U.S. DEP'T OF HEALTH & HUMAN SERVS., https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/201810/Statement_0900.html (last visited May 13, 2019).

imported food products from harming consumers, while also holding importers accountable for the products they bring into the United States.¹⁴⁵ While this appears to be a partial privatization of a traditionally governmental function, it is possible that, if carried out correctly, it will enable efficiency and actually extend the reach of the government.¹⁴⁶

Because we are in a paradoxical era distinguished by diminishing governmental resources and increasing regulatory demands, the concept of partial privatization of governmental functions is justifiable.¹⁴⁷ Scholars of “private governance” have suggested that the “public/private hybrids are involved in three principal functions traditionally assigned to public agencies: the setting, implementation, and enforcement (including monitoring) of standards.”¹⁴⁸ While assigning additional responsibilities to private actors may be more cost-effective, there remains a major concern with accountability issues.¹⁴⁹ Privatizing roles traditionally ascribed to government agencies could potentially jeopardize public purposes by “pressing for market-style competition, by sidestepping norms that apply to public programs, and by eradicating the public identity of social efforts to meet human needs.”¹⁵⁰ For the public/private hybrid model to be successful in enhancing regulatory compliance, the government must be willing and able to create a regulatory structure for private actors to operate within that protects and promotes public goals.¹⁵¹

145. See *What Do Importers Need to Know About FSVP*, *supra* note 96.

146. See Lesley K. McAllister, *Regulation by Third-Party Verification*, 53 B.C. L. REV. 1, 4 (2012) (stating that partial privatization from third-party verification can potentially “jeopardize the fulfillment of public purposes,” or “enable innovation, efficiency, and quality in the provision of governmental services”). See generally Jody Freeman, *Extending Public Law Norms Through Privatization*, 116 HARV. L. REV. 1285 (2003) (imagining privatization as an avenue for increasing the government’s reach into new domains).

147. See McCallister, *supra* note 146, at 1–2 (stating that while regulatory failures often make headlines, they are most often explained by the fact that “regulatory agencies lack the capacity to adequately implement and enforce the law”).

148. Michael Vandenberg, *The Private Life of Public Law*, 105 COLUM. L. REV. 2029, 2038 (2005) (stating that private participation in setting standards includes negotiated rule-making and agency encouragement of private codes of conduct; private participation in implementation includes agency encouragement of voluntary self-regulation programs and site-specific agreements with private actors; and private participation in enforcement includes citizen suits and regulations requiring industries to self-monitor and report).

149. See *id.* at 2039.

150. Martha Minnow, *Public and Private Partnerships: Accounting for the New Religion*, 116 HARV. L. REV. 1229, 1230 (2003).

151. See McCallister, *supra* note 146, at 5 (suggesting that an oversight tool such as high accreditation standards is just one mechanism that can function within a new regulatory framework).

Although the FSVP rule is a good step in contributing to the safety of our imported food, there are several loopholes that could decrease its effectiveness. Generally, the FSVP provision allowing importers or their suppliers to create, implement, and maintain their own HACCP systems has the potential to adversely affect the safety of imported food.¹⁵² The primary concern of corporations is their profit margin—not public health.¹⁵³ The system provided for under the FSVP rule takes the power away from the FDA to truly determine the safety of imported food, essentially giving companies free rein to self-regulate. While information on the effectiveness of FSVPs and whether they have increased imported food safety is sparse, the frequency of foodborne illness outbreaks seems to indicate that the food industry is not yet able to self-regulate.¹⁵⁴ At the very least, the FDA should be involved in assisting companies develop their HACCP programs to ensure consistency among all importers and suppliers.¹⁵⁵

Further, allowing importers to use a third party to conduct their hazard analyses potentially poses a problem regarding reliability and consistency. The reliability of third-party auditor determinations depends largely upon the competence and independence of the third party.¹⁵⁶ Put simply, third-party programs may suffer from a lack of reliability, specifically when the third party is not impartial in its assessment.¹⁵⁷ Because the third party is compensated by the company they are assessing, the auditor may fall victim to conscious or unconscious biases.¹⁵⁸ Further, when discrepancies in safety ratings between a third party and a government agency like the FDA come to light, the competence of third-party systems comes into question.¹⁵⁹ In addition to these concerns, agencies using third-party assessors should be concerned with the consistency of determinations.¹⁶⁰

152. See Strom, *supra* note 104 (citing three circumstances where major food U.S. manufacturers, distributors, or both deliberately ignored proven food contamination issues and knowingly sold infected, or potentially infected, food products).

153. See *id.*

154. See Pape, *supra* note 86, at 447.

155. *Id.*

156. See McAllister, *supra* note 100, at 40 (stating that auditors must be competent in their ability to conduct an unbiased assessment, and programs should be designed to enhance consistency of third-party determinations and avoid problems that would undermine reliability).

157. *Id.* at 40–41 (providing the example of the Peanut Corporation of America, which had received a “superior rating” from the third-party auditors it used, but a later FDA investigation showed product samples had tested positive for Salmonella).

158. *Id.* at 42.

159. *Id.* at 41.

160. *Id.* at 43 (finding that if assessments by third parties are conducted in different ways, determinations may be less consistent than governmental determinations).

Because FSVPs essentially rely on the “honor system,” the FDA needs to have a strong system for either incentivizing companies to adhere to or deterring them from violating the requirements.¹⁶¹ The FDA must be able to motivate companies to comply with regulations that are not always in their financial interest. While the FSVP rule provides some options for addressing noncompliance,¹⁶² a glaring issue remains: the use of these tools in response to whether an importer has provided the proper paperwork, not whether the food is actually safe.

For years, the Environmental Protection Agency (EPA) has utilized incentive programs to address a wide range of environmental issues, such as air pollution and acid rain.¹⁶³ While traditional command-and-control policies are criticized for only inducing companies to meet the regulated standards, economic incentives are often praised for encouraging companies to innovate further and to the extent that renders them most profitable.¹⁶⁴ Although the issues the EPA deals with are different than those overseen by the FDA, the FDA could still explore implementing market-based policies to not only encourage compliance with the FSVP requirements, but also to incentivize importers to take further steps to guarantee the safety of imported food. These policies could work in tandem with the traditional regulatory approach already being utilized by the FDA to achieve a higher guarantee of food safety.¹⁶⁵

The FDA should also develop a stronger enforcement system that involves more oversight than simply reviewing paperwork. At a minimum, the FDA needs an improved method of inspection that allows FSVP inspectors to ensure the documents provided by importers and their suppliers are honest representations. Food companies have not always taken the necessary corrective actions to keep our food products safe, nor supplied honest information about their operations. Accordingly, the FDA needs a way to check the information provided. Because the FDA has neither the funding nor the

161. See Pape, *supra* note 86, at 438–39 (characterizing the HACCP system as an “honor system” where the onus is on facilities to ensure the safety of food products rather than government inspectors).

162. These examples include: refusing importations, 21 C.F.R. § 1.514 (2012); bringing civil or criminal actions in federal court, 21 U.S.C. § 333 (2012); and debarring individuals convicted of a felony related to importation of food, *id.* § 335a.

163. See *Economic Incentives*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/environmental-economics/economic-incentives> (last visited May 13, 2019) (stating that policymakers can utilize traditional regulatory approaches that set specific standards all parties must meet or implement economic incentives or market-based policies that provide continuous monetary and near-monetary inducements for private-sector actors to comply with).

164. *Id.*

165. *Id.* (asserting that a hybrid approach is appealing to policymakers because it combines the certainty associated with a regulatory standard with the flexibility of allowing companies to pursue the method that is most cost effective based on their unique organization).

manpower to have inspectors at every port, utilizing third-party certifiers could be a good alternative.¹⁶⁶

A third-party program could be helpful in overseeing compliance with the FSVP rule because it is large and international in scope, and incorporating private actors around the globe could be an effective way to achieve the regulatory goal.¹⁶⁷ However, since the FSVP rule deals directly with the issue of public health, problems may arise from the use of a third-party program as it could reduce an agency's control over regulatory implementation.¹⁶⁸ If the FDA chose to implement a third-party program to better enable its oversight of importer compliance with the FSVP requirements, it is imperative that the program be calibrated to the level of risk associated with noncompliance. In this case, the potential public harm resulting from noncompliance is high as it could result in unsafe food entering into the homes of American consumers.¹⁶⁹ Further, the information gathered through a third-party program must be accessible to the public in order to ensure accountability.¹⁷⁰ When a third party assumes the responsibility of conducting compliance assessments, the information from those assessments must be made available to the responsible regulatory agency and accessible to the public in order to ensure accountability.¹⁷¹ Ultimately, oversight by the FDA is essential to ensuring the success of a third-party program.¹⁷²

Because the FSVP rule has only recently gone into full effect, it is unclear how much the program will contribute to improving the safety of our imported food. However, it is clear that while the FSVP is good in theory, for

166. See McAllister, *supra* note 100, at 54 (maintaining that regulatory third-party programs pose risks in that if they are ill-conceived and poorly operated, the programs can lead to high costs for regulated entities and undermine the achievement of regulatory goals, but they also offer benefits by harnessing expertise within the private sector to extend the reach of the regulatory agency, increase compliance, and improve performance of regulated entities).

167. *Id.* at 58 (noting that agencies may have difficulty overseeing private actors in foreign countries).

168. *Id.* at 57–58 (stating that if noncompliance with a regulatory standard results in significant risks to health and it is vital that a certain regulatory outcome be avoided, the agency should retain full regulatory control).

169. *Id.* at 62–63 (asserting that if the risks associated with noncompliance are high, the program must be designed in a way that provides maximum degree of reliability in third-party determinations).

170. *Id.* at 66 (explaining that information from compliance assessments completed by regulatory agencies are accessible by the public).

171. *Id.* (stating the level of accountability for third-party programs should be the same as when regulatory agencies conduct assessments themselves).

172. See McAllister, *supra* note 100, at 68 (stating that the role of the regulatory agency changes from “guardian to guarding the guardians” and oversight is vital to ensuring the fulfillment of the regulatory purpose).

it to work effectively the FDA needs to strengthen its oversight and compliance enforcement abilities. Whether it is an incentive program, establishing a third-party program to oversee compliance, or having robust penalties for those importers and suppliers that fail to meet the requirements, there are several options available to the FDA.

CONCLUSION

As the United States has dramatically increased the portion of food imported from other countries, ensuring the safety of imported food is more important than ever. It is too early to tell whether the FSVP rule will be effective in increasing the safety of imported food, but the FDA is facing an uphill battle when it comes to truly verifying that importers and suppliers are adhering to the requirements. The partial privatization of ensuring safe food products make their way into the U.S. market could be an innovative and efficient choice; however, because importers are likely primarily concerned with making money, there are legitimate concerns as to whether they will take steps that actually promote food safety, or just meet the rule's minimum requirements in the most low-cost way. To truly hold importers accountable for the products they import, the FDA needs to develop stronger compliance and enforcement tools that make the FSVP effective. Otherwise, why have the regulation at all?