New Food Regulations: Safer Products or More Red Tape?

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Peanuts, cookie dough, hamburgers, jalapeño peppers, tomatoes; this is not the grocery list for the upcoming week but instead a look at some of the most recent instances of food-borne illness in the United States alone. The Center for Disease Control and Prevention ("CDC") estimates seventy-six million Americans become ill with food-borne illnesses on a yearly basis. Interestingly enough, the United States has one of the safest food supplies in the world, and the number of food-borne illnesses has not increased in recent years. The Food and Drug Administration ("FDA") and the United States Department of Agriculture ("USDA") are the primary authorities that oversee the United States food supply, which despite their distinct areas of focus, occasionally overlap in authority.

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1 Kristin Choo, Hungry For Change, 95 A.B.A. J. 56, 56-62 (Sept. 2009) (cataloging the most recent food-borne illness outbreaks). The list of outbreaks also includes alfalfa sprouts, pistachios, and spinach. Id. at 56. There is a new outbreak nearly every month in the United States. Id. Each outbreak, regardless of how widespread it may be, affects individual people and families to varying degrees, ranging from a simple stomach bug to concerns over the health and well-being of children. See id. at 58.

2 U.S. FOOD AND DRUG ADMINISTRATION, Food-borne Illness-Causing Organisms in the U.S.: What You Need to Know, http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm103263.htm (last visited Nov. 23, 2010) (reporting seventy-six million Americans get some sort of food-borne illness on a yearly basis). Of these cases, more than three hundred thousand result in hospitalization and nearly five thousand Americans die each year due to food-borne illness. Id. The number of Americans stricken with food-borne illness represents nearly a quarter of the population as a whole. See Choo, supra note 1, at 57.

3 See Choo, supra note 1, at 57 (citing one concern is America’s growing reliance on food imports). The number of cases may not be increasing, but another concern is that the number is also not decreasing; instead, it is merely remaining flat. Id.

4 See Choo, supra note 1, at 58 (referring to the United States Department of Agriculture
A recent nationwide survey of American consumers shows that although there is not much fear about food safety itself, there is a strong concern about the quality of food safety inspections in the United States.\footnote{Press Release, Harvard School of Public Health, Even Before Tomato Warning, a Substantial Proportion of Americans Lacked Confidence In the System For Protecting Food Safety (2008), http://www.hsph.harvard.edu/news/press-releases/2008-releases/before-tomato-warning-americans-lacked-confidence-in-food-safety.html (summarizing a 2008 survey completed by the Harvard School of Public Health). Although most people felt food producers were either very safe (37\%) or somewhat safe (58\%), more than half (52\%) of the population had “some or very little confidence in the inspection system.” See id. The survey went on to state that of the people who remembered certain outbreaks and recalls, 80\% avoided eating that product out of a continued concern for becoming ill. See id. A major concern was the ability of meat producers and restaurants to keep food safe, while people were less concerned about supermarkets and produce growers. See id.} The biggest concerns came, not from American grown and produced food, but from imported food produced in other nations, as well as the food safety inspection process within the United States.\footnote{Harvard School of Public Health, supra note 5. The survey results show 47\% of Americans think food from Mexico is unsafe and 56\% feel the same way about imported food produced in China. \textit{Id}. Robert Blendon, Professor of Health Policy and Political Analysis at Harvard says, “With growing globalization of the food supply, Americans are likely to worry more about the safety of the food they buy . . . many are [also] not confident that the system for protecting their food is working.” \textit{Id}.} Additionally, people are becoming more knowledgeable about the risk of food-borne (“USDA”) as well as the Food and Drug Administration (“FDA”) and their duties. The Food Safety and Inspection Service is an agency under the Department of Agriculture that is largely responsible for overseeing USDA regulatory work. See United States Department of Agriculture – Agencies & Offices, http://www.usda.gov/wps/portal/?navtype=MA&navid=AGENCIES_OFFICES (last visited Nov. 23, 2010) (listing the agencies under the Department of Agriculture’s umbrella). The agencies encompass several agencies focused solely on food and food safety, including smaller agencies such as the Food and Nutrition Service (“FNS”), National Institute of Food and Agriculture (“NIFA”), and the Grain Inspection, Packers, and Stockyards Administration (“GIPSA”). See \textit{id}. The Food Safety and Inspection Service (“FSIS”) is responsible for overseeing all meat and poultry, as well as processed eggs in the United States. See Choo supra note 1, at 58; see also Meat Inspection Act, 21 U.S.C. §§ 601-695 (2006); Poultry Products Inspection Act of 1957, 21 U.S.C. §§ 451-471 (2006) (defining the authority of the agencies and existing regulations). On the other hand, the FDA is responsible for the remainder of the food supply including produce, breads and bakery, beverages, and many multi-ingredient foods. See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, \textit{Outbreak Alert 2008!: Closing the Gaps in Our Federal Food-Safety Net}, 5 (2008), http://cspinet.org/new/pdf/outbreak_alert_2008_report_final.pdf; Pure Food and Drug Act, ch. 3915, 34 Stat. 768 (1906) (codifying the original FDA and its responsibilities); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399 (updating the Pure Food and Drug Act in 1938). See \textit{Press Release, Harvard School of Public Health, Even Before Tomato Warning, a Substantial Proportion of Americans Lacked Confidence In the System For Protecting Food Safety} (2008), http://www.hsph.harvard.edu/news/press-releases/2008-releases/before-tomato-warning-americans-lacked-confidence-in-food-safety.html (summarizing a 2008 survey completed by the Harvard School of Public Health). Although most people felt food producers were either very safe (37\%) or somewhat safe (58\%), more than half (52\%) of the population had “some or very little confidence in the inspection system.” See \textit{id}. The survey went on to state that of the people who remembered certain outbreaks and recalls, 80\% avoided eating that product out of a continued concern for becoming ill. See \textit{id}. A major concern was the ability of meat producers and restaurants to keep food safe, while people were less concerned about supermarkets and produce growers. See \textit{id}.
illnesses and are increasingly aware of recent outbreaks and recalls. In response to these concerns, there have been new advancements in the food safety industry. In March 2009, President Barack Obama created the Food Safety Working Group (“FSWG”) to determine flaws in the food safety industry and develop proposals for improving the system. Additionally, both the House of Representatives and the Senate have proposed and passed new legislation to implement changes to current food safety regulation.

Part I of this note will consider the development of food safety in the United States, looking at both the FDA and USDA, as well as touching upon a few of the influential statutes in this field. Part II will explore food-borne illness information, the concerns and shortcomings of the current statutory and regulatory landscape, and finally the recent cases resulting from food-borne illnesses. Part III of this note will examine newly proposed recommendations and take a more in-depth look into the President’s Food Safety Working Group (“FSWG”) and the proposed Food Safety Enhancement Act, H.R. 2749, 111th Cong. (2009) (as passed by House of Representatives, July 30, 2009). The bill provides for stronger regulation of the food supply and for tougher sanctions for farms and facilities found to be distributing contaminated food. See id. § 102 (defining a new hazard analysis for finished food products); § 418 (describing the hazard analysis and risk-based preventive controls); § 418A (outlining a new food safety plan); § 419 (detailing new safety standards for produce); § 134 (availability of criminal penalties for failure to follow food safety protocol); § 135 (describing new civil penalties for violations of food safety procedures). See also Gardiner Harris & William Neuman, Senate Passes Overhaul of Food Safety Regulations, NY TIMES, Nov. 30, 2010, available at http://www.nytimes.com/2010/12/01/health/policy/01food.html?_r=2&hp (discussing the Senate’s passing of a similar version of the food safety bill). The legislation passed with a 73 to 25 vote, giving hope that the FDA would receive the additional strength and support needed to continue to police and protect the American food supply. Id.
Act to determine their effectiveness and potential for the future of food safety. The conclusion will analyze whether the new focus on regulation will be successful in creating a safer food industry or merely encircle the industry with more red tape. Finally, the conclusion advocates for the passage and enactment of the bill and the continued funding of the FSWG.

I. Food Safety in the United States

The President’s Cabinet, while divided into various departments, oversees the affairs of the country as a whole.\(^1\) Two of the Cabinet’s departments, among other responsibilities, are in charge of food safety in the United States.\(^2\) The Department of Health and Human Services ("HHS") and the USDA, relying heavily on both the FDA and the Food Safety & Inspection Service ("FSIS"), regulate nearly all of the food supply in the United States.\(^3\)

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\(^{1}\) \textit{The White House Administration: The Cabinet}, http://www.whitehouse.gov/administration/cabinet/ (last visited Nov. 23, 2010) (listing Cabinet positions, their Secretaries, and each Department’s website). There are fifteen departments in the Cabinet, including the Department of State, Department of Treasury, Department of Health and Human Services, Department of Agriculture, Department of Defense, Department of Justice, and the Department of Homeland Security among several others. \textit{Id.} A secretary, who is a direct advisor to the President, oversees each department. \textit{Id.}

\(^{2}\) \textit{See id.} (describing the structure of the Cabinet). The two food safety departments are the Department of Agriculture, currently headed by Secretary Thomas J. Vilsack, and the Department of Health and Human Services, currently headed by Secretary Kathleen Sebelius. \textit{Id.} The USDA’s main food safety division is the Food Safety and Inspection Service ("FSIS") that oversees the majority of the USDA’s food regulation. \textit{See Food Safety and Inspection Service}, USDA, http://www.usda.gov/wps/portal/ut/p/_s.7_0_A/7_0_10B?contentidonly=true&contentid=FSIS_Agency_Splash.xml&x=16&y=3 (last visited Nov. 23, 2010) (referring to the FSIS’s role as the public health agency of the USDA). The second division, the Department of Health and Human Services ("HHS") relies on the Food and Drug Administration, the Center for Disease Control & Prevention, as well as nine other agencies. \textit{See About HHS, Health and Human Services}, http://www.hhs.gov/about/ (last visited Nov. 23, 2010) (describing the eleven agencies under the Health and Human Services umbrella).

\(^{3}\) \textit{See Choo, supra note 1, at 58} (stating the USDA, as a whole oversees 20% of the food supply, while the FDA alone oversees the remaining 80%). The USDA, and in turn the FSIS, are “responsible for ensuring that the nation’s commercial supply of meat, poultry and egg products is safe, wholesome, and correctly labeled and packaged.” \textit{See Food Safety and Inspection Service, supra note 12} (citing the responsibilities of the Food Safety and Inspection Service). On the other hand, the FDA is responsible for the remaining food supply. \textit{See Choo, supra note 1, at 58} (stating the FDA is responsible for the food supply not under the USDA umbrella). Other agencies responsible, in some form, for food safety and regulation are:

HHS’s Center for Disease Control & Prevention, the USDA’s Agricultural Marketing Service ("AMS"), Animal and Plant Health Inspection Service
A. Food and Drug Administration

The FDA oversees more than eighty percent of the American food supply.\textsuperscript{14} The FDA, originally created in 1862 as a subsidiary of the USDA, has since grown into its own division within the Department of Health and Human Services, with more than nine thousand employees and a $1.2 billion budget.\textsuperscript{15} While the changes in scope and regulation of what is under the purview of the FDA have been drastic, the controlling statute, the Federal Food, Drug, and Cosmetic Act of 1938 ("FFDCA"),\textsuperscript{16} remains the same as it was nearly one hundred years ago.\textsuperscript{17} Of particular import is Subchapter IV of ("APHIS"), Agricultural Research Service ("ARS"), and Grain Inspection, Packers and Stockyards Administration ("GIPSA"); the Department of Commerce’s National Marine Fisheries Service; the Department of the Treasury’s U.S. Customs Service and Bureau of Alcohol, Tobacco, and Firearms; the Environmental Protection Agency ("EPA"); and the Federal Trade Commission.


\textsuperscript{14} See Choo, supra note 1, at 58 (indicating that the FDA oversees 80% of the food supply); see also Centers and Offices, U.S. FOOD AND DRUG ADMIN., \url{http://www.fda.gov/AboutFDA/CentersOffices/default.htm} (last visited Nov. 23, 2010) (stating the FDA responsibilities as protecting the public health by “assuring the safety, efficacy, and security” of food and drugs – both human and veterinary). The FDA oversees items “accounting for twenty-five cents on the dollar” spent by U.S. consumers on an annual basis. John P. Swann, FDA'S ORIGIN, U.S. FOOD AND DRUG ADMIN., \url{http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm} (last visited Nov. 23, 2010).

\textsuperscript{15} Swann, supra note 14 (describing the FDA as growing from a single chemist in the USDA to the ninety-one hundred employee, $1.29 billion budget department that it is today).


\textsuperscript{17} See Swann, supra note 14 (describing the modern FDA as resulting from the passage of the Pure Food and Drug Act of 1906). Originally, under the Pure Food and Drug Act, the FDA was the Bureau of Chemistry until 1927 when it became the Food Drug and Insecticides Administration. Id. The name was shortened to the Food and Drug Administration in 1930. Id. Congress enacted the Pure Food and Drug Act to prevent the “manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors.” See Pure Food and Drug Act of 1906, Pub. L. No. 59-384 (1906) (also known as the Wiley Act), available at\url{http://prescriptiondrugs.procon.org/sourcefiles/FEDERAL_FOOD_AND_DRUGS_Act_1906.pdf}. In 1938, the Wiley Act received a major overhaul when the Federal Food, Drug, and Cosmetic Act was passed, which further prohibited
the FFDCA, which solely regulates food; it contains two statutes dedicated to preventing the adulteration of and misbranding of food in the United States food supply.18

The adulterated food provision in the FFDCA, codified as 21 U.S.C. § 342, regulates not only preventing the inclusion of poisonous ingredients and the absence or substitution of substances, but it also regulates dietary supplements and their safety.19
Under the current statutory definition, food is considered adulterated if it consists of a “filthy, putrid, or decomposed substance, or if it is otherwise unfit for [human consumption].”20 Due to the wide array of definitions and breadth of interpretations, “adulterated food” has been the subject of many lawsuits.21

Misbranded food, governed by 21 U.S.C. § 343, receives similar scrutiny on food labels and packaging.22 This section of the statute focuses on misleading labels, misleading containers, and a lack of prominence of label information.23 Currently, misbranding does not extend to facilities that are not registered with the Secretary of the interstate transport of goods that had been adulterated or misbranded, and allowed the FDA to set food standards and regulations. See Choo, supra note 1, at 58 (describing the changes the Federal Food, Drug, and Cosmetic Act made to the Wiley Act). See also 21 U.S.C. § 301.

18 See 21 U.S.C. §§ 342, 343 (referencing two statutes which define adulterated and misbranded food).
19 See 21 U.S.C. §§ 342(a), (b), (f), (g) (defining the various forms of adulterated food). Poisonous food focuses mainly on substances that would render the food injurious to health and even goes so far as to not regulate food that contains a small inherent quantity of poisonous substance that is not generally injurious to public health. See 21 U.S.C. § 342(a)(1).
21 21 U.S.C. § 342(a)(3) (defining adulterated food under very broad terms); see, e.g., United States v. H.B. Gregory Co., 502 F.2d 700, 701 (7th Cir. 1974), cert. denied, 422 U.S. 1007 (1975) (holding food is adulterated if it has been held “under unsanitary conditions whereby it may have become contaminated with filth”); Berger v. United States, 200 F.2d 818, 821 (8th Cir. 1952) (holding food does not necessarily need to be contaminated, merely held under unsanitary conditions); United States v. Anderson Seafoods, Inc., 447 F. Supp. 1151, 1155 (1978) aff’d, 622 F.2d 157 (holding food is not adulterated unless the added substance makes the food injurious to health).
22 See 21 U.S.C. § 343 (2006) (describing under what circumstances a food may be deemed to be misbranded). Misbranded or mislabeled food is an issue that is combated diligently in other nations, including in Germany and Finland. See Case C-465/98, Verein Gegen Unwesen in Handel Koln v. Adolf Darbo, 2000 E.C.R. I-2297 (European Union case holding food labeled as pure must be free of any impurity or extraneous substance).
23 See 21 U.S.C. §§ 343(a), (d), (f) (2006) (describing misleading label information in further detail). The focus here is on the packaging and labels, instead of the food itself, which is the focus of section 342 (adulterated food). Compare 21 U.S.C. § 342 (referring to food products themselves and regulating items that may and may not be present in food), with 21 U.S.C. § 343 (focusing on the packaging and labeling of food).
Health and Human Services. This results in a gap between food that is deemed to be manufactured, processed, packed, or held at an unregistered facility and food that is considered to be misbranded, something that will only be reported if at a registered facility.

B. United States Department of Agriculture

Congress created the United States Department of Agriculture (“USDA”) in 1862; however, the USDA adopted its current form following the passage of the Meat Inspection Act in 1906. Since the passage of the Meat Inspection Act, there have been several amendments, changes, and additions to the scope of the USDA’s regulatory power. While the USDA only oversees the regulation of meat, poultry, and processed eggs, food products that comprise only approximately twenty percent of the food supply, the USDA currently receives more than double the funding allocated to the FDA. The USDA has seen meat and poultry consumption nearly double in the past decades.

24 See generally 21 U.S.C. § 343 (noting no rule as to items manufactured at unregistered facilities as being deemed “mislabeled”).

25 See 21 U.S.C. § 350(d) (2006) (requiring food facilities to register with the Secretary of Health and Human Services). The statute requires all facilities “engaged in the manufacturing, processing, packing, or holding of food for consumption in the United States” to be registered. Id. § 350(a)(1).


27 See Food Safety and Inspection Services, supra note 12 (describing the FSIS’s current responsibilities to also include the Poultry Products Inspection Act and the Egg Products Inspection Act). The Poultry Products Inspection Act provides the public an assurance that poultry products distributed to them are “wholesome, not adulterated, and properly marked, labeled, and packaged.” 21 U.S.C. § 451 (2006) (describing the Congressional findings prior to the passing of the Poultry Products Inspection Act). This Act gave authority to the inspection service further described as the United States Department of Agriculture. See 21 U.S.C. § 453(q) (2006); see also Poultry Products Inspection Act, 21 U.S.C. §§ 451-471. On the other hand, the Egg Products Inspection Act gave the USDA authority to enact similar regulations in regards to processed eggs, but the Egg Products Inspection Act granted the remainder of regulation oversight to the FDA. See Egg Production Inspection Act, 21 U.S.C. §§ 1031-1056 (2006).

28 See Choo, supra note 1, at 58 (describing the USDA as having twice as much money and only 20% of the food supply to monitor); see also CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 2 (describing food-borne illnesses from USDA-regulate products as constituting...
three decades, while the budget has only grown by twenty-five percent.  

II. Food-borne Illnesses and Outbreaks

The terms food-borne illness and food poisoning are often mistakenly used interchangeably even though they have very different meanings. Broadly defined, a food-borne illness is a type of disease which also covers food-borne infections, food-borne toxicoinfections, and food-borne intoxications. On the contrary, food poisoning refers only to the food-borne illness caused after the consumption of the contaminated food.

In recent years, while there has not been an increase in cases of food-borne illnesses, there has also not been any decline. There are estimates on the number of cases of food-borne illnesses per year in the United States, but most data collection efforts only focus on an outbreak of a food-borne illness. In defining the term

29 See Choo, supra note 1, at 58, 60 (detailing the difficulties the USDA has faced even with a budget larger than the FDA). As the demand for food grows in the United States and regulations continue to change, the two departments face further struggles as a result of the lack of funding and being short-staffed. Id. at 60.

30 See Morton Satin, Food Alert! The Ultimate Sourcebook for Food Safety 16 (Checkmark Books 1993). The term food-borne disease covers food-borne illnesses and is described as reflecting “three kinds of causes: food-borne intoxications (from ingestion of food-borne poisons); food-borne infections (caused by food-borne pathogenic microorganisms such as Salmonella that, when ingested, cause infections); and food-borne toxicoinfections (from food-borne pathogens such as E. coli O157:H7 that, once ingested, produce harmful toxins).” Id. at 17. On the contrary, food poisoning only refers to an illness caused by consuming contaminated food. See Food Poisoning, Mayo Clinic, http://www.mayoclinic.com/health/food-poisoning/DS00981 (last visited Nov. 23, 2010) (providing the definition of food poisoning).

31 See Satin, supra note 30, at 17 and accompanying text.

32 See Mayo Clinic, supra note 30 (defining food poisoning).

33 Choo, supra note 1, at 57 (stating instances of food-borne illness have not declined in recent history).

34 See U.S. Food and Drug Administration, supra note 2 and accompanying text (estimating the number of cases of food-borne illnesses per year in the United States); OutbreakNet Team Overview, Center for Disease Control and Prevention, http://www.cdc.gov/outbreaknet (last visited Nov. 23, 2010) (explaining that the CDC only investigates instances of food-borne illness outbreaks). The CDC maintains an “OutbreakNet Team” that works to coordinate detection and response to multi-state outbreaks of food-borne illness and promotes comprehensive outbreak surveillance. See Center for Disease Control and Prevention, http://www.cdc.gov/outbreaknet/ (last visited Nov. 23, 2010).
outbreak, the CDC asserts “a cluster of food-borne illnesses is considered an outbreak if an investigation demonstrates that two or more infections caused by the same agent are linked to the same food.”

At one time it was believed that the majority of food-borne illnesses resulted from meat and poultry—both regulated by the USDA—but recent statistics show FDA-regulated food is implicated in more yearly outbreaks. Over a seventeen-year span from 1990 to 2006, produce, an FDA-regulated food product, caused the largest number of food-borne illness cases and the second largest number of outbreaks, resulting in nearly twice as many illnesses than poultry-caused illnesses, which had the third largest occurrence of outbreaks. Of the reported outbreaks, more than sixty percent occurred as a result of a bacterial pathogen in the food supply. Because of the strict definition of an outbreak, the 5778 outbreaks between 1990 and 2006, leading to more than 150,000 instances of food poisoning, comprised only a small number of the estimated seventy-six million cases of food poisoning each year in the United States.

A. Data Collection

Three separate groups are responsible for various aspects of data collection, creating a disconnect in the collection of information about food-borne illness.

36 See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at i (describing food regulated by the FDA is associated with twice as many outbreaks as USDA-regulated food).  
37 See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at i (classifying outbreaks of food-borne illnesses into major categories). Beef and poultry, both USDA-regulated food categories, resulted in less than half of the outbreaks as compared to FDA-regulated eggs, seafood, and produce. Id. Produce refers to both fruits and vegetables. Id. at 9.  
38 CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 6 (describing bacterial infection as the culprit of the majority of food poisoning cases). While bacterial pathogens result in 60% of the outbreaks, 24% are caused by viruses (most notably the Norovirus – 90% of the virus related outbreaks), 15% are caused by chemicals or toxins, and parasites are responsible for only 1% of outbreaks. Id. Game is the only food where parasites, not bacteria, cause the majority of outbreaks. Id.  
39 Compare CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at i (identifying 5778 food-borne illness outbreaks resulting in 168,898 illnesses between 1990 and 2006) with U.S. FOOD AND DRUG ADMINISTRATION, supra note 2 (estimating more than seventy-six million instances of food-borne illness, resulting in five hundred 25,000 hospitalizations, and 5000 deaths). The large discrepancy comes from the majority of instances going unreported, as they are either misdiagnosed or undetected due to a lack of severity. See Choo, supra note 1, at 57 (stating the difficulty in determining the exact number of food-related illnesses).
outbreaks. FoodNet, the first of the three programs, is responsible for the active surveillance of laboratory cases of food-borne illnesses. PulseNet, the second program, compiles “microbial sub-typing data on several species of bacteria, and [it] maintains a national database for reference and comparison of sub-typing information,” which the CDC coordinates. Finally, the Center for Science in the Public Interest’s ("CSPI") Outbreak Alert catalogues “identified food-borne illness outbreaks into food categories, a process known as food attribution,” and is limited in its collection ability.

Beyond the problems with three programs charged with collecting food-borne illness information, there are a multitude of additional concerns regarding the statistical accuracy of reporting. First and foremost is the fact that state and local health departments are responsible for investigating potential outbreaks, which can create confusion due to different collecting and reporting requirements across the nation.

41 See Smith DeWaal, supra note 40, at 2 (defining the scope of FoodNet). A major shortcoming of FoodNet is the only cases collected are food-borne illnesses that have been diagnosed through laboratory testing. Id. at 3. Also, it is nearly impossible to distinguish food-borne pathogens from non-food-borne pathogens, i.e. contaminated water, direct animal contact, or person-to-person contact. Id.
42 Smith DeWaal, supra note 40, at 2 (defining the scope of PulseNet). PulseNet is comprised of the CDC in conjunction with a network of state and local health departments, as well as other federal agencies. Id. The major issue with PulseNet is that it currently lacks major funding, and unlike FoodNet, PulseNet is not an active surveillance program but instead, a passive collection program. Id. at 4.
43 Smith DeWaal, supra note 40, at 2 (detailing the scope of CSPI’s Outbreak Alert). Once again, this program has its shortcomings, and here, the information collected represents only 25-30% of the food-borne illnesses in the country. Id. at 5. This is a result of many cases of food-borne illnesses going undetected. See Choo, supra note 1, at 57 (stating the difficulty in pinning down the exact number of food-related illnesses). Sporadic cases are excluded from the database and only incidents that meet the CDC’s two plus person outbreak requirement are reported. See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 3. Even the majority of the cases reported have incomplete information. Id. at 4. Additionally, 56-73% of “outbreaks reported to the CDC have no known etiology or food vehicle . . . and are therefore not included in CSPI’s database.” Id.
44 See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 1 (describing the challenges faced in obtaining statistical data).
45 See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 1 (investigating potential food-borne illness outbreaks are the responsibility of state and local health departments). There is currently no requirement to report the investigative results or findings to the CDC, even if there is an outbreak, resulting in incomplete data at the federal level. Id. There are measures in
Another major cause of confusion, when reporting food-borne illness outbreak data, is the fact that the CDC classifies all instances of outbreak by pathogen, instead of by food. Accordingly, limiting the collection of data to outbreaks, rather than collecting all instances of reported food poisoning, results in far less reporting than actual occurrences of food-borne illness across the United States.

B. Current Problems with Statutory Regulation

Not only is it difficult to collect accurate data, but the current statutory scheme makes it even more challenging for the FDA and USDA to contain contaminated food due to their inability to require companies to cease the distribution of contaminated or potentially contaminated food. The current scheme for testing of facilities and the lack of place to foster stronger relationships, but there is still a long process of notifying the CDC and then working with Attorney Generals from other states to come up with the best possible solution. See KENNETH R. PINA & WAYNE L. PINES, A PRACTICAL GUIDE TO FOOD AND DRUG LAW AND REGULATION 388 (Food & Drug Law Institute ed., 2008). An additional concern is that within the fifty states, there are fifty different sets of rules and regulations regarding food production and safety. See FDA.gov, State Retail and Food Service Codes and Regulations by State, (July 2006), http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FederalStateCooperativePrograms/ucm122814.htm. On top of having fifty different sets of regulations, many states, including Wisconsin, New York, Maine, Florida, and Connecticut, have two, and even three, divisions within their states dedicated to food safety. See id. This inevitably creates confusion, and while many of the regulations are consistent, there is not complete uniformity when it comes to food regulation. See id.

46 See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 1 (reporting is collected by pathogen and not by food source). This makes it extremely difficult to determine the contaminated food source and even more difficult in determining the necessary steps to contain the outbreak. Id. Although there can be strong connections between certain pathogens and specific foods, such as the norovirus being prevalent in “greens-based salads,” there is the problem with the fact that the norovirus is prevalent in fruit and lettuce as well. Id. at 10. By merely classifying outbreaks by pathogen, people will not necessarily know which products to buy and which products to shy away from, and instead, people will only know when there is an ongoing outbreak. Id. at 1.

47 See Center for Disease Control and Prevention, supra note 35 (defining an outbreak “as a cluster of two or more infections caused by the same agent . . . [in the] same food”). Symptoms of food poisoning include diarrhea, cramps, vomiting, loss of appetite, fever, and muscle fatigue; symptoms often last only a few days. See U.S. FOOD AND DRUG ADMINISTRATION, supra note 2 (describing symptoms of various forms of food poisoning). Many people suffering from these symptoms do not seek medical attention, and thus, the instance of food poisoning goes unreported. See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 4.

48 See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 2 (stating recalls of contaminated food are done solely at the discretion of the manufacturer). The FDA and USDA do not currently have the authority to recall contaminated food and can only request...
of timely inspections completed by the FDA, especially when compared to the USDA’s inspection requirements, creates an additional concern for detecting and containing contaminated food.\textsuperscript{49} Furthermore, the FDA has a multi-step notification process which, while thorough, can create roadblocks and delays in the system.\textsuperscript{50} This process results in an extended period of time between the outbreak and any governmental intervention and notification.\textsuperscript{51} Additionally, the fact that the FSIS has some regulatory authority over imported food, while the FDA lacks any authority over such food, creates a further dilemma involving importation of food into the United States.\textsuperscript{52}

The current manufacturers to do so voluntarily. \textit{Id.} The USDA currently has the authority to “(1) require food firms to register so that they can be inspected, (2) prohibit the use of processing equipment that may potentially contaminate food products, and (3) temporarily detain any suspected food.” GAO Testimony, GAO-05-212, \textit{supra} note 13, at 6. The FDA does not have any authority to detain food, and thus, outbreaks are not contained as quickly. \textit{Id.} The USDA, on the other hand, can detain food for twenty days and seek a court order to seize the food all together. \textit{Id.} There have been numerous suits against the USDA, which have limited the USDA’s ability to shut down facilities producing contaminated meat and detain the food products. \textit{See} CENTER FOR SCIENCE IN THE PUBLIC INTEREST, \textit{supra} note 4, at 2. Even with a voluntary recall system, more than thirty million pounds of ground beef was recalled by twenty different companies, across the country, between June 2007 and November 2007. \textit{Id.} at 12. The current statutory scheme is broken into multiple statutes that have been around for nearly a century. \textit{See supra} note 4 and accompanying text (discussing the current statutory scheme).

\textsuperscript{49} \textit{See} CENTER FOR SCIENCE IN THE PUBLIC INTEREST, \textit{supra} note 4, at 2 (describing facility inspections by both the USDA and FDA). Meat producing plants, overseen by the USDA, are inspected daily, while companies producing “many high-risk foods such as seafood, eggs, lettuce, or processed foods containing less than two percent meat are inspected by the FDA on average just once every five to ten years.” \textit{Id.}

\textsuperscript{50} FDA Notification Process, \textit{What You Should Know about Government Response to Food-borne Illness Outbreaks}, Jan. 2009, available at http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm180323.htm. The several step process is as follows:

(1) Alert the public about which foods are causing illness, and ask the firm that produces them to remove them from the market. (2) Monitor recalls by the producers of illness-causing foods. (3) Identify how the food became contaminated—for example, on the farm, in processing, during shipment, or in storage. (4) Take necessary regulatory action, such as requiring changes in a food processing plant in which food became contaminated to eliminate the sources of contamination. (5) Evaluate all the information gathered in order to prevent similar problems in the future. This may involve changes in FDA’s good agricultural practices guidance or good manufacturing practices regulations or other regulatory tools.

\textit{Id.} (emphasis omitted). This is a time-consuming process since it is detailed and takes several steps to complete, which means potential delays in public notification. \textit{See id.}

\textsuperscript{51} \textit{See} FDA Notification Process, \textit{supra} note 50 (detailing the lengthy process of involvement by the FDA).

\textsuperscript{52} \textit{See} GAO Testimony, GAO-02-47T, \textit{supra} note 13, at 7. Currently, the FSIS has the authority
statutory scheme also causes plenty of confusion when dealing with terms and defining the breadth of the two regulatory agencies’ ability to locate and enforce food safety violations.\(^{53}\)

### C. Current & Pending Cases

State law tort claims of negligence and vicarious liability are the basis for food poisoning claims.\(^{54}\) Food poisoning from the consumption of various types of food, including jalapeños and alfalfa sprouts, resulted in many cases across the country.\(^{55}\)

to inspect all meat and poultry entering the U.S., but often, FSIS places this burden on the exporting country. \(\text{Id.}\) Yet once again, the FDA lacks the authority to require other countries to have food safety systems. \(\text{Id.}\) The FDA, unlike FSIS, does not require imported food to be kept in a registered warehouse prior to FDA approval of its release into the food supply. \(\text{Id.}\) This results in food being released into United States commerce, which is later deemed an adulterated import, and ultimately is refused official entry by the FDA. \(\text{Id.}\)

\(^{53}\) See supra notes 18-25 and accompanying text. The lack of the ability to enforce violations through recalls and plant shutdowns is also a major concern. See also CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 2 (stating recalls of contaminated food are done solely at the discretion of the manufacturer). The FDA and USDA do not currently have the authority to recall contaminated food and can only ask the manufacturers to do so voluntarily. \(\text{Id.}\) The type of food and the way it is processed can cause confusion as to which organization, the FSIS or the FDA, is to oversee the inspection of the item. See GAO Testimony, GAO-05-212, supra note 13, at 3. A potent example of this is “FSIS inspects manufacturers of packaged open-face meat or poultry sandwiches (e.g., those with one slice of bread), but FDA inspects manufacturers of packaged closed-face meat or poultry sandwiches (e.g., those with two slices of bread).” \(\text{Id.}\) Here, the big concern is the timing of inspections of each plant, with the FSIS inspecting facilities daily, while the FDA only inspects on average every five to ten years. \(\text{Id.}\)

\(^{54}\) “A tort is a breach of duty (other than a contractual or quasi-contractual duty) which gives rise to an action for damages.” WILLIAM L. PROSSER ET AL., PROSSER AND KEETON ON TORTS 1 (W. Page Keeton ed., West Pub. Co. 1984) (1898). “A common thread woven into all torts is the idea of unreasonable interference with the interests of others . . . [i.e. negligence, etc.].” See id. at 6.

Numerous claims against Peanut Corporation of America (“PCA”), for salmonella in peanut butter, forced the company to file for bankruptcy in recent months. After a full investigation of the plant, the FDA revealed startling information about the salmonella test results and unsanitary conditions at the PCA facility.

hundred fifty confirmed illnesses in ten states. See Sprout Seed Manufacturer Named in Amended Lawsuit Filed by Markert Clark, supra note 55; Bob Von Sternberg, Family Sues Peanut Butter Maker Over Death Linked to Salmonella Outbreak, Minneapolis-St. Paul Star Tribune, Apr. 22, 2009, available at http://www.startribune.com/local/43450257.html?rel=KArks:DGiUHe3E7_V_nDaycUiacy (discussing suit against Kanan Enterprises, maker of King Nut peanut butter, sued for the death of a seventy-eight year old Minnesotan). The peanut butter salmonella outbreak has been linked to hundreds of instances of food poisoning. Id.

See Peanut Corp. of America, www.peanutcorp.com (last visited Nov. 23, 2010) (filing for bankruptcy protection as a result of pending suits for salmonella outbreak); see also Allbusiness.com, Lawsuit Filed in Nationwide Outbreak of Salmonella in Peanut Butter, Jan. 20, 2009, available at http://www.allbusiness.com/legal/legal-services-litigation/11754821-1.html (stemming from outbreak of Salmonella in peanut butter a suit has been filed against PCA). PCA was a supplier to many other companies for their peanut butter products, including Keebler, a subsidiary of Kellogg. See Lawsuit Filed in Nationwide Outbreak of Salmonella in Peanut Butter, supra note 56. The outbreak has already been linked to more than seven hundred illnesses and nine deaths. See Choo, supra note 1, at 59. The FDA faced a major barrier because of their inability to review PCA’s records and they eventually invoked a bioterrorism law to discover PCA was knowingly shipping contaminated peanut products. Id.

Business Wire Inc., FDA Disclosures Prompt Additional Action in Salmonella Lawsuit Jan. 28, 2009, available at www.lexis.com/lawschool (follow “News and Business” hyperlink, “News Most Recent Two Years” hyperlink, search “FDA Disclosures Preempt Additional Action in Salmonella Lawsuit” with a natural language search) (pending suits amended to included punitive damages after FDA discloses findings of investigation). The outbreak and investigation resulted in more than thirty million pounds of peanut butter and peanut products being recalled. Id. The FDA found several violations including:

12 positive tests of Salmonella in product manufactured by PCA; 4 different strains of Salmonella detected on site in Blakely, GA; failure to maintain equipment, containers and utensils used to convey, hold, and store food in a manner that protects against contamination; failure to perform mechanical manufacturing steps so as to protect food against contamination; failure to store finished food under conditions that would protect against microbial contamination; plant is not constructed in such a manner as to allow ceilings to be kept in good repair, design of equipment and utensils fails to preclude the adulteration of food with contaminants; proper precautions to protect food and food-contact surfaces from contamination with microorganisms cannot be taken because of deficiencies in plant construction and design, devices and fixtures are not designed and constructed to protect against recontamination of clean, sanitized hands; failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of...
The salmonella outbreak, as is the case with most major instances of food poisoning, will hurt more than just PCA and will affect the industry as a whole.\footnote{Emily Fredrix, \textit{Salmonella Recall Could Cost Peanut Producers $1B}, Allbusiness.com, Mar. 11, 2009, available at http://www.allbusiness.com/company-activities-management/company-structures-ownership/1222580-1.html (discussing that fears of further outbreak and recall of peanut products will cost the industry).} The food industry will be adversely affected because people are trying to prevent food poisoning from happening to themselves and their families; thus, they hold off on purchasing any of the contaminated products, regardless of whether the contamination only pertained to one brand or type of food.\footnote{See \textit{id}. The concern over peanut butter led to weakened prices and limited sales because companies using peanut butter removed it from the marketplace. \textit{See id.} Even though jarred peanut butter was, for the most part, not involved in the recall, peanut butter sales have reached a three year low. \textit{See id.} The industry will not realize its actual losses until the outbreak is over and the recalls have finished. \textit{Id.}}

\section*{III. Moving Forward}

There have been widespread cries for improvements to food safety from victims of food-borne illnesses, industry experts, and researchers in the field.\footnote{See Choo, \textit{supra} note 1, at 60. According to Michigan State’s Neil Fortin, director of the Institute for Food Laws and Regulation, “[i]f the people responsible for regulating food safety [do not] have adequate funding and support, they [cannot] do the job.” \textit{Id.} (referring to the lack of funding and support food safety has seen in the past decade). There is a strong need to improve the surveillance and reporting of food-borne illnesses, both confirmed and alleged. \textit{See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra} note 4, at 15. Improving surveillance would “(1) identify emerging problems, (2) evaluate existing programs, and (3) set goals and priorities for food safety.” \textit{Id.} \textit{See also} supra note 55 and accompanying text (discussing recent lawsuits due to food contamination leading to illness).} A recent recommendation would require all state and local health departments to report all investigative findings to the CDC.\footnote{See \textit{CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra} note 4, at 16. This consolidation would allow for a faster and more efficient processing of information that would now be more centralized and complete. \textit{Id.}} Another recommendation would extend testing and prevention of a facility’s contamination vulnerability, referred to as hazards analysis and critical-control-points (“HACCP”) plans, to all food industries and not just the few that currently require them.\footnote{See Choo, \textit{supra} note 1, at 58. HACCP plans identify “vulnerable links in the food processing chain and institutes safety measures to counteract the risk.” \textit{Id.}} An HACCP plan lays out steps for: “conduct[ing] hazard food; and effective measures not being taken to protect against contamination of food on the premises by pests.

\textit{Id.}
analysis[,] . . . identifying control points[,] . . . establishing critical limits for control points[,] . . . monitoring procedures[,] . . . [taking necessary] corrective actions[,] . . . recordkeeping[,] . . . [and conducting] verification procedures." HACCP plans identify "vulnerable links in the food processing chain and institute[] safety measures to counteract the risk." A recommendation during the Government Accountability Office ("GAO") Testimony on October 10, 2001 was to establish one food safety agency that would oversee all food safety regulation in the United States. Instead, in beef, seafood, and dairy products are required to have such plans, but the FDA does not require these plans for produce products. Id. The FCIS produces a seventy-four page manual to instruct the plants it inspects on how to create an effective HACCP plan. See generally USDA, Guidebook for the Preparation of HACCP Plans (Sept. 1999), available at http://www.fsis.usda.gov/OPP DE/nis/outreach/models/HACCP-1.pdf. The plans were created to require plants to take responsibility for aiding in the reduction of contaminated products. Id. at 3.

63 Guidebook for the Preparation of HACCP Plans, supra note 62, at 1 (outlining the contents of the guidebook). Each plant is to develop a plan to fit their own company needs, using the guidebook as a starting point. Id. at 3-4.

64 Choo, supra note 1, at 58 (defining a hazard analysis plan).

65 GAO Testimony, GAO-05-212, supra note 13 at 11. This would aid in the establishment of creating uniform national and international laws regarding food safety. See id.; see also GAO Report to Congressional Requestors, supra note 13, GAO-02-47T, at 1-2 (addressing the experiences of other nations in their quest to bring food safety under a single agency). The seven countries involved in this study were Canada, Denmark, Germany, Ireland, the Netherlands, New Zealand, and the United Kingdom; all listed countries completed this consolidation based on public concerns about food safety and need for improved efficiency—two other problems the U.S. faces. See GAO Testimony, GAO-02-47T, supra note 13, at 2. While these countries have not completed their analysis on the effects of this consolidation, the effects of better communication and efficiency, seem positive. Id. Furthermore, despite that these countries are smaller than the U.S., they are all high income nations with high expectations of food quality. Id.; Timothy M. Hammonds, It is Time to Designate a Single Food Safety Agency, 59 Food Drug L.J. 427, 427 (2004) (arguing for the consolidation of the food safety industry into a single agency). With more than a dozen agencies involved, the "patchwork quilt creates inconsistencies, gaps, overlaps, and duplication of effort," all of which could be avoided by combining these efforts. See Hammonds, 59 Food Drug L.J. at 427. Furthering the argument is the example of pizza, which falls under FDA jurisdiction until more than 2% of the toppings are cooked meat or poultry, then authority is relinquished to the USDA. See id. at 430. Additionally with the stringent budget, the two agencies compete against each other to obtain further funding instead of collaborating, which would foster better improvements for the American people. See id.; Official: Food Safety Must be Under One Agency, MSNBC.com, Feb. 6, 2009, available at http://www.msnbc.msn.com/id/29060603/ (citing the need for a single food safety agency); Alan Bjera, Vilsack Says Single Food-Inspection Agency Needed, Bloomberg.com, Feb. 6, 2009, available at http://www.bloomberg.com/apps/news?sid=amatSeULKjEf&pid=20601087 (stating a need to modernize food safety by merging into one food safety agency). But see M.J. Gilsdorf, Thoughts on Food Safety Agency Restructuring in the U.S., available at http://www.nal.usda.gov/awi/pubs/FoodSafetyRestructuring.pdf (last visited Nov. 23, 2010)
the past two years, the President established a Food Safety Work Group (“FSWG” or the “Group”), the House of Representatives proposed and passed a new Food Safety Enhancement Act, and the Senate recently passed its own version of the bill.66

A. Food Safety Work Group

President Obama created the FSWG and introduced it to the public on March 14, 2009.67 The Secretaries of the USDA and the HHS head the group, which will also include representation from several other agencies.68 After its creation, the Group alerted the President and the public of their founding principles: “(1) [p]reventing harm to consumers[,] . . . (2) [e]ffective food safety inspections and enforcement depend upon good data and analysis[,] . . . [and] (3) [o]utbreaks of food-borne illness should be identified quickly and stopped.”69

The Group is aiding the President and the respective agencies in an overhaul of the food safety system that seeks to update old laws and implement new strategies to

66 See Choo, supra note 1, at 56-57 (describing the new Food Safety Working Group and the Food Safety Enhancement Act); Harris & Neuman, supra note 10 (discussing the Senate’s recent passage of the bill which will overhaul food safety regulations).
67 See Food Safety Working Group Website, supra note 9 (describing the new group); see also Harris, supra note 9 (announcing the creation of the Food Safety Working Group). The new group will advise the President of necessary changes after a careful review of existing food safety laws. Harris, supra note 9.
68 See Food Safety Working Group, Key Findings at 2, http://www.foodsafetyworkinggroup.gov/FSWG_Key_Findings.pdf (naming the agencies participating in the group). The Group, headed by the Department of Agriculture and the Department of Health and Human Services, has representatives from the FDA, FSIS, CDC, the Department of Homeland Security, Department of Commerce, Department of State, the Environmental Protection Agency, and several other White House offices. Id.
69 Food Safety Working Group, supra note 68, at 3. The Group has already recommended food regulators prioritize prevention and set rigorous standards for food safety. Id. The Group also stressed the need to have stronger inspection and enforcement activities worldwide. Id. There is also a need to establish a food tracing system to shorten the time between “outbreak, detection, resolution, and recovery.” Id.
make the United States food supply even safer than it is today.\textsuperscript{70} The Group recommended improvements to regulations regarding the management of salmonella and E. coli, both areas of concern due to recent outbreaks.\textsuperscript{71} The group proposed a new trace back and response system, which will be implemented across the country and should improve response time and awareness across the entire food safety system.\textsuperscript{72} The main goal of the Group is to provide a coalition that will increase the effectiveness of all food safety organizations by attempting to reduce overlap and increase

\textsuperscript{70} See Food Safety Working Group, supra note 68, at 3-4 (describing steps Group took to improve food safety). The major steps are focused on a reduction of salmonella and E. coli. \textit{Id.} at 3-4. There is also a push for creating a nationwide illness source trace back and response system to shorten the time between the outbreak, as well as work to contain the contaminated food and notifying the public. \textit{Id.} at 4.

\textsuperscript{71} See Food Safety Working Group, supra note 68, at 3-4. According to the CDC, salmonella is the most common bacterial cause of food-borne illness. \textit{Id.} at 3. The new focus for reducing salmonella is to improve the safety of eggs and poultry. \textit{Id.} A new FDA ruling is expected to reduce the “number of food-borne illnesses associated with consumption of raw and undercooked contaminated shell eggs by approximately 60% . . . and will generate annual savings of over $1 billion.” \textit{Id.} The FSIS responded similarly by establishing a salmonella verification program and hopes to implement this system in 90% of poultry establishments by the end of 2010. \textit{Id.} E. coli has seen a similar response with stronger enforcement in beef facilities. \textit{Id.} at 4. The FDA is also looking to reduce contamination in leafy greens, melons, and tomatoes. See Food Safety Working Group, supra note 68, at 4; see also Gardiner Harris, \textit{E. Coli Kills 2 and Sickens Many; Focus is on Beef}, N.Y. TIMES, Nov. 2, 2009, at A12, available at http://www.nytimes.com/2009/11/03/health/03beef.html (discussing an outbreak that claimed two lives and resulted in a recall of more than 250 tons of ground beef products); Michael Moss, \textit{E. Coli Outbreak Traced to Company that Halted Testing on Ground Beef Trimmings}, N.Y. TIMES, Nov. 12, 2009, at A16, available at http://www.nytimes.com/2009/11/13/us/13ecoli.html (referring to a facility in Ashland, New York that halted testing on beef trimmings and an outbreak ensued). Beef slaughterhouses are reluctant to allow independent testing out of fear more recalls would soon follow. See Moss, supra note 71 at A16; \textit{Salmonella Outbreak Sickens 388 Across US: CDC, Reuters.com}, (Jan. 7, 2009), available at http://www.reuters.com/article/topNews/idUSTRE5066E420090107 (stating the outbreaks that have occurred in forty-two states have sent 18% of these people to the hospital); Elizabeth Weise, \textit{Salmonella Outbreaks Lead to Food-Safety Changes}, USA TODAY, Apr. 2, 2009, at B1, available at http://www.usatoday.com/news/health/2009-04-01-nuts-salmonella-food-safety_N.htm (discussing changes made to regulating various nuts after major peanut recall earlier in the year). In 2004, raw almonds caused widespread sickness, earlier in 2009 there was a major peanut recall, and at the end of October 2009 contamination concerns caused for the recall of two million pounds of pistachios. See Weise, supra note 71 at B1.

\textsuperscript{72} See Food Safety Working Group, supra note 68, at 4. According to the Group, updating the food regulation system would provide for a unified front and allow response time to be reduced drastically through an update to the system. \textit{Id.} The group developed a plan for the FDA to create a better product tracing system, incident command system within three months, and a better collaboration with states to expand outreach within the next year. \textit{Id.}
collaboration between agencies.73

**B. Food Safety Enhancement Act of 2009**

The Food Safety Enhancement Act proposes to “amend the Federal Food, Drug, and Cosmetic Act to improve safety of food in the global market.”74 The new focus on food safety is a result of continued problems with food-borne illnesses and a growing global economy that has increased the number of sources and nations from which the United States receives its food supply.75 The bill, which has already passed in the House of Representatives and the Senate, would create a safer food industry by implementing stricter food safety standards across the United States.76

A major portion of the Act concerns the increase of hazard analysis and the expansion of the definition of adulterated food.77 The updated hazard analysis plan would require a multi-step process, calling for much stricter standards.78 In addition to

73 See Food Safety Working Group, supra note 68, at 5. The Group will increase coordination of food safety activities and allow for stronger communication between the agencies by, among other things, creating an additional leadership position at the FDA to increase inter-agency efficiency. Id.


75 See Choo, supra note 1, at 57 (describing the current state of food safety in the United States). Although the U.S. has one of the safest food industries in the world, there is room for improvement. Id. Choo reports, every year the national Centers for Disease Control and Prevention in Atlanta estimates that one quarter of the American population falls ill with food-borne illnesses. Id.

76 See generally Food Safety Enhancement Act of 2009 H.R. 2749, 111th Cong. (2009) (outlining the bill as a whole); see also Harris & Neuman, supra note 10 (announcing the recent passing of the food safety bill by the Senate).

77 See H.R. 2749 § 102. “Adulterated food—Section 402 (21 U.S.C. § 342) is amended by adding the following to the end of the section: “[i]f it has been manufactured, processed, packed, transported, or held under conditions that do not meet the requirements of sections 418 and 418A.” Id. This expands the definition of adulterated food and requires all facilities to have a hazard analysis, as well as risk based preventive controls. See id.; see also id. § 418 (describing the required hazard analysis).

78 See H.R. 2749 § 418 (describing the hazard analysis plan). A hazard analysis would now be as follows:

1. conduct a hazard analysis (or more than one if appropriate);
2. identify and implement effective preventive controls;
3. monitor preventive controls;
4. institute corrective actions when—
   - (A) monitoring shows that preventive controls have not been properly implemented; or
the prevention of the spread of contaminated foods that would occur from these newly implemented standards, the Act would also allow the FDA to establish additional preventive controls.\textsuperscript{79} These new food safety plans would not affect existing HACCP plans, but the new plans would instead require similar plans in other areas not currently protected.\textsuperscript{80}

The Food Safety Enhancement Act would codify the FDA’s ability to request recalls from facilities that have only been suspected, but not positively found, to be distributing contaminated food, as well as require mandatory recalls for facilities that test positive for distributing contaminated food.\textsuperscript{81} The largest difference between the proposed legislation and the current statutory scheme, in regard to food recall, is that the FDA would have the authority to order facilities to cease distribution of potentially contaminated food.\textsuperscript{82} This would be a great improvement to the FDA’s current multi-step notification process, which creates inherent delays in stopping the distribution of

\begin{itemize}
\item[(B)] monitoring and verification show that such controls were ineffective;
\item[(5)] conduct verification activities;
\item[(6)] maintain records of monitoring, corrective action, and verification; and
\item[(7)] reanalyze for hazards.
\end{itemize}

\textit{Id.} The FDA Secretary will be able to alter and add any additional preventive controls as he or she sees fit. \textit{Id.} In addition, the FDA will provide guidance as to the proper procedure for following the new protocol. \textit{See id.}

\textsuperscript{79} See H.R. 2749 § 418. The proposed bill also allows the Secretary to establish other preventive controls as he or she sees fit. \textit{Id.} There must be a review of the facility and hazard analysis no less than every two years and as often as the owner, operator, or agent of a facility sees fit. \textit{See id.} Additionally, a food safety plan would be required by section 418A for all facilities involved in interstate commerce. \textit{See id. § 418A.}

\textsuperscript{80} See H.R. 2749 § 418A (extending food safety plans to other areas but not having an effect on existing HACCP plans). The food safety plan would include not only the section 418 hazard analysis, but also several other steps that will be important to making the food industry more accountable. \textit{See id.}

\textsuperscript{81} See H.R. 2749 § 420 (describing new food recall requirements). The Secretary can request that the facility recall all food suspected to be contaminated, as well as provide notice to persons who may be affected by this recall. \textit{See id.}

\textsuperscript{82} See H.R. 2749 § 420. “If the Secretary has reason to believe that the use or consumption of, or exposure to, an article of food may cause serious adverse health consequences or death to humans or animals,” the Secretary can order the ceasing of distribution. \textit{Id.} The Secretary can also, as the Secretary deems necessary, notify the public, as well as health officials, of any recall or contaminated food. \textit{See id. § 420(g).} The distribution must be ceased until an appeal has been heard; something that may be filed within twenty-four hours of issuance. \textit{Id. § 420(d).} An informal hearing will be held in a timely manner and no later than five days after the appeal has been filed to ensure proper food safety. \textit{Id.}
contaminated foods.83

International food importation would also receive an overhaul with newer, stricter standards.84 The program, in conjunction with Customs and Border Protection, would facilitate the movement of food, thus affording the FDA and USDA the ability to enforce stricter inspection and regulation standards.85 In fact, the proposed bill would allow the FDA to mandate tougher importation standards and require facilities importing food into the United States to follow a set of standardized guidelines.86

The major changes to the Federal Food, Drug, and Cosmetic Act involve the

83 See supra notes 50-51 and accompanying text (detailing the FDA’s current multi-step notification process).
84 See H.R. 2749 § 805 (describing the new food importation policies). When it comes to imported products, the USDA has a far superior process than the FDA. See Michael R. Taylor, Lead or React? A Game Plan for Modernizing the Food Safety System in the United States, 59 FOOD & DRUG L.J. 399, 399-402 (2004) (presenting ideas for improving and updating food safety regulations). The USDA “sends inspectors to every foreign meat plant producing for the U.S. market,” while the FDA relies on spot checking 1-2% of the imports as the imports cross into the United States. Id. at 400. Currently, even though the food is to be imported to and sold in the U.S., the FDA must rely on the sampling of post-entry food because of a lack of the authority to regulate food products outside the United States. See Note, Reforming the Food Safety System: What if Consolidation isn’t Enough?, 120 HARV. L. REV. 1345, 1364 (2007). Beyond the current inability to regulate imported food, the concern is that even if that authority is given, the FDA will not have sufficient funding to complete the necessary work. See id. at 353, 358. Some of the food regulatory agencies do not even have the power to negotiate with foreign countries to develop agreed upon food safety standards and regulations, a power the FDA fortunately already possesses. See Hammonds, supra note 65, at 431 (discussing the inability of some agencies to negotiate with foreign countries for uniform standards).
85 See H.R. 2749 § 805. The new regulation:

(1) verifies that each facility involved in the production, manufacture, processing, packaging, and holding of the food is in compliance with the food safety and security guidelines developed under subsection (b) with respect to such food;

(2) ensures that appropriate safety and security controls are in place throughout the supply chain for such food; and

(3) provides supporting information to the Secretary.

Id.
86 See H.R. 2749 § 805 (taking into account several factors when determining guidelines applicable to the importation of food). Such factors include: personnel of the importer, physical and procedural safety of importer’s supply chain, as well as the sufficiency of preventive controls in place. Id. § 805(b)(2). There would also be a requirement to register as a processor with the FDA. See Choo, supra note 1 at 61.
agencies’ interventions and responses. Food safety education would become another priority for the continued prevention of food-borne illnesses. Preventive measures would allow the FDA and USDA to prohibit and restrict the movement of food within the United States. Stricter rules and tougher sanctions give the Food Safety Enhancement Act the teeth that the old laws lacked when confronting violations and resolving concerns over food-borne illnesses. Accordingly, enacting the Food Safety Enhancement Act, thus giving the FDA stronger regulatory power, would be the biggest change to the industry.

C. The Need to Improve Funding

Both the FDA and USDA are currently under-funded, understaffed, and controlled by statutes more than a century old. Safety changes in the food industry are

87. See H.R. 2749 §§ 121, 122, 133 (describing new authority given to the agencies when dealing with food-borne illness outbreaks).

88. See H.R. 2749 § 122. Making information available to consumers, health professionals, and the general public will allow for people to make more educated decisions. See id. The Secretary will also have the ability to distribute national and regional food safety advisories. Id. § 122(b). Additionally, creating a standardized format will disperse these messages and advisories more efficiently at the national and local levels. See id.

89. See H.R. 2749 § 133. The restrictions would last for fourteen days and would then be reevaluated within small geographical areas. See id. The Secretary would be allowed to continue the prohibition and could confine large contaminated areas or small contaminated areas, as well as state level confinements. See id.

90. See generally H.R. 2749 (outlining the proposed bill). Others feel as though the bill is not enough of an improvement to the poor regulation authority currently in place. See Michael Thomas, Food safety act a start, but needs to be stronger, ATLANTA J. CONST., July 30, 2009, at A21, available at http://www.ajc.com/opinion/food -safety-act-a-104736.html (stating the act is a step in the right direction, but food safety standards need to be even stronger in the future). But see Carolyn Lochhead, Food Safety Enhancement Act Draws Ire, S.F. CHRONICLE, July 17, 2009, at A13, available at http://www.sfgate.com/cgi- bin/article.cgi?f=/c/a/2009/07/17/MNB618Q3UU.DTL (expressing concerns that the act may go too far and small local farmers will be hurt by these changes).

91. See generally H.R. 2749 (revealing the increased regulatory ability of the FDA).

92. See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 2; see also Choo, supra note 1, at 60. The FDA currently oversees 80% of the food supply, yet receives half the funding of the USDA. CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 58. The under-funding and understaffing has caused the agencies to struggle to keep up with the current demands in food safety. Id. at 60. Congress has expanded the FDA’s duties with more than one hundred new laws that have increased its breadth but not its budget. Id. The USDA has seen similar problems as their budget has increased by 25% over the past two and a half decades, but the consumption of food it protects increased twofold. Id. Inadequate funding and insufficient power has been a larger cause of concern than the lack of agency unification. See Note, Reforming
not only imminent, but they are also extremely necessary. If the FDA were to receive funding in proportion to the amount of food under its authority, its budget would be nearly three billion dollars; however, the FDA’s budget is not nearly that big. Even the USDA has seen its share of funding issues as it has nearly doubled the amount of investigative work, yet it has only had a budget increase of twenty-five percent in the past twenty-seven years.

Following an analysis similar to that of the FDA budget, the USDA’s budget should be more than one.

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93 See Choo, supra note 1, at 56, 61. While food safety has not decreased over the past half decade, the United States has also not seen an increase in their ability to prevent food-borne illnesses. Id. at 57. Michigan State’s Neil Fortin cited the concern that the agencies are currently being starved (and have been for quite some time). Id. at 60. The continually high instances of food-borne illnesses create concern in the industry, and there is a widespread desire to do something to correct this problem immediately. Id. There are talks of creating a single food safety group in the long run, but the concerns with the FDA are too imminent to wait for such a large change; instead, steps need to be taken immediately to reduce food safety concerns. See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 2 (describing the necessity of improving food safety as soon as possible). The creation of the Food Safety Work Group and the House of Representatives’ Food Safety Enhancement Act are steps to improve food safety in the U.S. See Choo, supra note 1, at 56, 57. The Food Safety Enhancement Act was passed by the full House on July 30, 2009 in an overwhelming 283-142 vote. Id. at 61. In addition, the bill was just passed by the Senate on November 30, 2010 by a vote of 73 to 25. See Harris & Neuman, supra note 10.

94 See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 2. Both food safety agencies have had a great financial strain due to funding increases that have not kept up with the anticipated growth of either agency. See Choo, supra note 1, at 58-60.

95 See GAO Testimony, GAO-02-47T, supra note 13, at 5. In 1999, the FSIS’s (the USDA’s major regulatory body) budget was $712 million; thus, while looking at funds, basically and proportionally, the FDA’s budget should be four times as much because four times as much food passes through its organization as compared to the USDA. See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 8 (describing food-borne illnesses from USDA-regulated products as only accounting for 27% of all outbreaks); see also Choo, supra note 1, at 58. Following this analysis and forgoing any inflationary adjustment, efficiency improvements, economies of scale, or funding increases due to a further expansion of responsibilities, the FDA’s budget is more than ten times less than it should be. See GAO Testimony, GAO-02-47T, supra note 13, at 5 (describing the FDA’s 1999 budget as $283 million).

96 See Choo, supra note 1, at 60 (discussing the USDA’s financial instability).
billion dollars, but it is not. Based on these projected results, protection of the food industry as a whole is based on a budget $2.5 billion less than what appears to be the calculated optimum amount of funding.

Although most industry experts and insiders agree on the necessity for changes beyond the appropriation of additional funds, there are several industry leaders who believe the current plan is sufficient if funding is increased. While some of these approximated numbers may be higher than necessary—due to potential economies of scale in inspecting and overseeing the food supply as well as necessary improvements to efficiency—they do paint a rather grim picture, demonstrating the lack of the agencies’ abilities to sufficiently protect the American food supply.

The biggest proposed changes in food safety are not increases in budgets, something that has been debated for years, but regulatory changes emanating from the Food Safety Enhancement Act, which will result in the ability to better protect the food supply. Within the Food Safety Enhancement Act, the major alterations will be to the

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97 See GAO Testimony, GAO-05-212, supra note 13, at 5 (defining FSIS’s 1999 budget as $712 million for food safety expenditures). If FSIS’s budget has only increased by 25%, its budget in 1981 would be approximately $540 million. See Choo, supra note 1, at 60. Seeing as how the consumption of meat and poultry has doubled in the same period, it would seem as though the amount of regulatory work would have also doubled—resulting in what should have been a doubling in funding over the same course of time. See id. This reasoning results in the USDA being more than $300 million under-funded, as their budget should be $1.08 billion. See GAO Testimony, GAO-05-212, supra note 13, at 5.

98 See supra notes 95-97 and accompanying text (mathematically analyzing the current financial position of both the FDA and USDA); see also GAO Testimony, GAO-05-212, supra note 13, at 5 (describing the current budgets for the FDA and USDA).

99 See Choo, supra note 1, at 62. Peter Hutt, the FDA’s former chief counsel, believes the FDA “already knows how to protect the public’s health if it were only given the resources to do so.” Id. Nevertheless, it is nearly unanimously agreed that food safety needs more funding across the board to continue to protect the U.S. food supply. See id. at 58-62.

100 See generally Choo, supra note 1 (noting the pitfalls of FDA and USDA regulations and funding, as well as the need for change); CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4 (discussing the current financial and regulatory challenges the FDA and USDA currently face).

101 Compare Choo supra note 1, at 58-62 (discussing the restricted powers and lack of funding for food regulatory agencies), and CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 5 (referring to the financial difficulties faced in the food safety business), with Food Safety Enhancement Act of 2009, H.R. 2749, 111th Cong. (2009), at Title 1 (outlining the proposed bill through the general table of contents). This comparison reveals how the overhaul of the old food safety regulations proposed by the Food Safety Enhancement Act will have a more drastic effect on the industry. See Choo, supra note 1, at 61-62 (discussing concerns over the effects of the proposed bill by certain people in the industry).
Federal Food, Drug, and Cosmetic Act. Most notably, the authority of the FDA will drastically increase, and the FDA will have stronger regulatory abilities.

**D. Forget Voluntary, it is Time for Mandatory Recalls; Plus Community-wide Education**

Currently, the FDA does not have the regulatory ability to mandate that companies recall potentially infected food; without a directive, outbreaks are becoming larger and more widespread. The proposed Food Safety Enhancement Act gives the FDA the authority to require companies to immediately cease distribution of infected foods, and the FDA can even order these companies to recall potentially infected foods. The major difference, besides the severity of the recall, between the emergency recall and the amended recall, is the timetable set for recall and the hearing process for appeals. Additionally, the FDA would have the authority to notify state and local

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102 See H.R. 2749, at preamble (stating that the Act is intended to “amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes”). While other food safety regulations will be affected by the changes presented in the new act, the bulk of the changes will be to the Federal Food, Drug, and Cosmetic Act, as it is the statute from which the FDA receives the majority of its regulatory powers. See also The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399 (2006) (entirety of the Federal Food, Drug, and Cosmetic Act and within it, the authorities granted to the FDA).

103 See Choo, supra note 1, at 61 (discussing the proposed improvements to FDA authority).

104 See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4, at 8. Due to the fact that the FDA can only ask companies to voluntarily make recalls, there are major gaps in time between when the potential infection is discovered and when the food companies issue recalls to their consumers. Id.

105 See H.R. 2749 §§ 111, 420. Section 111 of the proposed Act amends section 301 of the Federal Food, Drug, and Cosmetic Act by adding: “failure to notify of a violation . . . or comply with an order issued under section 420” of the proposed Act is prohibited. Id. Compare 21 U.S.C. § 331 (2006) (listing activities currently viewed as prohibited under Federal Food, Drug, and Cosmetic Act), with H.R. 2749 § 111. Under section 420 of the proposed Act, the Secretary may order a cease on distribution of foods which the FDA believes the “use or consumption of, or exposure to [said food] may cause serious adverse health consequences or death to humans or animals.” H.R. 2749 § 420(c). Section 420 goes on to grant the FDA the power to order recalls in two instances: (1) if after the chance for an informal hearing the FDA determines the cease of distribution should be amended to require a recall, or (2) if the FDA has “credible evidence or information that an article of food . . . presents an imminent threat of serious adverse health consequences or death.” See H.R. 2749 §§ 420(c), (f) (describing orders to recall as well as emergency recall procedures).

106 Compare H.R. 2749 § 420(c) (discussing the amended recall procedure), with H.R. 2749 § 420(f) (articulating the emergency recall procedure). When the FDA amends the initial cease of distribution to include the recall, the decision is completed after the opportunity for an informal hearing, held within five days of the appeal and no more than six days after the initial order has
health agencies of the alleged violations and current recalls that potentially affect consumers in the area.\textsuperscript{107} The FDA’s new ability to require recalls instead of requesting voluntary recalls would drastically reduce lag time between discovery and recall, causing for a reduction in the number of illnesses per outbreak.\textsuperscript{108}

The Food Safety Enhancement Act would improve upon the current flawed surveillance and data collection system.\textsuperscript{109} The data collection and notification systems currently in place would be overhauled allowing for a more prompt, widespread notification and sharing of information with various state and national health agencies.\textsuperscript{110} Additionally, the method of classifying and storing data in the federal system would be improved to allow for a better ability to recognize outbreaks and notify the public of any known outbreaks.\textsuperscript{111} The proposed Act would also provide additional tools and

\textsuperscript{107} See \textit{id.} §§ 420(d), (e). The amended recall would have three procedural requirements to be properly instated: (1) specify a timetable for recall, (2) require reports to the FDA on recall progress, and (3) provide for notice to consumers who may be affected. \textit{id.} § 420(c)(2). On the other hand, an emergency recall would deliver the requirements the company alleged to be in violation, with the possibility for recall to occur after the issuance of the order. \textit{Contra H.R. 2749} § 420(6)(1). The affected company would still have the ability to appeal, as they do with amended recalls, but the issuance of the order would already be distributed. \textit{id.} § 420(6)(2).

\textsuperscript{108} See \textit{CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4}, at 8 (indicating delay from voluntary recalls decreases effectiveness); \textit{see also H.R. 2749} § 420(6) (explaining the process for emergency recalls). As discussed in recent analysis, recall delay causes an increase in illnesses. \textit{See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4}, at 8. Thus by giving the FDA authority to recall, it may be fairly presumed the number of instances of illness will also be curbed. \textit{See id.}

\textsuperscript{109} \textit{Compare supra notes} 40-48 and accompanying text, \textit{with H.R. 2749} §§ 121-23 (codifying the new intervention techniques to be utilized). The three sections address the concerns of surveillance and the currently mismanaged data collection (section 121), public education and advising (section 122), and newly improved research (section 123). \textit{See H.R. 2749} §§ 121-23.

\textsuperscript{110} H.R. 2749 § 121. Although there is at present very little information sharing between federal health agencies and their state and local counterparts, the proposed act will “facilitate [the] sharing of findings on a more timely basis” to allow for improved prevention of the spread of an outbreak. \textit{Id. Compare supra notes} 44-48 (describing the lack of current reporting requirements), \textit{with H.R. 2749} § 121(b)(2) (requiring information be shared on a more timely basis).

\textsuperscript{111} \textit{Compare CENTER FOR SCIENCE IN THE PUBLIC INTEREST, supra note 4}, at 1 (reporting that illnesses are classified by pathogen and not by food source), \textit{with H.R. 2749} § 121(b)(3)-(6) (discussing the new method of collection). The new process would categorize outbreaks with specific food instead of by pathogen so that specific foods could be identified as the cause of outbreaks. \textit{See H.R. 2749} § 121(b)(4)-(5). Additionally, this information would become public knowledge in a more timely manner to help ensure that the public has proper notification of any
resources to the state and local agencies to allow for improvements to their individual investigative abilities.\textsuperscript{112} Moreover, the proposed Food Safety Enhancement Act would address the need to have better public education about food safety issues and prevention to create improved awareness of the dangers.\textsuperscript{113} The new system would provide for both outreach education, as well as health advisories to the public.\textsuperscript{114} The food education plan, combined with improved research, would allow for the proposed Act to improve current communication shortfalls within the system.\textsuperscript{115}

E. Redefining Food Safety

In addition, the proposed Food Safety Enhancement Act provides a narrower definition of the term adulterated food and creates stricter regulatory standards.\textsuperscript{116} By potential dangers with the food supply. See id. § 121(b)(6).

\textsuperscript{112} See H.R. 2749 § 121(c)(1). This section will require the FDA to develop and implement strategies that will allow for the attainment of numerous goals, including:

[A] [I]mproving . . . outbreak response and containment (B) Accelerat[ing] food-borne illness surveillance and outbreak investigation . . . (C) Stren[then] the capacity of State and local agencies to carry out inspections and enforce safety standards (D) Improv[ing] the effectiveness of Federal, State, and local partnerships . . . (E) Shar[ing] information on a timely basis.

\textit{Id.} The Secretary of Health and Human Services will also conduct a review of the capacity and ability of the agencies at the State and local levels to determine any potential needs for enhancement. See H.R. 2749 § 121(c)(2) (examining staffing, laboratory capacity, and information systems to make this determination).

\textsuperscript{113} See H.R. 2749 § 122. It is presumed that a more educated public will contribute to the improvement of the food industry as a whole. See id.

\textsuperscript{114} \textit{Id.} In order to promote public awareness, a “national public education program on food safety” would be created to make the public more informed. \textit{Id.} § 122(a). The information and education will be provided to individuals so they can know of potential dangers and learn of preventive measures that can be taken to reduce the risk of infection. \textit{Id.} § 122(a)(1)-(2). The education will also educate health professionals to allow for an improvement in diagnosis and treatment. \textit{Id.} The health advisories will be used to provide some uniformity to the notification system that currently exists at both the regional and national levels. \textit{Id.} § 122(b). Additionally, the state and local agencies will have their advisories incorporated into the aforementioned education program. \textit{See H.R. 2749 § 122(b)(3)}.

\textsuperscript{115} See H.R. 2749 §§ 122-123. Research will be conducted to improve sanitation and food safety practices, develop improved techniques for monitoring inspection and implementation (along with better methods of detection to determine sources of contamination to improve containment), improve antibiotic resistance treatments, and develop methods to reduce or destroy pathogens during processing. \textit{Id.} § 123(1)-(11).

\textsuperscript{116} \textit{Compare} 21 U.S.C. § 342 (2006) (defining adulterated food under the FFDCA), with H.R. 2749 §§ 102, 418 (broadening the definition of adulterated food to include further violations). Section
creating harsher regulations, the proposed Act would give the FDA more proactive authority to prevent adulterated foods from entering into the food supply, reduce the availability of tainted foods, and decrease instances of food-borne illness outbreaks.\textsuperscript{117} A major portion of the burden to produce higher quality and safer food would be shifted to companies by requiring them to determine and implement preventive controls.\textsuperscript{118} Although the major burden may be on the food companies themselves, a significant amount of power and authority would remain vested with the FDA.\textsuperscript{119} Additionally, there would be strict review requirements preventing the hazard analyses and preventive controls from becoming severely outdated, as they have in the past.\textsuperscript{120}

102 of the proposed act would add “[i]f it has been manufactured, processed, packed, transported, or held under conditions that do not meet the requirements of §§ 418, 418(A)” to the definition of adulterated foods. H.R. 2749 § 102. This addition adds a hazards analysis to the definition of adulterated food and makes this FDA regulation similar to the HACCP plans in place for other FDA foods and all USDA regulated facilities. Compare H.R. 2749 § 418 (describing the new hazard analysis), with USDA, \textit{Guidebook for the Preparation of HACCP Plans}, \textit{supra} note 62 (discussing the current HACCP plans and requirements). Essentially the proposed hazards analysis would require companies that handle food at some point in the production or distribution stages to have plans in place for identifying preventive controls and preventive actions. \textit{See} H.R. 2749 § 418.

\textsuperscript{117} \textit{See} H.R. 2749 § 418 (describing the new analysis required by and the intervention abilities of the FDA). By expanding the meaning of adulterated food, the FDA would be able to recall food in violation of the new definition because such food would be deemed hazardous to the food supply. \textit{See id.} § 420 (stating the FDA’s authority to recall adulterated or misbranded food). Under section 418 of the proposed act, the FDA also has the authority to intervene and identify both potential hazards and preventive controls. \textit{See id.} §§ 418(b)(2), (c)(2).

\textsuperscript{118} \textit{See} H.R. 2749 § 418. Coupling the new responsibilities of the companies with the ability of the FDA to intervene and offer assistance will provide for stronger safety regulation without requiring massive growth to the FDA, either financially or in terms of manpower. \textit{See id.} (indicating the majority of the burden would be upon the companies to act as their own regulatory authority).

\textsuperscript{119} \textit{See} H.R. 2749 § 418(c)(2). The FDA is still allowed to establish its own preventive controls which companies, in turn, would be required to implement at their facilities. \textit{See id.} Additionally, this would afford the FDA the opportunity to establish more national standards as they learn of various individual plant implementations. \textit{See id.}

\textsuperscript{120} \textit{See} H.R. 2749 § 418(g). There are three instances in which a review and potential revision of the hazard analysis must be completed: “(i) not less than every two years; (ii) if there is a change in the process or product that could affect the hazard analysis; and (iii) if the [FDA] determines that it is appropriate to protect public health . . . .” \textit{Id.} § 418(g)(1)(A). A similar proposed overhaul by the World Health Organization (“WHO”) occurred in 2002 to reduce instances of food-borne illnesses internationally. \textit{See} World Health Organization, \textit{WHO Global Strategy for Food Safety: Safer Food for Better Health} (2002), available at http://www.who.int/foodsafety/publications/general/en/strategy_en.pdf (outlining a proposed plan to improve international food safety). The WHO, in a joint effort with the United Nation’s Food and Agriculture Organization (“FAO”), will develop
To further bolster the safety of food, the proposed Food Safety Enhancement Act takes the hazard analysis one step further by requiring an additional food safety plan. The food safety plan has ten distinct requirements that are subject to the FDA’s inspection and regulation. With these additional standards comes the necessity of balancing the United States’ interest in importing food, with the necessity of ensuring appropriate food safety standards.

See id. at 2. The resulting risk analyses would be shared regularly with the hopes of improving the system on a regular basis. See id. at 3. These standards would improve the safety of food in the domestic market, as well as at the global level. See id. at 7. While the WHO serves all Member States, their major concern with these proposals is in developing any underfunded nations, but if these standards can be implemented internationally, then the stricter standards of the Food Safety Enhancement Act should be implemented in the United States. Compare id. (outlining WHO’s proposed changes), with Food Safety Enhancement Act of 2009, H.R. 2749, 111th Cong. (referring to the Food Safety Enhancement Act). In 2002, the European Union (“EU”) also established new food safety standards by determining the general principles and requirements of food law in the European Union. See Official Journal of European Communities, Regulation (EC) No. 178/2002 of the European Parliament and of the Counsel (Jan. 28, 2002), available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:EN:NOT (outlining the new procedures in place throughout the EU).

H.R. 2749 § 418A. This plan is required to be written and implemented before any facility “introduces or delivers for introduction into interstate commerce any shipment of food . . . .” Id. These plans are not designed to reduce the presence of existing HACCP authorities, but instead, these plans bolster the existing HACCP authorities with further regulatory ability. See id. § 418A(4).

See H.R. 2749 §§ 418A(b), 418A(3). The plan is required to have the following elements:

1. The hazard analysis and any reanalysis . . . ;
2. A description of the preventative controls being implemented . . . ;
3. A description of the procedures for monitoring preventative controls;
4. A description of the procedures for taking corrective action;
5. A description of verification activities for the preventative controls . . . ;
6. A description of the facility’s recordkeeping procedures;
7. A description of the facility’s procedures for the recall of articles of food . . . ;
8. A description of the facility’s procedure for tracing the distribution history of articles of food . . . ;
9. A description of the facility’s procedures to ensure a safe and secure supply chain . . . ;
10. A description of the facility’s procedure to implement the science-based performance standards under section 419.

Id. § 418A(b). In addition, the FDA will issue guidance or “promulgate regulations” to establish science-based standards for conducting much of this analysis. Id. § 418A(3).

See H.R. 2749 § 418A(3)(B). The FDA will consult other nations’ food safety regulations to be sure the new proposed regulations and guidelines will be consistent with international standards. Id. This will be done only where the additional efforts are both practical and appropriate to ensure the most beneficial standards possible. See id.
With a growing global economy and the United States becoming more reliant on importing foods, there is a need to have screening measures in place to ensure imported food meets the new standards as well. The proposed Food Safety Enhancement Act would provide the FDA with the authority to create regulations and guidelines to coordinate the movement of food into the United States. International food quality would be up to the new standards of the United States through the implementation of specific guidelines and food registration requirements. However, these additional regulations, implemented by the passing of the Food Safety Enhancement Act, would place a much larger financial burden on small, local farmers’ ability to stay afloat and survive.

124 See Choo, supra note 1, at 57 (referring to concerns of an increasing global food supply). Farmers across the country are alarmed at the possibility of such strong reforms. Id. at 61. William Marler, a Seattle food safety attorney, states that in his experience, no outbreaks have been linked to farmers’ market products. Id. Therefore, he argues, local farmers should not be the ones to shoulder the burden of larger plants, which are truly to blame for the large majority of the crisis. Id.

125 See H.R. 2749 § 805(a) (2009). This section would verify each facility is in compliance with section 805(b), ensure sufficient safety and security controls are in place, and provide this information to the appropriate parties. See id. § 805(a)(1)-(3).

126 See H.R. 2749 § 805(b). The guidelines will take into account the following factors to ensure proper compliance:
   - The personnel of the person importing the food;
   - The physical and procedural safety and security of such person’s food supply chain;
   - The sufficiency of preventative controls for food and ingredients . . .;
   - Vendor and supplier information;
   - Other programs for certification or verification by a qualified certifying entity used by the importer, and
   - Such other factors . . . deemed necessary.

Id. § 805(b)(2). This will allow for the appropriate preventive measure to be taken to again improve the food supply in the United States. See id. § 805.

127 See Choo, supra note 1, at 61. Small farmers and producers are concerned the fees and plans will drive up their costs and could even put many of them out of business. Id. The article goes on to quote an attorney and food-borne illness litigation expert, Marler Clark, as saying, “[i]n [sixteen] years, I’ve never had an outbreak linked to a farmers market,” thus, raising the question as to why they should essentially be punished for the larger corporations’ wrongdoings. Id. To respond to this, the proposed act would account for the impact these regulations and future guidelines will have on small businesses and issue guidance to these companies to assist them with compliance. See H.R. 2749 § 418A(3)(D). Additionally, the small businesses would have more time to comply than the larger facilities, which will have eighteen months after the enactment of this act to take to appropriate steps necessary towards compliance. Id. §§ 418A(6)(A), (B). The smaller businesses shall have two years to comply, and a further exception will be made to very small businesses that would have three years to implement measures to comply with all of the new regulations. Id. §§ 418A(6)(B)(i), (ii).
F. Stronger Sanctions Could Improve Compliance

To complement the new regulations that would be implemented with the passage of the Food Safety Enhancement Act, there would also be stricter penalties, both civilly and criminally, to deter non-compliance, particularly in regards to a violation based on willful non-compliance.\(^{128}\) By implementing higher maximum sentencing periods, larger fines, and increased penalties for willful violations, the Act provides more severe criminal penalties for misbranding and adulteration.\(^{129}\) The Act would also make potential civil penalties faced by violators more robust by raising fines and giving heftier penalties to companies that intentionally violate the rules.\(^{130}\) These increased penalties should incentivize companies involved in any of the multiple steps of food processing, production, distribution, and storing to strictly adhere to the regulations and deter them from willingly or knowingly violating the rules.\(^{131}\)


\(^{129}\) See H.R. 2749 § 134(3). Currently the maximum sentence that can be imposed for a first time violation is one to three years and does not leave room for taking mens rea into account when it comes to sentencing. See 21 U.S.C. § 333 (revealing mens rea is not taken into account). The new law will allow for a prison term of up to ten years for knowingly violating any of several subsections of section 333. H.R. 2749 § 134(3). The proposed act will crack down on the production of food that is knowingly misbranded or adulterated. See id. Additionally, the violator could face fines in accordance with Title 18 of the United States Code, which codifies crimes and criminal procedures within the U.S. Federal system. Id. While the fines are not anything new, the combination of a hefty fine and a jail term, that could be more than three times the original term, will become an even stronger deterrent to companies contemplating a willful violation. Compare 21 U.S.C. § 333 (2006), with H.R. 2749 § 134 (comparing the old criminal sanctions with the newly proposed sanctions).

\(^{130}\) Compare 21 U.S.C. § 333 (2006) (discussing the current civil penalties violators are subject to), with H.R. 2749 § 135(a) (making monetary amounts for civil penalties much larger). Civil penalties will now be $20,000 for an individual, which cannot exceed $50,000 in a single instance, and $250,000 in the case of any one person, not to exceed $1,000,000 in a single proceeding. See H.R. 2749 § 135(a)(2)(A). Keeping with the section regarding criminal penalty’s new focus on mens rea, the civil penalties will also be much harsher for violations done knowingly. See id. § 135(a)(2)(B). The penalties for knowingly committing a violation will be: $50,000 in the case of an individual, not to exceed $100,000 in a single instance, and $500,000 in the case of any one person, not to exceed $7,500,000 in any single proceeding. See id. Additionally, a separate offense will be counted for each day that the person is held in violation. See id. § 135(a)(2)(C).

\(^{131}\) See H.R. 2749 §§ 134(3), 135(a)(2). Fines that could quickly accumulate into millions of dollars, if there are multiple violations and due to how each day during which the violation occurs counts as an offense, are a very strong deterrent for even the largest companies. Id. Further, the possibility of going to jail for up to ten years will certainly keep many executives in check as well. Id.
G. Other Proposals and Their Potential for Success

Although the proposed Food Safety Enhancement Act has already passed through the House of Representatives and recently received approval by the Senate, it has received a significant amount of resistance from various industry insiders, ranging from large company owners to small local farmers, who believe it will be increasingly difficult to comply with the harsh new sanctions and argue that the burdens could outweigh the potential benefits of change. These members of the industry have suggested, in the alternative, that there should be an increase in funding to the food safety agencies, as well as an increase in manpower. The most controversial suggestion is combining all food safety agencies, including the USDA and the FDA, into one parent agency that would oversee all food safety nationwide. However, the major differences between the USDA and FDA make it very unlikely that the two organizations will integrate in the near future, or even further down the road.

IV. Conclusion

132 See Harris & Neuman, supra note 10 (discussing the Senate’s recent passing of a food safety bill); see also Choo, supra note 1, at 61. Opponents’ concerns range from small businesses being unable to afford the costs of compliance to dismay over possible international repercussions. Id. The argument is that the $500 registration fee for all companies involved in the supply chain of most foods being consumed in the U.S., as well as the costs of implementing the new standards, will destroy many small businesses. Id. See also Lochhead, supra note 90, at A13 (discussing concerns many industry leaders and local farmers have with the pending bill and the impact it will have on the food industry as a whole); Roger Buddenberg, Food Safety Proposal Isn’t Going Down Smoothly, Omaha World Herald, July 18, 2009 at D1, available at http://www.omaha.com/article/20090718/MONEY/707189950 (presenting concerns of small area farmers who would be drastically impacted by the passage of this legislation).

133 See Choo, supra note 1, at 62. Funding and staffing are the major keys to protecting public health as the FDA is already experienced with the process itself. Id. His main concern is that merely adding more regulation will overwhelm an already overwhelmed agency and create further inefficiency. Id.

134 See Choo, supra note 1, at 62. Agriculture Secretary Tom Vilsack has led the charge in bringing all the responsibilities under one roof. Id.

135 See Choo, supra note 1, at 62. Merging the two agencies seems like something that could only be accomplished over the long-term, and even then it appears that the USDA and FDA are too different in their approaches to be combined into one agency. Id. The argument for a unified agency, led by Vilsack, is countered by the extreme disagreement of many others involved who believe the two groups are far too different to allow for them to efficiently be brought under one umbrella. Id. According to Hutt, the FDA “check[s] labels, and reviews good manufacturing practices” while the USDA are “trained veterinarians who look at dead animals and decide if they are diseased.” Id.
Considering the recent wave of food recalls and instances of food-borne illness outbreaks across the country, there is clearly a need for the reformation of the food safety system. The problem is there is not a consensus on what to do and how to do it. The President’s Food Safety Working Group, while not a consolidation of food safety regulation, does allow all of the agencies to have access to information produced by each other and promotes collaboration between the agencies to improve food safety nationwide. The group will be beneficial in fostering future improvements needed to ensure that it is not another century before a major food reform is completed again. With the growing global market and an increasing reliance on imported food products, it is important that the United States takes the necessary steps to ensure the safety of all food within its borders.

The Food Safety Enhancement Act will provide safety with its newer, harsher standards that will place more of the burden and responsibility on the companies themselves, instead of relying completely on outside inspections. The Act will provide for increased accountability and stricter sanctions for food safety violations. Additionally, allowing companies to develop their own plans and control such plans enables them to adapt the guidelines to their needs and capabilities. Nonetheless, it is clear these new regulations will be a major burden upon smaller farms and something needs to be done to help reduce the impact on the local farmers and not force local farmers out of existence. Companies of all sizes are concerned about the increase in their own costs, but the costs they face do not outweigh the reality that thousands of people are dying of food-borne illnesses every year in the United States alone—deaths that can be prevented.

The Food Safety Enhancement Act is not without its flaws and opposition, but it is a necessary step towards ensuring better, safer food in the United States. To complete the overhaul of the outdated system, more needs to be done, but this is a step in the right direction. Although the old laws withstood the test of time, they have become old and less effective over the past century; this new law will fix that, assuring Americans in knowing the food they consume will be better protected.