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FOOD AND DRUG LAW JOURNAL

*Analyzing the Laws, Regulations, and Policies
Affecting FDA-Regulated Products*

An Analysis of the FDA Food Safety Modernization Act: Protection for Consumers and Boon for Business

Debra M. Strauss

An Analysis of the FDA Food Safety Modernization Act: Protection for Consumers and Boon for Business

DEBRA M. STRAUSS*

INTRODUCTION

According to the newest figures from the Centers for Disease Control and Prevention, “each year roughly one out of six Americans (or 48 million people) gets sick, 128,000 are hospitalized and 3,000 die from foodborne diseases.”¹ Although some critics have contested the calculation of these estimates,² it is undisputed that recent incidents involving food contamination, particularly salmonella and *E. coli* in eggs, peanuts and produce have been numerous and widespread.³ A recent consumer survey found that nearly half of Americans are concerned they may get sick from eating contaminated food and are changing their buying habits to avoid items they normally would have purchased.⁴ The poll also reported that consumers overwhelmingly support setting up a tracing system for produce and new federal standards for fresh produce.⁵ Tainted foods have caused illnesses and deaths that

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¹ Centers for Disease Control and Prevention (CDC), *CDC Estimates of Foodborne Illness in the United States*, “CDC 2011 Estimates: Findings,” <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>.

² Jim Prevor, *New Foodborne Illness Numbers Dramatically Lower: Points to Danger of Basing Public Policy on Faulty Statistics*, 27 *PRODUCE BUSINESS* 5 (Feb. 2011), available at <http://www.producebusiness.com/e-books/PB11Feb.pdf>; Jim Prevor’s Perishable Pundit, *New Foodborne Illness Numbers Dramatically Lower: Points to Danger of Basing Public Policy on Faulty Statistics*, Dec. 24, 2010, <http://www.perishable-pundit.com/index.php?date=12/24/10&pundit=3>. But see Elaine Scallan et al., *Foodborne Illness Acquired in the United States—Major Pathogens*, 17 *EMERGING INFECTIOUS DISEASES*, Jan. 2011, <http://www.cdc.gov/eid/content/17/1/pdfs/7.pdf>; Elaine Scallan et al., *Foodborne Illness Acquired in the United States—Unspecified Agents*, 17 *EMERGING INFECTIOUS DISEASES*, Jan. 2011, <http://www.cdc.gov/eid/content/17/1/pdfs/16.pdf>.

³ See, e.g., Gardiner Harris, *More Money for Food Safety is Sought: After Outbreak of Salmonella, Department Asks for \$275 Million*, N.Y. TIMES, A17, June 10, 2008; Lauran Neergaard, *FDA Says It’s OK to Eat Tomatoes Again*, ASSOCIATED PRESS, July 17, 2008, <http://news.consumerreports.org/safety/2008/07/tomato-warning.html>; Dan Flynn, *Peanut, Pistachio Recalls Keep FDA Busy*, FOOD SAFETY NEWS, Oct. 31, 2009, <http://www.foodsafetynews.com/2009/10/peanut-pistachio-recalls-keep-fda-busy/>; Saundra Young, *Salmonella outbreak linked to alfalfa sprouts*, CNN, Dec. 24, 2010, <http://www.cnn.com/2010/HEALTH/12/23/salmonella.outbreak.sprouts/index.html>; *Salmonella outbreak linked to sprouts has sickened nearly 100 people*, CNN, Dec. 28, 2010, <http://www.cnn.com/2010/HEALTH/12/28/salmonella.produce/index.html>; Dan Flynn, *Top Food Safety Stories of 2010: Number four in our top food safety stories of the year was the recall of more than 500 million shell eggs in August*, FOOD SAFETY NEWS, Dec. 30, 2010, <http://www.foodsafetynews.com/2010/12/top-food-safety-stories-of-2010-no-4/>.

⁴ Ricardo Alonzo-Zaldivar, *Food safety worries change buying habits*, ASSOCIATED PRESS, July 18, 2008, http://www.usatoday.com/news/nation/2008-07-18-3531246574_x.htm# (In the wake of a salmonella outbreak first linked to tomatoes and then hot peppers, 46% of consumers surveyed said they were worried they might get sick from eating contaminated food and that they have avoided foods because of safety warnings; 29% have thrown out food earlier than usual and 14% have returned food to the store). As one consumer observed, “[w]hen you have almost half of the population avoiding certain foods because of safety concerns, that’s very significant from the standpoint of economic impact for the people selling the food, and from the standpoint of peace of mind for consumers.” *Id.*

⁵ *Id.* (poll reported that 86% of consumers believed produce should be labeled in order to be tracked back to the farm through layers of processors, packers, and shippers; and 80% favored new federal standards for fresh produce); see also Caroline Scott-Thomas, *Skepticism about ‘natural’ products continues, finds survey*, FOOD NAVIGATOR-USA.COM, Dec. 22, 2010, <http://www.foodnavigator-usa.com/Financial-Industry/Skepticism-about-natural-products-continues-finds-survey> (reporting that one in three consumers surveyed were “not very” or “not at all” confident in “natural” labeling, while two-thirds would favor a uniform standard to certify the term for both processes and ingredients).

could have been prevented by a more rigorous and proactive policy.⁶ Such a policy is now on the horizon, as embodied by the Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA).⁷

The U.S. House of Representatives and Senate recently approved a bill that will overhaul the nation's food safety laws for the first time since the Great Depression. On January 4, 2011, President Obama signed the bill into law. After a difficult journey through technical and procedural hurdles, FSMA has now become law, enlarging the powers of FDA to inspect plants and order recalls of tainted foods.

Through the crescendo of these recent incidents, recognition has emerged that the U.S. consumer needs greater protection before these outbreaks occur, through more stringent requirements and better enforcement of food safety standards, including inspections.⁸ Moreover, traceability and recall powers are essential to resolve the problems that do arise. The limited response options available to the agency to trace and withdraw these products from the market have prompted this shift in approach to mandate efforts to prevent outbreaks from occurring in the first place. Through these new measures, consumers are being sent the message that their health does matter, with the hopes that doing so will also restore their confidence in the safety of the food supply.

FDA has the responsibility for overseeing 80 percent of the nation's food supply, with the U.S. Department of Agriculture (USDA) handling meat and poultry, products not covered by the new law. However, the new law empowers FDA by granting it far-reaching authority to establish food safety standards for farmers and food processors and to recall food. In past outbreaks of contamination, FDA had to rely upon food companies to voluntarily remove their products from stores. Moreover, FDA lacked the funding to do inspections and enforce the regulations that it did promulgate.⁹ By providing the agency with resources and authority to

⁶ See, e.g., J. Glenn Morris, Jr., *How safe is our food?*, 17 EMERGING INFECTIOUS DISEASES, Jan. 2011, <http://www.cdc.gov/eid/content/17/1/pdfs/126.pdf>; CDC, *FDA asked about possible lag in warning about eggs*, CNN, Aug. 27, 2010, <http://www.cnn.com/2010/HEALTH/08/27/eggs.salmonella/index.html>; Drew Falkenstein, *Spinach recall among Huffington Post's worst product recalls of all time*, FOOD POISON J., Feb. 24, 2010, <http://www.foodpoisonjournal.com/foodborne-illness-outbreaks/spinach-recall-among-huffington-posts-worst-product-recalls-of-all-time/> (recounting E-coli spinach recall of 2006 in which, after 204 outbreak-related cases with 102 hospitalizations, thirty-one cases of hemolytic uremic syndrome, and three deaths, FDA eventually determined source was bagged Dole baby spinach originating from Natural Selection).

⁷ FDA Food Safety Modernization Act (FSMA), 21 U.S.C. § 2201, Pub. L. No. 111-353, 124 Stat. 3885 (2011), amending the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (1938). Note that the bill signed into law by President Obama on Jan. 4, 2011 was the version that originated in the Senate as S. 510 and passed the House of Representatives as H.R. 2751 in the 111th Congress, as discussed below, see *infra* Part I.

⁸ Amazingly enough, the numbers cited by the CDC of Americans suffering from foodborne illnesses and death, *supra* note 1, are similar to the past number of yearly polio deaths that led to public panic and demand for a vaccine before one was ultimately developed in 1955. Yet this is the first time Congress had given the same degree of attention to the food safety problem. See Deborah Kotz, *New Food Safety Regulations? It's About Time*, U.S. NEWS AND WORLD REPORT, Dec. 1, 2010, <http://health.usnews.com/health-news/diet-fitness/infectious-diseases/articles/2010/12/01/new-food-safety-regulations-its-about-time> (discussing the limited tools available to the FDA in its food safety toolbox prior to the passage of the new food safety law and the need for more).

⁹ A recent report from the Institute of Medicine found that in view of the fact that the FDA is responsible for more than 150,000 food facilities, more than one million restaurants and other retail food establishments, and more than two million farms, along with millions of tons of imports, it lacks the resources to monitor the entire food supply adequately. See Caroline Scott-Thomas, *Obama says new food safety legislation would promote prevention*, FOOD NAVIGATOR-USA.COM, July 9, 2010, <http://www.foodnavigator-usa.com/Legislation/Obama-says-new-food-safety-legislation-would-promote-prevention>.

stop outbreaks before they begin, FSMA shifts the government's policy from reactive to proactive.¹⁰

As the first law in 70 years to substantially change food law, this new law represents an initial but significant step in the direction of improving food safety.¹¹ Part I of this article explores the dramatic history of its passage as the initiative had bounced between the House of Representatives and the Senate, at times floundering but ultimately overcoming technical and procedural hurdles to secure passage in the final hours of the 111th Congress. In Part II, this article analyzes the specific components of FSMA that enlarge the powers of FDA to inspect plants and order recalls, require food producers to develop food safety plans, establish a food tracing system and strengthen restrictions on imported foods. Part III examines the limitations of the new law and the hurdles it is likely to face in the future, including funding and the need for initiatives from other agency partners. Part IV discusses the significance and breadth of its mandate from the perspectives of Congress, the President, agencies such as FDA, food safety and consumer groups and industry. With unprecedented support for the priority of food safety coming from such diverse constituencies, Part V presents other areas that are ripe for reassessment—particularly genetically modified organisms (GMOs) in food and the use of milk and meat from cloned animals and their progeny—which are allowed under current U.S. law with no labeling, preapprovals or post-market monitoring. Accordingly, Part VI concludes that the United States should seize this time as a unique opportunity through improvements in the law to make further strides towards securing the safety of the U.S. food supply.

I. DRAMATIC HISTORY OF ITS PASSAGE

At times the initiative to overhaul the nation's food laws had floundered and skeptics feared it would not pass, yet the bill that became the FDA Food Safety Modernization Act surmounted technical and procedural hurdles to secure passage in the final hours of the 111th Congress. This odd journey through Congress would not have resulted in eventual success had it not been for the strong mandate that carried this initiative forward.

The dramatic saga of the law's passage in the 111th Congress began with a stronger version that had passed in the House of Representatives but did not gain approval in the Senate.¹² After being passed in the House with strong bipartisan support the year before, the previous bill (H.R. 2749) stagnated in the Senate largely due to opposition from small farmers and producers, who were concerned that the new regulations would be too costly and cumbersome for their businesses to survive, and

¹⁰ See New Law Tightens FDA's Grip On Food Safety: *Q&A talks about food safety with Debra M. Strauss, associate professor of business law at Fairfield University*, HARTFORD BUS. J., Jan. 10, 2011, available at <http://www.hartfordbusiness.com/news16301.html>; Gabriella Tutino, "FDA Law Shifts Gov. from 'Reactive to Proactive,'" *Fairfield Mirror*, Jan. 26, 2011, available at <http://fairfieldmirror.com/2011/01/26/fda-law-shifts-gov-from-%E2%80%99Creactive-to-proactive%E2%80%99D/>.

¹¹ See, e.g., Convenience Store Decisions, "New Bill to Overhaul Food Safety Laws" (Dec. 30, 2010), <http://www.csdecisions.com/new-bill-to-overhaul-food-safety-laws/>; Food Logistics (Information for Grocery and Food Distributors/Manufacturers), "Food Safety Act Will Strengthen Food Law By Expanding FDA's Powers," <http://www.foodlogistics.com/online/article.jsp?siteSection=8&id=4231&pageNum=1>.

¹² See William Neuman, *House Approves New Food-Safety Laws*, N.Y. TIMES, July 30, 2009, <http://www.nytimes.com/2009/07/31/us/politics/31fda.html>. See generally Shannon G. May, *Importing a Change in Diet: The Proposed Food Safety Law of 2010 and the Possible Impact on Importers and International Trade*, 65 FOOD & DRUG L.J. 1 (providing a preliminary analysis of the original House bill, H.R. 2749, with a focus on its potential impact on imported trade industry).

fears among consumer groups that excluding them would hinder the safety of the food supply.¹³ In response to their concerns, the Senate version of the bill (S. 510) added an amendment by Senator Jon Tester (D-Mont.) along with other changes that satisfied most food safety advocates and brought the legislation back to life.¹⁴

Although many consumer and industry groups preferred the original House version because it included more money for inspections and fewer exceptions, most supported the Senate bill as far better than the alternative of no new food safety law.¹⁵ However, Senator Tom Coburn (R-Okla.) staunchly fought the bill, claiming it was unnecessary and prohibitively expensive. His opposition nearly derailed the passage of the law, which caused months of delay and forced the Senate majority leader, Harry Reid (D-Nev.) to call a series of time-consuming procedural votes to end the debate. Eventually, on November 30, 2010, the bill passed the Senate by a vote of 73 to 25 with strong bipartisan support as well as the backing from the U.S. Chamber of Commerce and major business groups representing food producers and grocery stores.¹⁶

Among its many provisions, FSMA increases funding for FDA, but this component caused difficulties for the Senate version of the bill, temporarily derailing its progress as it was sent back to originate in the House of Representatives, which is the constitutionally appropriate body to handle monetary appropriations. In the waning days of the lame-duck Congress, this procedural error of including revenue raisers that technically pre-empted the House's tax-writing authority nearly proved fatal for the bill.¹⁷ The House Democratic leaders decided to fold the Senate bill into an omnibus spending bill to fund the U.S. government, which passed the House on December 8th by a vote of 212 to 206.¹⁸ However, as the bill would then need to be approved again by the Senate, the food safety provisions faced further jeopardy due to Republican resistance to the many earmarks also contained in the massive funding bill.¹⁹ As the Senate worked into overtime, Senator Reid reached a deal with Minority Leader Mitch McConnell (R-Ky.) and Senator Coburn dropped his filibuster threat.²⁰

¹³ Michael Pollan & Eric Schlosser, *A Stale Food Fight*, N.Y. TIMES, Nov. 28, 2010, <http://www.nytimes.com/2010/11/29/opinion/29schlosser.html>.

¹⁴ See RENÉE JOHNSON ET AL., CRS REPORT FOR CONGRESS, FOOD SAFETY IN THE 111TH CONGRESS: HR 2749 AND S. 510, R40443 (Dec. 1, 2010), available at <http://www.fas.org/sgp/crs/misc/R40443.pdf> (detailed comparison of the provisions of the original House bill and the Senate version that ultimately became law).

¹⁵ *Id.*

¹⁶ Gardiner Harris & William Neuman, *Senate Passes Sweeping Law on Food Safety*, N.Y. TIMES, Nov. 30, 2010, <http://www.nytimes.com/2010/12/01/health/policy/01food.html>; see also Ann McFeaters, *Food safety legislation a bipartisan success*, NASHUA TELEGRAPH.COM, Dec. 7, 2010, <http://www.nashuatelegraph.com/opinionperspectives/901567-263/food-safety-legislation-a-bipartisan-success.html>; Amanda Becker, *For food-safety overhaul, lobbyists rushed to the table*, THE WASHINGTON POST, Dec. 6, 2010, <http://www.washingtonpost.com/wp-dyn/content/article/2010/12/03/AR2010120306058.html>; Alicia Mundy & Bill Tomson, *Senate Acts on Food Safety*, WALL ST. J., Dec. 1, 2010, <http://online.wsj.com/article/SB10001424052748704679204575646643189833562.html>.

¹⁷ John Stanton, *House May Block Food Safety Bill Over Senate Error*, ROLL CALL, Nov. 30, 2010, <http://www.rollcall.com/news/-201012-1.html> (predicting that, as a result, House Democrats would use a procedure known as "blue slipping" to block the bill).

¹⁸ Charles Abbott & Jackie Frank, *Food-safety overhaul rides on funding bill*, REUTERS, Dec. 8, 2010, <http://www.reuters.com/article/2010/12/08/us-usa-food-safety-idUSTRE6B76PL20101208>; Helena Bottemiller, *Senate May Clear Path for Food Safety This Week*, FOOD SAFETY NEWS, Dec. 14, 2010, <http://www.foodsafetynews.com/2010/12/senate-may-clear-path-for-food-safety-this-week/>.

¹⁹ Ted Barrett, *Food safety bill could die*, CNN.COM, Dec. 17, 2010, http://articles.cnn.com/2010-12-17/politics/food.safety.bill_1_food-safety-bill-food-supply-government-inspections?_s=PM:POLITICS.

²⁰ Lyndsey Layton, *Senate passes food-safety bill*, THE WASHINGTON POST, Dec. 20, 2010, <http://www.washingtonpost.com/wp-dyn/content/article/2010/12/19/AR2010121904201.html>; Patricia Murphy, *Food-Safety Bill Clears Senate in Wake of 2010's Massive Recalls*, POLITICS DAILY, Dec. 20, 2010, <http://www.politicsdaily.com/2010/12/20/food-safety-bill-clears-senate-in-wake-of-massive-food-recalls/> (Senator Coburn had argued the bill failed to solve the huge overlap of authority between the FDA and the USDA and objected to the \$1.4 billion expense).

In a last minute reprieve late on the night of December 19, Senator Reid stripped the bill from the scrapped omnibus package, replaced it for the text of an unrelated House bill (H.R. 2751)²¹ as a stand-alone measure, and brought it to the floor for a unanimous voice vote.²²

Supporters of the legislation rejoiced: “It is a huge victory for consumers following a weekend cliffhanger,” said Caroline Smith DeWaal, food safety director at the Center for Science in the Public Interest.²³ Senator Reid said that “Our food safety system has not been updated in almost a century. We unanimously passed a measure to improve on our current food safety system by giving FDA the resources it needs to keep up with advances in food production and marketing, without unduly burdening farmers and food producers.”²⁴

In the final move, with time running out for the legislative session on December 22, the House passed the bill by a vote of 215 to 144.²⁵ With broad bipartisan and bicameral support of the Congress, the bill progressed swiftly to the President’s desk where he was expected to give his ultimate approval.²⁶ In a press conference that accompanied his signing of several bills prior to the holidays, the President commended the food safety bill as a major achievement: “In addition, we came together across party lines to pass a food safety bill—the biggest upgrade of America’s food safety laws since the Great Depression.”²⁷ Upon his return on January 4, 2011, President Obama signed the bill into law.²⁸

Most experts support the new legislation. The executive director of Center for Science in the Public Interest commented that “Everyone who eats will benefit from

²¹ H.R. 2751, originally the Consumer Assistance to Recycle and Save Act, passed the House in June 2009 and was a “vehicle” for the passage of S. 510 in a House-originating bill because S. 510 was a revenue-raising bill. S.510: FDA Food Safety Modernization Act, 111th Congress (2010), Govtrack.us, <http://www.govtrack.us/congress/bill.xpd?bill=s111-510> (last visited Apr. 17, 2011).

²² Matthew Jaffe, *Back from the Dead: Food Safety Bill Passes Senate in Unexpected Last-Minute Move*, ABC NEWS, Dec. 19, 2010, <http://blogs.abcnews.com/thenote/2010/12/back-from-the-dead-food-safety-bill-passes-senate-in-unexpected-last-minute-move.html>; Mary Clare Jalonick, *Senate Passes Food Safety Bill, Again*, AOL NEWS, Dec. 19, 2010, <http://www.aolnews.com/2010/12/19/senate-passes-food-safety-bill-again/>; Associated Press, *Fixing Error, Senate Passes Food Bill Again*, N.Y. TIMES, Dec. 19, 2010, <http://www.nytimes.com/2010/12/20/us/politics/20food.html>.

²³ Britt Erickson, *Food Safety Bill Fixed, Legislation: Senate corrects mistake, passes long-delayed bill*, C&E NEWS, Dec. 20, 2010, <http://pubs.acs.org/cen/news/88/i51/8851news11.html>.

²⁴ *Id.*

²⁵ See Helena Bottemiller, *House Expected to Approve Food Safety Bill Today*, FOOD SAFETY NEWS, Dec. 21, 2010, <http://www.foodsafetynews.com/2010/12/house-expected-to-approve-food-safety-bill-today/>; Andrew Zajac, *Congress poised to pass ambitious food-safety bill*, LOS ANGELES TIMES, Dec. 21, 2010, <http://articles.latimes.com/2010/dec/21/business/la-fi-food-safety-20101221>; Lyndsey Layton, *Food-safety bill backed by House*, THE WASHINGTON POST, Dec. 22, 2010, <http://www.washingtonpost.com/wp-dyn/content/article/2010/12/21/AR2010122106190.html>; William Neuman, *House approved nation’s food safety laws*, N.Y. TIMES NEWS SERVICE, Dec. 22, 2010.

²⁶ Helena Bottemiller, *Food Safety Bill Heads to President’s Desk*, FOOD SAFETY NEWS, Dec. 22, 2010, <http://www.foodsafetynews.com/2010/12/food-safety-bill-clear-final-hurdle-heads-for-presidents-desk/>; Andrew Zajac, *House approves final safety bill*, LOS ANGELES TIMES, Dec. 22, 2010, <http://articles.latimes.com/2010/dec/22/business/la-fi-food-safety-20101222>; CNN Wire Staff, *House passes food safety bill to send to Obama*, CNN.COM, Dec. 21, 2010, http://articles.cnn.com/2010-12-21/politics/house.food.safety_1_food-safety-modernization-act-government-inspections-food-supply?_s=PM:POLITICS.

²⁷ Helena Bottemiller, *President to Sign Food Safety Bill in Early 2011*, FOOD SAFETY NEWS, Dec. 23, 2010, <http://www.foodsafetynews.com/2010/12/president-to-sign-food-safety-bill-in-early-2011/>.

²⁸ The White House, Statement by the Press Secretary, Jan. 4, 2011, <http://www.whitehouse.gov/the-press-office/2011/01/04/statement-press-secretary>; see CNN Wire Staff, *Obama signs food safety bill*, CNN.COM, Jan. 4, 2011, http://articles.cnn.com/2011-01-04/politics/obama.food.safety_1_food-safety-fda-power-commissioner-margaret-hamburg?_s=PM:POLITICS; Darlene Superville & Mary Clare Jalonick, Associated Press, *Obama Signs Bill to Improve Nation’s Food Safety*, ABC NEWS, Jan. 4, 2011, <http://abcnews.go.com/US/wireStory?id=12537737>.

this historic legislation. FDA will have new tools to help ensure that America's food supply is safer, causing fewer illnesses and deaths.²⁹ Although not as strong as the original House version, the Senate version that became law contains many constructive components, as discussed below. Overall, FSMA represents a shift to a more effective proactive policy as well as a major step forward towards making further strides in food safety.

II. COMPONENTS OF THE FDA FOOD SAFETY MODERNIZATION ACT

Prompted by the recently increasing incidents of contamination, FSMA will strengthen food law by enlarging FDA powers to inspect plants and order recalls.³⁰ In addition, the new law will require food producers to develop food safety plans, including identifying potential risks of contamination or other hazards, and identifying the mechanisms through which those risks would be controlled. The legislation establishes a food tracing system through which consumers can be rapidly identified and deaths and illnesses minimized in the event of a contamination outbreak, requiring farms and processors to keep records to help the government trace recalled foods. Strengthening restrictions on imported foods, FDA will be empowered to deny entry to foods that do not comply with U.S. food safety requirements or requests for inspections of overseas facilities.

The legislation also requires that FDA create new produce safety regulations for producers of the highest risk fruits and vegetables and increase inspections of domestic and foreign food facilities, directing the most resources to those operations with the highest risk profiles. The riskiest domestic facilities would be inspected every three years (in contrast to the rare inspections conducted currently). In addition, the law will require grocery stores to proactively alert consumers about recalls.

In essence, FSMA contains five key elements: preventive controls, inspection and compliance, imported food safety, response and enhanced partnerships.³¹ Each of these areas endows FDA with new authorities and responsibilities to develop specific scientific standards, provide oversight to increase conformance, act effectively when problems emerge and build collaboration with other local, state and foreign government agencies in order to carry out an integrated approach to food safety.³²

It is significant to observe how FDA describes the change in the way it will regulate foods:

This new law puts prevention up front for FDA. For the first time, FDA will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply. Under the Act, implementation of mandatory preventive controls for food facilities and compliance with mandatory produce safety standards will be required. FDA is in the process of developing a proposed rule that will establish science-based

²⁹ CNN Wire Staff, *Obama signs food safety bill*, *supra* note 28 (statement of Michael Jacobson).

³⁰ See RENÉE JOHNSON, CRS REPORT FOR CONGRESS, FOOD SAFETY IN THE 111TH CONGRESS, R40443 (Sept. 23, 2010), available at http://assets.opencrs.com/rpts/R40443_20100923.pdf.

³¹ FDA, Food Safety Modernization Act (FSMA), Frequently Asked Questions, <http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm#general7> (last visited Apr. 10, 2011).

³² For a more detailed description by the FDA of its authorities and mandates in these key areas, see FDA, Background on the FDA Food Safety Modernization Act (FSMA), <http://www.fda.gov/Food/FoodSafety/FSMA/ucm239907.htm> (last visited Apr. 10, 2011); see also *Food Safety Law Authorizes Mandatory FDA Recalls*, 19 No. 12 FDA ENFORCEMENT MANUAL NEWSL. 2 (2011).

minimum standards for the safe production and harvesting of fruits and vegetables and will address soil amendments, worker health and hygiene, packaging, temperature controls, water and other issues. Food facilities will be required to implement a written preventive control plan, provide for the monitoring of the performance of those controls and specify the corrective actions the facility will take when necessary.³³

A closer look at some of the more unusual and controversial elements of this comprehensive legislation is warranted, particularly the staggered timeline and Congressional oversight, the extraterritorial reach beyond U.S. borders, the exemptions for small producers and the protections for whistleblowers. In addition, the myths and misconceptions will be examined in more detail and debunked.

A. Congressional Oversight and Timeline

The implementation of these changes will follow in stages, within a timeline specified by Congress in the legislation. Under FSMA, certain powers will go into effect immediately, such as FDA's new authority to order recalls, and others require guidance documents and regulations to be issued by FDA. For example, in the prevention category, mandatory preventive controls for food facilities will require the implementation of a written preventive controls plan (final rule due 18 months after the enactment of FSMA); mandatory produce safety standards must be developed (final regulation due in two years) and FDA must issue mitigation strategies to protect against intentional adulteration of food (final rule due in 18 months).³⁴ In response to its mandate under FSMA, FDA has already launched a new website redesigned to make information on food recalls easier for consumers to obtain.³⁵

Especially noteworthy are the sections of FSMA that involve continuing Congressional oversight over evaluating food safety programs, developing independent laboratories for food analysis and testing and improving tracking and tracing. Section 110 requires the Secretary of Health and Human Services (HHS), in coordination with the Secretary of Agriculture and the Secretary of Homeland Security, to submit "a comprehensive report that identifies programs and practices that are intended to promote the safety and supply chain security of food and to prevent outbreaks of foodborne illness and other food-related hazards that can be addressed through preventive activities" to Congress within two years.³⁶ In addition, the Secretary of HHS must submit biennial reports that review past and identify future food safety programs and practices.³⁷

Section 202 requires the Secretary of HHS to recognize and provide oversight to bodies that accredit laboratories, develop standards for mandatory analytical testing of food products and report to the relevant Congressional committees on the progress in implementing a national food emergency response laboratory

³³ FDA, Food Safety Modernization Act (FSMA), Frequently Asked Questions, *supra* note 31.

³⁴ FDA, Background on the FDA Food Safety Modernization Act (FSMA), *supra* note 32.

³⁵ See FDA, Recalls, Market Withdrawals, & Safety Alerts, <http://www.fda.gov/Safety/Recalls/ucm2005683.htm> (last visited Apr. 10, 2011) (includes recall search engine and email alerts); Andrew Zajac, *FDA launches Web page on recalled foods*, LOS ANGELES TIMES, Apr. 4, 2011, <http://www.latimes.com/news/politics/la-pn-fda-website-20110404,0,1272799.story>.

³⁶ 21 U.S.C. § 2204, Pub. L. No. 111-353, 124 Stat. 3913 (2011) ("Building domestic capacity").

³⁷ *Id.*

network.³⁸ Section 204 directs the Secretary of HHS 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.”³⁹ This section also provides that, within 18 months of the enactment, the Secretary shall report the findings of the pilot projects to Congress, along with recommendations for improving the tracking and tracing of fruits, vegetables and processed food.⁴⁰ “High risk” foods, still to be further identified and defined, are given heightened scrutiny and subject to additional recordkeeping requirements.⁴¹

Thus, FSMA sets forth an integrated partnership between food regulatory agencies and networks of laboratories, under the ongoing oversight of Congress, as well as consultation with “a diverse and broad range of experts and stakeholders, including representatives of the food industry, agricultural producers and nongovernmental organizations that represent the interests of consumers.”⁴²

B. *Control Over Imported Food*

According to USDA, imported food comprises 15 percent of the U.S. food supply by value and is on the rise at \$76 billion, a 12 percent increase over last year and twice the figure from 1998.⁴³ Today approximately 80 percent of seafood and 60 percent of fresh fruits and vegetables are imported;⁴⁴ one-third of fruits and nuts come from abroad, as do numerous ingredients that are components of U.S. products.⁴⁵ After Canada and Mexico, which at one-third share of total imports have been the largest suppliers of food, agricultural and seafood imports,⁴⁶ China is the third-largest food importer.⁴⁷ Despite the high-profile problem of the industrial chemical melamine in imports from China, most of the publicized incidents thus far have involved problems with domestic producers.⁴⁸

FSMA grants FDA more control over food imports, including increased inspection of foreign plants and the ability to set standards for how fruits and vegetables

³⁸ 21 U.S.C. § 350k (2011). Chapter IV (21 U.S.C. § 341 et seq.), as amended by section 201, is amended by adding at the end the following: “SEC. 422. LABORATORY ACCREDITATION FOR ANALYSES OF FOODS.”

³⁹ 21 U.S.C. § 2223 (2011).

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ Andrew Zajac, *Congress poised to pass ambitious food-safety bill*, LOS ANGELES TIMES, Dec. 21, 2011, <http://articles.latimes.com/print/2010/dec/21/business/la-fi-food-safety-20101221>.

⁴⁴ FDA, Food Safety Legislation Key Facts, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm237934.htm> (last updated Mar. 4, 2011).

⁴⁵ Zajac, *supra* note 43.

⁴⁶ GEOFFREY S. BECKER, CRS REPORT FOR CONGRESS: U.S. FOOD AND AGRICULTURAL IMPORTS: SAFEGUARDS AND SELECTED ISSUES, RL 34198, at 1-2 (Mar. 17, 2010), available at <http://www.nationalaglawcenter.org/assets/crs/RL34198.pdf>.

⁴⁷ Zajac, *supra* note 43.

⁴⁸ *Id.* But see BECKER, *supra* note 46, at 4-5 (discussing incidents involving adulterated pet food ingredients, farmed seafood, and dairy products and ingredients from China); SARAH A. LISTER & GEOFFREY S. BECKER, CRS REPORT FOR CONGRESS: FOOD SAFETY: FOODBORNE ILLNESS AND SELECTED RECALLS OF FDA-REGULATED FOODS, R40916, at 17-18 (Apr. 15, 2010), available at <http://www.nationalaglawcenter.org/assets/crs/R40916.pdf> (discussing melamine contamination of pet food ingredients from China—intentionally added to raise protein levels—which sickened or killed hundreds of dogs and cats in North America in 2007; and melamine or cyanuric acid contamination in milk).

are grown abroad. The new law further allows FDA to require importers to certify the safety of their foods before entering the U.S. food supply, based on risk criteria that the imported food is in compliance with food safety requirements, and authorizes FDA to refuse admission to imported food if the foreign facility or country refuses to allow an FDA inspection.⁴⁹ In addition, the legislation requires importers to perform supplier verification activities to ensure imported food is safe and provides an incentive for importers to take additional food safety measures by directing FDA to establish a voluntary program through which imports may receive expedited review of their shipments if the importer has taken certain measures to assure the safety of the food.⁵⁰

As an outgrowth of this new safety law, FDA has announced that it plans to work more closely with other countries and share findings, potentially reducing the number of plant inspections necessary per year.⁵¹ In an effort to leverage its limited resources, FDA intends to increase its reliance on third-party inspectors in an effort to outsource its oversight of overseas plants.⁵²

C. *Exemption for Small Farmers and Processors*

The Tester amendment exempts some producers and processors based on the size of their business, their geographic location or to whom they sell their products. Industry trade organizations have argued this inclusion of exemptions based on non-scientific qualifications will limit the ability of FDA to assure consumers that all foods they purchase, whether at grocery stores, restaurants, farm markets or elsewhere, have met the same food safety standards.

This concern was raised on the floor of the House of Representatives as a criticism of the Senate version of the bill, which has now become law.⁵³ The House version was more restrictive and did not contain these exclusions. However, the stronger House version did not gain support in the Senate and prompted strong opposition from small farmers and local producers.⁵⁴ Small farmers originally opposed this legislation fearing the increased costs and paperwork of regulation, while many grassroots organizations genuinely feared that the existence of small local farmers would be in jeopardy.

⁴⁹ Sections 301-310 of the FSMA, 21 U.S.C § 381 et seq. (2011).

⁵⁰ FDA, Food Safety Legislation Key Facts, *supra* note 44.

⁵¹ Catherine Larkin & Anna Edney, *More Outsourcing Planned for FDA Overseas Factory Inspections*, BLOOMBERG BUSINESSWEEK, Feb. 14, 2011, available at <http://www.bloomberg.com/news/2011-02-10/fda-to-outsource-international-plant-inspections-as-oversight-criticized.html>.

⁵² *Id.*; see also Sandra Hoffmann & William Harder, *The Future of Food Regulation: Food Safety and Risk Governance in Globalized Markets*, 20 HEALTH MATRIX 5 (2010) (recommending that global coordination of food safety management involve both collaboration among national governments, while maintaining national sovereignty, and private industries to ensure the safety of products along their international supply chains). See generally Adam I. Muchmore, *Private Regulation and Foreign Conduct*, 47 SAN DIEGO L. REV. 371, 419 (2010) (favoring a targeted ex ante approach that would focus on imported goods in narrowly defined regions and product categories).

⁵³ See 156 CONG. REC. H8212-13 (daily ed. Dec. 8, 2010) (statement of Rep. Lucas opposing the bill's inclusion of the Tester Amendment: "With respect to the Tester amendment, I question the value of any law that is so onerous to an industry that Senators believe segments of that industry should be excluded from it. It would be wise to reconsider the entire legislative approach.").

⁵⁴ See, e.g., Shermain D. Hardesty, *Do Government Policies Grow Local Food?*, 25 CHOICES (Agricultural & Applied Economics Association 2010), <http://ageconsearch.umn.edu/bitstream/93826/2/2010107%5B1%5D.pdf> (characterizing the FSMA as "another potential challenge to local food" in that the bill as originally introduced in Congress failed "to acknowledge the diversity of agriculture or different risks associated with various production and processing practices" and subjected small growers to increased expenses for record-keeping, food safety plans, and on-farm inspections).

In response to the fears expressed by small farmers, Senator Tester added an amendment providing exemptions from the most burdensome obligations such as food safety plans for small farmers and food processors, as well as traceability and recordkeeping requirements for small farms if they sell directly to consumers or grocery stores. The exemptions from FDA registration requirements only apply to farms that market more than 50 percent of their product directly from the farm or from farm stands or farmer's markets. The concessions made to accommodate their interests included less costly alternatives to HACCP (Hazard Analysis and Critical Control Plans) and a competitive grant program for food safety training with priority to small and mid-sized farms.

As stated by the National Sustainable Agriculture Coalition, “[a]s a result of grassroots mobilization and much negotiation this bill now provides scale-appropriate food safety rules for small farms and mid-sized farms and local processors that sell to restaurants, food coops, groceries, wholesalers and at farm stands and farmers markets.”⁵⁵

Major fruit and vegetable producers, along with some food safety advocates, opposed these exemptions but sensibly gave way to allow the broader measures to secure passage. Moreover, the modifications purportedly include safety measures that are more “scale-appropriate,” such as allowing on-farm processing and other flexible mechanisms through which small farms may comply with the preventative control plan and produce standards requirements, and providing a competitive grant program for food safety training with priority to small and mid-sized farms, beginning and socially disadvantaged farmers and small food processors.⁵⁶ FSMA does contain provisions that will have a direct effect on on-farm activity, particularly new on-farm safety standards, hazard analysis and risk-preventative controls and requirements for facility registration, records access and/or inspection and food traceability.⁵⁷ However, as enacted, the language takes into consideration the “potential economic and regulatory effects to small business.”⁵⁸

Although this component has raised questions about food safety at farmer's markets, gaining the support of a broad group of constituents was critical to securing passage of the bill. As noted earlier, this law is only a first measure—and a monumental one at that. But food safety benefits everyone. Accordingly, there should be continued FDA oversight and scrutiny of these smaller entities; nothing in the new law precludes such appropriate food safety regulation. One critic has further urged that “It remains imperative that the industry stays engaged throughout the proposed rulemaking process, submitting comments to FDA and ensuring that the loopholes created by Senator Tester's amendment are closed.”⁵⁹ As with any

⁵⁵ 156 CONG. REC. H8212 (daily ed. Dec. 8, 2010) (statement of Rep. Holt).

⁵⁶ See Center for Food Safety, FOOD SAFETY MODERNIZATION BILL Q&A, <http://true-foodnow.org/campaigns/food-safety/food-safety-modernization-bill-qa/> (last visited Apr. 12, 2011) (listing amendments added to support small farmers and processors who sell directly to consumers and end users) [hereinafter Center for Food Safety Q&A]; see, e.g., Section 204(d)(1)(E) of the FSMA, 21 U.S.C. § 2223 (2011) (“scale-appropriate” additional recordkeeping requirements for high risk foods).

⁵⁷ See RENÉE JOHNSON, CRS REPORT FOR CONGRESS, FOOD SAFETY ON THE FARM, RL34612, at 10-15 (Jan. 18, 2011), available at http://assets.opencrs.com/rpts/RL34612_20110118.pdf (discussing sections 105, 103, 102, 101, and 201 of the FSMA, respectively).

⁵⁸ *Id.* at 10, 15-18 (addressing mitigating effects on small businesses and farms) [hereinafter JOHNSON, CRS REPORT RL34612].

⁵⁹ Robert Guenther, *Why Wasn't Tester Tested?*, 27 PRODUCE BUSINESS 6 (Feb. 2011), available at <http://www.producebusiness.com/e-books/PB11Feb.pdf> (Senior Vice President of Public Policy, United Fresh Produce Association, characterizing the Tester Amendment as a loophole that will send the wrong message to the consumer and a weak link in the system, as food safety risk is not related to size or geography: “If we allow small producers to avoid oversight, the outbreaks that are likely to occur will result in the harm of all growers, handlers, processors, and shippers.”).

legislation, the finished product represents a compromise; but in the face of initial opposition from small grassroots farmers, by accommodating their needs the end result kept the business community relatively satisfied and able to comply with the newly tailored regulations.

D. Whistleblower Provision

FSMA contains a whistleblower provision that protects workers at food companies regulated by FDA from being fired, demoted or denied promotions or raises if they tell their employers or government officials about anything they reasonably believe violates the Federal Food Drug Cosmetic Act.⁶⁰ Section 402 of FSMA establishes protections for employees of entities involved in “the manufacture, processing, packing, transporting, distribution, reception, holding or importation of food” who provide information relating to any violation of this law, testify or assist in a proceeding concerning such a violation or object to performing work they reasonably believe would violate this law.⁶¹ Such entities may not “discharge an employee or otherwise discriminate against an employee with respect to compensation, terms, conditions or privileges of employment.”⁶²

Moreover, the burden of proof under this provision favors workers. Once a worker shows his or her participation in the protected activity may have been a factor leading to repercussions, the employer must show with “clear and convincing evidence” that the company would have taken the same action even if the worker had not been a whistleblower. The Department of Labor and federal courts can reinstate fired employees and award back pay, interest, attorneys’ fees and other damages.⁶³

Senator Tom Harkin (D-Iowa) made a written statement in support of this component: “Workers on the front lines should never have to hesitate to sound the alarm when they discover practices that could compromise public safety. Unless workers are free to speak out without fear of retaliation, we might never learn about threats to public safety until it’s too late.”⁶⁴

In addition, Government Accountability Project, a non-profit whistleblowing organization that supported the new safeguards, recently sponsored a conference in Washington to raise awareness of this provision.⁶⁵ As Tom Devine, the group’s legal director, explained, “Whistleblowers are the informational lifeline to warn the public when government-approved food might be a public health hazard. It occurs frequently because the regulatory system can’t hope to catch all the violations through spot checks.”⁶⁶

⁶⁰ Steve Karnowski, *New food safety law protects whistleblowers*, BLOOMBERG BUSINESSWEEK, Feb. 11, 2011, <http://www.businessweek.com/ap/financialnews/D9LAETEO0.htm>; STEPHEN MARTIN KOHN, *THE WHISTLEBLOWER’S HANDBOOK: A STEP-BY-STEP GUIDE TO DOING WHAT’S RIGHT AND PROTECTING YOURSELF* 41, 219, 285 (Globe Pequot 2011); *Protection for Whistleblowing Employees*, 19 No. 12 FDA ENFORCEMENT MANUAL NEWSL. 4 (2011).

⁶¹ 21 U.S.C. § 399d, amending Chapter X of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 391 et seq., by adding at the end the following: “SEC. 1012. EMPLOYEE PROTECTIONS.”

⁶² *Id.*

⁶³ *Id.*

⁶⁴ Karnowski, *supra* note 60.

⁶⁵ Lindsay Bigda, *AP – New Food Safety Law Contains Little-Noticed Whistleblower Protection: Whistleblower Daily News*, GOVERNMENT ACCOUNTABILITY PROJECT, Feb. 14, 2011, <http://www.whistleblower.org/blog/31-2010/990-ap-new-food-safety-law-contains-little-noticed-whistleblower-protection-whistleblower-daily-news> (linking to the Food Integrity Campaign conference, “*Employee Rights and the Food Safety Modernization Act*,” held in Washington on Feb. 11, 2011, <http://foodwhistleblower.org/learn-more/fic-conference-2011>).

⁶⁶ *Id.*

However, it is important to note that the law only covers food businesses regulated by FDA. Workers in the meatpacking and poultry industries, which are regulated by USDA, remain unprotected. Devine indicated that his group will advocate for similar protection for workers at USDA-regulated operations.⁶⁷

E. *Dispelling the Myths*

Opponents of the new food law have raised issues and concerns that are inaccurate or widely exaggerated. These unfounded fears have caused states' rights advocates in at least one state to propose exempting that state's food from federal regulation; a Utah legislator is proposing legislation that would exempt food grown and consumed entirely within his state from any federal regulation.⁶⁸ If the Utah bill passes, in a modern era of food and food products flowing frequently across state lines, it could be detrimental to a national system of food protection.⁶⁹

In support of the new law, the Center for Food Safety has published a list of several myths that circulated in the months leading to passage of the bill, emphasizing their lack of veracity.⁷⁰ For example, the claim that this legislation would regulate or outlaw backyard gardens or prohibit seed saving was dispelled by the language of the legislation and its focus on foods sold in supermarkets. Likewise, fears that farmers markets would be penalized or disbanded proved unwarranted as the amendments discussed above specifically excluded from the more onerous regulations smaller farmers and producers that sell directly to consumers. The myth that organic farming would be banned had no foundation in the new law, which only addressed the authority of FDA, whereas the National Organic Program (NOP) falls under the jurisdiction of USDA. Another rumor that lacked merit was the implementation of an animal ID tracking system, as such issues also remain in USDA's purview. Lastly, contrary to misconceptions, although FSMA allows FDA to issue recalls for tainted food supplements, the law does not initiate burdensome new regulations for the food supplement industry.⁷¹

This sweeping legislation is, however, expected to have a tremendous impact on all constituencies in the supply chain. The United Fresh Produce Association has released a report detailing the impacts and ramifications for produce growershippers, wholesalers and distributors, fruit and vegetable importers, retailers and foodservice operators, food transporters and the industry as a whole, and providing charts with an implementation timeline of these changes.⁷² Its Senior Vice President of Public Policy concludes: "The FDA Food Safety Modernization Act will mean

⁶⁷ Karnowski, *supra* note 60.

⁶⁸ Robert Gehrke, *Proposal would exempt Utah food from federal regulation*, THE SALT LAKE TRIBUNE, Feb. 5, 2011, <http://www.sltrib.com/sltrib/politics/51177864-90/bill-farmers-fda-federal.html.csp>.

⁶⁹ *Id.* (statement of David Plunkett, an attorney who specializes in food safety at the Center for Science in the Public Interest).

⁷⁰ See Center for Food Safety Q&A, *supra* note 56.

⁷¹ However, although the FSMA did not in its final version include provisions that would have addressed supplements, the issues that were debated—product safety, increasing penalties for unsafe products, mandatory reporting for all adverse effects, and expanding allowable health claims—could be raised again in the next Congress. See RENÉE JOHNSON, CRS REPORT FOR CONGRESS, FOOD SAFETY ISSUES FOR THE 112TH CONGRESS, R41629, at 12 (Feb. 10, 2011), available at http://assets.opencrs.com/rpts/R41629_20110210.pdf [hereinafter JOHNSON, CRS REPORT R41629].

⁷² United Fresh Produce Association, FDA FOOD SAFETY MODERNIZATION ACT OF 2010 LIKELY IMPACT ON THE PRODUCE INDUSTRY, Jan. 2011, http://www.unitedfresh.org/assets/food_safety/FDA_Food_Safety_Modernization_Act_White_Paper_January_2011.pdf.

significant changes for the fruit and vegetable industry.”⁷³ The United Fresh Produce Association has long supported food safety as a priority in its policy statements:

In addition to our own efforts, the produce industry also supports a strong role by the federal government in ensuring that produce sold in the United States is grown, packed and distributed in accordance with appropriate science-based safety standards. It is critical that American consumers have confidence that the federal government is exercising diligent and appropriate oversight of food safety standards and compliance for all foods, including fresh produce. For fresh fruits and vegetables, any breakdown in consumer trust of either government or industry in our mutual food safety responsibilities will lead to a loss of confidence in the very foods that we should all be eating more of to improve public health.⁷⁴

This trade association and others thus realize that safety is in the best interest of the food industry.

III. FUTURE HURDLES AND LIMITATIONS

Some of the features of FSMA have sparked criticism, such as the incremental timeframe that may be viewed as “weak” in that companies are permitted as long as 18 months to put in place food safety plans and government inspectors have up to five years to visit high-risk facilities with inspections required every three years thereafter.⁷⁵ The food safety director for the Center for Science in the Public Interest noted that “FDA asked for and was given a very long lead time for implementation. But it’s still a vast improvement over what we have today.”⁷⁶ Moreover, as discussed above, the law does not reach farmer markets and smaller producers with the same level of stringency, although some have lauded the flexibility of such scale-appropriate regulation.

In addition, this section will explore the potential limitations ahead due to funding challenges, the lack of increased penalties among the types of responses available to FDA and the continued fractionation of U.S. food policy. Most importantly, the success of this regulatory scheme in protecting the food supply relies upon the cooperation of and initiative from other administrative agency partners.

A. *Threat of Restricted Funding*

Despite the good intentions that gave rise to this legislation, there may be a potential problem due to funding, as implementing these enlarged powers for FDA will cost \$1.4 billion over the next five years.⁷⁷ The financial component of this

⁷³ Press Release, United Fresh Produce Association, United Fresh White Paper Details Impact of Food Safety Law On Produce, Produce Highlights, PerishableNews.com, Jan. 13, 2011, <http://www.perishablenews.com/index.php?article=0012385> (statement of Robert Guenther).

⁷⁴ United Fresh Produce Association, UNITED FRESH PRODUCE ASSOCIATION FOOD SAFETY POLICY WHITE PAPER, Jan. 25, 2009, <http://www.unitedfresh.org/assets/files/GR/United%20Fresh%20Food%20Safety%20White%20Paper%28final%20document%29.pdf>.

⁷⁵ See Center for Food Safety Q&A, *supra* note 56.

⁷⁶ Neuman, *House approves nation's food safety laws*, *supra* note 12 (statement of Caroline Smith DeWaal).

⁷⁷ The Congressional Budget Office (CBO) estimated that implementing the FSMA could increase net federal spending subject to appropriation by about \$1.4 billion over a five-year period (FY2011-FY2015). See JOHNSON, CRS REPORT R41629, *supra* note 71, at 6. It also authorizes an increase in FDA staff upwards of 5,000 in FY2014. *Id.*

legislation is critical to enable FDA to enforce the new requirements and carry out inspections.⁷⁸ According to FDA:

The funding we have available through the annual budget cycle and fees impacts the number of FTEs we have and will be a factor in the way that FDA handles its significant and far-ranging activities, including the way that this legislation is implemented. For example, the inspection schedule in the legislation would increase the burden on FDA's inspection functions. Without additional funding, FDA will be challenged in implementing the legislation fully without compromising other key functions. We look forward to working with Congress and our partners to ensure that FDA is funded sufficiently to achieve our food safety and food defense goals.⁷⁹

Some in the health care community are concerned that recent changes in Congress could stand in the way of funding some of the law's initiatives.⁸⁰ In the wake of recent budget battles, obtaining these essential appropriations may be difficult.⁸¹

However, as pointed out by the director of food and consumer safety programs for the Pew Health Group, "the health care costs associated with an outbreak of contaminated food alone run into the tens of billions of dollars—far beyond what it would cost to put the law's new requirements into place."⁸² Moreover, as Senator Harkin, a lead sponsor of the bill, emphasized: "Fiscal responsibility does not necessitate abandoning or neglecting the need of American consumers for safe food."⁸³

In spite of recent political rhetoric, there has been and should continue to be a broad coalition of support because this initiative actually benefits business. Businesses have lost enormous amounts of money in recent years from food scares, as these incidents caused by the poor practices of a small number of suppliers have cost entire industries billions of dollars (e.g., *E. coli* bacteria in spinach, Salmonella in eggs and sprouts), many of which are still building back consumer confidence and recovering their market share years later. The Grocery Manufacturers Associa-

⁷⁸ See SARAH A. LISTER, CRS REPORT FOR CONGRESS, PUBLIC HEALTH AND MEDICAL EMERGENCY MANAGEMENT: ISSUES IN THE 112TH CONGRESS, R41646, at 19 (Feb. 18, 2011), available at http://assets.opencrs.com/rpts/R41646_20110218.pdf.

⁷⁹ FDA, Food Safety Modernization Act (FSMA), Frequently Asked Questions, <http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm#general5> (last visited Apr. 10, 2011).

⁸⁰ Charlotte Tucker, *New law will empower FDA to improve safety of U.S. food: Act requires inspections, improves recalls*, 41 THE NATION'S HEALTH 1 (2011), <http://thenationshealth.aphapublications.org/content/41/1/1.3.short>.

⁸¹ See, e.g., Helena Bottemiller, *Food Safety Funding Unclear in Budget Deal Cutting*, FOOD SAFETY NEWS, Apr. 5, 2011, <http://www.foodsafetynews.com/2011/04/congress-works-to-cut-budget-deal-food-safety-impact-unclear/>; Helena Bottemiller, *Continuing Resolution Has Food Safety Cuts*, FOOD SAFETY NEWS, Feb. 22, 2011, <http://www.foodsafetynews.com/2011/02/house-approves-continuing-resolution-with-61-billion-in-cuts/>; Helena Bottemiller, *Dingell Demands Congress Fund New Food Safety Law*, FOOD SAFETY NEWS, Feb. 11, 2011, <http://www.foodsafetynews.com/2011/02/dingell-demands-congress-fund-new-food-safety-law/>; Helena Bottemiller, *GOP Plan May Slash Food Safety Funding 42 Percent*, FOOD SAFETY NEWS, Jan. 26, 2011, <http://www.foodsafetynews.com/2011/01/gop-proposal-could-slash-food-safety-funding-42-percent/>; Rebecca W. Rimel & Pamela G. Bailey, *More FDA funding needed to ensure food safety*, THE HILL'S CONGRESS BLOG, Jan. 13, 2011, <http://thehill.com/blogs/congress-blog/healthcare/137701-more-fda-funding-needed-to-ensure-food-safety>; Molly Peterson, *Food-Safety Funding Battle Looms as Obama Prepares to Sign Reform Bill*, BLOOMBERG, Jan. 4, 2011, <http://www.bloomberg.com/news/2011-01-04/food-safety-funding-battle-looms-as-obama-prepares-to-sign-reform-bill.html>. See also Food Safety Network, *Lawmakers grill Vilsack on USDA food safety budget*, MCPHERSONSENTINEL.COM, Mar. 11, 2011, <http://www.mcphersonsentinel.com/agriculture/x1777802219/Lawmakers-grill-Vilsack-on-USDA-food-safety-budget>.

⁸² Superville & Jalonic, Associated Press, *supra* note 28 (statement of Erik Olson).

⁸³ *Id.*

tion supports the new safety standards as necessary for the industry, pointing to a spinach recall in 2006 from *E. coli* at one California grower that scared consumers and retailers nationwide so that sales have not fully recovered: “One actor can impact the sales of an entire category.”⁸⁴

The fact that this law has received such widespread support from industry trade groups of food producers and grocery stores and the U.S. Chamber of Commerce, as well as food safety and consumer groups, indicates that the food industry realizes a preventative approach of heightened food safety is actually a boon to business.

B. *Limits to FDA Responses for Compliance Failures*

One of the criticisms of the new law is that it does not increase FDA penalties against producers who knowingly ship tainted food to consumers.⁸⁵ However, Section 106 of FSMA requires the Secretary of HHS, in coordination with the Secretary of Homeland Security and in consultation with the Secretary of Agriculture, to promulgate regulations to protect against the intentional adulteration of food with mitigation strategies and protective measures that target high risk foods and provide for the assessment of fees to cover the administrative costs.⁸⁶

Moreover, FSMA provides a range of possible responses available to FDA, from mandatory recall to expanded administrative detention to suspension of the registration of a facility.⁸⁷ Included in Section 202 is a national food emergency response laboratory network that “provides ongoing surveillance, rapid detection and surge capacity for large-scale food-related emergencies, including intentional adulteration of the food supply.”⁸⁸ In addition, Section 206 provides authority to issue a civil penalty against any person who does not comply with a recall order.⁸⁹ Although stricter criminal and civil penalties were not included in the final bill, there are signs that legislation to increase these enforcement measures may be considered again in the current Congress.⁹⁰

⁸⁴ Mundy & Tomson, *supra* note 16 (statement of Scott Faber, a vice president of the Grocery Manufacturers Association, which represents companies such as Del Monte Foods Co.). *But see* Sarah Taylor Roller et al., *FDA's Expanding Postmarket Authority to Monitor and Publicize Food and Consumer Health Product Risks: The Need for Procedural Safeguards to Reduce “Transparency” Policy Harms in the Post-9/11 Regulatory Environment*, 64 *FOOD & DRUG L.J.* 577, 597-98 (2009) (cautioning further expansions of FDA authority without procedural safeguards to protect public and regulated companies from undue harm from FDA enforcement actions and product safety warnings).

⁸⁵ Center for Food Safety Q&A, *supra* note 56; *see* Rena Steinzor, *High Crimes, Not Misdemeanors: Deterring the Production of Unsafe Food*, 20 *HEALTH MATRIX* 175 (2010) (proposing enhancing the penalty provisions in the legislation while pending and providing a defense for corporate actors who exercise due diligence in complying with strengthened regulations).

⁸⁶ 21 U.S.C. § 350i (2011); Chapter IV (21 U.S.C. § 341 et seq.), as amended by section 105, is amended by adding at the end the following: “SEC. 420. PROTECTION AGAINST INTENTIONAL ADULTERATION.”

⁸⁷ FDA, Background on the FDA Food Safety Modernization Act (FSMA), *supra* note 32. *See, e.g.*, Section 207, providing language that strengthens FDA authority for administrative detention of food, 21 U.S.C. § 334(h)(1)(A) (2011); and Section 102(b), that the FDA can suspend registration of a facility for food which has a “reasonable probability of causing serious adverse health consequences or death to humans or animals,” 21 U.S.C. § 350d (2011).

⁸⁸ 21 U.S.C. § 350k (2011).

⁸⁹ 21 U.S.C. § 350l (2011); Chapter IV (21 U.S.C. 341 et seq.), as amended by section 202, is amended by adding at the end the following: “SEC. 423. MANDATORY RECALL AUTHORITY.”; *see also* FDA, Food Safety Modernization Act (FSMA), Frequently Asked Questions, <http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm#fees3>.

⁹⁰ *See* JOHNSON, CRS REPORT R41629, *supra* note 71, at 11.

C. Need for Initiative from Other Agency Partners

FSMA only addresses the powers of FDA. However, FDA is only one of the regulatory agencies in this area, given responsibility for overseeing most of the nation's food supply. The new law does not deal with the safety of meat and poultry, which are in the purview of USDA. Nor does FSMA cover the scope and powers of the Environmental Protection Agency (EPA), which as the third "partner" is given a particularly prominent role in the regulation of genetically modified (GM) crops.⁹¹

A recent study estimated that nearly half of the U.S. meat and poultry supply is tainted with staph bacteria, much of which is antibiotic resistant.⁹² Moreover, although recalls of *E. coli* in meat and poultry remained relatively low in 2010, the number was more than double the figure from the previous year.⁹³ Apparently in reaction to 2008 abuse allegations that led to the largest beef recall in U.S. history, and as part of an initiative announced by President Obama, USDA recently altered the rule that allowed cows that are too sick or injured to stand to be slaughtered for meat.⁹⁴ Changes in nutrition labels for meat are also on the horizon.⁹⁵

Some critics say food policy and its implementation are too fractionated.⁹⁶ In every Congress since the 105th, the idea of a single federal food agency has been

⁹¹ For a discussion of genetically modified (GM) crops, see *infra* Part V.

⁹² After testing 136 packages of chicken, turkey, pork, and ground beef purchased at 26 grocery stores in five cities around the country, the researchers discovered that 47 percent contained *Staphylococcus aureus* (*S. aureus*), a common cause of infection in people. In addition, roughly half of the contaminated samples contained strains of the bacteria that were resistant to at least three antibiotics, such as penicillin and tetracycline; and some strains were resistant to a half dozen or more. See Amanda Gardner, *Bacteria seen in nearly half of U.S. meat*, CNN: HEALTH.COM, Apr. 15, 2011, <http://www.cnn.com/2011/HEALTH/04/15/bacteria.in.half.US.meat/index.html>; Aman Ali, *Bacteria in grocery meat resistant to antibiotics*, REUTERS, Apr. 15, 2011, <http://www.reuters.com/article/2011/04/15/us-bacteria-meat-idUSTRE73E7FJ20110415>.

⁹³ Dan Flynn, *E. coli Meat Recalls Remain Low in 2010*, FOOD SAFETY NEWS, Dec. 14, 2010, <http://www.foodsafetynews.com/2010/12/e-coli-recalls-up-about-one-third-over-09-but-still-low/> (recalls of meat and poultry contaminated with the most dangerous *E. coli* bacteria, although relatively low, were up by more than double from the previous year, with 11 recalls involving 2,339 million pounds of meat according to the USDA).

⁹⁴ See *U.S. toughens rules on sick cattle*, STAR-TELEGRAM, Dec. 22, 2010, <http://www.star-telegram.com/2010/12/22/v-print/2723799/usda-toughens-rules-on-sick-cattle.html>; The White House, Remarks of President Barack Obama, Weekly Address: President Barack Obama Announces Key FDA Appointments and Tougher Food Safety Measures, Mar. 14, 2009, http://www.whitehouse.gov/the_press_office/Weekly-Address-President-Barack-Obama-Announces-Key-FDA-Appointments-and-Tougher-F/; see also Farm Sanctuary, Petition to Amend 9 C.F.R. § 309.3(e) to Prohibit the Slaughter of Non-Ambulatory Pigs, Sheep, Goats, and Other Livestock and to Require that Such Animals be Humanely Euthanized, Mar. 15, 2010, http://www.fsis.usda.gov/PDF/Petition_Humane_Handling.pdf.

⁹⁵ Elizabeth Weise, *Nutrition labels on cuts of meat to debut in 2012*, USA TODAY, Dec. 29, 2010, http://www.usatoday.com/yourlife/food/diet-nutrition/2010-12-29-1Ameatlabels29_ST_N.htm (USDA announced nutrition labels will be required on meats beginning Jan. 1, 2012, listing calories, calories from fat, total fat, saturated fat, cholesterol, sodium, protein, and vitamins for 40 of the most commonly purchased cuts of beef, poultry, pork, and lamb).

⁹⁶ In the United States, food safety is regulated by 30 federal statutes, 15 federal agencies, and 400 state agencies. *Hearing to Review Current Food Safety Systems Before the H. Comm. on Agriculture*, 111th Cong. 50-57 (2009) (statement of Carol L. Tucker-Foreman, Distinguished Fellow, The Food Policy Institute at Consumer Federation of America), cited in Sara M. Benson, *Guidance for Improving the Federal Response to Foodborne Illness Outbreaks Associated with Fresh Produce*, 65 FOOD & DRUG L.J. 503, 504 (2010) (providing guidelines and suggestions for improving the way FDA and CDC respond to foodborne illness outbreaks caused by fresh produce); see also Caroline Scott-Thomas, *Food safety fragmentation still a problem says GAO*, FOOD NAVIGATOR-USA.COM, Mar. 21, 2011, <http://www.foodnavigator-usa.com/Legislation/Food-safety-fragmentation-still-a-problem-says-GAO/>; Sandra Hoffmann, *Food Safety Policy and Economics: A Review of the Literature*, RESOURCES FOR THE FUTURE, Discussion Paper RFF DP 10-36, at 14 (July 2010), <http://indiaenvironmentportal.org.in/files/Food%20Safety%20Policy.pdf>; Nathan M. Trexler, Note, "Market" Regulation: Confronting Industrial Agriculture's Food Safety Failures, 17 WIDENER L. REV. 311 (2011) (proposing a framework for reform of U.S. food safety by prioritizing prevention, strengthening surveillance and enforcement, improving response and recovery, and increasing support of local food systems).

debated.⁹⁷ According to the Center for Food Safety, a separate and effective government agency dedicated to food safety must be established: “We need to separate out the ‘Food’ part of the Food and Drug Administration and consolidate all authority under a new Food Safety Agency.”⁹⁸ Others question the limits of FDA in terms of its scientific expertise.⁹⁹ At the very least, in keeping with the new mandate of food safety, the regulations and authority of these agencies should be reexamined.

Bringing together these agencies in a coordinated effort is a goal of President Obama in establishing the Food Safety Working Group (FSWG), which was created in March 2009 to advise the president on modernizing food safety laws in the United States.¹⁰⁰ Chaired by the Secretary of HHS and the Secretary of Agriculture, FSWG is “recommending a new, public health-focused approach to food safety based on three core principles: prioritizing prevention; strengthening surveillance and enforcement and improving response and recovery.”¹⁰¹

A recent report by the Government Accountability Office (GAO) concluded that more work needs to be done to address fragmented oversight of U.S. food safety:¹⁰²

Through FSWG, federal agencies have taken steps designed to increase collaboration in some areas that cross regulatory jurisdictions—in particular, improving produce safety, reducing *Salmonella* contamination and developing food safety performance measures. However, FSWG has not developed a governmentwide performance plan for food safety that provides a comprehensive picture of the federal government’s food safety efforts.¹⁰³

Regarding FSMA, GAO observed that it “strengthens a major part of the food safety system; however, it does not apply to the federal food safety system as a whole or create a new risk-based food safety structure.”¹⁰⁴ As a consequence of this substantial action for securing food safety, the time is ripe for a reassessment of other areas of food laws, as well as the roles these agencies will play together in implementing their charge.

⁹⁷ JOHNSON, CRS REPORT R41629, *supra* note 71, at 13 (explaining that while some continue to push for this level of consolidation on the grounds that it would improve the efficiency and effectiveness of food safety regulation, others worry that it could “unnecessarily compromise day-to-day food safety efforts”). See, e.g., Richard J. Durbin, *Food Safety Oversight for the 21st Century: The Creation of a Single, Independent Federal Food Safety Agency*, 59 FOOD & DRUG L. J. 383, 383 (2004).

⁹⁸ Center for Food Safety Q&A, *supra* note 56.

⁹⁹ Erik Stokstad, *Food Safety Law Will Likely Strain FDA Science*, 331 SCIENCE 270 (2011). See generally ENHANCING FOOD SAFETY: THE ROLE OF THE FOOD AND DRUG ADMINISTRATION (Robert B. Wallace & Maria Oria, eds., National Academies Press 2010).

¹⁰⁰ Scott-Thomas, *Food safety fragmentation still a problem says GAO*, *supra* note 96; President’s Food Safety Working Group, <http://www.foodsafetyworkinggroup.gov/> (last visited Apr. 17, 2011).

¹⁰¹ President’s Food Safety Working Group, About the President’s Food Safety Working Group (FSWG), <http://www.foodsafetyworkinggroup.gov/ContentAboutFSWG/HomeAbout.htm> (last visited Apr. 17, 2011).

¹⁰² Scott-Thomas, *Food safety fragmentation still a problem says GAO*, *supra* note 96, citing U.S. GOVERNMENT ACCOUNTABILITY OFFICE (GAO), REPORT TO CONGRESSIONAL COMMITTEES, FEDERAL FOOD SAFETY OVERSIGHT: FOOD SAFETY WORKING GROUP IS A POSITIVE FIRST STEP BUT GOVERNMENTWIDE PLANNING IS NEEDED TO ADDRESS FRAGMENTATION, GAO-11-289 (2011), available at <http://www.gao.gov/new.items/d11289.pdf> [hereinafter GAO REPORT]; see also Teddi Dineley Johnson, *2012 budget proposal would mean cuts for public health: CDC programs slated for reduction*, 41 THE NATION’S HEALTH 1 (Apr. 2011), <http://thenationshealth.aphapublications.org/content/41/3/1.4.full> (President’s proposed budget seeks to strengthen the President’s Food Safety Working Group as well as to fund key provisions of the FSMA). See generally GAO, FEDERAL FOOD SAFETY AND SECURITY SYSTEM: FUNDAMENTAL RESTRUCTURING IS NEEDED TO ADDRESS FRAGMENTATION AND OVERLAP, GAO-04-588T, at 7 (2004), available at <http://www.gao.gov/new.items/d04588t.pdf>.

¹⁰³ GAO, HIGHLIGHTS OF GAO REPORT, available at <http://www.gao.gov/highlights/d11289high.pdf>.

¹⁰⁴ *Id.*; see also GAO, FOOD SAFETY: AGENCIES NEED TO ADDRESS GAPS IN ENFORCEMENT AND COLLABORATION TO ENHANCE SAFETY OF IMPORTED FOOD, GAO-09-873 (2009), available at <http://www.gao.gov/new.items/d09873.pdf>.

IV. SIGNIFICANCE AND BREADTH OF THIS MANDATE

With bipartisan support from both houses of Congress and the President, this new legislation represents a mandate that food safety is at this moment becoming a priority.¹⁰⁵ Other voices have contributed to the passage of this legislation and will be necessary partners for the successful implementation of this food safety initiative. This section explores the significance and breadth of this mandate from the perspectives of Congress, the President, agencies such as FDA, food safety and consumer groups and the food industry itself.

A. *Congressional Consensus*

FSMA represents a rare moment of bipartisan support, although it will depend on continual support and funding to sustain its mandate, thereby ensuring that this legislation was not merely a fleeting and illusory promise. In addition, as at least one specialist in agricultural policy has observed, Congress will need to “provide oversight and scrutiny over how the law is implemented, including FDA’s coordination with other federal agencies, such as those in the U.S. Department of Agriculture (USDA) and the Department of Homeland Security (DHS).”¹⁰⁶ Overall, as Representative Rush Holt (D-N.J.) asserted from the floor of the House, “These clear instances of food contamination highlight that we are long overdue in passing comprehensive food safety legislation. . . the bill before us today includes many of those important reforms, and represents the most comprehensive set of food safety reforms put forth since the 1930’s.”¹⁰⁷

B. *Presidential Priority*

Improving food safety in the United States has been one of the top goals of the Obama administration. In highlighting the recent incidents of food contamination and announcing the creation of FSWG, the President stressed that the lack of inspections of 95 percent of the food processing plants and warehouses each year due to underfunding was “a hazard to public health” and “unacceptable,” and he affirmed that “Protecting the safety of our food and drugs is one of the most fundamental responsibilities government has.”¹⁰⁸ Acknowledging that there is more work to be done, President Obama commented earlier on the food safety initiative:

Today, I thank the House for its work and support efforts in the Senate to pass S. 510, the FDA Food Safety Modernization Act. This bipartisan bill would complement the work already undertaken by the Food Safety Working Group. The bill addresses longstanding challenges in the food safety and defense system by promoting a prevention-oriented approach to the safety of our food supply and provides the Federal Government with the appropriate tools to accomplish its core food safety goals.¹⁰⁹

¹⁰⁵ See *Professor says nation’s pending landmark food safety law represents a mandate*, FAIRFIELD MINUTEMAN, Dec. 30, 2010, A6; Fairfield University Press Release, Fairfield University professor Debra M. Strauss says nation’s pending landmark food safety law represents a mandate, Dec. 22, 2010, http://www.fairfield.edu/press/pr_index.html?id=2935.

¹⁰⁶ JOHNSON, CRS REPORT RL34612, *supra* note 57, at 10.

¹⁰⁷ 156 CONG. REC. H8212 (daily ed. Dec. 8, 2010) (statement of Rep. Holt).

¹⁰⁸ Remarks of President Barack Obama, Mar. 14, 2009, *supra* note 94.

¹⁰⁹ The White House, Statement by the President on Food Safety, July 7, 2010, <http://www.whitehouse.gov/the-press-office/statement-president-food-safety>, cited in Scott-Thomas, *Obama says new food safety legislation would promote prevention*, *supra* note 9.

He also noted the work of FDA in conducting a pilot study on a tracing system and HHS, which in collaboration with USDA implemented an enhanced website to provide consumers with more readily available information on food recalls.¹¹⁰

C. *FDA Feedback*

In support of FSMA, FDA Commissioner Margaret Hamburg proclaimed:

Today's passage of the Food Safety Modernization Act has laid the critical foundation for a prevention-based 21st Century food safety system. This law makes everyone responsible and accountable at each step in today's global food supply chain. Under this new law, FDA will now have new prevention-focused tools, as well as a clear regulatory framework, to help make substantial improvements in our approach to food safety. Preventing foodborne illness is a core public health principle that is especially critical in an increasingly complex and globalized world. This law helps us take the critical steps toward strengthening the food safety system that is vital to the health and security of the American people.¹¹¹

Commissioner Hamburg further explained that although the idea of prevention is not new, "What's new is the recognition that, for all the strengths of the American food system, a breakdown at any point on the farm-to-table spectrum can cause catastrophic harm to the health of consumers and great disruption and economic loss to the food industry. So, we need to look at the food system as a whole, be clear about the food safety responsibility of all of its participants, and strengthen accountability for prevention through the entire food system – domestically and internationally."¹¹² She pledged, in accordance with the law, to establish science-based standards for the safe production and harvesting of fruits and vegetables and to set standards for the safe transportation of food. "Moreover, with the signing of the law FDA will for the first time have a congressional mandate for risk-based inspection of food processing facilities."¹¹³ In implementing this mandate, FDA recognizes the need to strengthen its collaboration with all food safety agencies—Federal, state, local, territorial, tribal and foreign: "Building and leveraging the capacity of these food safety partners is how we can have a well-integrated, national food safety system that is as effective *and* efficient as it can be."¹¹⁴

D. *Consumer Confidence*

FSMA has received the support of a broad group of food safety and consumer groups. At the time of its passage, the Director the Food Policy Institute at the Consumer Federation of America commented:

¹¹⁰ *Id.* (referencing www.foodsafety.gov, a website for consumers with food safety recalls that includes the following statement by President Obama: "There are certain things only a government can do. And one of those things is ensuring that the foods we eat are safe and do not cause us harm.").

¹¹¹ FDA, Commissioner's Statement on the Food Safety Modernization Act, Statement by Margaret A. Hamburg, Commissioner of Food and Drugs, Dec. 21, 2010, <http://www.fda.gov/Food/FoodSafety/FSMA/ucm238000.htm> (last visited Apr. 15, 2011).

¹¹² Margaret A. Hamburg, *Food Safety Modernization Act: Putting the Focus on Prevention*, THE WHITE HOUSE BLOG, Jan. 3, 2011, <http://www.whitehouse.gov/blog/2011/01/03/food-safety-modernization-act-putting-focus-prevention>.

¹¹³ *Id.*

¹¹⁴ *Id.*

Passage of this legislation has been critical to providing FDA with the tools and authorities necessary to better protect consumers from foodborne illness. Importantly, this bill requires a fundamental shift in the FDA's food safety program from reacting to illnesses and deaths to preventing them in the first place.¹¹⁵

Likewise, the Director for the Center for Food Safety stated: "Passing Food Safety legislation is a significant victory for consumers who stand at the front lines of this country's war on food-borne illness. This legislation will finally give FDA the long awaited mandatory recall authority it needs to ensure that the same companies who sicken the public do not dictate the recall of their products."¹¹⁶ In sum, the Director of Food Policy Initiatives of the Consumers Union explained:

This is a big victory for consumers that finally brings food-safety laws into the 21st century. This win is a powerful testament to the people across the country who came to Washington to tell their lawmakers how contaminated food had killed their loved ones or left them horribly sick. This win is for them and all Americans.¹¹⁷

This initiative clearly came from consumers to Congress, joined by industry representatives with a shared goal of food safety.

E. *Industry Interests*

When incidents of tainted food mounted in recent years, causing declines in consumer confidence in food companies and increases in recall costs, the industry also came forward to call for an upgrade in food safety laws.¹¹⁸ The resulting bill received the blessing of such prominent food and beverage industry organizations as the Grocery Manufacturers Association, the Food Marketing Institute and the American Frozen Foods Institute.¹¹⁹ Upon the bill's passage, the Grocery Manufacturers Association issued a statement of support: "The food and beverage industry is committed to partnering with Congress, the administration and FDA to strengthen and modernize our nation's food safety system."¹²⁰

The fact that this law has received such widespread backing from industry trade groups of food producers and grocery stores and the U.S. Chamber of Commerce, as well as food safety and consumer groups, indicates that the food industry realizes a preventative approach of heightened food safety is economically prudent.

V. OTHER AREAS FOR REASSESSMENT

In light of this considerable movement in the right direction towards enhancing food safety, the moment is ideal for a reexamination of other areas of food

¹¹⁵ Bottemiller, *Food Safety Bill Heads to President's Desk*, *supra* note 26 (statement of Chris Waldrop).

¹¹⁶ Press release, Center for Food Safety, Obama to Sign Landmark Food Safety Legislation, Dec. 22, 2010, <http://www.centerforfoodsafety.org/2010/12/22/obama-to-sign-landmark-food-safety-legislation/> (statement of Andrew Kimbrell); *see also* Mike Mitka, *Food Safety Bill*, 305 JAMA: J. AM. MED. ASSOC. 1385 (2011).

¹¹⁷ Layton, *Food-safety bill backed by House*, *supra* note 25 (statement of Jean Halloran).

¹¹⁸ Scott-Thomas, *Obama says new food safety legislation would promote prevention*, *supra* note 9.

¹¹⁹ *Id.*

¹²⁰ Neuman, *House approves nation's food safety laws*, *supra* note 12.

laws—particularly GM foods and the use of milk and meat from cloned animals and their progeny—which are allowed under current U.S. law with no labeling, preapprovals or post-market monitoring, unlike our counterparts overseas.¹²¹ In addition to causing agricultural trade problems, these areas warrant special regulation because they raise concerns for consumers on the safety of the national and global food supply.¹²²

Much attention has been focused on the component of the new law that gives FDA authority to restrict imports by holding overseas suppliers to U.S. safety standards, mandating inspections of overseas plants and requiring importers to certify the safety of their foods before entering the U.S. food supply. Ironically in the area of genetically modified organisms (GMOs) in food, which are not addressed by FSMA, the laws overseas are more stringent than those of the United States. The international community generally applies a precautionary approach in the face of scientific uncertainty that does not allow GM crops unless they are proven to be safe, whereas the United States takes the opposite stance.¹²³ In fact, the United States has had more difficulty getting its food products accepted into overseas markets because U.S. agricultural products are largely viewed as “contaminated” with GMOs as the United States fails to label, monitor or even segregate these crops. Instead of adopting the stricter international standards, the United States has been pushing to open foreign markets to its products through filing trade actions with the World Trade Organization (WTO).¹²⁴

As a conservative estimate according to the Grocery Manufacturer’s Association, more than 75 percent of the products in U.S. grocery stores contain GM ingredients.¹²⁵ The lack of labeling of these GM foods also raises numerous ethical issues. For instance, does the failure to require labeling and monitoring violate the right of consumers to informed consent by not allowing them a choice as to whether they knowingly and willingly assume the risks of ingesting GMOs? Is the government breaching its duties to and responsibilities for the public by failing to ensure the safety of the food supply?¹²⁶

¹²¹ See Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 182-89 (2006) (discussing the U.S. laissez-faire regulatory treatment of GMOs).

¹²² See Debra M. Strauss, *Genetically Modified Organisms in Food: A Model of Labeling and Monitoring With Positive Implications for International Trade*, 40 INT’L LAW. 95, 96 (2006) (analyzing the differing regulatory approaches of the United States and the EU as a reflection of the cultural views of risk and scientific uncertainty with an impact on international trade).

¹²³ See Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the EU Ban of GM Foods*, 45 AM. BUS. L.J. 775, 781-82 (2008) (characterizing the EC-Biotech dispute as a disruption in trade between the United States and EU caused by their different regulatory approaches toward GMOs, which are in turn a reflection of the differing views and levels of concern about genetically modified food in the face of scientific uncertainty).

¹²⁴ *Id.* at 782-83.

¹²⁵ The Grocery Manufacturers of America (GMA) estimates that 75% of all processed foods in the United States contain a genetically modified ingredient, including almost every product with a corn or soy ingredient and some containing canola or cottonseed oil. The Associated Press, *Americans Clueless About Gene-Altered Foods*, Mar. 23, 2005, <http://www.msnbc.msn.com/id/7277844/> (statement of Stephanie Childs, GMA), cited in Debra M. Strauss, *The Application of TRIPS to GMOs: International Intellectual Property Rights and Biotechnology*, 45 STAN. J. INT’L L. 287, 289 (2009) (analyzing the intellectual property treatment of genetically engineered seeds as asserted by the industry and proposing a model that would promote constructive innovation for the public benefit by encouraging “socially responsible technology”).

¹²⁶ See Debra M. Strauss, *Defying Nature: The Ethical Implications of Genetically Modified Plants*, 3 J. FOOD L. & POL’Y 1, 8-9 (2007) (discussing the failed promise of this technology and presenting an ethical framework in support of labeling and monitoring).

A precautionary approach would be more in keeping with the new mandate for FDA to be proactive in the area of food safety, embodied in both FSMA and FSWG. Rather than waiting to see if GMOs are proven to be unsafe—at which point it would be exceedingly difficult, if not impossible, due to the lack of labeling or traceability to withdraw these substances—it would seem to make more sense at the very least to require labeling and segregation from non-GM foods at the outset. Moreover, a strict regulatory structure that would mandate additional studies and pre-screening for approval, as well as post-market monitoring, would be the most prudent approach consistent with the new proactive policy.¹²⁷ Doing so would also signal to our overseas counterparts that the United States is serious about the new emphasis on food safety and expects foreign suppliers to comply with the inspection and certification requirements imposed on them under the new U.S. law. By enacting regulations more consistent with international law in the area of GMOs, the U.S. government would be opening foreign markets to U.S. agricultural products, thereby strengthening international trade as well as FSMA.¹²⁸ Thus, U.S. policy would appear consistent with and reciprocal to the international community.

Similarly, in the area of cloned food products, the United States is at odds with the safety concerns expressed by the international community.¹²⁹ Despite health and environmental fears raised in the public comments to the proposed rule, FDA relied upon its doctrine of “substantial equivalence” to reason that no hazards had been shown to be inherent in the technology sufficient to justify treating these substances differently than non-cloned food.¹³⁰ FDA’s recent perfunctory approval of the use of milk and meat from cloned animals and their progeny without labeling, tracing, or monitoring now seems to be inconsistent with the mandate of their new proactive policy.¹³¹

There are signs that this new climate of food safety may translate into further changes in the law. Currently Congress is considering such issues as “food safety initiatives covering meat, poultry and seafood products; legislation intended to curtail the non-medical use of antibiotics in animal feeds and to ban the use of

¹²⁷ See Debra M. Strauss, *We Reap What We Sow: The Legal Liability Risks of Genetically Modified Food*, 16 J. LEGAL STUD. BUS. 149 (2010) (analyzing the legal liability risks of GMOs and concluding that the interests of seed companies, farmers, and consumers will converge in this area to mandate greater certainty and safety) [hereinafter Strauss, *Legal Liability Risks*].

¹²⁸ See generally Debra M. Strauss & Melanie C. Strauss, *Globalization and National Sovereignty: Controlling the International Food Supply in the Age of Biotechnology*, 15 J. LEGAL STUD. BUS. 75 (2009) (analyzing the implications of the WTO’s food trade dispute decision on nation-state control in the regulation of its food supply, and multilateral environmental and trade agreements; concluding that the WTO has exceeded its scope of international trade and that perhaps another supranational organization should be formed to regulate the world’s food supply as a scientific and policy-making entity that would take into account public health, safety, and sustainability).

¹²⁹ See Charlie Dunmore, *EU talks on food from cloned animals collapse*, REUTERS, Mar. 29, 2011,

¹³⁰ <http://www.reuters.com/article/2011/03/29/us-eu-food-clones-idUSTRE72S1SL20110329> (after three years of debate within the European Union, the EU nation governments rejected a compromise that would have dropped their ban on the sale of food from the conventionally bred offspring of cloned animals in return for mandatory labeling, risking a “full blown trade war” with the United States, which already exports food products derived from the young of cloned animals). See Animal Cloning Risk Assessment, 73 Fed. Reg. 2923 (Jan. 16, 2008); FDA, CVM and Animal Cloning, <http://www.fda.gov/cvm/cloning.htm> (last visited Apr. 16, 2011); see also FDA, For Consumers, Animal Cloning and Food Safety, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm148768.htm?sms_ss=email&at_xt=4cffd4e737cf833e%2C0 (last visited Apr. 16, 2011).

¹³¹ See, e.g., Center for Food Safety, Cloned Animals, <http://www.centerforfoodsafety.org/campaign/cloned-animals/> (last visited Apr. 16, 2011) (warning that the FDA acted irresponsibly in ignoring the public comments and the will of Congress in assuming that foods from cloned animals is safe; moreover, FDA’s own veterinary medicine advisory panel criticized the agency for its position because not enough research has been done to overcome the numerous health and ethical concerns).

certain plastic components commonly used in food containers; food labeling and the use of plant and animal biotechnology.”¹³²

In the area of genetically modified food, although supporters of this technology from agricultural states have previously prevailed, the new focus on safety issues may turn the tide to scrutinize the adequacy of a U.S. regulatory framework that predates the advent of agricultural biotechnology. Ongoing issues associated with the widespread use of GM crops include concerns about increased herbicide resistant weeds as well as the cross-contamination of other traditional and organically grown crops.¹³³ In addition, while FDA appears poised to approve genetically engineered (GE) salmon as the first GE food animal to be approved for human consumption, the Senate has reintroduced a bill to ban GE salmon and a bill to require labeling if GE fish are approved.¹³⁴ Citing the lack of consideration of the potential health and safety issues, a group of senators supported by environmental groups such as Food & Water Watch has urged FDA to shift the approval process to FDA's Center for Food Safety and Applied Nutrition to study the potential consequences to human health.¹³⁵ On June 15, 2011, the House passed an amendment to the Fiscal Year 2012 Agriculture and FDA appropriations bill, put forth by Representatives Don Young (R-Ark.) and Lynn Woolsey (D-CA), to prohibit the use of FDA funds to approve any application for approval of GE salmon.¹³⁶ Meanwhile the debate in Congress on other bills involving GM food continues.¹³⁷

U.S. food law has not changed substantially in 70 years. Hopefully now that the importance of food safety is being widely recognized at last, other areas of U.S. food policy will be reexamined, particularly genetically modified foods and the use of milk and meat from cloned animals and their progeny. With the new focus on “prioritizing prevention,” this would be an appropriate time to make meaningful change in the area of biotechnology and food safety standards.

VI. CONCLUSION

With bipartisan support from both houses of Congress and the President, this new legislation represents a mandate that food safety is at this moment in history becoming a priority. Will it be effective in protecting our food supply? The answer to this query hinges in great measure on an integrated approach to implementation by U.S. regulatory agencies and the continued oversight and funding by Congress. Certainly there is a broad and unusual coalition of constituents with shared goals

¹³² See JOHNSON, CRS REPORT R41629, *supra* note 71, at 6.

¹³³ *Id.* at 12.

¹³⁴ Developed by AquaBounty Technologies, the AquaAdvantage salmon are engineered by inserting into an Atlantic salmon a growth gene from a Chinook salmon and an antifreeze gene from an ocean pout. They grow twice as fast as typical ocean pout with 10 percent less feed. The company is also developing advanced-hybrid trout and tilapia. See Helena Bottemiller, *Senators Introduce Bill to Ban GE Salmon*, FOOD SAFETY NEWS, Feb. 2, 2011, <http://www.foodsafetynews.com/2011/02/senators-introduce-bill-to-ban-genetically-engineered-salmon/>.

¹³⁵ *Id.* (arguing that the FDA has not studied the environmental effects on Alaska's wild salmon fisheries or the economic impacts on the seafood market).

¹³⁶ Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2012, H. Amdt. 449 to H.R. 2112, 112th Cong. (2011).

¹³⁷ See, e.g., Dallas Duncan, *Genetically engineered food sparks 'vigorous debate'*, REDANDBLACK.COM, Jan. 25, 2011, <http://www.redandblack.com/2011/01/25/genetically-engineered-food-sparks-%E2%80%98vigorous-debate%E2%80%99/> (discussing genetically modified research at the University of Georgia and the contentious debate this technology has generated both in the university community and in Congress); see also Strauss, *Legal Liability Risks*, *supra* note 127, at 179-89 (analyzing bills recently introduced in Congress that would mandate safety screening and labeling of GM foods, protect farmers from crop contamination, and assess liability for injuries from GMOs).

in this area, ranging from consumer groups to industry leaders who recognize that increased regulation is ultimately in their best interest.

FSMA represents only a first but significant step towards enhancing food safety—and an ideal occasion to reconsider other areas. Now that the importance of preventative food safety is being widely recognized at last, the United States should seize this precious opportunity to make further strides towards securing the safety of its food supply through improvements in the law.