Florida Law Review

Volume 65 | Issue 4 Article 8

July 2013

Hunger, Food Prices, and the Food Safety Modernization Act: Balancing Physical Safety and Food Security

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NOTE

HUNGER, FOOD PRICES, AND THE FOOD SAFETY MODERNIZATION ACT: BALANCING PHYSICAL SAFETY AND FOOD SECURITY

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Abstract

The Food and Drug Administration (FDA) Food Safety Modernization Act (Modernization Act) was signed into law by President Barack Obama on January 4, 2011. The goal of the Act is to reform the United States' food safety regulations that attempt to safeguard the American public from foodborne illness. However, America is also in the middle of a hunger crisis—millions of Americans are unable to provide enough food for themselves and their families due to a lack of financial resources. The Modernization Act has the potential to increase the cost of food production and pass this cost along to the public through increased food prices, creating an even more serious hunger crisis. Some of these increases in cost of production may stem from new produce-harvesting and food-import regulations, among other sources. Additionally, the Modernization Act completely ignores several key areas of food safety, including the opportunity to work with other government agencies to control contamination that spreads from other industries, enhance natural protections from contaminants, and maintain appropriate nutritional quality of food. Finally, the FDA, by its own admission, lacks funding to adequately implement the rules it creates. Poor implementation of even a perfect plan could mean imposition of adverse effects—including increased food prices—on the American public.

This Note argues that, while ensuring the safety of the food supply is vital to the health of the American people, the Modernization Act's increased regulation has the potential to bring increased costs to the food industry, and that cost may not be worth the potentially small improvement in safety. It is understandable that food prices may have to increase to ensure a safer food supply, but the benefit gained by the American public in food safety must significantly outweigh the cost. Currently, it is not clear that will happen. As the rulemaking process progresses, to avoid detrimentally affecting the public and promoting further food insecurity, the FDA should conscientiously consider the effect that its rulemaking will have on the cost of food production.

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INTRODUCTION

"[F]amine is like a creeping monster" that is easily overlooked until it devours thousands of lives.[1] This is true of the recently publicized famine in Kenya and Ethiopia, and of suffering in places such as Sarajevo, Haiti, and Darfur.[2] But the "creeping monster" has been silently engulfing even prosperous nations. Hunger cost the United States, one of the world's wealthiest countries,[3] $167.5 billion in 2010.[4]

1. Moni Basu, *Horn of Africa Crisis Shocks Even Seasoned Aid Workers*, CNN (Aug. 12, 2011, 8:15 AM), http://www.cnn.com/2011/WORLD/africa/08/11/africa.famine/index.html?iref=allsearch.

2. *Id.*

3. *See* Nathaniel Cahners Hindman, *The 11 Wealthiest Countries in the World By Financial Assets*, HUFFINGTON POST (Sept. 15, 2010, 6:25 PM), http://www.huffingtonpost.com/2010/09/15/11-richest-countries_n_717558.html#s140020&title=1 _USA (listing the United States as the wealthiest country in the world, holding the largest share of global financial assets); Abby Rogers & Robert Johnson, *The 10 Richest Countries in the World*, BUS. INSIDER (Sept. 25, 2011, 5:30 AM), http://www.businessinsider.com/worlds-richest-countries-2011-9?op=1 (listing the United States as the sixth richest country, with a per capita GDP of $47,084).

4. Rudy Ruitenberg, *U.S. Cost of Hunger was $167.5 Billion in 2010, Researchers Say*, BLOOMBERG BUSINESSWEEK (Oct. 6, 2011), http://www.businessweek.com/news/2011-10-06/u-s-

However, hunger is not the only food-related problem in the United States. Another serious concern is food safety. In 2010, the United States experienced several significant food recalls, including more than a half-billion eggs in one crisis alone.[5] At the intersection of these concerns, hunger and safety, is the Food and Drug Administration (FDA) Food Safety Modernization Act (Modernization Act), passed by Congress on December 21, 2010.[6] The Act modifies existing food safety laws with the intention of overhauling the food safety system and holding food producers "responsible and accountable at each step [in the food-production process] for controlling hazards that can cause [foodborne] illness."[7] But increased regulation can also mean increased production cost, thereby raising the price of food in the midst of a national hunger crisis where millions of Americans are considered food-insecure.[8]

A brief overview highlights the importance of the hunger and safety concerns. During 2010, 48.8 million Americans were food-insecure,[9] meaning they were unable to obtain "consistent, dependable access to enough food for active, healthy living" and "at some time during the year, they had difficulty providing enough food for all members due to insufficient resources."[10] The number of food-insecure Americans rose significantly between 2007 and 2010, with the sharpest increases occurring in Florida and California.[11] Though the issue has been largely unseen, Americans are beginning to take notice.[12] Even Sesame Street has

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cost-of-hunger-was-167-5-billion-in-2010-researchers-say.html ("Hunger's cost to society includes lost productivity, poor education, additional healthcare costs and charity donations to keep families fed . . . .").

5. Other significant recalls included celery, black pepper, beef, cheese, lettuce, lunch meat, frozen vegetables, lobster, and raw milk cheese. Linda Doell, *Eggs, Beef and Produce: The Top 10 Food Recalls of 2010*, DAILYFINANCE (Dec. 13, 2010, 8:00 AM), http://www.daily finance.com/2010/12/13/eggs-beef-and-produce-the-top-10-food-recalls-of-2010/.

6. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2010); U.S. FOOD & DRUG ADMIN., FOOD SAFETY LEGISLATION KEY FACTS (July 12, 2011), http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM263777.pdf.

7. *Food Safety Modernization Act: Frequently Asked Questions*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm (last updated Feb. 4, 2013).

8. Ruitenberg, *supra* note 4.

9. *Id.*

10. Margaret Andrews, *More Americans Relied on Food Assistance During Recession*, AMBER WAVES, Dec. 2010, at 4, 4, *available at* http://webarchives.cdlib.org/sw1vh5dg3r/http://ers.usda.gov/AmberWaves/December10/PDF/AW_December10.pdf.

11. Kate Santich, *Florida's 'Hunger Bill' is Fastest-Growing in Nation*, ORLANDO SENTINEL (Oct. 5, 2011), http://www.orlandosentinel.com/health/os-true-cost-hunger-florida-20111005,0,6886009.story ("[T]he three year rise [in the hunger cost to the state] was steepest in Florida, where it increased nearly 62 percent to $11.7 billion . . . . That rise was substantially greater than the second-hardest-hit state, California, where the cost rose 43 percent.").

12. Several newspaper articles on America's food insecurity have recently been published. *See, e.g.*, Ruitenberg, *supra* note 4; Santich, *supra* note 11; Kate Santich, *Nearly a Third of Central Florida Children May Lack Adequate Nutrition*, ORLANDO SENTINEL (Aug. 30, 2011), http://www.o

addressed the problem with the introduction on October 9, 2011, of Muppet Lily, a character "whose family deals with food insecurity."[13]

The food safety statistics are just as chilling. The United States' Centers for Disease Control and Prevention (CDC) estimates that 48 million Americans (one out of every six) get sick, 128,000 are hospitalized, and 3,000 die annually as a result of foodborne illness.[14] Some argue that low-income populations may lack knowledge of proper food storage and handling methods, and are therefore at increased risk for foodborne disease.[15] While this correlation is speculative, at best,[16] it is important to note that regardless of the specific populations affected, the high CDC estimates indicate that foodborne illness is a significant public policy concern.

The passage of the Modernization Act[17] gives the FDA the authority to implement mandatory, "comprehensive, science-based preventive controls across the food supply," including mandatory standards for the production and harvesting of fruits and vegetables, recall capabilities, enhanced record-keeping and product tracing requirements, and augmented authority over the food import industry.[18] When the President signed the Modernization Act into law on January 4, 2011, the FDA began the long process of putting the legislation into effect.[19] Some provisions went into effect immediately and others will be developed and implemented over the coming years.[20]

This Note argues that, while ensuring the safety of the food supply is vital to the health of the American people, increased regulation has the potential to bring increased costs to the food industry, and that cost may

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rlandosentinel.com/health/os-hunger-child-orlando-20110830,0,2519164.story. On October 5, 2011, the Center for American Progress also published a comprehensive report on food insecurity in America. *See* DONALD S. SHEPARD, ELIZABETH SETREN, & DONNA COOPER, CENTER FOR AMERICAN PROGRESS, HUNGER IN AMERICA (2011).

13. Piya Sinha-Roy, *Hungry Muppet to Appear on "Sesame Street*," REUTERS (Oct. 4, 2011), http://www.reuters.com/article/2011/10/04/us-sesamestreet-idUSTRE7935LU20111004.

14. *CDC Estimates of Foodborne Illness in the United States: Findings*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_A_FINDINGS_updated4-13.pdf (last updated Feb. 2011).

15. FAMILY & CONSUMER SCIENCES, NUTRITIONAL STATUS OF LOW-INCOME FAMILIES 1 (2003), *available at* http://www.ces.ncsu.edu/depts/fcs/pdfs/nut.pdf.

16. *See* Valerie L. Darcey, GIS Mapping of Retail Food Access to Assess Risks of (Chronic and Acute) Illness in Populations of Different Socioeconomic Status 9-13 (May 2010) (unpublished M.S. thesis, Drexel University), http://idea.library.drexel.edu/bitstream/1860/3231/1/Darcey,%20Valerie%20L.pdf.

17. U.S. FOOD & DRUG ADMIN., *supra* note 6; *see* FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2010).

18. U.S. FOOD & DRUG ADMIN., BACKGROUND ON THE FDA FOOD SAFETY MODERNIZATION ACT, http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM263773.pdf (last updated July 12, 2011) [hereinafter U.S. FOOD & DRUG ADMIN., BACKGROUND].

19. *Id.*

20. *Id.*

not be worth the improvement in safety. For instance, regulation of harvesting may increase the overall cost of farming. This increase may be passed onto consumers in the form of higher prices. A continued rise in the price of food will only exacerbate the hunger problem. Therefore, food safety regulations imposed by the Modernization Act must be effective enough to justify the increased cost. Balance is necessary.

Part I explores food safety concerns and the history of food safety regulation in the United States. Part II explains the purpose of the Modernization Act and the principal provisions that may affect food prices. Finally, Part III weighs the benefits and the risks of several principal Modernization Act provisions that have the power to increase food-production costs, identifies several aspects of food safety that the Modernization Act neglects, and proposes a reasonable balance between food safety and food security.

I. FOOD SAFETY CONCERNS AND REGULATORY HISTORY

In his weekly address to the nation on March 14, 2009, President Barack Obama explained that the mission of the FDA, together with the United States Department of Agriculture (USDA), is "[to ensure] that the foods we eat, and the medicines we take, are safe and don't cause us harm."[21] He lauded the United States as "one of the safest places in the world to buy groceries at a supermarket."[22] Yet, he admitted that the food safety system currently in place still needs work.[23]

Each year, millions fall sick and thousands die as a result of foodborne illness in the United States.[24] The average number of outbreaks in the Unites States from contaminated food increased from approximately 100 per year in the 1990s to nearly 350 per year in recent years.[25] Recent outbreaks include E. coli in spinach and shredded lettuce in 2006 (from which 356 people became ill and at least three died),[26] Salmonella in tomatoes in 2006 (from which 183 people became ill),[27] Salmonella in jalapeños in 2008 (which caused 1,442 people to become sick, 286 hospitalizations, and possibly two deaths),[28] Salmonella-tainted peanut

21. Barack Obama, President of the United States, Weekly Address: Reversing a Troubling Trend in Food Safety 0:21–:29 (2009), *at* Cammie Croft, *Weekly Address: Reversing a Troubling Trend in Food Safety*, THE WHITE HOUSE (Mar. 14, 2009, 5:30 AM), http://www.whitehouse.gov/blog/2009/03/14/weekly-address-reversing-a-troubling-trend-food-safety.

22. *Id.* at 0:52–:58.

23. *Id.* at 1:13–2:35.

24. *CDC Estimates of Foodborne Illness in the United States: Findings*, *supra* note 14.

25. Charlotte Tucker, *New Law Will Empower FDA to Improve Safety of U.S. Food*, NATION'S HEALTH, Feb. 2011, at 1; Obama, *supra* note 21, at 1:40–:53.

26. *See* Caroline Smith DeWaal, *Food Safety and Security: What Tragedy Teaches Us About Our 100-Year-Old Food Laws*, 40 VAND. J. TRANSNAT'L L. 921, 928 (2007).

27. *Id.*

28. Elena Fagotto, *Governing a Global Food Supply: How the 2010 FDA Food Safety*

butter crackers in 2009 (from which 700 people became ill and nearly 12 died),[29] and contaminated eggs in 2010,[30] just to name a few.

President Obama acknowledged that the increase in outbreaks is due, at least in part, to antiquated food safety laws that have remained largely untouched since they were created in the early 1900s under the administration of President Theodore Roosevelt.[31] These food safety regulations were designed to be, and remain, reactive.[32] Instead of focusing proactively on preventative and risk-based measures, the regulations are based on inspections in response to occurrences of foodborne illness.[33]

After the terrorist attacks of September 11, 2001, Congress acknowledged the weaknesses in the food safety system and passed the Bioterrorism Act of 2002.[34] The Act's goal was to protect the nation's food from intentional contamination.[35] However, while beneficial in that respect, the new legislation has not "reduced the threat from *natural* contaminants in the food supply."[36]

Another reason for the increased number of outbreaks is that the governmental system of inspection and enforcement is fragmented.[37] Food safety authority is shared between the FDA, the USDA, and other federal, state, and local agencies.[38] This fragmentation makes oversight of the food safety system incredibly challenging—the departments struggle to communicate and cannot work together to resolve problems.[39] An example is the system of identification numbers assigned to firms that import food into the United States. Each firm is supposed to have a unique

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Modernization Act Promises to Strengthen Import Safety in the US, 3 ERASMUS L. REV. 257, 259 (2010).

29. Melody Finnemore, *Looking Out For The Little Guy*, OR. ST. B. BULL., Apr. 2011, at 19, 20.

30. Tucker, *supra* note 25.

31. Obama, *supra* note 21, at 1:54–2:02.

32. DeWaal, *supra* note 26, at 923 (citing Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, 770 (repealed 1938)) (explaining that the Pure Food and Drug Act, originally passed in 1906, granted the FDA the "authority to act only when foods were adulterated or misbranded"); Fagotto, *supra* note 28, at 262.

33. Fagotto, *supra* note 28, at 266.

34. DeWaal, *supra* note 26, at 923 (citing Bioterrorism Act of 2002, Pub. L. No. 107-188, 116 Stat. 594).

35. *Id.* at 924.

36. *Id.* at 923–24 (emphasis added).

37. Fagotto, *supra* note 28, at 261; Obama, *supra* note 21, at 2:02–:13.

38. Fagotto, *supra* note 28, at 261 ("At the federal level alone, [fifteen] agencies administer some [thirty] laws related to food safety."). For example, the FDA oversees most foods, except certain categories of meat, processed eggs, and poultry, which are overseen by the USDA. *Id.* Additionally, the CDC oversees the prevention of foodborne illness, the Environmental Protection Agency regulates pesticide use, the Federal Trade Commission supervises food advertising, the Department of Commerce's National Marine Fisheries Service oversees the seafood industry, and the Department of Homeland Security guards overall food security. *Id.*

39. Fagotto, *supra* note 28, at 261; Obama, *supra* note 21, 2:02–:13.

identification number, but a recent report found that, as a result of the FDA and Customs and Border Protection failing to collaborate, each firm has, on average, three identifiers, with one firm having as many as seventy-five.[40] This confusion makes it easier for importers to evade the FDA's control and to circumvent food safety regulations.[41]

Finally, the FDA is underfunded and understaffed.[42] Of the nearly 150,000 food processing plants and warehouses in the United States, the FDA is able to inspect only about 7,000 annually.[43] Foods regulated by the FDA (such as produce, eggs, dairy, and baked and processed goods) are linked to two-thirds of foodborne illness outbreaks,[44] yet the FDA receives just over one-third of the federal food safety budget.[45] Instead, the USDA receives most of the federal food safety funding, which it uses for the Food Safety and Inspection Service (FSIS).[46]

In short, the current food regulatory system, though applauded as one of the safest in the world, has deficiencies in resources, organization, and communication, which allow a large number of illnesses and deaths to occur annually due to pathogen contamination of the food supply. President Obama recognized these deficiencies and created a working group to recommend improvements to the outdated food safety legislation.[47] In 2009, two bills were introduced, one in the House of Representatives and one in the Senate, to reform the FDA and to give it more control over the food regulatory system.[48] In 2010, these two bills

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40. Fagotto, *supra* note 28, at 261 (citing U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-873, FOOD SAFETY: AGENCIES NEED TO ADDRESS GAPS IN ENFORCEMENT AND COLLABORATION TO ENHANCE SAFETY OF IMPORTED FOOD 21 (2009)).

41. Fagotto, *supra* note 28, at 261–62 (citing U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-873, FOOD SAFETY: AGENCIES NEED TO ADDRESS GAPS IN ENFORCEMENT AND COLLABORATION TO ENHANCE SAFETY OF IMPORTED FOOD 21 (2009) & INTERAGENCY WORKING GROUP ON IMPORT SAFETY, PROTECTING AMERICAN CONSUMERS EVERY STEP OF THE WAY: A STRATEGIC FRAMEWORK FOR CONTINUAL IMPROVEMENTS IN IMPORT SAFETY (Sept. 10, 2007)).

42. Obama, *supra* note 21, at 2:13–:20.

43. *Id.* at 2:13–:27. These numbers are shocking, but another government source indicates the number of inspections to be higher. Either way, the number of inspections is still a small fraction of the total number of food-production plants in the industry. RENÉE JOHNSON, CONG. RESEARCH SERV., THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER 3 (RS 22600, 2011) [hereinafter JOHNSON, FOOD SAFETY SYSTEM] (reporting a decline in domestic inspections "from about 17,000 in 2004 (29% of the total) to about 15,000 in 2008 (22%). During the five-year period examined by the OIG, 56% of food facilities were not inspected at all.")

44. CAROLINE SMITH DEWAAL, XUMAN AMANDA TIAN, & FARIDA BHUIYA, CTR. FOR SCI. IN THE PUB. INTEREST, OUTBREAK ALERT! 2008: CLOSING THE GAPS IN OUR FEDERAL FOOD-SAFETY NET 2 (2008).

45. *Id.*; JOHNSON, FOOD SAFETY SYSTEM, *supra* note 43, at 1.

46. JOHNSON, FOOD SAFETY SYSTEM, *supra* note 43, at 1 (explaining that the budget for the FSIS for fiscal year 2010 was "approximately 60% of the two agencies' combined food safety budget," while the "FDA had the other approximately 40%")

47. Obama, *supra* note 21, at 3:55–4:26.

48. Fagotto, *supra* note 28, at 263. In the House, The Food Safety Enhancement Act of 2009

converged and created the Modernization Act.[49]

II. OVERVIEW: FOOD SAFETY MODERNIZATION ACT

The Federal Food, Drug, and Cosmetic Act is the chief law authorizing FDA actions.[50] The Modernization Act, signed into law in January 2011,[51] overhauls the Food, Drug, and Cosmetic Act by expanding the FDA's authority.[52] The focus of the Modernization Act is to utilize a risk-based approach that "shift[s] food safety regulation to prevention, rather than control or investigation after a problem is found."[53] As it implements the Modernization Act, the FDA must create fifty new rules as well as a series of guidance documents,[54] which will be aimed at educating food processors about the government's safety expectations.[55] These safety expectations concentrate on "four [interrelated] areas: prevention, inspections compliance and response, enhanced partnerships, and import safety."[56]

The FDA identifies prevention of contamination and foodborne illness as the cornerstone of the Modernization Act.[57] A beginning step in the prevention process is the requirement for hazard analysis.[58] This analysis calls for each facility to "evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility."[59] Hazards to be

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(H.R. 2749) was approved in July of 2009; the Senate version, the FDA Food Safety Modernization Act (S. 510), was approved in December 2009. *Id.*

49. *Id.*; *see* FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2010).

50. RENÉE JOHNSON, CONG. RESEARCH SERV., THE FDA FOOD SAFETY MODERNIZATION ACT (P.L. 111-353) 3 (R 40443, 2011) [hereinafter JOHNSON, MODERNIZATION ACT]; *see* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

51. JOHNSON, MODERNIZATION ACT, *supra* note 50, at 7; U.S. FOOD & DRUG ADMIN., BACKGROUND, *supra* note 18.

52. JOHNSON, MODERNIZATION ACT, *supra* note 50, at 7.

53. *FDA Food Safety Modernization Act of 2010: Likely Impact on the Produce Industry*, UNITED FRESH PRODUCE ASSOCIATION 1 (Jan. 2011), http://www.unitedfresh.org/assets/food_safety/FDA_Food_Safety_Modernization_Act_White_Paper_January_2011.pdf; *accord* U.S. FOOD & DRUG ADMIN., BACKGROUND, *supra* note 18.

54. U.S. FOOD & DRUG ADMIN., PUBLIC MEETING ON THE FOOD SAFETY MODERNIZATION ACT: FOCUS ON PREVENTIVE CONTROLS FOR FACILITIES 27 (2011), *available at* http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM253612.pdf [hereinafter U.S. FOOD & DRUG ADMIN., PUBLIC MEETING].

55. *Id.* at 40.

56. *Id.* at 17; *see also* JOHNSON, MODERNIZATION ACT, *supra* note 50, at 7–8; U.S. FOOD & DRUG ADMIN., BACKGROUND, *supra* note 18. Some sources break down inspections compliance and response into two separate areas, thus bringing the total number of areas on which safety expectations concentrate to five. *See* JOHNSON, MODERNIZATION ACT, *supra* note 50, at 7–8; U.S. FOOD & DRUG ADMIN., BACKGROUND, *supra* note 18.

57. U.S. FOOD & DRUG ADMIN., PUBLIC MEETING, *supra* note 54, at 18.

58. *Id.* at 34; FDA Food Safety Modernization Act, Pub. L. No. 111-353, § 103, 124 Stat. 3885, 3889–99 (2011).

59. § 103(a), 124 Stat. at 3889.

evaluated are those that are "known or reasonably foreseeable,"[60] including hazards that occur naturally, or are intentionally or unintentionally introduced.[61] The facility is then supposed to put the analysis in writing for the benefit of both the facility and the regulator.[62]

Once the hazards are identified, the facility must then develop preventive controls, or mitigation strategies, to minimize the occurrence of the hazards.[63] To ensure they will be sufficient to minimize the identified risks, the preventive controls should be validated as scientifically sound[64] and should be continually monitored. Procedures for corrective action should be instituted to ensure that the facility takes appropriate action when a preventive control fails.[65] Such action should include inspection of food to ensure safety, prevention of affected food from entering the market, and action to ensure there will not be a recurrence of the problem.[66] The facility must also maintain records of the overall hazard analysis and preventative control process for at least two years.[67] To assist the food safety industry in minimizing risk, the FDA is required to "review and evaluate [every two years] relevant health data and other relevant information . . . to determine the most significant foodborne contaminants."[68] As a result of this review, the FDA should publish, "when appropriate to reduce the risk of serious illness or death to humans or animals[,] . . . contaminant-specific and science-based guidance documents."[69]

Another key prevention specification set forth in the Modernization Act is the provision for "minimum standards for the safe production and harvesting of . . . fruits and vegetables."[70] These standards are supposed to be science-based and should not "conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990."[71] The Food, Drug, and Cosmetic

60. § 103(b), 124 Stat. at 3890.

61. *Id.*

62. *Id.*; U.S. FOOD & DRUG ADMIN., PUBLIC MEETING, *supra* note 54, at 34.

63. § 103(c), 124 Stat. at 3890; U.S. FOOD & DRUG ADMIN., PUBLIC MEETING, *supra* note 54, at 34.

64. U.S. FOOD & DRUG ADMIN., PUBLIC MEETING, *supra* note 54, at 35.

65. § 103(d), (e), 124 Stat. at 3890; U.S. FOOD & DRUG ADMIN., PUBLIC MEETING, *supra* note 54, at 34–35.

66. § 103(e), 124 Stat. at 3890.

67. § 103(g), 124 Stat. at 3891.

68. § 104(a), 124 Stat. at 3899. The FDA should consider "toxicological and epidemiological studies and analyses, current Good Manufacturing Practices . . . relating to food, and relevant recommendations of relevant advisory committees, including the Food Advisory Committee." *Id.*

69. § 104(b), 124 Stat. at 3899. These guidance documents should specify, when appropriate, whether the guidance applies to food for human or animal consumption, and should apply to individual products or classes of products rather than specific facilities. *Id.*

70. § 105, 124 Stat. at 3899–900.

71. *Id.* at 3900. The science-based minimum standards should "[relate] to soil amendments,

Act previously relied on voluntary adoption of good agricultural practices to reduce food safety hazards in farming operations before harvest.[72] The new produce safety standards, in contrast, will be compulsory regulations enforceable by "audit-based verification systems or other inspection methods."[73]

After prevention, inspections compliance and response is the next step. "Prior to [the Modernization Act], [the Food, Drug, and Cosmetic Act] authorized but did not require [the] FDA to inspect food facilities."[74] Under the Modernization Act, however, the FDA is required to inspect food facilities and to target types of food facilities based on risk, allocating resources accordingly to higher risk facilities.[75] A given facility's level of risk should be determined through an evaluation based on known risks, compliance history, strength of the facility's hazard analysis and preventive control plan, and any other relevant factors.[76] Domestic high-risk facilities must be inspected at least once in the five years following enactment of the Modernization Act and must be inspected at least once every three years after that.[77] Domestic facilities not deemed high risk must be inspected at least once within seven years of the Modernization Act's enactment and at least once every five years thereafter.[78] Foreign facilities are not inspected based on risk; instead, the FDA must inspect 600 facilities in the year following enactment of the Modernization Act, then double that number for each of the five subsequent years.[79]

Regarding response to an incident when unsafe food does inevitably make its way into the marketplace,[80] the Modernization Act gives the FDA the authority, for the first time ever, to issue mandatory recalls.[81] These mandatory recalls should be issued only when a voluntary option to cease distribution and recall the product are refused and "there is a reasonable probability that an article of food . . . is adulterated . . . or misbranded . . . and the use of or exposure to such article will cause serious

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hygiene, packaging, temperature controls, animals in the growing area, and water . . . consider hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced . . . [and] take into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies." *Id.*

72. JOHNSON, MODERNIZATION ACT, *supra* note 50, at 14.

73. *Id.* at 14–15.

74. *Id.* at 16.

75. § 201, 124 Stat. at 3923; JOHNSON, MODERNIZATION ACT, *supra* note 50, at 18.

76. § 201, 124 Stat. at 3923; JOHNSON, MODERNIZATION ACT, *supra* note 50, at 18.

77. § 201, 124 Stat. at 3924; JOHNSON, MODERNIZATION ACT, *supra* note 50, at 18.

78. § 201, 124 Stat. at 3924; JOHNSON, MODERNIZATION ACT, *supra* note 50, at 18.

79. § 201, 124 Stat. at 3924; JOHNSON, MODERNIZATION ACT, *supra* note 50, at 18.

80. U.S. FOOD & DRUG ADMIN., PUBLIC MEETING, *supra* note 54, at 9.

81. § 206, 124 Stat. at 3939–44; JOHNSON, MODERNIZATION ACT, *supra* note 50, at 20–21; U.S. FOOD & DRUG ADMIN., PUBLIC MEETING, *supra* note 54, at 22.

adverse health consequences or death to humans or animals . . . ."[82] Along with recall authority, the Modernization Act expands the FDA's response authority by enhancing the record-keeping requirements related to tracking high-risk foods.[83]

A final key category of Modernization Act provisions to enhance food safety deals with food importation. Food imports account for approximately 15% of the food supply in the United States, with approximately 60% of fresh fruits and vegetables and 80% of seafood coming from international sources.[84] This result is due in part to consumers' demand for a broad array of food products year round.[85] The global nature of the food supply poses unique challenges to food safety, because "[f]ood imports may originate from countries that have inadequate food controls and spread threats rapidly across borders."[86]

The Modernization Act addresses the import concerns in several ways. First, the Act requires importers "to verify that their foreign suppliers have adequate preventive controls in place to ensure the food they produce is safe."[87] The Food, Drug, and Cosmetic Act did not previously authorize or require this kind of verification.[88] Following the verification requirement, each importer must "be able to assure that each of its foreign suppliers produces the imported food employing processes and procedures, 'including reasonably appropriate risk-based preventive controls,' that are documented in a written plan and [are] equivalent in preventing adulteration and reducing hazards to requirements of other relevant provisions of [the Food, Drug, and Cosmetic Act]."[89]

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82. § 206, 124 Stat. at 3940; JOHNSON, MODERNIZATION ACT, *supra* note 50, at 21; *accord* U.S. FOOD & DRUG ADMIN., PUBLIC MEETING, *supra* note 54, at 23 (explaining that the mandatory recall authority will be used "judiciously" and "only if voluntary recall is not effective."). Along with authority to invoke a mandatory recall, the Modernization Act also "provides for the assessment of civil penalties as well as criminal penalties for failure to comply with or follow a recall order." JOHNSON, MODERNIZATION ACT, *supra* note 50, at 21.

83. § 204, 124 Stat. at 3930–37; JOHNSON, MODERNIZATION ACT, *supra* note 50, at 21–22. The Modernization Act directs the FDA to "establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated . . . or misbranded . . . ." § 204, 124 Stat. at 3930. Based on such pilot programs, the FDA must establish a product tracing system to effectively and quickly trace contaminated food in the United States. § 204, 124 Stat. at 3930–31.

84. U.S. FOOD & DRUG ADMIN., *supra* note 6.

85. JOHNSON, MODERNIZATION ACT, *supra* note 50, at 26; Fagotto, *supra* note 28, at 258.

86. Fagotto, *supra* note 28, at 258. The threats have the potential to be entirely new threats to the United States' food market, or they may be old threats eliminated in the United States but reintroduced as a result of less effective controls in the originating country. *Id.* at 259.

87. U.S. FOOD & DRUG ADMIN., BACKGROUND, *supra* note 18; *accord* § 301, 124 Stat. at 3953–55.

88. JOHNSON, MODERNIZATION ACT, *supra* note 50, at 26.

89. JOHNSON, MODERNIZATION ACT, *supra* note 50, at 27 (quoting FDA Food Safety

The Modernization Act also provides for a certification program for imported foods.[90] Under this provision, the FDA "may require, as a condition of granting admission to an article of food imported or offered for import into the United States, that [an accredited certifying entity] provide a certification . . . that the article of food complies with applicable requirements of [the Modernization Act]."[91] Certification may be required of imported foods based on multiple factors, including "known safety risks associated with the food . . . [or] with the country, territory, or region of origin of the food," or a finding by the FDA that the country of origin has inadequate food safety systems in place and a certification would assist the FDA in determining whether to allow admission into the United States.[92] Any food that requires certification but does not have it will be refused admission at the United States border.[93]

To ease entry into the United States, the Modernization Act requires the FDA to establish a voluntary qualified-importer program that allows for "expedited review and entry of foods from participating importers."[94] This program is available to those importers who agree to higher safety standards in return for the expedited review.[95]

Overall, the Modernization Act provides the authority to create, and often requires, numerous new food safety regulations in the key areas of prevention, inspections compliance and response, and food importation. An important theme running through the implementation of these areas is enhanced agency partnerships. While the FDA takes a primary role in implementing the Modernization Act, "there are other agencies and departments within the federal government that have significant work to do."[96] The Modernization Act specifically mandates that the FDA build or enhance existing partnerships between other areas of federal and state governments.[97] The partnership requirement recognizes that "all food safety agencies need to work together in an integrated way to achieve our

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Modernization Act, Pub. L. No. 111-353, § 301, 124 Stat. 3885, 3953 (2010)).

90. § 303, 124 Stat. at 3956–57; JOHNSON, MODERNIZATION ACT, *supra* note 50, at 26; U.S. FOOD & DRUG ADMIN., BACKGROUND, *supra* note 18.

91. § 303(b), 124 Stat. at 3956.

92. *Id.*

93. § 303(a), 124 Stat. at 3956.

94. U.S. FOOD & DRUG ADMIN., BACKGROUND, *supra* note 18; *accord* § 302, 124 Stat. at 3955–56; JOHNSON, MODERNIZATION ACT, *supra* note 50, at 27.

95. JOHNSON, MODERNIZATION ACT, *supra* note 50, at 27. The Modernization Act lists a set of factors to be used in evaluating the voluntary qualified-importer program applications for admission. § 302, 124 Stat. at 3955.

96. U.S. FOOD & DRUG ADMIN., PUBLIC MEETING, *supra* note 54, at 45.

97. U.S. FOOD & DRUG ADMIN., BACKGROUND, *supra* note 18. Other agencies that already have specified roles are the CDC, United States Department of Agriculture, Department of Homeland Security, Environmental Protection Agency, and United States Department of Health and Human Services. U.S. FOOD & DRUG ADMIN., PUBLIC MEETING, *supra* note 54, at 45.

public health goals"[98] since the food industry is not regulated by a single agency, but is instead fragmented across numerous agencies, both federal and state.[99] This means that the FDA can and should "leverage and enhance the food safety and defense capacities of [s]tate and local agencies," as well as develop a plan to expand similar capacities of foreign governments.[100] The FDA is also authorized to work with state and other local agencies to complete the required number of inspections under the Modernization Act.[101] The goal for enhancing partnerships, then, is to "build[] a formal system of collaboration with other government agencies, both domestic and foreign" to strengthen the food safety system in the United States.[102]

III. BALANCING FOOD SAFETY & AFFORDABLE FOOD PRICES

A. *Increased Regulation Leads to Higher Food Prices*

Food safety is certainly an important public policy and public health concern: the CDC estimates that, each year, 48 million Americans get sick, and about 3,000 die, from foodborne pathogens.[103] "Government intervention to provide food safety is [also] justified by the fact that markets alone do not provide optimal protection against food-borne illnesses . . . ."[104] Markets do not suffice because consumers cannot usually discern at the time of purchase whether foods are perfectly safe and because consumers cannot easily distinguish, after suffering a foodborne illness, which particular food caused the illness.[105]

Additionally, even if consumers choose to sue, they face tough obstacles concerning proof. "To meet his or her burden of proof in a food poisoning case, the plaintiff must prove that the deleterious condition existed in the product when it was purchased."[106] Moreover, "[t]he plaintiff must further prove the existence of a causal relationship between the

98. U.S. FOOD & DRUG ADMIN., BACKGROUND, *supra* note 18.

99. *See supra* note 38 and accompanying text.

100. U.S. FOOD & DRUG ADMIN., BACKGROUND, *supra* note 18. One required component of building relationships with foreign countries is to educate those countries and their food producers about the United States' food safety regulations. *Id.*

101. *Id.*

102. *Id.*

103. *CDC Estimates of Foodborne Illness in the United States: Findings*, *supra* note 14.

104. Fagotto, *supra* note 28, at 264.

105. *Id.*

106. Crosby v. Wal-mart Stores, Inc., 10-1015 (La. App. 5 Cir. 6/14/11); 67 So. 3d 695, 697 (citing Landreneau v. Copeland's Cheesecake Bistro, L.L.C., 08-647 (La. App. 5 Cir. 1/13/09); 7 So. 3d 703); *see also* Crowell v. First Nat'l Stores, Inc., 173 N.E.2d 609, 610 (Mass. 1961) (holding that the plaintiff had to prove that allegedly unwholesome frankfurters were unwholesome at the time of purchase and not at the time of consumption); Hebert v. Loveless, 474 S.W.2d 732, 737, 739 (Tex. Civ. App. 1971) (holding that plaintiffs had to prove that the food, beverage, or ice served to them was unwholesome at the time of service).

illness or injury and the consumption of the food."[107] The plaintiff must show that the food's defective condition more likely than not caused the plaintiff's illness.[108] This is challenging since, again, consumers have a difficult time discerning which food or foods made them sick.[109] Proving causation will likely require experts, who may testify to things as varied as how the food was handled, how toxins may be formed in certain foods, or the results of medical and scientific tests.[110] Finally, given the common occurrence of food poisoning, as well as the length and cost of court proceedings, consumers may choose not to pursue expensive litigation to recover the costs associated with their foodborne illness.[111] When it comes to food safety, the food market is stacked against consumers—which is why government safety measures are needed.

However, the price of food still follows conventional market reasoning. When production costs rise, so must prices. The rising price of food has only exacerbated the hunger problem in recent years. The price of food in the world market reached an all-time high in February 2011, causing consumers to suffer, especially those with the lowest incomes, who spend half or more of their earnings on food.[112] Rising food costs can be attributed to many things, including increased demand, diversion of crops to biofuel production, increased speculation, poor harvests due to severe weather,[113] and the changing price of oil,[114] just to name a few. An important factor in setting the price of food is the cost of production, including energy, seed, and fertilizer prices.[115] The cost of implementing food safety measures also falls under this "cost of production" heading.

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107. *Crosby*, 67 So. 3d at 697.

108. *Id.*

109. Fagotto, *supra* note 28, at 264.

110. See, e.g., the proffered testimony of an expert physician and expert on food safety, and the counterarguments made by the opposing party in *San Francisco v. Wendy's International, Inc.*, 656 S.E. 2d 485, 496–501 (W. Va. 2007).

111. Fagotto, *supra* note 28, at 264.

112. Christopher B. Barrett & Marc F. Bellemare, *Why Food Price Volatility Doesn't Matter: Policymakers Should Focus on Bringing Down Costs*, FOREIGN AFFAIRS (July 12, 2011), http://www.foreignaffairs.com/articles/67981/christopher-b-barrett-and-marc-f-bellemare/why-food-price-volatility-doesnt-matter; *FAO Food Price Index*, FOOD & AGRIC. ORG. OF THE UNITED NATIONS (July 3, 2013), http://www.fao.org/worldfoodsituation/wfs-home/foodpricesindex/en/ (noting the price peak in February 2011).

113. Barrett & Bellemare, *supra* note 112.

114. Michael T. Klare, *The Oil-Food Price Shock*, NATION, March 28, 2011, at 6, 8, *available at* http://www.thenation.com/article/159165/oil-food-price-shock (explaining that oil is a necessity for farmers to complete the most essential of their tasks, including fueling farm machinery and vehicles, transporting crops to market, and forming the chemical precursor for pesticides and fertilizers).

115. *Crop-Production Costs Will Jump Dramatically in 2009, Study Predicts*, SCIENCE DAILY, July 25, 2008, http://www.sciencedaily.com/releases/2008/07/080723134449.htm

1. Mandatory Produce Safety Regulations Increase Production Costs

The Modernization Act increases costs on farmers and other food producers in several ways. The main "provision that could have the most direct effect on on-farm activity is the establishment of new standards for produce safety."[116] The FDA's current guidance for fresh fruits and vegetables "address[es] common areas of concern in the growing, harvesting, sorting, packing, and distribution of fresh produce."[117] The current guidance, among many other things, explains the quality of water to be used in a variety of situations, prescribes microbial testing of water, describes how to control the potential microbial hazards associated with manure and municipal biosolids through active and passive treatments to reduce pathogens, provides guidelines for worker health and hygiene, prescribes appropriate location and management of sanitary facilities, and explains considerations to be taken into account by packing facilities and during produce transportation.[118] But currently, this guidance is *voluntary*—a sort of "best practices" advice—to assist farmers in maintaining the safe production of food by reducing the number and kind of pathogens that could come in contact with produce and cause foodborne illness in consumers.[119] The FDA's position has been that specific food safety guidelines for each crop and industry are impracticable. The guidance documents themselves explain that due to the "diversity of agricultural practices and commodities, practices recommended to minimize microbial contamination will be most effective when adapted to specific operations."[120] The guidance also expressly acknowledges that "[t]he scientific basis for reducing or eliminating pathogens in an agricultural setting is evolving and not yet complete."[121] The suggestions are just examples of practices that will help reduce microbial

116. RENÉE JOHNSON, CONG. RESEARCH SERV., FOOD SAFETY ON THE FARM 10 (RL 34612, 2011) [hereinafter JOHNSON, FOOD SAFETY ON THE FARM].

117. *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, U.S. FOOD & DRUG ADMIN. (Oct. 26, 1998), http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm [hereinafter *Guidance: Fruits & Vegetables*].

118. *Id.*; *see also Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Draft Guidance*, U.S. FOOD & DRUG ADMIN. (July 2009), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm174200.htm; *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes; Draft Guidance*, U.S. FOOD & DRUG ADMIN. (July 2009), http//www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm173902.htm; *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons; Draft Guidance,* U.S. FOOD & DRUG ADMIN. (July 2009), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm174171.htm.

119. *Guidance: Fruits & Vegetables*, *supra* note 117.

120. *Id.*

121. *Id.*

contamination and may not apply to all produce types.[122]

Section 105 of the Modernization Act authorizes the FDA to create *mandatory* produce safety regulations.[123] While these "science-based minimum standards"[124] may improve overall food safety, this could mean that what was once voluntary, and adapted as needed to benefit specific farming operations, could become mandatory and inflexible. That will necessarily increase costs as farms are forced to institute new operations and procedures, buy new equipment, or hire new or different workers to perform the newly required tasks. Farms may even lose profit if the new regulations decrease efficiency or productivity. This leads to the question of whether, given the incredible variety of agricultural commodities and practices already acknowledged by the FDA, mandatory guidelines are even practical.[125]

2. Mandatory Recalls Based on Insufficient Proof Damage Food Industries

Another Modernization Act provision with the potential to increase production costs for food producers is § 206, which gives the FDA brand-new authority to issue mandatory recalls when unsafe food is found in the marketplace.[126] The mandatory recall authority goes hand-in-hand with another provision, § 102(b), which authorizes the FDA to suspend the registration of a food facility "[i]f the Secretary determines that food manufactured, processed, packed, received, or held by [the] facility registered under this section has a reasonable probability of causing serious adverse health consequences or death to humans or animals."[127] These powers became effective when the Modernization Act was signed into law on January 4, 2011.[128]

The new produce safety standards, once issued, will assist farmers in keeping tainted food from entering the marketplace; the power to suspend a facility's food facility registration will assist in closing dangerous facilities when problems are found, hopefully before serious health issues arise; and the mandatory recall authority assists the government and the consuming public in removing tainted food from the marketplace in the event of an outbreak. Together, these standards and authorities stand to be a powerful force in the food safety scheme. So far, the FDA has only suspended one

122. *Id.*

123. FDA Food Safety Modernization Act, Pub. L. No. 111-353, § 105, 124 Stat. 3885, 3899–900 (2010).

124. *Id.*

125. *See supra* note 120 and accompanying text.

126. § 206, 124 Stat. at 3939–44; JOHNSON, MODERNIZATION ACT, *supra* note 50, at 20–21; U.S. FOOD & DRUG ADMIN., PUBLIC MEETING, *supra* note 54, at 22.

127. § 102(b), 124 Stat. at 3887.

128. *Food Safety Modernization Act: Frequently Asked Questions*, *supra* note 7.

food facility registration, that of Sunland, Inc., which produces nut seeds and spreads.[129] Suspension of Sunland's facility registration, predicated on an outbreak of Salmonella linked to Sunland products and Sunland's history of food safety violations, means Sunland "is prohibited from introducing food into interstate or intrastate commerce."[130] While this is the only instance in which the FDA has used its suspension authority so far, and it appears that the FDA used its suspension authority only after a thorough investigation, the FDA's track record with recalls in general is less comforting.

Prior to the passage of the Modernization Act, the FDA requested voluntary recalls, and food companies could decide whether to issue them.[131] Under the Modernization Act, the FDA has "the authority to recall a product if there is a reasonable probability that it is adulterated or misbranded and is capable of causing a serious adverse health consequence."[132] Under the process set forth by the Modernization Act, the FDA must "first give a responsible party the opportunity to cease distribution and conduct a voluntary recall of an article of food. If the responsible party refuses to or does not [perform the recall] within the time and manner prescribed by [the] FDA, [the] FDA may proceed under the mandatory recall authority . . . ."[133] Failure to comply could also result in civil penalties.[134]

This certainly sounds beneficial. Fast and efficient removal of tainted items logically appears to be an important step in keeping the public safe from discovered contaminants, and allowing the government to force recalls when responsible parties are delaying their responses could save lives. However, the mandatory recall authority does elicit some concern. While the FDA explains that such authority will be used very rarely and that alleged responsible parties will be given an informal hearing before a mandatory recall is implemented,[135] it is noteworthy that recalls impose significant costs on the food industry.[136] While these costs seem warranted

129. *Cf. FDA Investigation Summary: Multistate Outbreak of Salmonella Bredeny Infections Linked to Peanut Butter Made by Sunland Inc.*, U.S. FOOD & DRUG ADMIN. (Feb. 5, 2013), http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm320413.htm.

130. *Id.*

131. *See* DeWaal, *supra* note 26, at 934.

132. *Food Safety Frequently Asked Questions*, NAT'L SUSTAINABLE AGRIC. COAL. 5 (June 13, 2011), http://sustainableagriculture.net/wp-content/uploads/2011/06/NSAC-Food-Safety-FAQ-June-2011.pdf.

133. *Food Safety Modernization Act: Frequently Asked Questions*, *supra* note 7.

134. *Food Safety Frequently Asked Questions*, *supra* note 132, at 5.

135. *Food Safety Modernization Act: Frequently Asked Questions*, *supra* note 7.

136. *See* Shannon Dininny, *Food-Borne Illnesses Cost U.S. $152 Billion Annually: Study*, HUFFINGTON POST (Mar. 3, 2010, 8:05 AM), http://www.huffingtonpost.com/2010/03/05/food-borne-illnesses-cost_n_487710.html; Gale Prince, *The Economic Impact of Recalls*, SAGE FOOD SAFETY CONSULTANTS (Feb. 12, 2011), http://www.sagefoodsafety.com/2011/02/the-economic-impact-of-recalls (giving examples of costs associated with recalls including lost value in stock

when the alleged responsible parties are actually responsible for the outbreak, the justification disappears when such alleged parties are improperly accused. Consider the Salmonella outbreak of 2008. The initial investigation blamed tomatoes grown in the southwestern United States.[137] However, the CDC never microbiologically proved this allegation.[138] Eventually, the outbreak was determined to have stemmed from Mexican jalapeños and serranos.[139] In the meantime, however, the tomato industry lost an estimated $200 million.[140]

A shift to mandatory recalls presents the possibility that mistakes, similar to those that occurred with the 2008 Salmonella outbreak, could become more commonplace, as food producers are less capable of defending their commodities. Since "traceability mechanisms are still limited, when food scares erupt it is difficult to immediately pinpoint the culprit and losses may extend to sectors only indirectly involved in the contamination."[141] These losses are an extensive burden for the American food industry to bear given that the burden does not increase food safety when the recalled food products are not actually contaminated.

In an attempt to remedy the traceability problem, the Modernization Act also requires the FDA to improve its capacity to track and trace products when there is an outbreak of foodborne illness.[142] The FDA will accomplish this through pilot projects with both the processed food industry and fruit and vegetable distributors.[143] The focus of the pilot programs will be on "determin[ing] what data are most needed to trace a product that has been distributed widely in the marketplace back to a common source. Tracing product forward, such as in the case of an ingredient known to be contaminated, also will be tested."[144] At least three different types of food will be used in the projects, and the foods chosen will be those that were involved in significant foodborne illness outbreaks in the last five years.[145] The pilot projects seek a system that is functional,

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prices, loss of sales, and legal costs); *see also* UNIV. OF MINN., THE FOOD INDUS. CTR., WESTLAND/HALLMARK: 2008 BEEF RECALL A CASE STUDY BY THE FOOD INDUSTRY CENTER 5 (2010) (explaining the causes and costs of the largest beef recall in history); UNIV. OF MINN., THE FOOD INDUSTRY CENTER: 2009 – 2010 ANNUAL REPORT 9 (2010) (summarizing two recent case studies completed by the Center quantifying the costs of food recalls).

137. Dennis G. Maki, *Coming to Grips with Foodborne Infection—Peanut Butter, Peppers, and Nationwide Salmonella Outbreaks*, 360 NEW ENG. J. MED. 949, 949 (2009); *see also* Fagotto, *supra* note 28, at 260.

138. Maki, *supra* note 137, at 949.

139. Fagotto, *supra* note 28, at 260; Maki, *supra* note 137, at 949.

140. Fagotto, *supra* note 28, at 260; Maki, *supra* note 137, at 949.

141. Fagotto, *supra* note 28, at 260.

142. FDA Food Safety Modernization Act, Pub. L. No. 111-353, § 204, 124 Stat. 3885, 3930–37 (2010); JOHNSON, FOOD SAFETY ON THE FARM, *supra* note 116, at 14.

143. JOHNSON, FOOD SAFETY ON THE FARM, *supra* note 116, at 14.

144. *Food Safety Modernization Act: Frequently Asked Questions*, *supra* note 7.

145. *FDA Goal: Quickly Tracing Tainted Foods*, U.S. FOOD & DRUG ADMIN., 1 (Sept. 2011),

practical, and efficient, and the data gathered from the pilot programs will be used to assist the FDA in establishing record-keeping requirements for foods that are considered "high-risk" for contamination.[146] However, these pilot programs and the subsequent data analysis and rulemaking process will take time, while the mandatory recall authority is already in effect.[147] In the meantime, the FDA should establish protocols that require proof of the source of contamination—more than mere allegations—before invoking mandatory recall authority.

3. Third-Party Import Certification and Conflicts of Interest

Yet another important category of provisions in the Modernization Act that may increase food-production costs deals with foreign food producers and the importation of foreign foods into the United States.[148] About 60% of fresh fruits and vegetables consumed in the United States and 80% of seafood comes from foreign sources, with foreign food imports accounting for about 15% of the United States' food supply overall.[149] So any provisions that increase costs for foreign food imports will affect a significant portion of food purchased and consumed in the United States. The Modernization Act provisions will require importers to verify that their foreign producers have appropriate preventive controls in place,[150] and may require certification by an accredited certifying agency that the food was produced under processes complying with the Modernization Act.[151]

These provisions will hopefully be effective in preventing contaminated goods from entering the United States' food market. There exists a real concern, however, with utilizing third-party, private companies to certify goods.[152] "[T]he problem with third-party certifiers is that they appear to serve as agents for three principals: retailers who want to maximise profits, consumers who demand safe foods, and finally governments who rely on third-party certifiers to verify regulatory compliance."[153] For example, conflicts of interest can arise since producers have to pay to have their goods certified; the certifiers "may opt for more leniency to maintain profits."[154] Should the Modernization Act rulemaking go forward with

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http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm270923.htm.

146. *Id.* at 2.

147. *Food Safety Modernization Act: Frequently Asked Questions*, *supra* note 7.

148. FDA Food Safety Modernization Act, Pub. L. No. 111-353, §§ 301–09, 124 Stat. 3885, 3953–67 (2010).

149. U.S. FOOD & DRUG ADMIN., *supra* note 6.

150. § 301, 124 Stat. at 3953–55; U.S. FOOD & DRUG ADMIN., *supra* note 6.

151. § 303, 124 Stat. at 3956.

152. Fagotto, *supra* note 28, at 270.

153. *Id.*

154. *Id.* For another example of a conflict of interest, see William Neuman & David Barboza, *U.S. Drops Inspector of Food in China*, N.Y. TIMES (June 13, 2010), http://www.nytimes.com/2010

certification requirements, procedures should be in place to monitor third-party certifiers.[155] Otherwise, the safety of food imports may still be compromised,[156] while food costs rise due to payment for ineffective or invalid certification.

While Congress, throughout the legislative process, continually modified the Modernization Act to address the potential effect new regulations could have on small farming and food processing operations,[157] any new regulations will still necessarily affect the food-production industry. Smaller farms may be given more time to comply, more lenient requirements, or even exemptions.[158] But large farming operations, which would not fall under the modified requirements for small businesses, still constitute a significant portion of the U.S. food supply.[159] Therefore, new regulations that cause costs to increase will necessarily mean that at least some of those costs will be passed on to consumers in the form of higher prices, through consumption of food produced in large farming operations. The question continues to be whether the increase in food safety outweighs the burden of increased costs and higher food prices, causing further food insecurity and hunger across America.

B. *Modernization Act: An Incomplete Plan*

Additionally, the broad topic of "food safety" encompasses more than just the contaminants and pathogens that attach to food products during production, harvest, storage, and transportation. The total food safety picture also includes concerns such as animal feeding operations, antibiotic use, nutritive value of food consumed, healthy ecosystems for food production, agrochemical use (such as pesticides), genetically modified crops, and food irradiation.[160] A food safety plan that misses important

/06/14/business/global/14organic.html (noting that a no-conflict-of-interest requirement for third-party organic certifiers led to the USDA banning an organic certifier from operating in China because the third-party certifier "used employees of a Chinese government agency to inspect state-controlled farms and food processing facilities," violating a USDA rule "barring certifiers from reviewing operations in which they held a commercial interest").

155. *Cf.* Fagotto, *supra* note 28, at 270–71.

156. *See id.*

157. JOHNSON, FOOD SAFETY ON THE FARM, *supra* note 116, at 10.

158. *Id.* at 15.

159. *See* Maki, *supra* note 137, at 951 ("[V]irtually all food consumed domestically is grown and processed on a vast industrial scale or, increasingly, is imported . . . . Relatively little of the fresh food we eat is now grown or produced locally.").

160. NAT'L SUSTAINABLE AGRIC. COAL., FOOD SAFETY ON THE FARM: POLICY BRIEF AND RECOMMENDATIONS 4–5 (2009), *available at* http://sustainableagriculture.net/wp-content/uploads/2008/08/NSA C-Food-Safety-Policy-Brief-October-2009.pdf; JOHNSON, FOOD SAFETY ON THE FARM, *supra* note 116, at 3. This Section touches on some of the topics outlined above. The topic of genetically modified organisms (GMOs) is broad and sufficiently beyond the scope of this Note, but GMOs are controversial in terms of health and the potential for raising the price of food. For a brief history of genetic engineering, see *The Global Politics of Food: Engineering Crops in a Needy*

opportunities to control or prevent contamination will be limited in effectiveness. The following are just a few of the food safety factors that the Modernization Act neglects.

1. Environmental Considerations and Antibiotic Use

A topic as expansive as food safety must be tackled in pieces, so it is understandable that the Modernization Act focuses on pathogen contamination[161] as one of the first steps in the process of overhauling the food safety system. However, bacterial contamination can occur at many stages of the food-production process; while the Modernization Act targets bacterial contamination during and after food production, the Act misses the opportunity to control bacteria earlier in the process.[162] For example, the prevalence rates of E. coli in the commercial livestock industry vary between cattle fed on crowded feedlots and those fed on rangeland, with cattle grazing on rangeland showing a lower prevalence of E. coli at

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World, History of Genetic Engineering, AM. RADIOWORKS, http://americanradioworks.publicradio.org/features/gmos_india/history.html (last visited Feb. 2, 2012). For an overview of the FDA's role in regulating GMOs, see *Consultation Procedures under FDA's 1992 Statement of Policy - Foods Derived from New Plant Varieties*, U.S. FOOD & DRUG ADMIN. (Oct. 1997), http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096126.htm; *Genetically Engineered Foods: Statement of James H. Maryanski, Ph.D Before the Subcommittee on Basic Research, House Committee on Science*, U.S. FOOD & DRUG ADMIN. (Oct. 19, 1999), http://www.fda.gov/NewsEvents/Testimony/ucm115032.htm; *Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use*, U.S. FOOD & DRUG ADMIN. (June 2006), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096156.htm; *Statement of Policy - Foods Derived from New Plant Varieties*, U.S. FOOD & DRUG ADMIN. (May 29, 1992), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm. For some examples of concerns surrounding GMOs, including health and intellectual property concerns, see Matthew Rich, Note, *The Debate Over Genetically Modified Crops in the United States: Reassessment of Notions of Harm, Difference, and Choice*, 54 CASE W. RES. L. REV. 889 (2004); KEVIN E. SOUBLY, A MULTIDIMENSIONAL INTERNATIONAL EXAMINATION OF THE IMPACTS OF GMOS: A BIOLOGICAL, ECONOMIC, INTERNATIONAL TRADE, INTELLECTUAL PROPERTY, AND GEOPOLITICAL VIEW (2009), *available at* http://digitalcollections.sit.edu/isp_collection/779/; *Food Safety: 20 Questions on Genetically Modified Foods*, WORLD HEALTH ORG., http://www.who.int/foodsafety/publications/bio tech/20questions/en/ (last visited Feb. 2, 2012); Carey Gillam, *U.S. Organic Food Industry Fears GMO Contamination*, REUTERS (Mar. 12, 2008, 8:54 AM), http://www.reuters.com/article/2008/03/12/us-biotech-crops-contamination-idUSN1216250820080312; Katherine Goldstein & Gazelle Emami, *Monsanto's GMO Corn Linked To Organ Failure, Study Reveals*, HUFFINGTON POST (Mar. 18, 2010, 6:12 AM), http://www.huffingtonpost.com/2010/01/12/monsantos-gmo-corn-linked_n_4 20365.html; Catherine Saez, *US Farmers Sue Monsanto Over GMO Patents, Demand Right To Conventional Crops*, INTELLECTUAL PROP. WATCH (Mar. 30, 2011, 3:00 PM), http://www.ip-watch. org/2011/03/30/us-farmers-sue-monsanto-over-gmo-patents-demand-right-to-conventional-crops/print/.

161. *Food Safety Frequently Asked Questions*, *supra* note 132, at 7.

162. NAT'L SUSTAINABLE AGRIC. COAL., *supra* note 160, at 4.

slaughter than the feedlot cattle.[163] Given that these bacteria travel from livestock operations to produce fields through dust, runoff, manure, and other mechanisms, it is essential to also take action on livestock-related and other traveling sources of bacteria as part of a combined effort with action taken further along the production chain.[164] With the understanding that the Modernization Act requires the FDA to build or enhance existing partnerships between other areas of federal and state governments,[165] the area of livestock operations is an important subject for collaborative work with authorities and agencies that oversee the livestock industry.

The Modernization Act also overlooks the opportunity to control preventative antibiotic use for livestock.[166] Increased antibiotic resistance is traceable to the overuse of antibiotics.[167] Beyond the use of antibiotics by humans worldwide for personal medicinal purposes, farmers all over the world use antibiotics not only to treat sick livestock, but also in low doses to prevent livestock illness and to promote animal growth.[168] This prolonged use of antibiotics promotes resistance of bacteria to antibiotics

163. H.S. Hussein, *Prevalence and Pathogenicity of Shiga Toxin-producing* Escherichia Coli *in Beef Cattle and Their Products*, 85 J. ANIMAL SCI. E63, E65 (2007) ("Prevalance rates of E. coli O157 ranged from 0.3 to 19.7% in feedlot cattle . . . and from 0.9 to 6.9% in cattle grazing rangeland forages."); Sinisa Vidovic & Darren R. Korber, *Prevalence of* Escherichia Coli *O157 in Saskatchewan Cattle: Characterization of Isolates by Using Random Amplified Polymorphic DNA PCR, Antibiotic Resistance Profiles, and Pathogenicity Determinants*, 72 APPLIED & ENVTL. MICROBIOLOGY 4347, 4351 (2006) (finding statistically significant correlations between the prevalence rate of E. coli O157 and the density of cattle in pens, and the prevalence rate of E. coli O157 and the ratio of housed cattle to feedlot capacity; and explaining that "[h]igh pen densities increase contact between infected and noninfected animals as well as pose a stressful condition for cattle, resulting in a higher shedding rate of the pathogen").

164. JOHNSON, FOOD SAFETY ON THE FARM, *supra* note 116, at 3; NAT'L SUSTAINABLE AGRIC. COAL., *supra* note 160, at 4. For an analysis of a variety of preharvest strategies for controlling E. coli from livestock operations, see J. T. LeJeune & A. N. Wetzel, *Preharvest Control of* Escherichia Coli *O157 in Cattle*, 85 J. ANIMAL SCI., E73, E75 (2007). Research suggests that bacteria can be controlled by creating healthy ecosystems and vegetative buffers. *See, e.g.*, NAT'L SUSTAINABLE AGRIC. COAL., *supra* note 160, at 4 ("Healthy, living soil will harbor a greater number and variety of both macroscopic and microscopic organisms, and will thus be less susceptible to colonization by unwanted pathogens. Vegetative buffers can filter pathogens from streams and runoff, and protect cropland from windborne pathogens." (footnote omitted)); Stuart B. Levy, *The Challenge of Antibiotic Resistance*, SCI. AM., Mar. 1998, at 46, 47 (explaining that bacteria are a necessary part of life: "[T]hey often protect us from disease, because they compete with, and thus limit the proliferation of, pathogenic bacteria—the minority of species that can multiply aggressively (into the millions) and damage tissues or otherwise cause illness").

165. U.S. FOOD & DRUG ADMIN., BACKGROUND, *supra* note 18.

166. *Food Safety Frequently Asked Questions*, *supra* note 132, at 7.

167. Mary J. Gilchrist et al., *The Potential Role of Concentrated Animal Feeding Operations in Infectious Disease Epidemics and Antibiotic Resistance*, 115 ENVTL. HEALTH PERSP. 313, 313 (2007).

168. Gilchrist et al., *supra* note 167, at 313–14; *Our Big Pig Problem*, SCI. AM., Apr. 2011, at 12, 12 (2011); *see also* JOHNSON, FOOD SAFETY ON THE FARM, *supra* note 116, at 3; NAT'L SUSTAINABLE AGRIC. COAL., *supra* note 160, at 4.

by killing only some of the bacteria, leaving the resistant bacteria to survive and multiply.[169] The resistance genes pass between different kinds of bacteria[170] and eventually find their way into people.[171] Hence, "diseases that were formerly treatable [become] capable of causing severe illness or death."[172]

By focusing solely on bacterial contamination, the Modernization Act overlooks the opportunity to help treat foodborne illnesses when they do occur by aiding in the reduction of resistance to antibiotics. Often, resistant strains of bacteria in humans can be traced to resistant strains of bacteria in animals.[173] This is one factor that led Denmark to ban nontherapeutic dosing of farm animals with antibiotics.[174] While the short-term antibiotic resistance results in humans are mixed, Denmark, the world's largest exporter of pork, reports higher productivity in the pork industry as a result of the ban.[175] Other studies have confirmed that eliminating antibiotic use in farm animals for reasons other than to cure actual illness does not spread disease when appropriate environmental changes are made to protect animals without antibiotics.[176] The nontherapeutic dosing of livestock with antimicrobials is therefore another area where collaboration with other agencies during the Modernization Act rulemaking process could bring about safer food consumption in the future. In so doing, the Modernization Act could better protect consumers by increasing the likelihood that antibiotics will work properly to cure those who do contract foodborne

169. Gilchrist et al., *supra* note 167, at 314; *Our Big Pig Problem*, *supra* note 168, at 12.

170. Gilchrist et al., *supra* note 167, at 314 (citing Levy, *supra* note 164, at 46–53); *see also* Levy, *supra* note 164, at 48–49 (explaining the variety of ways bacteria can acquire resistance genes, including inheriting them, taking them from other bacteria in the vicinity, and obtaining them from viruses that extract a resistance gene from one bacterial cell and inject the gene into another bacterial cell).

171. *Our Big Pig Problem*, *supra* note 168, at 12.

172. Gilchrist et al., *supra* note 167, at 314.

173. *Our Big Pig Problem*, *supra* note 168, at 12; *see also* Rodney Baker, *Health Management with Reduced Antibiotic Use—The U.S. Experience*, 17 ANIMAL BIOTECH. 195, 196 (2006) ("[M]any food related outbreaks associated with resistant bacteria are circumstantially traced to food animal production.").

174. *Our Big Pig Problem*, *supra* note 168, at 12.

175. *Id.*

176. *See* K. Schwaiger, E.M.V. Schmied, & J. Bauer, *Comparative Analysis on Antibiotic Resistance Characteristics of* Listeria *spp. and* Enterococcus *spp. Isolated from Laying Hens and Eggs in Conventional and Organic Keeping Systems in Bavaria, Germany*, 57 ZOONOSES & PUB. HEALTH 171, 179 (2010) (finding that hens raised organically with no antibiotic use were contaminated with no more bacteria than hens raised traditionally and given antibiotics, but that organically kept hens had significantly lower bacterial resistance rates, reaffirming that "organic husbandries may contribute to further effectiveness of antibiotics"). *But see* Baker, *supra* note 173, at 203 (arguing that it costs more to produce antibiotic free pigs than it does to raise pigs conventionally, and that it is difficult to raise healthy pigs without antibiotics even on small farms when the farm is located in an area dense with swine, but that if forced to give up antimicrobials, the industry would "adapt and continue its competitive nature").

illnesses.

2. Food Irradiation

As a final note on the many facets of food safety, new rules created as a result of the Modernization Act need to ensure that any food sterilization that the FDA decides to require does not harm the nutritional quality of the food.[177] Research has been conducted on irradiation as a technique for food sterilization for more than fifty years.[178] Irradiation, using electron beams, gamma rays, or x-rays,[179] has been shown to destroy pathogens in meat,[180] fruits, vegetables, poultry, and spices.[181] These techniques are known as "non-thermal technologies."[182]

Overall, food treated with radiation through non-thermal technologies appears safe for consumption.[183] The United States and other countries have approved these techniques for use, and the process of irradiating food for consumption has been endorsed by the World Health Organization, among others.[184] The food itself does not become radioactive.[185]

However, irradiation can compromise the quality of food.[186] "[I]rradiation causes physico-chemical and biochemical changes that may affect the nutritional value and the sensory characteristics of irradiated food."[187] Vitamins, nutrients, and other healthful compounds may be destroyed through the process of irradiation, and irradiation can also create new compounds not naturally present in food.[188] The following are a few examples. In a study involving the irradiation of frozen lamb meat, various

177. NAT'L SUSTAINABLE AGRIC. COAL., *supra* note 160, at 4.

178. Corliss A. O'Bryan et al., *Impact of Irradiation on the Safety and Quality of Poultry and Meat Products: A Review*, 48 CRITICAL REVS. FOOD SCI. & NUTRITION 442, 442–43 (2008); Kim Krisberg, *Despite Wide Support, Food Irradiation Debate Continues*, NATION'S HEALTH, Sept. 2004, at 19.

179. Krisberg, *supra* note 178, at 19.

180. M.C. Cabeza et al., *Safety and Quality of Ready-to-Eat Dry Fermented Sausages Subjected to E-beam Radiation*, 83 MEAT SCI. 320, 321 (2009); M. Concepción Cabeza et al., *Optimization of E-beam Irradiation Treatment to Eliminate* Listeria Monocytogenes *from Ready-to-Eat (RTE) Cooked Ham*, 8 INNOVATIVE FOOD SCI. & EMERGING TECHS. 299, 304 (2007); M.C. Gámez et al., *Irradiation of Ready-to-Eat Sausages Containing Lycopene*, 23 ITALIAN J. FOOD SCI. 260, 261 (2011); Meijun Zhu et al., *Control of* Listeria Monocytogenes *Contamination in Ready-to-Eat Meat Products*, 4 COMPREHENSIVE REVS. FOOD SCI. & FOOD SAFETY 34, 40 (2005); Krisberg, *supra* note 178.

181. Krisberg, *supra* note 178.

182. Gámez et al., *supra* note 180.

183. Krisberg, *supra* note 178.

184. Maki, *supra* note 137, at 953 (explaining that "[f]ood irradiation has been endorsed by the World Health Organization, the CDC, the FDA, the USDA, the American Medical Association, and the European Commission's Scientific Committee on Food"); Krisberg, *supra* note 178.

185. NAT'L SUSTAINABLE AGRIC. COAL., *supra* note 160, at 5.

186. *Id.*

187. Gámez et al., *supra* note 180, at 261.

188. NAT'L SUSTAINABLE AGRIC. COAL., *supra* note 160, at 5.

isomers in the meat appeared to be affected by the process of irradiation, though the researchers ultimately concluded that "the nutritional value of meat fatty acids for human diet is not significantly lost" as a result of the process.[189] A study involving irradiated papayas and mangoes showed that "irradiation treatment reduces significantly . . . the level of respiration of [the fruit] and significantly . . . weakens the texture of [the] mangoes," though irradiation did not appear to significantly alter the vitamin C content of the fruit.[190] Irradiation and heat treatment were found to affect the antioxidant properties of culinary herbs and spices.[191] "[A] 2002 study conducted by German and French researchers . . . found that 2-alkylcyclobutanones, which are unique to irradiated foods, can promote tumor growth when given to lab animals in high concentrations" and recommended further research to determine the risk associated with human consumption of irradiated foods.[192]

Additionally, proponents of food irradiation proffer the technique as a useful "technology that can protect against safety breakdowns during production, preparation, or cooking: routine irradiation of the final commercial product in the case of poultry and hamburger, processed foods containing eggs or milk, and selected leafy and other vegetables eaten raw could greatly reduce the incidence of bacterial foodborne disease."[193] Like pasteurization, proponents argue, irradiation "reinforces delivery of a safe product."[194] But others oppose irradiation for the very same reason, arguing that "irradiation could eclipse [the food] industry's motivation for ensuring proper food handling and safety procedures" and may be used to conceal otherwise unsanitary conditions during processing.[195] Since irradiation appears to work better on already relatively clean foods,[196] reducing the motivation for proper food handling procedures could mean delivery of substandard, and unsafe, foods to the marketplace.

The debate over irradiated foods continues to be highly polarized.[197] Medical professionals, public health officials, and consumer groups continue to disagree about the safety of irradiated foods.[198] The European

189. Cristina M.M. Alfaia et al., *Irradiation Effect on Fatty Acid Composition and Conjugated Linoleic Acid Isomers in Frozen Lamb Meat*, 77 MEAT SCI. 689, 694 (2007).

190. Monique LaCroix et al., *Effect of Irradiation on the Biochemical and Organoleptic Changes During the Ripening of Papaya and Mango Fruits*, 35 INT'L J. RADIATION APPLICATIONS & INSTRUMENTATION, PART C, RADIATION, PHYSICS, & CHEMISTRY 296, 300 (1990).

191. Martin Polovka & Milan Suhaj, *The Effect of Irradiation and Heat Treatment on Composition and Antioxidant Properties of Culinary Herbs and Spices—A Review*, 26 FOOD REVS. INT'L 138, 151 (2010).

192. Krisberg, *supra* note 178.

193. Maki, *supra* note 137, at 953.

194. Krisberg, *supra* note 178.

195. *Id.*

196. *Id.*

197. *Id.*

198. *Id.*

Union put a moratorium on adding items to the list of permitted irradiated foods,[199] and many professionals and consumer groups alike are calling for further study,[200] including an attempt to "develop a standardized protocol for assessing the effects of irradiation"[201] before irradiated foods become commonplace.[202] It is true that the FDA currently allows irradiation for many foods.[203] However, in light of the controversy and the lack of data available about the long-term effect of food irradiation on humans, any rules that may be proposed to enhance food safety through requirement of non-thermal sterilization or irradiation should be rejected until further study clarifies both the benefits and the risks.

C. *Limited Funding, Ineffective Implementation*

Finally, even if the Modernization Act could be considered the perfect plan to overhaul the food safety system, the FDA still has a funding problem.[204] Prior to the adoption of the Modernization Act, the FDA and the USDA were already limited in their ability to complete inspections "by insufficient personnel and inadequate budgetary support."[205] The Modernization Act only increases the FDA's responsibilities. The FDA acknowledges this fact, explaining that the funding it receives "will be a factor in the way that FDA handles its significant and far-ranging activities, including the way that [the Modernization Act] is implemented. . . . Without additional funding, [the] FDA will be challenged in implementing the legislation fully without compromising other key functions."[206] So not only will the Modernization Act be difficult to implement without significant changes in funding, but the FDA's other longstanding functions may also be compromised.

It can be argued that without funding, new regulations cannot be created or enforced, and therefore there will be little change to the industry. However, the FDA will continue to do its job as best it can, as demonstrated by the progress it has already made on rulemaking and implementation of the Modernization Act in the two years since it became law.[207] This means there is potential for partial or otherwise poor implementation of the Modernization Act, as the lack of funding could restrict efficient implementation. Partial or poor implementation could

199. *Id.*
200. *Id.*
201. O'Bryan et al., *supra* note 178, at 455.
202. *See* Krisberg, *supra* note 178.
203. *Id.*
204. *Food Safety Modernization Act: Frequently Asked Questions*, *supra* note 7.
205. Maki, *supra* note 137, at 952.
206. *Food Safety Modernization Act: Frequently Asked Questions*, *supra* note 7.
207. *See* U.S. Food and Drug Administration, *FDA Food Safety Modernization Act One-Year Progress Report*, U.S. FOOD & DRUG ADMIN. (Jan. 2012), http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM286002.pdf.

create confusion across the food-production industry, which may lead to higher costs and higher food prices, but even less safe food products in the end.

CONCLUSION

Taken as a whole, the Modernization Act is an ambitious and much needed attempt to overhaul the outdated safety protocols and regulations that guide the food-production industry. The Act's strength lies in the broad application of FDA power to food-production processes to eliminate contaminants and pathogens during food growth, harvest, storage, and transportation. The Modernization Act's main strength, however, is also a weakness. The Act's broad application of FDA power provides the opportunity to force increased production costs on farming operations, both large and small. While significantly improved food safety in the United States may be worth the increased production costs and increased food prices, regulations that provide only marginally safer food at a substantially increased cost hurt Americans more than they help. In the long run, it will not matter if food in the United States is slightly safer, if being slightly safer means that many more Americans cannot afford to eat.

Since the FDA's rulemaking and implementation process for the Modernization Act will take time, it is too soon to tell how much cost the Modernization Act will impose on food-production industries. What is clear is that the potential exists for that cost to be great. Through increased regulation, including mandatory safety measures for both American-produced food and foreign-produced food imported into the United States, the FDA could force food-production costs to rise, thereby inflating the overall price of food in the United States. At a time when millions of Americans are already considered food-insecure,[208] rising prices will mean that even more people go hungry.

Balancing policy concerns has long been a part of the American legal tradition.[209] The fact that food prices may have to increase to insure a safer food supply is understandable, but the benefit gained by the American public must significantly outweigh the cost. If the rules created by the FDA as it implements the Modernization Act cause food production and distribution costs to rise, those rules and regulations need to be thoroughly researched, appropriate to each individual industry, and effective enough in the fight to ensure a safe national food supply to warrant the increased

208. Ruitenberg, *supra* note 4.

209. *See, e.g.*, United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947) (balancing the safety of people and property in a seaport against the barge attendant's freedom to come and go according to his needs and custom in the seafaring business at the time); David G. Owen, *Bending Nature, Bending Law*, 62 FLA. L. REV. 569, 571 (2010) ("It is the job of law, drawing from customs, morals, and practical politics, to prescribe who bears the economic risk of harmful consequences . . . .").

price tag. If new minimum produce safety regulations, for instance, cause significant confusion, force a considerable portion of the industry out of the food-production market due to increased cost, or require actions for all crops and commodities even if such actions are only appropriate for some, then the regulations may not be warranted in terms of balancing cost and safety. Under such circumstances, other avenues of promoting food safety, such as educational programs to instruct consumers on safer food handling and preparation practices, may be more appropriate than imposing new regulations on the producers themselves. As the rulemaking process progresses, to avoid detrimentally affecting the public and promoting further food insecurity, the FDA should consider the effect its rulemaking will have on the cost of food production.

Additionally, the FDA must ensure that enough time is allotted in the process to weigh risks and benefits and to consider the entirety of the food safety problem. While focusing purely on pathogen contamination, the Modernization Act neglects numerous other factors that affect food safety and misses opportunities to work with other government agencies to control contamination that spreads from other industries, enhance natural protections from contaminants, and maintain appropriate nutritional quality of food. Finally, the FDA must receive enough funding to effectively implement the *entire* food safety plan it devises, including protecting against risks such as improper product tracing related to recall authority and the opportunity for fraud in the food import industry. Even the best-laid plan will fail if improperly implemented. The FDA should continue to seek appropriate funding so that it can implement the Modernization Act properly. A poorly implemented food safety system is only a detriment to the health of the American public.