

**Integrating Stakeholder Roles in Food
Production, Marketing, and Safety Systems:
An Evolving Multi-Jurisdictional Approach‡**

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The Jeffersonian ideal of the citizen-farmer has been reduced to mere folklore. Although farmers undoubtedly remain engaged citizens and agriculture continues to be the primary economic driver in rural communities, the declining number of farms¹ and the increasing size and intensity² of remaining farming operations has transformed the rural landscape from the pastoral images of the *American Gothic*³ to one of industrialization portrayed in the recent documentary *Food, Inc.*⁴

On the demand side of this agricultural supply chain, a disconnect emerged in the latter half of the twentieth century between the consumer and farmer. Populist songs such as *Old McDonald's Farm* faded from the public consciousness. In an age of plenty, many consumers did not bother to think seriously about where their food came from, who produced it, and the environmental consequences of the evolving mass-production systems dotting the rural landscape. The 1960s and 1970s era of social engagement and “back to the land” movement was replaced with consumerism, the Walmart effect, and increasing isolation from the realities of agricultural production. The turn of the twenty-first century, however, witnessed a renewal of food awareness and accompanying consumer demand for transparency, along with calls for a shortening of the food supply chain to provide better quality products that supported the local farm economy.

¹ See U.S. DEP'T OF AGRIC., STATISTICAL REPORTING SERVICE, TREND CONTINUES TOWARD FEWER AND LARGER FARMS (Jan. 10, 1968), available at <http://usda.mannlib.cornell.edu/usda/nass/NumbFarmLa//1960s/1968/NumbFarmLa-01-10-1968.pdf> (discussing decrease in number of farms from 1959 through 1968); CAROLINE S. GLEATON & CARL G. ANDERSON, FACTS ABOUT TEXAS AND U.S. AGRICULTURE, 86–90 (May 10, 2010), available at http://agecoext.tamu.edu/fileadmin/user_upload/Documents/Resources/Publications/Facts/2010/AgFacts.pdf (discussing decrease in number of farms from 1964 through 2009).

² One example is in the dairy industry, where the number of dairy farms has decreased by thirty-eight percent between 2000 and 2009, while milk production has increased thirteen percent over the same time frame. See U.S. Dep't of Agric., *Milk Cows: Number of Operations by Year, US*, NAT'L AGRIC. STATISTICS SERV., http://www.nass.usda.gov/Charts_and_Maps/Milk_Production_and_Milk_Cows/cowoper.asp (last visited Apr. 21, 2011); U.S. Dep't of Agric., *Milk: Production by Year, U.S.*, NAT'L AGRIC. STATISTICS SERV., http://www.nass.usda.gov/Charts_and_Maps/Milk_Production_and_Milk_Cows/milkprod.asp (last visited Apr. 21, 2011).

³ Grant Wood's *American Gothic* epitomizes the rural work ethic of Midwestern farmers. See The Art Institute of Chicago, *About This Artwork*, ARTIC.EDU, <http://www.artic.edu/aic/collections/artwork/6565> (last visited Apr. 21, 2011).

⁴ FOOD, INC. (Robert Kenner & Eric Schlosser 2009).

Although garnering considerable media attention,⁵ the revival of food movements has for the most part remained confined to a relatively small segment of the American market. Sales of organic food—one measure of consumers' food consciousness—have grown tremendously,⁶ but still comprise a small percentage of total food sales.⁷ The number of farmers' markets has more than doubled in this decade,⁸ but is insignificant when compared to traditional grocery stores.⁹ The United States Department of Agriculture's (USDA) "Know Your Farmer, Know Your Food" program has sought to bridge this gap and elevate the status of the farmer, but even this program raised the ire of some farming groups, who claim that USDA was unfairly denigrating large-scale commodity agriculture production by highlighting the achievements of localized specialty crop farmers selling fruits and vegetables.¹⁰ In sum, a growing number of consumers are now more aware of food production issues, but the overall percentage with in-depth understanding remains small.

The disconnect between farmer and consumer is not solely a rural-urban divide. The Environmental Working Group's annual publication of government subsidy payments received by farmers has engendered significant discord in rural communities. Townfolk struggling to keep local stores open look with disgust—or perhaps

⁵ For example, a Westlaw database search of *The New York Times* from 2008–2010 resulted in 314 hits for the phrase "local food" and 229 hits for "organic food."

⁶ U.S. sales of organic products have increased from \$1 billion in 1990 to \$24.8 billion in 2009. Organic Trade Ass'n, *Industry Statistics and Projected Growth*, OTA.COM, <http://www.ota.com/organic/mt/business.html> (last visited Apr. 21, 2011).

⁷ The Food Marketing Institute, the trade group for the grocery wholesale and retail industry, reported total supermarket sales in 2009 of \$556.973 billion. FMI, *Supermarket Facts*, FMI.ORG, http://fmi.org/facts_figs/?fuseaction=superfact (last visited Apr. 21, 2011).

⁸ Agric. Marketing Serv., *USDA Announces that National Farmers Market Directory Totals 6,132 Farmers Markets*, U.S. DEP'T OF AGRIC. (Aug. 4, 2010), <http://www.ams.usda.gov/AMSV1.0/ams.printData.do?template=printPage&navID=&page=printPage&dDocId=STELPRDC5085966&dID=136193&wf=false&docTitle=USDA+Announces+that+National+Farmers+Market+Directory+Totals+6%2C132++Farmers+Markets> (noting a sixteen percent growth in farmers markets from 2009 to 2010); U.S. Dep't of Agric., *Number of Operating Farmers Markets*, USDA.GOV, http://www.usda.gov/img/content/Numbers_of_Farmers_Markets_1994-2010.jpg (last visited Apr. 21, 2011) (indicating an increase from 2863 markets in 2000 to 6132 in 2010).

⁹ The Food Marketing Institute reported more than 35,000 supermarkets with annual sales above \$2 million. Food Mktg. Inst., *Supermarket Facts*, FMI.ORG (2009), http://fmi.org/facts_figs/?fuseaction=superfact.

¹⁰ Letter to The Honorable Tom Vilsack, Secretary, U.S. Dep't of Agric., from Senators John McCain, Saxby Chambliss, and Pat Roberts (April 27, 2010), *available at* <http://www.agri-pulse.com/uploaded/KnowYourFarmers.pdf>.

envy—at the farmer cashing a six-figure subsidy check and driving a new pickup to shop at the regional Walmart supercenter. Although rural communities certainly understand the connection between farming and food, the postmodern scale of commodity grain farming and animal confinement facilities has begun to unravel the previously robust fabric of rural communities.¹¹

The broader public's general apathy with regard to food production, however, rests upon shaky ground. Over the past decade a series of major food safety incidents has captured the public's attention—at least for a few days, until the collective attention returns to the latest development on the Jersey Shore or other reality TV fixation. For example, in 2010 ninety-four people in sixteen states fell ill from *Salmonella* 14,[5],12:i:- in alfalfa sprouts,¹² almost 2000 suffered from *Salmonella enteritidis* in eggs,¹³ and 272 individuals in forty-four states contracted *Salmonella montevideo* from spices used in Italian-style deli meats.¹⁴ In 2009, two individuals were sickened by *Escherichia coli* O157:H7 in raw cookie dough,¹⁵ another 235 consumers were struck by *Salmonella saintpaul* from alfalfa sprouts,¹⁶ and more than 700 individuals were sickened by *Salmonella typhimurium* in peanut butter, with nine deaths attributed to the

¹¹ See Caroline Tauxe, *Family Cohesion vs. Capitalist Hegemony: Cultural Accommodation on the North Dakota Farm*, 17 DIALECTICAL ANTHROPOLOGY 291, 291 (1992) (discussing role of large agribusiness on changing social fabric).

¹² See Ctrs. for Disease Control & Prevention, *Investigations of a Multistate Outbreak of Human Salmonella I 4,[5],12:i:- Infections Linked to Alfalfa Sprouts*, DEP'T OF HEALTH & HUMAN SERV. (Dec. 28, 2010), <http://www.cdc.gov/salmonella/i4512i-/122810/>.

¹³ Ctrs. for Disease Control & Prevention, *Investigation Update: Multistate Outbreak of Human Salmonella Enteritidis Infections Associated with Shell Eggs*, DEP'T OF HEALTH & HUMAN SERV. (Dec. 2, 2010), <http://www.cdc.gov/salmonella/enteritidis/#investigation>; see Food & Drug Admin., *Frequently Asked Questions and Answers: FDA's Investigations into the Salmonella Enteritidis Outbreak Involving the Recall of Shell Eggs*, DEP'T OF HEALTH & HUMAN SERV. (Aug. 27, 2010), <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm223723.htm>.

¹⁴ Ctrs. for Disease Control & Prevention, *Investigation Update: Multistate Outbreak of Human Salmonella Montevideo Infections*, DEP'T OF HEALTH & HUMAN SERV. (May 4, 2010), <http://www.cdc.gov/salmonella/montevideo/>.

¹⁵ Ctrs. for Disease Control & Prevention, *Multistate Outbreak of E. coli O157:H7 Infections Linked to Eating Raw Refrigerated, Prepackaged Cookie Dough*, DEP'T OF HEALTH & HUMAN SERV. (Jun. 30, 2009), <http://www.cdc.gov/ecoli/2009/0630.html>.

¹⁶ Ctrs. for Disease Control & Prevention, *Investigation of an Outbreak of Salmonella Saintpaul Infections Linked to Raw Alfalfa Sprouts*, DEP'T OF HEALTH & HUMAN SERV. (May 8, 2009), <http://www.cdc.gov/salmonella/saintpaul/alfalfa/>.

strain.¹⁷ In comparison, 2008 was relatively mild with only 1442 cases of *Salmonella saintpaul* occurring across forty-three states; the strain was attributed to hot peppers and possibly tomatoes from farms around Tamaulipas, Mexico.¹⁸ Health officials linked 272 illnesses to *Salmonella* 4,[5],12:i:- in frozen pot pies in 2007.¹⁹ That same year, officials linked 425 illnesses to *Salmonella tennessee* in peanut butter²⁰ and thirty-two illnesses to ground beef with *E. coli* O157:H7, prompting the second largest meat recall in U.S. history and forcing Topps Ground Beef into bankruptcy.²¹ In 2006 *E. coli* O157:H7 in shredded iceberg lettuce caused seventy-one illnesses,²² and in bagged spinach caused over 200 illnesses and three deaths.²³ Other significant instances of foodborne illness included prepackaged lettuce in 2005,²⁴ raw almonds²⁵ and presliced Roma tomatoes²⁶ in 2004, green onions

¹⁷ Ctrs. for Disease Control & Prevention, *Investigation Update: Outbreak of Salmonella Typhimurium Infections, 2008-2009*, DEP'T OF HEALTH & HUMAN SERV. (Apr. 29, 2009), <http://www.cdc.gov/salmonella/typhimurium/update.html> (may have caused nine deaths).

¹⁸ Ctrs. for Disease Control & Prevention, *Investigation of Outbreak of Infections Caused by Salmonella Saintpaul*, DEP'T OF HEALTH & HUMAN SERV. (Aug. 28, 2008), <http://www.cdc.gov/salmonella/saintpaul/jalapeno/>.

¹⁹ Ctrs. for Disease Control & Prevention, *Investigation of Outbreak of Human Infections Caused by SALMONELLA 4,[5],12:i:-*, DEP'T OF HEALTH & HUMAN SERV. (Oct. 29, 2007), <http://www.cdc.gov/salmonella/4512eyeminus.html>.

²⁰ Ctrs. for Disease Control & Prevention, *Salmonellosis—Outbreak Investigation, February 2007*, DEP'T OF HEALTH & HUMAN SERV. (Mar. 7, 2007), http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_2007/030707_outbreak_notice.htm.

²¹ Recall Release, U.S. Dep't of Agric., Food Safety & Inspection Serv., Updated: New Jersey Firm Expands Recall of Ground Beef Products Due to Possible *E. Coli* O157:H7 Contamination, FSIS-RC-040-2007 (Oct. 6, 2007), available at http://www.fsis.usda.gov/PDF/Recall_040_2007_Exp_Update.pdf; Associated Press, *Topps Meat to Close Down After Meat Recall*, MSNBC.COM (Oct. 5, 2007), http://www.msnbc.msn.com/id/21149977/ns/business-us_business.

²² Ctrs. for Disease Control & Prevention, *Multistate Outbreak of E. coli O157 Infections, November–December 2006*, DEP'T OF HEALTH & HUMAN SERV. (Dec. 14, 2006), <http://www.cdc.gov/ecoli/2006/december/121406.htm>.

²³ Ctrs. for Disease Control & Prevention, *Update on Multi-state Outbreak of E. coli O157:H7 Infections From Fresh Spinach*, DEP'T OF HEALTH & HUMAN SERV. (Oct. 6, 2006), <http://www.cdc.gov/foodborne/ecolispinach/100606.htm>.

²⁴ Press Release, U.S. Food & Drug Admin., FDA Issues Nationwide Health Alert on Dole Pre-Packaged Salads (Oct. 2, 2005), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108495.htm>.

²⁵ Press Release, U.S. Food & Drug Admin., Paramount Farms Expands Recall of Raw Almonds (May 22, 2004), available at <http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2004/ucm111607.htm>.

in 2003,²⁷ ground beef²⁸ and poultry products²⁹ in 2002, and assorted beef products in 2000.³⁰ A 2011 report from the Centers for Disease Control and Prevention (CDC) estimated that *each year* there are 38.4 million episodes of foodborne illness in the United States, resulting in 71,878 hospitalizations and, tragically, 1686 deaths.³¹

Is industry to blame for these deaths? If so, why hasn't the tort system corrected this externality?³² Is it that consumers engage in unsafe food handling practices to cause these injuries? Or are the deaths a regulatory problem? As the Supreme Court noted in *United States v. Dotterweich*, food safety affects "the lives and health of

²⁶ Ctrs. for Disease Control & Prevention, *FDA Investigates Certain ROMA Tomatoes as Source of Foodborne Illness Outbreaks in Pennsylvania, Ohio, and Mid-Atlantic States*, DEP'T OF HEALTH & HUMAN SERV. (July 23, 2004), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108332.htm>.

²⁷ CTRS. FOR DISEASE CONTROL & PREVENTION, Vol. 52, No. 47, HEPATITIS A OUTBREAK ASSOCIATED WITH GREEN ONIONS AT A RESTAURANT—MONACA, PENNSYLVANIA, 2003, MORBIDITY & MORTALITY WEEKLY REPORT 1155–57 (Nov. 28, 2003), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5247a5.htm>.

²⁸ See Elizabeth Becker, *19 Million Pounds of Meat Recalled After 19 Fall Ill*, N.Y. TIMES, July 20, 2002, <http://query.nytimes.com/gst/fullpage.html?sec=health&res=9B01E2D91F39F933A15754C0A9649C8B63&pagewanted=1>.

²⁹ Marian Burros, *Eating Well; Listeria Thrives in Political Hotbed*, N.Y. TIMES, Oct. 30, 2002, <http://query.nytimes.com/gst/fullpage.html?sec=health&res=9A02E3DF123FF933A05753C1A9649C8B63>.

³⁰ Paola Farer, *Colorado Plant Linked to E. coli Outbreak Story*, MARLER CLARK (Aug. 25, 2000), http://www.about-ecoli.com/ecoli_outbreaks/news/colorado-plant-linked-to-ecoli-outbreak-story.

³¹ Elaine Scallan et al., *Foodborne Illness Acquired in the United States—Unspecified Agents*, 17 EMERGING INFECTIOUS DISEASES 16, 16 (2011). At first glance, one might conclude that the 71,878 hospitalizations and 1686 deaths per year from foodborne illness, *id.*, is an improvement from the numbers in the CDC's previous (1999) report of 325,000 hospitalizations and 5000 deaths. Paul S. Mead, et al., *Food-related Illness and Death in the United States*, 5 EMERGING INFECTIOUS DISEASES 605, 607 (1999), but the authors of the 2010 report noted that different data and methodologies used in the 2010 report prevent any comparison with the 1999 report. Scallan et. al., *supra* at 19–21 (discussing differences in methodology from the CDC's 1999 report). Scallan et. al., *Foodborne Illness Acquired in the United States—Major Pathogens*, 17 EMERGING INFECTIOUS DISEASES 7, 7 (2011).

³² For an insightful discussion of why the food industry has not embraced certain food safety practices despite the possibility of tort liability, see generally Neal D. Fortin, *The Hang-Up with HACCP: The Resistance to Translating Science into Food Safety Law*, 58 FOOD & DRUG L.J. 565 (discussing the difficulty of tracing back responsibility for foodborne illness and the reluctance of the food industry to embrace the HACCP food safety procedures that would reduce foodborne illness). See also Jean C. Buzby & Paul D. Frenzen, *Food Safety and Product Liability*, 24 FOOD POL'Y 637 (1999) (discussing weaknesses in product's liability system for foodborne illness).

people which, in the circumstances of modern industrialism, are largely beyond self-protection” and thus in need of government regulation.³³ Justice Jackson, in his dissent in *Dalehite v. United States*, further explained this justification for government intervention based on the changing nature of modern-day consumption:

This is a day of synthetic living . . . [when] our population is dependent upon mass producers for its food and drink . . . [that are no longer] natural or simple products but complex ones whose composition and qualities are often secret. Such a dependent society must exact greater care than in more simple days and must require from manufacturers or producers increased integrity and caution as the only protection of its safety and well-being. . . . Where experiment or research is necessary to determine the presence or the degree of danger, the product must not be tried out on the public, nor must the public be expected to possess the facilities or the technical knowledge to learn for itself of inherent but latent dangers. The claim that a hazard was not foreseen is not available to one who did not use foresight appropriate to his enterprise.³⁴

What can the government do to further prevent foodborne illness and promote food safety? Unfortunately, regulating the food system is not the same as regulating the mechanical safety of an automobile. Relatively straightforward command-and-control regulatory programs with which the government has a track record of success³⁵ do not fit squarely with the diffuse nature of food production and distribution. Nor can the externality of foodborne illness be controlled in the same manner as pollution from the smoke stack of a chemical factory. The regulatory paradigm facing government food safety reformers involves an agricultural industry that (1) remains the primary driver of economics, politics, and social engagement in rural society; (2) is of increasing scale and intensity; and (3) provides essential sustenance to

³³ 320 U.S. 277, 280 (1943). Until the mid-nineteenth century, most food regulation occurred at the local level, reflecting the scope of commerce at the time. As commerce expanded into regional and national food networks, states exercised jurisdiction over food regulation, with most states having some form of food regulation in place by 1900. Paul Hyman, *U.S. Food and Drug Law and FDA—A Historical Background*, in A PRACTICAL GUIDE TO FOOD AND DRUG LAW AND REGULATION 15 (2d ed. 2002). After the introduction of more than 100 food and drug bills in Congress between 1880 and 1906, Congress finally passed the 1906 Food and Drug Act and the 1906 Meat Inspection Act. *Id.* at 17–18.

³⁴ 346 U.S. 15, 51–52 (1953).

³⁵ See, e.g., William L. Andreen, *Water Quality Today—Has the Clean Water Act Been a Success?*, 55 ALA. L. REV. 537, 542 (2004) (discussing the remarkable success of the EPA and Clean Water Act in controlling point sources of pollution and slowing the loss of wetlands).

our nation and nations abroad. These factors do not preclude improvements in food safety, but do complicate the process of mustering the political will for necessary reform.

Evaluating prospects for reform require an understanding of the current system and its constituents—especially the agencies subject to change. Accordingly, Part I provides a brief overview of the historical development of the food safety system in the United States and an exploration of the split in regulatory authority between the two primary food safety agencies—the USDA and the Food and Drug Administration (FDA). This division of responsibility among government agencies adds to the difficulty of regulating the diverse food supply chain—an issue analyzed in Part I in greater detail and throughout this Article.

Part II explores the first of this Article’s two discussions of recent examples of food safety failures within this multiagency jurisdictional environment—fresh-cut leafy greens contamination. In 2006, several hundred people fell ill after consuming bagged spinach contaminated with *E. coli* O157:H7. In the prior ten years, there were twelve documented outbreaks of *E. coli* in leafy greens.³⁶ But rather than addressing the structural issues leading to the food safety lapse, the FDA issued draft guidelines.³⁷ Meanwhile, the processing industry organized a voluntary marketing agreement to safeguard against future outbreaks while retailers incorporated private “super-metrics” standards into their supply contracts. At the federal level, a group of large processors proposed the creation of a national marketing agreement, which would incorporate some disease-prevention measures. Although the USDA has not finalized the proposed marketing agreement, some aspects of the Food Safety Modernization Act may address safety issues in leafy green production and processing.³⁸

³⁶ Daniel Cohen, *The History, Politics & Perils of the Current Food Safety Controversy: CAFF Guide to Proposed Food Safety Regulations*, COMMUNITY ALLIANCE WITH FAMILY FARMERS, Jan. 2008, at 21, available at <http://www.caff.org/CAFF.Policy.Guide.1.pdf>.

³⁷ U.S. DEP’T OF HEALTH AND HUMAN SERVICES, FOOD & DRUG ADMIN, GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF LEAFY GREENS; DRAFT GUIDANCE (July 2009), available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm174200.htm>. For further discussion of FDA’s role in fresh-cut produce safety, see Part III.D, *infra*.

³⁸ See H.R. 2751, 111th Cong. §§ 103, 105 (2011) (Specifically, Section 418 requires implementation of hazard analysis and risk-based preventive controls (i.e., HACCP or

In 2010, more than 1900 people were struck with *Salmonella* from shell eggs, prompting the largest egg recall in history.³⁹ Unfortunately, this was not a new food safety issue, but one the government had grappled with for more than two decades without success.⁴⁰ The lack of progress in addressing the issue stemmed from the failure of multiple government agencies—the Animal and Plant Health Inspection Service (APHIS), Agricultural Marketing Service (AMS), and the Food Safety and Inspection Service (FSIS) in the USDA, and the FDA in the Department of Health and Human Services (HHS)—to coordinate responsibilities to ensure the safety and quality of eggs and egg products.⁴¹ Accordingly, Part III analyzes the shell egg regulatory regime in light of the most recent food safety failure.

This Article concludes with a comparative analysis of the government and private industry responses to the repeated instances of foodborne illness in fresh-cut greens and shell eggs. These stakeholder reactions expose several governance concerns—particularly issues of voice, accountability, and fairness—that both industry and government should consider in the wake of declining public confidence in the nation’s food safety system. Finally, the authors explore how passage of the FDA Food Safety Modernization Act may moderate some of the critical governance issues in the leafy greens context and impact future development of private “super-metrics” and industry-led marketing agreements.

Hazard Analysis Critical Control Point methodology) in all food processing facilities and Section 419 requires the FDA, in cooperation with USDA and other agencies, to issue production and harvesting standards for fruits and vegetables). “HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.” Food & Drug Admin., *Hazard Analysis and Critical Control Points (HACCP)*, U.S. DEP’T OF HEALTH & HUMAN SERV., <http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/default.htm> (last updated July 20, 2009).

³⁹ See Food & Drug Admin. *Salmonella Enteritidis Outbreak in Shell Eggs*, U.S. DEP’T OF HEALTH & HUMAN SERV. (Nov. 30, 2010), <http://www.fda.gov/food/newsevents/whatsnewinfood/ucm222684.htm>.

⁴⁰ U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-99-184, *FOOD SAFETY: U.S. LACKS A CONSISTENT FARM-TO-TABLE APPROACH TO EGG SAFETY 2* (July 1, 1999) [hereinafter GAO EGG SAFETY], available at <http://archive.gao.gov/f0902b/162324.pdf>.

⁴¹ *Id.* See also Lyndsey Layton, *Unsafe Eggs Linked to U.S. Failure to Act*, WASH. POST, Dec. 11, 2010, at A1, available at <http://www.washingtonpost.com/wp-dyn/content/article/2010/12/10/AR2010121007485.html> (noting that “Balkanization was a key factor in the government’s failure to regulate eggs over the past two decades”).

I

**DEVELOPING A SAFE FOOD PRODUCTION SYSTEM:
A PATCHWORK QUILT**

The history of the food safety system in the United States has been the subject of extensive scholarship over the years.⁴² Although comprehensive in its treatment of the agencies' regulatory authority, little attention has focused on the overall role of the agricultural production system and the development of the agencies' holistic role in promoting safety within the broader food supply chain. As described in more detail below, the regulatory system for the production of safe food is the product of ad hoc decision making arising from legislation designed to address the crisis du jour while appeasing an organized and active commodity production system rather than the development of a comprehensive, systematic program designed around the production of safe, nutritious food.

Tracing back to the earliest government engagement in food production, consumer safety has taken a back seat.⁴³ In 1820, the House of Representatives formed the House Committee on Agriculture,⁴⁴ followed by the Senate Committee on Agriculture, Nutrition, and Forestry five years later.⁴⁵ Interestingly, none of the twenty jurisdictional areas committed to the House Committee mention food safety.⁴⁶ The same is true of the jurisdiction for the five

⁴² See Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law: Cases and Materials*, 1–22 (2d ed. 1991); Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61 (2000); Peter Barton Hutt, *Food Law & Policy: An Essay*, 1 J. FOOD L. & POL'Y 1 (2005); Peter Barton Hutt, *Symposium on the History of Fifty Years of Food Regulation Under the Federal Food, Drug, and Cosmetic Act: A Historical Introduction*, 45 FOOD DRUG COSM. L.J. 17 (1990); Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2 (1984); Jesse D. Lyon, *Coordinated Food Systems and Accountability Mechanisms for Food Safety: A Law and Economics Approach*, 53 FOOD & DRUG L.J. 729 (1998).

⁴³ See generally Emily J. Shaffer, *Is the Fox Guarding the Hen House? Who Makes the Rules in American Nutrition Policy*, 57 FOOD & DRUG L.J. 371 (2002) (discussing the government's failed attempts to balance support for food production with nutrition goals).

⁴⁴ See H. Comm. Agric., *Committee History*, HOUSE.GOV <http://agriculture.house.gov/singlepages.aspx?NewsID=25&LSBID=23> (last visited Apr. 24, 2011).

⁴⁵ See S. Comm. Agric., Nutrition & Forestry, *Committee History*, SENATE.GOV, <http://agriculture.senate.gov/site/cmtehistory.html> (last visited Apr. 24, 2011).

⁴⁶ See H. Comm. Agric., *supra* note 44.

Senate subcommittees.⁴⁷ And yet agriculture is the starting point for the nation's safe food supply.

In 1862, Congress established the USDA⁴⁸ and the land-grant university system.⁴⁹ The 1887 Hatch Act created experiment stations affiliated with each state's land-grant university to facilitate agricultural research.⁵⁰ Not surprisingly, in light of the jurisdiction of the congressional committees and the relatively localized nature of food production and consumption, these institutions focused on facilitating a system of agricultural production to feed the country's westward expansion and growing population, not the safety of the food supply chain. This singular focus, however, remained steadfast despite the lengthening of the food supply system from local to international and the potential for widespread food contamination due to consolidation of processing and distribution in the supply chain. With the support of the USDA and the land-grant system, the post-war period through the 1970s witnessed a period of agricultural intensification using postwar technologies and capital investment focusing on increased per-acre yields for commodities under the USDA mantra of "get big or get out."⁵¹

Another famous USDA phrase from this era was to plant "fence row to fence row," thereby eliminating many of the buffer strips and natural habitat surrounding a farmer's fields.⁵² The resulting conversion of these areas to full-time crop production had a serious detrimental effect on environmental values such as water quality and

⁴⁷ See S. Comm. Agric., Nutrition & Forestry, *supra* note 45.

⁴⁸ Department of Agriculture Organic Act, ch. 72, 12 Stat. 387 (1862) (current version at 7 U.S.C. § 2201 (2010)).

⁴⁹ First Morrill Act, ch. 130, 12 Stat. 503 (1862) (current version at 7 U.S.C. §§ 301–308 (2010)).

⁵⁰ HATCH Act, ch. 314, 24 Stat. 440 (1887) (current version at 7 U.S.C. § 361a–361i (2010)).

⁵¹ Although often attributed to USDA Secretary Earl Butz in the 1970s, the policy of "get big or get out" originated in the Eisenhower administration and USDA Secretary Ezra Taft Benson. See Pete Daniel, *Not Predestination: The Rural South and Twentieth-Century Transformation*, in *THE AMERICAN SOUTH IN THE TWENTIETH CENTURY*, 91, 97 (Craig S. Pascoe et al. eds., 2005). Secretary Butz added further encouragement for the consolidation and industrialization of agricultural production with his slogan of "adapt or die." See Jim Chen, *Get Green or Get Out: Decoupling Environmental from Economic Objectives in Agricultural Regulation*, 48 OKLA. L. REV. 333, 335 (1995).

⁵² James M. Jeffords, *Soil Conservation Policy for the Future*, 37 J. OF SOIL & WATER CONSERVATION 10 (1982). As discussed below, many of the private industry safety standards for leafy greens require "sterile" fields, including the elimination of all vegetation. See *infra* note 178 and accompanying text.

soil erosion, not to mention habitat loss. This seemed inapposite to the agency's mission of fostering agricultural productivity as well as the USDA's lessons allegedly learned from the mistaken public policies responsible for creating the Dust Bowl.⁵³ But the potential risks embedded in technological solutions to industrial-scale externalities seemed of little consequence.

Despite the USDA's long-standing primary objective of maximizing agricultural production, the agency retained a major role in ensuring the safety of the food supply even after the 1940 transfer of the FDA from the USDA to the Federal Security Agency, reorganized as the Department of Health and Human Services.⁵⁴ This has, at times, placed the agency in a difficult position when food safety proposals conflict with agricultural productivity, such as yield-per-acre or animal slaughtering requirements.

Primary enforcement of the nation's first food safety statute—the Pure Food Act of 1906⁵⁵—resided with the USDA's Bureau of Chemistry,⁵⁶ which was later reorganized as the FDA.⁵⁷ The 1906 Meat Inspection Act similarly provided the USDA's Bureau of Animal Industry jurisdiction over meat safety.⁵⁸ Specifically, the Act required inspection of livestock before slaughter and sanitary standards of slaughterhouses and processing plants.⁵⁹ The 1940 transfer of the FDA to the Federal Security Agency included a transfer of enforcement powers over the 1938 Federal Food, Drug,

⁵³ See TIMOTHY EGAN, *THE WORST HARD TIME* 267 (2006) (discussing the mistaken production policies of the USDA in bringing about the Dust Bowl); citing REP. OF GREAT PLAINS DROUGHT AREA COMM. (Aug. 27, 1936), available at <http://newdeal.feri.org/hopkins/hop27.htm>.

⁵⁴ See Reorganization Plan No. IV of 1940, 54 Stat. 1237, § 12 (1940); see also Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 84 n.131 (2000) (describing the rationale for President Roosevelt's transfer of FDA from USDA).

⁵⁵ Pure Food & Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (June 30, 1906) (repealed 1938).

⁵⁶ *Id.* §§ 4, 5 (providing authority to USDA's Bureau of Chemistry).

⁵⁷ In 1930 the name of the Bureau of Chemistry changed to the Food and Drug Administration. See Michelle Meadows, *A Century of Ensuring Safe Foods and Cosmetics*, FDA CONSUMER MAG., Jan.–Feb. 2006, <http://www.fda.gov/AboutFDA/WhatWeDo/History/FOrgsHistory/CFSAN/ucm083863.htm>.

⁵⁸ Pub. L. No. 59-382, 34 Stat. 674 (June 30, 1906) (current version at 21 U.S.C. § 601).

⁵⁹ *Id.*

and Cosmetic Act,⁶⁰ the successor to the Pure Food Act. However, jurisdiction over meat products remained with the USDA, establishing a historical split in regulatory authority that remains today.

Subsequent food safety legislation concerning animals, such as the 1957 Poultry Products Inspection Act⁶¹ and the 1970 Egg Products Inspection Act,⁶² vested jurisdiction in the USDA, rather than under the FDA's general purview for food safety via the Food, Drug, and Cosmetic Act. The result is a confused regulatory system in which different agencies exercise jurisdiction over a product depending upon the stage in production and the relative meat or poultry content in the end product.

Pizza is an infamous example of this byzantine system of multiagency oversight. At the farm input stage of the supply chain, the USDA has jurisdiction over plant seeds, the FDA oversees the safety of animal feed, and the Environmental Protection Agency (EPA) regulates chemical inputs. On the farm, all three agencies have an oversight role in the production of wheat for the crust and tomatoes for the sauce, and the USDA and the FDA share jurisdiction over the animals. At the first level of processing, the FDA has jurisdiction over the milling of wheat into flour, the USDA and the FDA regulate tomato sauce processing and cheese production from the dairy cow, and the USDA has sole jurisdiction over the slaughter of the pigs and manufacturing of pepperoni. At the second stage of processing, the assembly of the ingredients into pizza, the FDA has sole jurisdiction over the manufacturing of a cheese pizza, while the USDA has sole authority over a meat pizza by virtue of the meat content.⁶³

The government's egg safety program presents a similar regulatory two-step between the USDA and the FDA, depending on whether the issue is egg safety or quality and whether the egg is in the shell—considered a “shell egg”—or broken to create an “egg product.”⁶⁴ In

⁶⁰ 52 Stat. 1040 (June 23, 1938) (codified at 21 U.S.C. § 301 et seq.).

⁶¹ 71 Stat. 441 (1957) (codified at 21 U.S.C. § 451 et seq.).

⁶² 84 Stat. 1620 (1970) (codified at 21 U.S.C. § 1031 et seq.).

⁶³ U.S. GOV'T. ACCOUNTING OFFICE, GAO/T-RCED-99-256, U.S. NEEDS A SINGLE AGENCY TO ADMINISTER A UNIFIED, RISK-BASED INSPECTION SYSTEM 6 (Aug. 4, 1999) (statement of Lawrence J. Dyckman), available at <http://www.gao.gov/archive/1999/re99256t.pdf>.

⁶⁴ U.S. GEN. ACCOUNTING OFFICE, *supra* note 40, at 4. The USDA's Animal and Plant Health Inspection Service (APHIS) also administers a program to control *Salmonella Enteritidis* in breeding flocks that supply hens to laying flocks. See USDA, *National Animal Health Surveillance System, National Poultry Improvement Plan—Salmonella*

general, the FDA has the responsibility for the safety of shell eggs throughout the supply chain. This responsibility included, in late 2009, implementation of a long-awaited *Salmonella enteritidis* eradication program.⁶⁵ Moreover, the 1991 amendments to the Egg Products Inspection Act provided FDA authority for shell egg safety at the retail level, including at groceries, restaurants, and institutions.⁶⁶ USDA's Food Safety Inspection Service (FSIS) assumes jurisdiction when shell eggs are directed to a processing plant for breaking to make egg products.⁶⁷ Once these egg products leave the factory and enter commerce, however, the regulatory responsibility shifts back to the FDA.⁶⁸ Another USDA agency, the Agricultural Marketing Service (AMS), regulates shell egg quality under both the voluntary egg grading program and the mandatory Shell Egg Surveillance Program.⁶⁹ Shell egg packers participating in fee-based grading program may affix the official USDA grade shield to products meeting USDA quality standards. The mandatory surveillance program seeks to ensure that shell eggs are wholesome, unadulterated, and properly labeled.⁷⁰ As part of the compulsory surveillance program, USDA inspectors visit each packing plant at least four times per year. In contrast, FDA inspectors rarely visit shell

Enteritidis, NSU.APHIS.USDA.GOV, http://nsu.aphis.usda.gov/inventory/activity.faces?INVENTORY_NUMBER=30 (last visited Apr. 24, 2011) (describing the agency's *Salmonella enteritidis* surveillance program).

⁶⁵ On July 9, 2009 the FDA issued a final rule, with a compliance date of July 9, 2010, requiring "shell egg producers to implement measures to prevent *Salmonella Enteritidis* (SE) from contaminating eggs on the farm and from further growth during storage and transportation." Prevention of *Salmonella Enteritidis* in Shell Eggs During Production, Storage, and Transportation, 74 Fed. Reg. 33,030, (July 9, 2009) (codified at 21 C.F.R. pt. 118) [hereinafter FDA SE Final Rule]. The legal authority for this program rests in both the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 342(a)(4), 371(a) (2010) and the Public Health Service Act, 42 U.S.C. §§ 243, 264, 271 (2010). For further analysis of the FDA program, see A. Bryan Endres & Michaela N. Tarr, *United States Food Law Update: Initial Food Safety Restructuring Efforts, Poultry Production Contract Reforms and Genetically Engineered Rice Litigation*, 6 J. FOOD L. & POL'Y 103, 119–123 (2010).

⁶⁶ See 21 U.S.C. § 1034(e)(3) (2010).

⁶⁷ U.S. GEN. ACCOUNTING OFFICE, *supra* note 40, at 33. An egg product is "any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry." 21 U.S.C. § 1033(f).

⁶⁸ U.S. GEN. ACCOUNTING OFFICE, *supra* note 40, at 33.

⁶⁹ *Id.* at 34.

⁷⁰ *Id.* at 35.

egg facilities.⁷¹ AMS also has developed a voluntary Plant Sanitation and Good Manufacturing Practices Program for shell egg processors and a fee-based service to conduct third-party monitoring for an industry-developed safety program.⁷² To help sort out their respective responsibilities between shell eggs and egg products to prevent overlaps and regulatory gaps, the USDA and the FDA have entered into a series of memorandums of understanding.⁷³

As described above, the USDA has a significant statutory role in ensuring a safe food supply. And yet the predominant view by many in the agency remains that production is the agency's primary, and perhaps sole, mission. For example, the stated mission of AMS is "to facilitate the competitive and efficient marketing of agricultural products,"⁷⁴ despite its responsibility for grading and labeling eggs, quarterly plant inspections, developing sanitation and good manufacturing practices, and implementing industry-developed safety programs—clear examples of food safety responsibilities. The Administrator of AMS explicitly rejected the agency's food safety mission, testifying bluntly to Congress that "AMS is not a food safety agency."⁷⁵

In stark contrast, the FDA has embraced its consumer protection role,⁷⁶ to the extent Congress has provided sufficient financial

⁷¹ *Id.* at 3.

⁷² *Id.* at 35–36.

⁷³ See Consumer and Marketing Service, Egg Products Inspection Act, Cooperative Agreement with Food and Drug Administration for Administration and Enforcement, 37 Fed. Reg. 2686-04 (Feb. 4, 1972); Regulatory Activities Concerning Residues of Drugs, Pesticides, and Environmental Contaminants in Foods, 50 Fed. Reg. 2,304-01 (Jan. 16, 1985); Refrigeration and Labeling Requirements for Shell Eggs, 57 Fed. Reg. 48,569, 48,572 (Oct. 27, 1992) (codified at 7 C.F.R. pt. 56, 59) (discussing memorandum of understanding executed between FDA and AMS on May 19, 1992; Memorandum of Understanding Between the Food and Drug Administration and the Agricultural Marketing Service, U.S. Dep't of Agric., 61 Fed. Reg. 55,646 (Oct. 28, 1996).

⁷⁴ Agric. Mktg. Serv., *AMS Mission, Vision and Values*, AMS.USDA.GOV, <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&navID=AMSMissionStatement&rightNav1=AMSMissionStatement&topNav=AboutAMS&leftNav=&page=AboutAMSMissionStatement&resultType=&acct=AMSPW> (last visited Apr. 24, 2011).

⁷⁵ *Ready to Eat or Not? Examining the Impact of Leafy Green Marketing Agreements: Hearing Before the Subcomm. on Domestic Policy of the H. Comm. of Oversight and Gov't Reform*, 111th Cong. 2 (July 2009) (statement of Rayne Pegg, Administrator, Agric. Marketing Serv., USDA) [hereinafter *Pegg Testimony*], available at <http://oversight.house.gov/images/stories/Hearings/pdfs/20090729Pegg.pdf>.

⁷⁶ Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 50 FOOD & DRUG L.J. 101, 104 (1995).

support.⁷⁷ But existing statutes limit its jurisdiction and the agency must coordinate and cooperate with the USDA and other agencies such as Homeland Security. Although the 2010 FDA Food Safety Modernization Act (FSMA)⁷⁸ significantly advanced the FDA's oversight authority, meat,⁷⁹ poultry, and some eggs remain beyond the FDA's jurisdiction. And the calls for the establishment of a single agency to administer food safety will continue.⁸⁰

Despite AMS's declaration that its focus is on product quality and does not have a food safety mission, the agency is considering a proposal to regulate safety directly through the conduit of quality through the proposed National Leafy Greens Marketing Agreement.⁸¹ This is a rather rare approach within the context of food regulation. The primary food safety statute—the Food, Drug, and Cosmetic Act—considers quality aspects within the adulteration rubric only in

⁷⁷ See, e.g., Bryan Walsh, *The Food Safety Bill Finally Passes, But It's Just the First Step*, TIME, Dec. 22, 2010, <http://healthland.time.com/2010/12/22/the-food-safety-bill-finally-passes-but-its-just-the-first-step/print/>. See also U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-1047, FOOD SAFETY: IMPROVEMENTS NEEDED IN FDA OVERSIGHT OF FRESH PRODUCE 18–21 (Sept. 2008) [hereinafter GAO FRESH PRODUCE REPORT], available at <http://www.gao.gov/new.items/d081047.pdf>.

⁷⁸ FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011).

⁷⁹ The FDA, however, does have limited jurisdiction over live animals intended for food. See *United States v. Tuent Livestock*, 888 F. Supp. 1416, 1424 (S.D. Ohio 1995) (“Accordingly, the Court concludes that, in light of the structure of the FDCA and the legislative history of the Act, it is permissible for the FDA to interpret the term ‘food,’ as used in 21 U.S.C. § 331(a), to include live animals raised for food and intended to be offered for slaughter.”).

⁸⁰ See, e.g., Single Food Safety Agency Act of 2010, H.R. 6552, 111th Cong. (2010) (calling for creation of a single agency to coordinate food safety in the United States); U.S. GOV'T. ACCOUNTING OFFICE, *supra* note 63 at 9 (“Creating a single agency to administer food safety activities that are uniform and risk-based is the most effective way for the federal government to resolve long-standing problems”); see U.S. GEN. ACCOUNTING OFFICE, GAO-04-588T, FEDERAL FOOD SAFETY AND SECURITY SYSTEM: FUNDAMENTAL RESTRUCTURING IS NEEDED TO ADDRESS FRAGMENTATION AND OVERLAP (Mar. 30, 2004), available at <http://www.gao.gov/new.items/d04588t.pdf>; 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, 401–02 (2004) (“[T]he current organizational fragmentation of the system . . . divides food safety leadership and defeats accountability for the system's successes and failures.”); Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 115–136 (2000) (arguing for consolidation of food safety responsibilities); Sandra B. Eskin, *Putting All Your Eggs in One Basket: Egg Safety and the Case for a Single Food-Safety Agency*, 59 FOOD & DRUG L.J. 441 (2004).

⁸¹ See discussion *infra* notes 183–192 and accompanying text.

the rarely used “otherwise unfit for food” classification.⁸² In other words, the FDA will consider a product adulterated only if the quality is so bad that it is unfit for human consumption.⁸³ As discussed in the following sections, the leafy greens industry—perhaps in an effort to stave off more intrusive federal regulation—has proposed an industry-designed and USDA-sanctioned marketing agreement to impose disease prevention measures through its quality control and orderly marketing process jurisdiction.

II

LEAFY GREENS: NUTRIENT-DENSE FOODS WITH POTENTIALLY DEADLY CONSEQUENCES

A. *Leafy Greens—A Blossoming Market*

It is difficult to pinpoint the precise historical origins of leafy greens as a food staple, though leafy greens have been around at least since Shakespeare’s “salad days.”⁸⁴ However, only in the last twenty years has the humble salad—long thought to be the food equivalent of a movie preview—come into its own as a major food industry. It is true that more people are eating more fruits and vegetables in general⁸⁵—no doubt a result of a fresh and healthy foods movement that has exalted organics and excoriated McDonald’s. Convenience has played a role in increased consumption as well: pre-bagged greens and pre-cut fruits save the time and hassle of slicing and dicing and drop easily into on-the-go brown bags and lunchboxes. The food service industry—including fast food restaurants, educational institutions, hospitals, and the military—benefits from the product uniformity, the lower sanitation costs, and the decreased preparation time that fresh-cut produce provides.⁸⁶ And “significant increases in imported produce have made a greater variety and volume of fresh produce available year round.”⁸⁷

⁸² 21 U.S.C. § 402(a)(3) (2010).

⁸³ See *United States v. 298 Cases*, 88 F.Supp. 450, 451 (D. Or. 1949) (finding some of the asparagus at issue tough and woody, but not unfit for consumption).

⁸⁴ WILLIAM SHAKESPEARE, *ANTONY AND CLEOPATRA*, act 1, sc. 5 (“My salad days, when I was green in judgment: cold in blood. . .”).

⁸⁵ See GAO FRESH PRODUCE REPORT, *supra* note 77, at 1 (“According to the U.S. Department of Agriculture (USDA), the average American annually consumed 13 pounds more fresh fruit and 50 pounds more fresh vegetables from 2003 through 2005 than from 1983 through 1985, an increase of about 14 percent and 41 percent, respectively.”).

⁸⁶ Cohen, *supra* note 36, at 8.

⁸⁷ GAO FRESH PRODUCE REPORT, *supra* note 77, at 1.

Even though Americans have been eating more leafy greens, the term itself is broad and escapes precise definition.⁸⁸ In any case, the category of produce marketed as leafy greens includes both whole-head or bunch greens, such as the head of lettuce found on a farm, and fresh-cut greens, which are cut, processed, perhaps mixed with other greens, and bagged as salad. This latter category—bagged salad mixes—has been the main driver of the leafy greens industry’s rapid growth in the past twenty years. The fresh-cut produce market rocketed from no sales in 1985 to \$3.3 billion in 1994, and then to an astounding \$15 billion in 2005.⁸⁹ Packaged salads represent fifty percent of the fresh-cut produce market, fruits represent twenty percent, all other vegetables represent fifteen percent, and baby carrots represent the final fifteen percent.⁹⁰

Like most major food processing industries, the leafy greens industry is segmented and highly structured; many different industry groups play roles in the “farm-to-fork” process. There are three main roles: producers, handlers and processors, and retailers. Leafy green

⁸⁸ “Leafy greens” can encompass a wide variety of produce, though leafy-greens mixes typically include lettuce (79% of market production value), cabbage (15%), and spinach (7%). *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, 1 (Sept. 22, 2009) (testimony of Diane Wetherington, Executive Vice President, Intertox), available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5079701> [hereinafter *Wetherington Testimony*]. The term could also include also include radicchio, cress, arugula, chard, cilantro, endive, escarole, kale, and potentially even certain herbs and spices. U.S. DEP’T OF AGRIC., DRAFT NATIONAL AGREEMENT REGULATING LEAFY GREEN VEGETABLES: DEFINITIONS at § 970.13 (2009) [hereinafter DRAFT LEAFY GREENS MARKETING AGREEMENT DEFINITIONS], available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5077208> (last visited Apr. 24, 2011). This wide variance in product has led at least one small grower of leafy greens to frame the category mainly as a marketing ploy: “Leafy greens’ are not a crop, not a species, not even a group of species in one genera. They are a marketing category defined only by the imagination of processors who include various products in processed salad bags or mixes” *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, 1244 (Sept. 24, 2009) (testimony of David Runsten, Director of Policy Programs, Community Alliance with Family Farmers), available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5080508>.

⁸⁹ Cohen, *supra* note 36, at 8.

⁹⁰ *Id.* at 9. One need only look at the ten-year leafy greens production trend to observe the shift in consumer preferences away from fresh leafy greens to processed salad mix: Overall consumption of leaf lettuce, romaine lettuce, and spinach nearly doubled from 2000 to 2007, and overall production of leafy greens has risen by 25% since 1997. *Wetherington Testimony, supra* note 88, at 3. However, per capita use of iceberg (head) lettuce has steadily declined since 1995, while leaf and romaine lettuce production grew at a rate of 144% from 1997. *Id.*

producers grow the greens and then harvest them in the fields—either by hand or mechanically, and either as whole plants or single leaves.⁹¹ After harvest, the greens are shipped by truck to handlers, who “receive, acquire, sell, process, ship, distribute, or import leafy greens” in their natural form.⁹² Processors receive whole greens and then wash, dry, cut, and bag them into value-added products such as salads—sometimes mixing different types of greens together in the process.⁹³

The group of farmers who grow leafy greens is as broad and diverse as the food category itself. According to 2007 USDA data, there are approximately 11,500 leafy greens growers in the United States, though the numbers are likely incomplete due to the self-reported nature of the data.⁹⁴ Of those 11,500, approximately eighty-nine percent, or 10,235, fall within the USDA’s definition of “small farm.”⁹⁵ Leafy greens are grown and produced throughout the United States, though the market is concentrated primarily in California and Arizona. California produces slightly more than half, or fifty-one percent, of the fresh vegetables by value grown in the United States—including eighty-two percent of head lettuce, eighty percent of romaine lettuce, seventy-nine percent of leaf lettuce, and seventy percent of spinach, according to 2008 estimates.⁹⁶ Though leafy greens production is not confined to farms of a certain size,⁹⁷ it is clear that large farms supply the bulk of California’s leafy greens. Indeed, eighty-three percent of all of California’s lettuce comes from just 102 California farms, and all of these farms exceed 500

⁹¹ *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, 4 (Sept. 22, 2009) (testimony of James Strachan, Grower’s Express), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5079702> [hereinafter *Strachan Testimony*].

⁹² DRAFT LEAFY GREENS MARKETING AGREEMENT DEFINITIONS, *supra* note 88, at § 970.10.

⁹³ *Strachan Testimony*, *supra* note 91, at 5.

⁹⁴ *Wetherington Testimony*, *supra* note 88, at 8.

⁹⁵ *Id.*

⁹⁶ *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, 1 (Sept. 23, 2009), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5079851> (testimony of Mechel Paggi, Director, Center for Agricultural Business).

⁹⁷ See Cohen, *supra* note 36, at 10 (“Leafy green farming appears distributed among a few mega-farms with over 10,000 producing acres, a modest number of mid-sized farms . . . and a large number of quite small farms with a small percentage of production.”).

production acres.⁹⁸ Therefore, despite the large number of farms growing leafy greens, the industry concentration of growers is high enough such that “large producers control enough of the supply that any one large producer can have a big impact on fresh leafy green pricing nationwide.”⁹⁹

The handling or processing segment of the leafy greens industry fits the same profile as the farm-production segment: broad and diverse, but highly concentrated in terms of market power. USDA survey data from 2007 show approximately 1285 handlers or processors in the United States.¹⁰⁰ There are two types of handlers: “first handlers,” who buy from growers and deal primarily in whole produce, and “second handlers,” who buy from first handlers and who may turn whole greens into value-added products that are then sold to retailers such as Walmart or Publix Super Markets.¹⁰¹ First handlers range from small companies that source from only a few local organic growers¹⁰² to large companies that contract with multiple farmers who have growing fields larger than 1000 acres.¹⁰³ The biggest players in the industry, however, are the second handlers—who have differentiated themselves by establishing nationally distributed leafy green brand names, which they supply with greens from both their own facilities and partnerships with leafy greens handlers that do not

⁹⁸ *Id.* at 12. And only the very largest of these large farms have the production capacity to meet the needs of the fresh-cut processing industry. One study estimates that only about 100 California farms supply leafy greens processors with uncut produce—just 2.6% of all California vegetable growers and 0.1% of California farms overall. *Id.*

⁹⁹ *Strachan Testimony*, *supra* note 91, at 4.

¹⁰⁰ *Wetherington Testimony*, *supra* note 88, at 8. “[H]andling and processing are . . . spread out across the country so that leafy greens may be produced in one state, processed in another state, and then shipped for consumption to many states.” *Id.* at 9.

¹⁰¹ *Strachan Testimony*, *supra* note 91, at 5.

¹⁰² *See, e.g., Leafy Green Vegetables Handled in the United States; Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, 1 (Sept. 22, 2009) (testimony of Dale Coke), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5079734> (describing Coke Farm as a handler that represents, sells, and ships “approximately 50 different kinds of fruits and vegetables for about 15 organic growers in California’s central coast region”).

¹⁰³ *See, e.g., Leafy Green Vegetables Handled in the United States; Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, 1 (Sept. 24, 2009) (testimony of Josh Hinerfeld, CEO, Organically Grown Company), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5079858> (describing Organically Grown Company as a handler that “[sources] produce from over 300 suppliers that range in size from a few acres to operators that operate in multiple states”).

have their own retail brands.¹⁰⁴ These major second handlers have worldwide supply chains and operate in a highly concentrated market, with just two firms—Fresh Express and Dole—controlling seventy-two percent of the market in 2006.¹⁰⁵

The takeaway point, then, is that the leafy greens industry represents a diverse group of players, from farmers with a single ten-acre plot of lettuce to multibillion-dollar companies. The sometimes divergent interests of these industry groups will come into play in the discussion of the proposed National Leafy Greens Marketing Agreement that follows.

B. Food Safety in Leafy Greens Leaves Much To Be Desired

Recently, leafy greens growers and producers have been facing a problem—a food that is supposed to keep consumers healthy has instead been making them sick. Indeed, in the last twenty years, fresh produce in general has increasingly been associated with bacterial disease outbreaks that have sickened consumers and halted production of some of the most popular salad-mix greens.¹⁰⁶

However, leafy greens—especially those processed, cut, and bagged for the fresh-cut industry—are a particular problem. The FDA has confirmed twelve distinct outbreaks of the bacterium *E. coli*

¹⁰⁴ For example, Ready Pac has partnered with two non-retail handlers—OBIM of Fort Worth, Texas, and Missa Bay of Swedesboro, New Jersey—who supply leafy greens that are sold under the Ready Pac brand. Ready Pac, *Company Profile*, READYPAC.COM, <http://www.readypac.com/about/> (last visited Apr. 24, 2011). Not surprisingly, the rise of a national market for fresh produce has led to increased formality in the way leafy greens are purchased from growers. Historically, most produce was sold through the “spot market”—that is, from farmer to processor without benefit of a formal contract. *Wetherington Testimony*, *supra* note 88, at 9. Though some small farmers still sell “on spot” to farmers’ markets, CSAs, and roadside stands, today’s large leafy greens producers almost invariably sell to handlers or producers through seasonal, long-term contracts. *Id.*

¹⁰⁵ Cohen, *supra* note 36, at 9. The next two firms on the list, Ready Pac and Earthbound Farms (Natural Selection Foods), controlled 8% and 6% of the market, respectively—meaning that in 2006, four firms controlled 86% of the leafy greens market. *Id.* The rise of formal contracting for the sale of leafy greens has had an effect on the market price for them: “Because so much of the industry does business by contract, spot markets have minimal affect on pricing with shipping point prices now serving as the pricing floor.” *Strachan Testimony*, *supra* note 91, at 5.

¹⁰⁶ Unpublished FDA data show that between 1996 and 2006, there were at least 96 bacterial outbreaks associated with the consumption of fresh produce, resulting in 14 deaths and another 10,253 illnesses. GAO FRESH PRODUCE REPORT, *supra* note 77, at 10. The Centers for Disease Control and Prevention (CDC) believes that these numbers are “greatly underestimate[d]” due to the number of people who do not seek medical treatment for food poisoning. *Id.*

O157:H7 in leafy greens between May 1996 and September 2005.¹⁰⁷ These outbreaks, which resulted in a total of 258 confirmed illnesses, were all traced back to leafy greens—mainly lettuce, romaine, or spinach—grown primarily for the fresh-cut processing industry in California.¹⁰⁸ But perhaps the most-publicized incident to date—and the one that has spurred the loudest calls for change among food safety advocates—is the September 2006 outbreak of *E. coli* O157:H7 traced to bagged spinach from California’s Salinas Valley. That outbreak, which lasted a month and eventually spread to twenty-six states, resulted in 3 deaths, 205 confirmed illnesses, and a virtual shutdown of the spinach industry in the United States—to the tune of \$100 million in economic damages.¹⁰⁹ And just three months later, in December, an *E. coli* outbreak eventually traced back to Salinas Valley bagged lettuce used at Taco Bell and Taco John’s restaurants resulted in another seventy-one confirmed illnesses and fifty-three hospitalizations.¹¹⁰

In a September 2008 report calling on the FDA to address the issue of fresh produce safety, the United States Government Accountability Office (GAO) specifically cited the 2006 spinach outbreak as an example of how foodborne illness outbreaks can “undermine consumer confidence in the safety of the nation’s food supply and have serious economic consequences.”¹¹¹ The report’s focus is evident from its bolded title—“Food Safety: Improvements Needed in FDA Oversight of Fresh Produce”—yet the outbreaks continued and the government failed to directly address this issue. In July 2009, for example, a Salinas-based grower recalled 22,000 cases of lettuce shipped to twenty-nine states after a random sample by the Wisconsin Department of Agriculture tested positive for *Salmonella*.¹¹²

So what makes leafy greens particularly susceptible to bacterial outbreaks? The question is important, because while produce is responsible for a significant number of bacterial outbreaks, it is not

¹⁰⁷ Cohen, *supra* note 36, at 21.

¹⁰⁸ *Id.*

¹⁰⁹ GAO FRESH PRODUCE REPORT, *supra* note 77, at 1.

¹¹⁰ Press Release, Ctrs. for Disease Control & Prevention, Multistate Outbreak of *E. coli* O157 Infections, November–December 2006 (Dec. 14, 2006), *available at* <http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00256>.

¹¹¹ GAO FRESH PRODUCE REPORT, *supra* note 77, at 1.

¹¹² Karina Rusk, *Tanimura and Antle Lettuce Recall Expanded*, ABC7 NEWS (July 23, 2009), <http://abclocal.go.com/kgo/story?section=news/state&id=6930422>.

the ultimate *source* of those bacteria—rather, it is merely a carrier.¹¹³ Bacteria such as *E. coli* and *Salmonella* grow primarily in the lower intestines of warm-blooded organisms,¹¹⁴ where they can grow either with or without oxygen. Virulent, illness-causing strains of these bacteria can be transmitted outside of the body of the host, most commonly through the expulsion of fecal matter,¹¹⁵ where they can survive for varying periods of time. While fecal matter can come into contact with fresh produce in a number of different ways—including through infected workers, unclean containers or tools used in the harvesting or packing process, and even the droppings of wild animals that wander onto production fields—one of the major sources of pathogenic bacteria is manure from large beef cattle feedlots.¹¹⁶ Therefore, any type of produce—including leafy greens—is immediately susceptible to bacterial contamination simply because it is grown on an open field. Moreover, fresh greens are most often “consumed raw, without cooking or other treatment that would reduce, control, or eliminate pathogens prior to consumption.”¹¹⁷ Yet another reason for leafy greens’ susceptibility to bacteria is the stubborn nature of the pathogens themselves. Several studies have shown that pathogens such as *E. coli* are particularly effective at adhering to the outer skin of lettuce leaves and infiltrating cuts left by coring devices used in field harvest, thereby reducing the effectiveness of chlorine washes designed to reduce the risk of

¹¹³ The point is worth emphasizing, since many media reports have incorrectly implied that fresh vegetables are the “source” of foodborne illness outbreaks. NATIONAL SUSTAINABLE AGRICULTURE COALITION, FOOD SAFETY ON THE FARM: POLICY BRIEF AND RECOMMENDATIONS 7 (2009) [hereinafter NSAC REPORT], available at <http://sustainableagriculture.net/wp-content/uploads/2008/08/NSAC-Food-Safety-Policy-Brief-October-2009.pdf>.

¹¹⁴ *Salmonella*, which is closely related to the *Escherichia* genus, can be found in cold-blooded organisms as well. *Id.*

¹¹⁵ See U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF FRESH-CUT FRUITS AND VEGETABLES 2 (2008) [hereinafter FDA FRESH-CUT PRODUCE GUIDE], available at <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/produceandplanproducts/ucm064458.htm> (“The major source of microbial contamination of fresh produce is indirect or direct contact with animal or human feces.”).

¹¹⁶ NSAC REPORT, *supra* note 113, at 4 (“Beef cattle finished on grain in crowded feedlots have been shown to shed much larger numbers of pathogenic strains of *E. coli* than grass-fed cattle on well-managed pasture These virulent . . . microbes can and do find their way into produce fields through manure, dust, runoff, or contaminated waterways that carry pathogens into irrigation and wash water.”).

¹¹⁷ GAO FRESH PRODUCE REPORT, *supra* note 77, at 1.

contamination.¹¹⁸ Clearly, then, it is not possible to grow leafy greens that are completely immune from contamination, and even small farmers who maintain meticulously clean fields must worry about bacterial contamination.

Cut and processed leafy greens are especially ripe for bacterial contamination because the value-added mixing and bagging process adds several additional opportunities for pathogens to be introduced into the produce. The first opportunity for contamination has to do with the nature of the product itself. The goal of conventional food processing is the long-term safety and stability of the product, and so the preservation process typically includes a “kill step”—generally freezing, pasteurizing, canning, or irradiation—designed to eradicate harmful bacteria and “stop[] all biological activity of the food.”¹¹⁹ Fresh-cut processing, by contrast, involves “the atypical processing goal of delivering still-living plant tissue in a ready-to-eat, appealing form to consumers” without such a kill step.¹²⁰ Because chlorine rinses are not typically sufficient to kill pathogens,¹²¹ the result is that any *E. coli* and *Salmonella* bacteria contained on leafy greens remain alive throughout the fresh-cut preparation process. Second, the cutting, peeling, and washing methods involved in leafy greens processing present additional risks of bacterial contamination. The cutting and chopping of greens increases the risk of microbial contamination in three ways: (1) by breaking the exterior skin of the greens, which serves as a protective barrier;¹²² (2) by releasing plant cellular fluids, which “provide[] a nutritive medium in which pathogens, if present, can survive or grow;”¹²³ and (3) by subjecting the greens to additional human handling and contact. Third, the aggregation and commingling of multiple kinds of leafy greens from various sources increases the statistical probability of bacterial

¹¹⁸ *Ready to Eat or Not? Examining the Impact of Leafy Green Marketing Agreements: Hearing Before the Subcomm. on Domestic Policy of the H. Comm. on Oversight and Government Reform*, 111th Cong. 3 (2009) (statement of Carolyn Smith DeWaal, Director of Food Safety, Center for Science in the Public Interest) [hereinafter *DeWaal Testimony*], available at <http://oversight.house.gov/images/stories/Hearings/pdfs/20090729DeWaal.pdf>.

¹¹⁹ Cohen, *supra* note 36, at 6.

¹²⁰ *Id.*

¹²¹ *DeWaal Testimony*, *supra* note 118, at 3.

¹²² FDA FRESH CUT PRODUCE GUIDE, *supra* note 115, at 1.

¹²³ *Id.*

contamination.¹²⁴ Finally, the long transportation chains needed to move fresh-cut greens from field to processing plant to retail outlets are an especially important area of potential bacterial contamination. As noted above, because fresh-cut processing does not use a kill step to remove harmful bacteria, curbing pathogen growth during the transport process depends critically upon maintaining a “cold chain” for the leafy greens.¹²⁵

The risks associated with the fresh-cut production process are simply not present in the case of uncut, fresh produce. The risks also suggest that leafy greens processors, transporters, and retailers, along with growers, share the responsibility of addressing the problem of leafy greens contaminated with pathogenic bacteria. It is impossible to overstate the importance of holding food processors accountable for curbing pathogenic risks present in the fresh-cut production process, considering that processors themselves are mainly responsible for assessing the safety and quality of their products. For example, FDA imposes no grading standards on fresh-cut produce and offers only nonbinding recommendations for use-by dates; individual processors and retail brands may decide when their products should be removed from grocery store shelves.¹²⁶

¹²⁴ See Cohen, *supra* note 36, at 7 (“When contamination is present, it has the opportunity to be spread throughout an entire production lot via: contact in mixing and product flow, contaminated processing equipment, or contaminated wash water. A contaminated lot can then be shipped nation-wide.”). Further, at least one study has shown that pathogenic bacteria can adhere to the walls of washing machines used in the fresh-cut production process, thereby allowing sporadic transfer to any uncontaminated greens placed in the machine. *DeWaal Testimony*, *supra* note 118, at 4.

¹²⁵ See Cohen, *supra* note 36, at 7 (“Any break in the temperature of a fresh-cut product at any step in the marketing chain increases the risk of contamination, unlike conventionally processed products.”); see also FDA testimony, *Ready to Eat or Not? Examining the Impact of Leafy Green Marketing Agreements: Hearing Before the Subcomm. on Domestic Policy of the H. Comm. on Oversight and Government Reform*, 111th Cong. 6 (testimony of Michael R. Taylor, Senior Advisor to the Commissioner, FDA) [hereinafter *Taylor Testimony*], available at <http://oversight.house.gov/images/stories/Hearings/pdfs/20090729Taylor.pdf> (“Storage temperature and length of storage time of ready-to-eat leafy greens are of critical importance for the control of bacterial pathogens and ultimately the safety of these products.”). Studies have shown that cold chains are particularly susceptible to temperature increases in two places: upon leaving the processing plant for long-distance transportation and in retail storage coolers before sale. Cohen, *supra* note 36, at 7.

¹²⁶ Cohen, *supra* note 36, at 8.

C. Food Safety as Perceived by Consumers: Standards and Brands

The risks associated with the consumption of leafy greens are so considerable that the Center for Science in the Public Interest placed leafy greens atop their 2009 list of the “10 riskiest foods regulated by the Food and Drug Administration.”¹²⁷ However, there is no way for consumers to know whether the salad they serve with dinner is objectively safe. This is so for several reasons: First and most obviously, the undesirable safety aspect of leafy greens—microbial contamination—is not visible to the human eye, meaning that consumers cannot make objective safety assessments of individual produce the way they can with other products, such as cars.¹²⁸ Second is the problem of informational asymmetry: Producers usually know whether their food is generally “safe”—if they do not know whether a particular batch of leafy greens is contaminated, at least they know “what safety procedures are maintained in their plants and whether their procedures surpass, meet, or fall below industry standards.”¹²⁹ Consumers, however, generally are not very knowledgeable about how food is produced, what it contains, or measures that industry can or *must* take to keep it free from microbial contamination.¹³⁰ In fact, most of what consumers know about food safety is reactive, in that “well-publicized outbreaks may be many consumers’ sole source of safety information.”¹³¹ In sum, consumers do not know whether the particular spinach they’re eating is contaminated with *E. coli*; they mainly just have to *trust* that it is not contaminated.¹³²

This is not to say that consumers do not have reliable indicators of food safety, thereby increasing their trust in certain products. One of

¹²⁷ *Leafy Greens, Eggs, and Tuna Top List of Riskiest FDA-Regulated Food*, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, (Oct. 9, 2009), <http://www.cspinet.org/new/200910061.html>.

¹²⁸ For example, an SUV with eight airbags is objectively safer than a small subcompact with two airbags.

¹²⁹ ELISE GOLAN ET AL., U.S. DEP’T OF AGRIC., ECON. RESEARCH SERV., FOOD SAFETY INNOVATION IN THE UNITED STATES: EVIDENCE FROM THE MEAT INDUSTRY 6 (2004), available at <http://www.ers.usda.gov/Publications/aer831/aer831c.pdf>.

¹³⁰ *Id.* at 7.

¹³¹ *Id.*

¹³² See Denis W. Stearns, *On (Cr)edibility: Why Food in the United States May Never Be Safe*, 21 STAN. L. & POL’Y REV. 245, 248–49 (2010) (describing food safety as a “credence attribute” that cannot be measured or evaluated by consumers).

these indicators is a government stamp of approval on a product.¹³³ Another reliable indicator is a brand name: Just as many car buyers think of Volvo when the word “safety” is mentioned, “food companies can . . . come to develop a reputation for higher quality over time, and thus brand names can come to serve as proxies for the more specific attribute of safety.”¹³⁴

However, branding as a reasonable proxy for food safety is difficult for the leafy greens industry for two reasons. First, lettuce and its leafy brethren are raw agricultural commodities, which, because they are “unchanging through time,” cannot be distinguished by brand.¹³⁵ From a consumer’s perspective, apples are apples are apples—though they might be safer to eat than oranges. Therefore, commodities such as leafy greens must maintain a good image *as a whole*, including every kind of value-added form that the commodity may take, whether whole, fresh-cut, or frozen.¹³⁶ However, media and even regulatory reaction to food safety outbreaks is often overly-reactive, at times implicating entire categories of produce for foodborne illnesses that eventually are traced to just one farm or processing plant.¹³⁷

Some leafy greens handlers change their commodities into food products such as bagged salad, which allows for branding possibilities and thus the establishment of a reputation for food safety. But the

¹³³ For example, in a study conducted by the California Leafy Greens Marketing Agreement (CLGMA), participants were told that certain produce buyers (such as grocery stores) sourced their leafy greens only from CLGMA signatories that passed mandatory government audits; eighty-eight percent said that this increased their confidence in the product. NATIONAL LEAFY GREENS MARKETING AGREEMENT, JUSTIFICATION OF PROPOSED MARKETING AGREEMENT FOR LEAFY GREEN VEGETABLES § 5 (2009), available at <http://www.nlgma.org/documents/9pointsofJustification.pdf>.

¹³⁴ Stearns, *supra* note 132, at 256.

¹³⁵ Daniel I. Padberg & Charles Hall, *The Economic Rationale for Marketing Orders*, 5 SAN JOAQUIN AGRIC. L. REV. 73, 82–83 (1995).

¹³⁶ *Id.* at 83.

¹³⁷ In the midst of the September 2006 spinach outbreak, the FDA issued four warnings to consumers in the span of six days. The first, on September 14th, advised consumers to “not eat bagged fresh spinach;” by the 17th the FDA had expanded its directive to “fresh spinach or fresh spinach-containing products that are consumed raw.” Cohen, *supra* note 36, at 24. The next day, the FDA dropped the distinction between raw spinach and cooked spinach, flatly advising consumers “not to eat fresh spinach or fresh spinach-containing products until further notice.” *Id.* at 25 (emphasis omitted). It was not until the 20th that FDA issued a notice clarifying that “frozen spinach, canned spinach and spinach included in pre-made meals” was safe to eat. *Id.* Faced with this breathless set of directives, it’s little wonder that confused and nervous consumers simply stopped eating spinach altogether.

problem here is that very few leafy greens industry players are able to create brands for their products. Most growers cannot; their output is raw agricultural commodities, which as noted above, typically cannot be successfully branded. And most handlers and processors cannot either, since they typically act only as middlemen who receive raw agricultural commodities and process and package them for sale under someone else's brand.¹³⁸ That leaves only two leafy greens industry players with branding opportunities: the very largest handlers and processors such as Fresh Express who, as noted earlier, exercise significant market control, and retailers such as Publix and Walmart. These groups, of course, are the largest and most powerful players in the market for leafy greens.

Therefore, stakeholders in the leafy greens industry can pursue consumer trust in leafy greens safety in one of two ways: (1) they can try to raise the safety level of the leafy greens industry as a whole, if they cannot distinguish their product by brand, or (2) they can develop and impose their own safety standards, if they can distinguish their product by brand. It is important to keep this point in mind as this Article examines the efforts the leafy greens industry took to increase safety in the wake of the 2006 *E. coli* outbreaks.

D. The FDA's Efforts to Address the Safety of Leafy Greens Produce

The Federal Food, Drug, and Cosmetic Act (FFDCA) assigns primary responsibility for the safety of fruits and vegetables to the FDA.¹³⁹ Pursuant to this authority, the FDA may issue food safety regulations, inspect and investigate growing and processing facilities, and recommend Department of Justice enforcement actions against violators.¹⁴⁰ The FDA also has the authority to take measures aimed at controlling the spread of diseases, including detaining food products if they present a threat of "serious adverse health consequences."¹⁴¹

¹³⁸ See, e.g., *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep't of Agric.*, 2 (Oct. 24, 2009) (testimony of Laura Giudici Mills), available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5079852> (noting that the handler Metz Fresh "contract[s] with a co-packer to process, package and vacuum-cool and/or freeze our fresh and frozen leafy green crops").

¹³⁹ GAO FRESH PRODUCE REPORT, *supra* note 77, at 2.

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 8.

However, the FDA has no formal program for regulating the safety of fresh produce, and therefore must allocate its scarce resources to leafy greens safety efforts as part of its overall food safety planning process.¹⁴² The 2010 FDA Food Safety Modernization Act (FSMA) attempts to correct the jurisdictional deficiency of the FFDCA.¹⁴³ The amendment, to be codified at section 419, directs the FDA to issue rules establishing production and harvesting standards for fruits and vegetables to minimize the risk of foodborne illness.¹⁴⁴

Though the FDA considers fresh produce safety to be a top priority,¹⁴⁵ the agency has been hobbled by diversions such as counterterrorism efforts and food safety outbreaks, as well as “serious deficiencies in agency funding, staffing, and authority.”¹⁴⁶ As a result, the FDA allots only about three percent of its annual food safety budget and about four percent of its manpower to food safety efforts in the produce sector as a whole¹⁴⁷—to say nothing about resources targeted towards the safety of leafy green produce. The FDA’s meager produce safety resources are stretched even more thinly by the burgeoning U.S. food system, which has grown in both size and complexity in recent years to meet consumer demand. Moreover, rapidly consolidating food companies commingle produce from farms across the United States at a few regional processing plants, use value-added processes such as bagging to extend the shelf life of the produce, and then scatter the produce across the globe by way of long, interconnected distribution networks. Larger volumes, longer supply chains, and extended shelf life times “make trace-back more difficult and put a larger number of consumers at risk.”¹⁴⁸ These challenges have hampered the FDA’s efforts to establish a federal safety protocol for the handling of fresh produce, including leafy greens—even though the agency has clearly recognized the risk associated with these

¹⁴² *Id.* at 11.

¹⁴³ See FDA Food Safety Modernization Act, S. 510, 111th Cong. § 105 (2010).

¹⁴⁴ *Id.*; H.R. 2751 § 105, 111th Cong. (2011).

¹⁴⁵ GAO FRESH PRODUCE REPORT, *supra* note 77, at 11.

¹⁴⁶ ELANOR STARMER & MARIE KULICK, FOOD & WATER WATCH, INST. FOR AGRIC. & TRADE POLICY, BRIDGING THE GAPS: STRATEGIES TO IMPROVE PRODUCE SAFETY, PRESERVE FARM DIVERSITY, AND STRENGTHEN LOCAL FOOD SYSTEMS 1 (2009), available at <http://www.iatp.org/iatp/publications.cfm?refid=106746>.

¹⁴⁷ *Id.* The GAO notes that the FDA has only two full-time staff members who devote their time exclusively to the issue of fresh produce safety, GAO FRESH PRODUCE REPORT, *supra* note 77, at 17, and that overall food safety staffing levels declined seventeen percent between 2003 and 2007. *Id.* at 19.

¹⁴⁸ STARMER & KULICK, *supra* note 146, at 2.

products, and even though the FDA has previously issued regulations outlining safety measures for other high-risk foods, such as seafood¹⁴⁹ and processed juice.¹⁵⁰ And although the FSMA provides the FDA explicit authority to implement regulations for fresh produce, it remains to be seen if Congress will provide the agency the necessary financial resources to close this food safety gap.¹⁵¹

Though the FDA has not issued any binding regulations dealing with fresh produce safety, it has undertaken several efforts that have resulted in nonbinding recommendations for leafy greens growers, handlers, and processors. In 1998, the FDA, in cooperation with the USDA, issued “Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” (hereinafter GAP Guide),¹⁵² which stands as the agencies’ most authoritative and comprehensive statement to date on the topic of produce safety.¹⁵³

¹⁴⁹ Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65,095 (Dec. 18, 1995) (codified at 21 C.F.R. pts. 123 and 1240).

¹⁵⁰ Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice, 66 Fed. Reg. 6137 (Jan. 19, 2001) (codified at 21 C.F.R. pt. 120).

¹⁵¹ See Lyndsey Layton, *Food Safety Overhaul Faces Obstacles*, WASH. POST, Dec. 24, 2010, <http://www.washingtonpost.com/wp-dyn/content/article/2010/12/24/AR2010122402748.html> (noting that the recently passed Food Safety Modernization Act “will take years to implement and could be undercut by Republicans who don’t want to fund an expansion of the Food and Drug Administration”).

¹⁵² U.S. DEP’T OF HEALTH AND HUMAN SERVICES, FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS FOR FRESH FRUITS AND VEGETABLES (1998) [hereinafter GAP GUIDE], available at <http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM169112.pdf>.

¹⁵³ While the voluntary GAPs remain the FDA’s primary means of regulating fresh produce safety, it has undertaken a few additional initiatives that specifically address the safety of leafy greens. In 2004, the agency launched its Produce Safety Action Plan, which consisted mainly of a set of general goals and objectives aimed at reducing the incidence of foodborne illness in produce. U.S. DEP’T OF HEALTH AND HUMAN SERVICES, FDA, PRODUCE SAFETY FROM PRODUCTION TO CONSUMPTION: 2004 ACTION PLAN TO MINIMIZE FOODBORNE ILLNESS ASSOCIATED WITH FRESH PRODUCE CONSUMPTION, (Oct. 2004), available at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/FDAProduceSafetyActivities/ProduceSafetyActionPlan/ucm129487.htm>. As part of this action plan, the FDA launched a multiyear “Lettuce Safety Initiative” in 2006 that targeted the state of California as a “geographic region historically associated with outbreaks.” U.S. DEP’T OF HEALTH & HUMAN SERV., FDA, LETTUCE SAFETY INITIATIVE (May 20, 2009), available at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/FDAProduceSafetyActivities/ucm115906.htm>. The agency partnered with California’s Departments of Health Services and Food and Agriculture in order to review bacterial outbreak data in lettuce and inspect farms, packing facilities, and processors while focusing on GAPs and GMPs. *Id.* The FDA

The GAP Guide, which generally addresses the “the growing, harvesting, sorting, packing, and distribution of fresh produce,”¹⁵⁴ identifies seven major areas of concern for fresh produce safety: water, manure and municipal biosolids, worker health and hygiene, sanitary facilities, field sanitation, packing facility sanitation, and transportation.¹⁵⁵ It then identifies “the broad microbial hazards associated with each area of concern, the scientific basis of that concern, and good agricultural and management practices for reducing the risk of microbial contamination in fresh produce.”¹⁵⁶ The guide encourages growers and handlers to adopt these “good agricultural practices” (GAPs) and “good manufacturing practices” (GMPs) as part of their day-to-day operations.

There is a way to turn the GAP Guide into somewhat of a binding requirement, though it has little to do with the FDA. In response to requests from industry for a quality control program, the USDA’s Agricultural Marketing Service (AMS) has established the GAP and good handling practices (GHP) Fresh Produce Audit Verification Program, which verifies continuing adherence to the GAP Guide.¹⁵⁷ Farmers and processors may voluntarily sign up for the audit program, but if they do, AMS requires their signature on an agreement that authorizes USDA auditors or state department of

subsequently expanded this Lettuce Safety Initiative in 2007 by renaming it the “Leafy Greens Safety Initiative” and broadening the scope of the program to include additional greens such as spinach. U.S. DEP’T OF HEALTH & HUMAN SERVICES, FDA, LEAFY GREENS SAFETY INITIATIVE—2ND YEAR (May 20, 2009), *available at* <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/FDAProduceSafetyActivities/ucm115898.htm>. This effort included visits to California farms “to assess the prevalence of factors in and near the field environment which may contribute to potential contamination of leafy greens with *E. coli* O157:H7 and the extent to which Good Agricultural Practices (GAPs) and other preventive controls are being implemented.” *Id.* Findings from this multiyear leafy greens safety initiative will be published and implemented in forthcoming GAPs guidance as appropriate. U.S. DEP’T OF HEALTH & HUMAN SERVICES, FDA, GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF LEAFY GREENS; DRAFT GUIDANCE (July 2009), *available at* <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm174200.htm>. Of course, none of these efforts amount to a comprehensive regulatory scheme for decreasing the risk of microbial contamination in leafy greens.

¹⁵⁴ GAP GUIDE, *supra* note 152, at 3.

¹⁵⁵ *Id.* at ii–iii.

¹⁵⁶ *Id.* at 9.

¹⁵⁷ Agric. Mktg. Serv., *Grading, Certification, and Verification, Fresh Produce Audit Verification Program*, USDA, <http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&page=GAPGHPAuditVerificationProgram> (last visited Apr. 24, 2011).

agriculture employees working under a cooperative agreement to enter the farm or facility for scheduled, unscheduled, and follow-up audits.¹⁵⁸ Auditors use checklists to document compliance with the GAP Guide, and they are obligated to report observed food safety risks to the appropriate authorities or the FDA.¹⁵⁹ Since the inception of auditing services in 1999, AMS has conducted more than 4,000 audits on 100 commodities in forty-five states, and USDA officials have noted that industry demand for GAP and GHP verification programs has increased.¹⁶⁰ The USDA audit programs, however, are at best a limited solution to the problem of leafy greens food safety, in no small part because of their voluntary nature and weak-kneed sanctions for non-complying facilities.¹⁶¹ And if the FDA and USDA's coordination on the issue of egg inspection is any indication, the promised agency coordination in reporting food safety hazards sounds better on paper than it actually works in practice.¹⁶²

At any rate, the FDA document upon which the AMS audits are based—the GAP Guide—has engendered its own share of criticism from both policymakers and industry leaders. First, the best practices outlined in the GAP Guide are voluntary, even if confirmed through a formal audit program. Second, they are not specific to leafy greens, nor do they offer “any quantitative or measurable criteria upon which to base an audit.”¹⁶³ This means that the GAP Guide may recommend testing a water source, but it does not specify “what to test for, what type of test to utilize, where to test, what the frequency of tests should

¹⁵⁸ *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep't of Agric.* (last modified Jan. 11, 2011) (testimony of Anthony Souza at 4) (hereinafter *Souza Testimony*), available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5080328>. The audit itself “consists of a physical visit to the farm and/or facility which involves a review of records and documentation, interviews of employees, observation of practices, and a closing meeting.” *Id.*

¹⁵⁹ *Id.* at 4.

¹⁶⁰ *Id.* at 3.

¹⁶¹ Companies that participate in the Fresh Produce Audit Verification Program are listed by state and commodity on AMS's website. If a participating company or farm flunks an audit, “the company's information will be removed from the website until a follow-up audit is conducted by AMS verifying that effective corrective actions have been taken.” *Souza Testimony*, *supra* note 158, at 4.

¹⁶² See *infra* notes 335–341 and accompanying text (discussing communication problems between FDA and USDA with respect to the SE outbreak in 2010).

¹⁶³ Q & A Session for NLGMA Proponent Group Presentation, National Leafy Greens Marketing Agreement Proponent Group 2 (Aug. 19, 2009), available at <http://www.nlgma.org/documents/090819QA.pdf>.

be or any parameters upon which to evaluate the results of tests.”¹⁶⁴ Policymakers have criticized the GAP Guide for failing to “place sufficient emphasis on the risk posed to fresh produce by beef and dairy cattle operations,” especially because cattle are the main source of the *E. coli* 0157:H7 bacteria in an agricultural setting.¹⁶⁵ Even though the FDA acknowledges in the GAP Guide that “the scientific basis for reducing . . . pathogens in an agricultural setting is evolving and not yet complete . . . ,”¹⁶⁶ the agency has not revised the GAP Guide since its introduction in 1998. In 2008, the FDA announced plans to update its produce GAPs and solicited public commentary on the issue; by July 2009 it had issued a revised draft version of the GAP Guide for additional public comment,¹⁶⁷ but to date has not yet issued a final version.

Finally, the scope of the FDA’s GAP Guide is limited to common food safety hazards in the “growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables . . . in an *unprocessed or minimally processed (raw) form.*”¹⁶⁸ The GAP Guide, therefore, does not address the significant risks inherent in the fresh-cut production process. The FDA has addressed food processing risks both by regulation and by nonbinding guidance, but as discussed below, the efforts do not adequately address the problem of microbial contamination in leafy greens.

E. Lack of Private Regulation in the Leafy Greens Industry

Just as the federal government has largely failed to adequately regulate the safety of leafy greens, commentators have repeatedly

¹⁶⁴ *Id.* That criticism appears to be fair enough: In the section titled “Microbial testing of agricultural water,” the bulk of the GAP Guide’s best practices advice is this:

Growers may elect to test their water supply for microbial contamination on a periodic basis, using standard indicators of fecal pollution, such as *E. coli* tests, which may be performed by commercial, State, or local government laboratories. However, bacterial safety of water does not necessarily indicate the absence of protozoa and viruses Growers can consult local water quality experts, such as state or local Environmental Protection or Public Health agencies, extension agents or land grant universities, for advice appropriate for individual operations.

GAP GUIDE, *supra* note 152, at 12–13.

¹⁶⁵ STARMER & KULICK, *supra* note 146, at 4.

¹⁶⁶ GAP GUIDE, *supra* note 152, at 3.

¹⁶⁷ FDA, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Draft Guidance*, U.S. DEP’T OF HEALTH AND HUMAN SERV., (July 2009), <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm174200.htm>.

¹⁶⁸ GAP GUIDE, *supra* note 152, at 1 (emphasis added).

characterized the lack of private safety efforts in the leafy greens industry as a market failure.¹⁶⁹ Some have characterized food safety as a “weaker-link public good” in which free riders in the industry are able to benefit from and therefore diminish the value of the safety efforts of other firms in the industry.¹⁷⁰ It is also true that the informational asymmetries in the food industry allow firms to externalize the cost of food safety to consumers, who must pay medical bills if they get sick. Because the market rewards those who cut back on safety efforts or free-ride on the efforts of others, one commentator has noted that “[w]hen market controls are inefficient and ineffective at producing the level of safety desired by consumers, the common approach has been to require firms to meet regulatory requirements for design or process standards.”¹⁷¹ But as we have seen, the government has done no such thing, perhaps in part because consumer demand for enhanced food safety controls directly correlates with food safety outbreaks.¹⁷² Also, until recently, contamination in leafy greens had not been a big problem—or at the very least, not a well-publicized one.

The 2006 *E. coli* outbreaks described in Part B, *supra*, spurred calls for change in the leafy greens industry. These calls came not just from policymakers such as the GAO, but also from the industry itself—in no small part because the same news reports that kept running totals of illnesses caused by leafy greens also characterized the leafy industry as being primarily self-regulated with inadequate oversight from the FDA.¹⁷³ As one industry player subsequently admitted to

¹⁶⁹ See, e.g., Stearns, *supra* note 132, at 247 (“A free market for safe food in the United States is impossible because there are no set of circumstances under which a free market could exist in which the food bought and sold there could be safe, and reliably known as such at the time of purchase”); Fortin, *supra* note 32, at 574 (“It is well documented that the market provides incomplete information on a product’s risk of inducing foodborne illness This market inefficiency creates an underproduction of food safety that a fully functional and competitive market would produce.”).

¹⁷⁰ Proponent Group’s Brief in Support of a Federal Marketing Agreement for Leafy Green Vegetables at 10, Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric., No. AO-FV-09-0138, available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5082273> [hereinafter NLGMA Proponent Group’s Brief].

¹⁷¹ Fortin, *supra* note 32, at 578.

¹⁷² Golan, *supra* note 129, at 7–8 (“[D]ramatic and highly publicized outbreaks have often driven sharp increases in demand for safety, at least in the short run.”).

¹⁷³ See, e.g., Marian Burros, *E. Coli Fears Inspire a Call for Oversight*, N.Y. TIMES, Dec. 9, 2006, <http://www.nytimes.com/2006/12/09/nyregion/09produce.html> (describing the leafy greens industry’s “newfound enthusiasm for regulation”).

Congress, “in the aftermath of the 2006 outbreak, farmers, shippers and processors [of leafy greens] recognized that more effort was needed to protect public health. The question was how to do it.”¹⁷⁴ As it turned out, the major players in the leafy greens industry—growers, handlers and processors, and retailers—had different answers to that question. Handlers and processors of leafy greens turned to a quasi-governmental solution—a marketing agreement—while retailers favored private regulation. In this section, this Article explores the reasons for those choices, as well as the implications that each choice has had for food safety regulation in the United States.

1. Retailer Response—Super-metrics

In the wake of the leafy greens outbreak, many businesses that sell leafy greens to end users—in particular, supermarkets, restaurants, and institutional food service providers—implemented their own best practice metrics, which must be followed by growers who supply produce to these companies. Because these requirements are often stricter than those imposed by the FDA’s GAP Guide or industry marketing agreements as discussed below, they have been called super-metrics.¹⁷⁵ These super-metrics are of particular concern to growers, handlers, and processors of leafy greens in no small part because of the secrecy that surrounds their promulgation and enforcement. While the Food Safety Leadership Council (FSLC)—a consortium of the country’s largest retail produce buyers, including Darden Restaurants, McDonald’s, Publix Super Markets, Walmart, and the Walt Disney Company—has made their super-metrics public, “many companies’ standards are considered a trade secret and are therefore confidential.”¹⁷⁶

Because of the secretive nature of these agreements, it is difficult to assess just how many companies are using them, though “anecdotal evidence shows that the number is large and growing.”¹⁷⁷ More

¹⁷⁴ *Ready to Eat or Not? Examining the Impact of Leafy Green Marketing Agreements: Hearing Before the Subcomm. on Domestic Policy of the H. Comm. of Oversight and Government Reform*, 111th Cong. 1 (statement of E. Scott Horsfall, CEO Cal. Leafy Green Products Handler Marketing Agreement), available at <http://oversight.house.gov/images/stories/Hearings/pdfs/20090729Horsfall.pdf>.

¹⁷⁵ Shermain Hardesty & Yoko Kusunose, UC Small Farm Program Research Brief, *Growers’ Compliance Costs for the Leafy Greens Marketing Agreement and Other Food Safety Programs* at 4 (2009), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5079865>.

¹⁷⁶ STARMER & KULICK, *supra* note 146, at 6.

¹⁷⁷ *Id.* at 2.

worrisome is the fact that objective observers are not able to assess or call into question the underlying scientific research upon which the metrics are based. Many metrics that have been publicized appear to be stricter than those suggested by the GAP Guide or mandated by industry-government marketing agreement partnerships, with many taking a sterile farm approach to growing produce that requires growers to strip all non-crop vegetation from the perimeter of growing fields because such vegetation can attract and harbor wild animals that carry pathogenic bacteria.¹⁷⁸ Several scientific studies have shown, however, that natural vegetation surrounding growing fields can in fact *reduce* the possibility of bacterial contamination by providing a filtering barrier that protects against bacteria carried by dust or water runoff.¹⁷⁹ While the science of field contamination remains incomplete, such conflicting reports emphasize the need for transparent standards that can be evaluated independently by the public and policymakers—something that many super-metrics agreements simply do not provide.

2. *Processor and Handler Response—Marketing Agreements*

Even as the fallout from the 2006 *E. coli* outbreaks in leafy greens continued to make headlines, industry leaders publicly announced plans for “an agreement that would call for a formal system of farm inspections, regulations of water and soil quality and sanitation and even cease-and-desist orders for violations.”¹⁸⁰ Early press reports stressed the mandatory nature of the agreement: “Anyone who ignores this will be out of business,” an industry group representative told the *New York Times* in December 2006.¹⁸¹ Oddly enough, however, the agreement spoken of at the height of the *E. coli* crisis eventually took the form of a voluntary public-private marketing agreement among industry players and regulators—one that created its own rules and was enforced mainly by the industry itself.

¹⁷⁸ *Id.* at 6. For example, the California Leafy Greens Marketing Agreement, discussed in more detail *infra*, requires growing fields to be, at minimum, 30 feet from animal grazing areas and 400 feet from animal feedlots. Hardesty & Kusunose, *supra* note 175, at 4, n.5. However, the FSLC’s standards are much stricter, requiring a minimum quarter-mile buffer between growing and grazing areas and a full mile between growing fields and animal feedlots. *Id.*

¹⁷⁹ STARMER & KULICK, *supra* note 146, at 2.

¹⁸⁰ Burros, *supra* note 173.

¹⁸¹ *Id.*

Basically, marketing agreements are agreements among certain industry players—primarily growers, handlers, and processors—to establish best practice metrics for the safe handling of a particular product. They are generally approved by a federal or state regulatory body that typically acts under the authority of legislation that enables the creation of such agreements. Agreement buy-in is voluntary, but the agreement metrics become mandatory and binding once a party becomes a signatory to the agreement.

In the spring of 2007, just months after the second *E. coli* outbreak in leafy greens had subsided, the first of these agreements came to fruition. The California Leafy Greens Marketing Agreement (LGMA), promulgated under authority of the California Marketing Act of 1937,¹⁸² is an agreement between leafy greens handlers in California. The LGMA prescribes best practices for agricultural growers of fourteen different kinds of leafy greens¹⁸³ in five main areas of risk: growing environment, soil amendments, water, worker practices, and field sanitation; and is enforced through periodic and random audits conducted by the California Department of Agriculture.¹⁸⁴ Though the agreement is signed by *handlers and processors* of leafy greens, the metrics affect *growers*: Many compliance requirements, such as soil testing and field barriers, are implemented at the field level, and signatory handlers pledge not to source greens from growers not in compliance with the LGMA.¹⁸⁵ The agreement is funded by signatories, who pay a 1.5-cent assessment per 24-pound carton of produce processed.¹⁸⁶ Two years after the LGMA was approved by the state of California, more than 100 handlers—together representing ninety-nine percent of the volume of leafy greens produced in the state—have signed onto the LGMA.¹⁸⁷ A similar agreement is in place in Arizona,¹⁸⁸ and the two

¹⁸² California Marketing Act of 1937, 21 Cal. Food & Agric. Code §§ 58601–58624.

¹⁸³ In alphabetical order: arugula, baby leaf lettuce, butter lettuce, cabbage (green, red, and savoy), chard, endive, escarole, green leaf lettuce, iceberg lettuce, kale, red leaf lettuce, romaine lettuce, spinach, and spring mix. *About Us*, CALIFORNIA LEAFY GREENS MARKETING AGREEMENT, <http://www.caleafygreens.ca.gov/about-us> (last visited Apr. 21, 2011).

¹⁸⁴ Hardesty & Kusunose, *supra* note 175, at 2.

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *About Us*, CALIFORNIA LEAFY GREENS MARKETING AGREEMENT, <http://www.caleafygreens.ca.gov/about-us> (last visited Apr. 21, 2011). Notably, some of the largest handlers of leafy greens—in particular, the ones who have established their own fresh-cut brands—signed on to the LGMA but still imposed standards that went

agreements combined cover nearly ninety percent of all the leafy greens grown in the United States.¹⁸⁹

Despite this success, major players in the leafy greens industry pushed for a marketing agreement that replicates the California and Arizona agreements on a national scale. In 2009, a group of leafy greens trade associations (hereinafter NLGMA Proponent Group)¹⁹⁰ submitted a petition to the Department of Agriculture asking the Secretary to use his authority under the Agricultural Marketing Agreement Act of 1937 (AMAA) to establish a national leafy greens marketing agreement (NLGMA) applicable to leafy greens handlers across the United States.¹⁹¹ Before describing the particulars of this proposed marketing agreement, however, it is important to examine the context in which the AMAA was passed. The AMAA and the market control devices it authorizes—marketing orders and marketing agreements—are primarily intended as a price control mechanism meant to give farmers a method of colluding to ensure a fair price for their commodities. But as we will see, marketing agreements—and the NLGMA in particular—are an imperfect way to regulate food safety in the United States.

3. *New Deal Farm Support Legislation: Marketing Orders and Marketing Agreements*

Without question, the purpose of the Agricultural Adjustment Act of 1933 (AAA), and its reenactment as the Agricultural Marketing Agreement Act of 1937, was to control the price of agricultural

beyond those mandated by the handler agreement. *See* STARMER & KULICK, *supra* note 146, at 5 (Fresh Express, Chiquita's fresh produce brand, is a signatory to the LGMA but uses additional requirements with its farmers).

¹⁸⁸ ARIZONA LEAFY GREENS MARKETING AGREEMENT, <http://www.azlgma.gov/>.

¹⁸⁹ *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep't of Agric.*, Oct. 9, 2009 [hereinafter *Giclas Testimony*], (testimony of Hank Giclas at 1), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5080125>.

¹⁹⁰ In alphabetical order, the Proponent Group comprises Arizona Farm Bureau, Arizona Leafy Green Products Shipper Marketing Agreement, California Farm Bureau, California Leafy Greens Marketing Agreement, Georgia Farm Bureau, Georgia Fruit and Vegetable Growers Association, Grower-Shipper Association of Central California, Imperial Valley Vegetable Growers Association, Leafy Greens Council, Produce Marketing Association, Texas Vegetable Association, United Fresh Produce Association, and Western Growers. NLGMA Proponent Group's Brief, *supra* note 170, at 1.

¹⁹¹ *Id.* at 2.

commodities for the benefit of the farmers who grew them.¹⁹² The AAA was the result of an unprecedented economic emergency that depressed the price of agricultural commodities nationwide, leaving many farmers unable to pay their bills and therefore freezing up the assets of many rural banks.¹⁹³ In a message to Congress, President Roosevelt previewed the AAA by framing it as legislation that would “increase the purchasing power of our farmers”¹⁹⁴—a statement echoed by Secretary of Agriculture Henry Wallace, who, in testimony before Congress, stressed the administration’s view that “restoration of farmers’ buying power is an essential part of the program to relieve the present economic emergency”¹⁹⁵ Congress’s grant of authority to the Secretary of Agriculture to enter into marketing orders and agreements with processors, associations, and producers under the AAA was therefore qualified by the requirement that “such agreements may be entered into only for the purpose of effectuating the declared policy of gradually establishing and maintaining such balance between production and consumption as will reestablish for agricultural commodities their pre-war purchasing power.”¹⁹⁶

After the AAA’s passage, a U.S. Supreme Court case, *United States v. Butler*,¹⁹⁷ invalidated the taxing provisions of the Act, and subsequent lower federal court litigation cast doubt on whether the marketing agreement provisions could be severed from the unconstitutional provisions.¹⁹⁸ Congress therefore reenacted the

¹⁹² See H.R. REP. NO. 6, at 489 (1933) (“The bill seeks to establish and maintain such a balance between production and consumption of agricultural commodities and such conditions in the marketing of agricultural commodities as will give to such commodities sold by farmers their pre-war purchasing power.”).

¹⁹³ *Id.* at 494 (“The present economic emergency is in large part the result of the impoverished condition of agriculture and the lack of ability of farmers to purchase industrial commodities.”).

¹⁹⁴ S. REP. NO. 16, at 414 (1933).

¹⁹⁵ *Agricultural Emergency Act to Increase Farm Purchasing Power: Hearings on H.R. 3835 Before the S. Comm. on Agric. and Forestry*, 73rd Cong. 128 (statement of Henry A. Wallace, Secretary of Agriculture).

¹⁹⁶ H.R. REP. NO. 6, at 491 (1933). While the primary purpose of the AAA was to benefit farmers, Congress recognized that consumers also stood to benefit from measures aimed at restoring the prices for agricultural commodities: So long as farmers were not guaranteed a “fair return to the labor and capital involved in producing the commodity,” agricultural prices would continue to spiral downward, “shortly [resulting] in the ruin of our agriculture. . . .” *Id.* at 494. Therefore, “[the] consumer as well as the farmer and businessman has everything to gain from a fair and balanced relationship between production and consumption” *Id.*

¹⁹⁷ 297 U.S. 1 (1936).

¹⁹⁸ See H.R. REP. NO. 468, at 30 (1937); S. REP. NO. 565 at 6 (1937).

marketing order and agreement provisions of the AAA as a separate piece of legislation—the Agricultural Marketing Agreement Act of 1937 (AMAA).¹⁹⁹ Even though the economic conditions that led to the passage of the AAA in 1933 had improved somewhat by 1937, Congress recognized that “continuing and constantly recurring [price] disparities do exist in the case of individual farm commodities, accompanying and caused by disruption of orderly marketing in the channels of interstate and foreign commerce.”²⁰⁰ The AMAA therefore amended the AAA by inserting a policy declaration of Congress’s intent to give the Secretary of Agriculture the power to establish marketing agreements for agricultural commodities that would establish parity prices for farmers and consumers alike.²⁰¹ To achieve the goal of parity pricing and orderly marketing conditions, the AMAA authorizes several regulatory actions, including but not limited to: restrictions on the quantity of a commodity entering the market; limits of the grade, size, or quality of a commodity; regulation of pack and container size; and the creation of commodity market research, development, and promotion programs.²⁰²

It is also important to understand why Congress chose to give the Secretary of Agriculture the power to enter into marketing orders and agreements, which by their very nature authorize anticompetitive practices such as industry collusion and price-fixing. This too was primarily to benefit farmers, though the explanation involves a rather complex combination of political and socioeconomic factors. The first reason is simply a consequence of a large rural population. In the first

¹⁹⁹ H.R. REP. NO. 468, at 30. *See also* S. REP. NO. 565 at 6 (“The immediate reenactment of the marketing agreement and order provisions of the Agricultural Adjustment Act would remove the technical basis upon which [court decisions questioning the provisions’ constitutionality] rest and enable producers to receive the benefits of such programs without the necessity of waiting until these cases have finally been acted upon by the Supreme Court.”).

²⁰⁰ H. REP. NO. 468, at 31.

²⁰¹ H.R. 5722, 75th Cong. 1st Sess. (1937) (codified at 7 U.S.C. § 602(1) and (2)) (“It is hereby declared that the disruption of the orderly exchange of commodities in interstate commerce impairs the purchasing power of farmers and destroys the value of agricultural assets which support the national credit structure and that these conditions affect transactions in agricultural commodities with a national public interest, and burden and obstruct the normal channels of interstate commerce.”).

²⁰² *See* Daniel Bensing, *The Promulgation and Implementation of Federal Marketing Orders Regulating Fruit and Vegetable Crops Under the Agricultural Marketing Agreement Act of 1937*, 5 SAN JOAQUIN AGRIC. L. REV. 3, 6 (1995) (citing 7 U.S.C. § 608c(6)).

half of the twentieth century, many U.S. citizens, as well as immigrants attracted to a seemingly endless supply of cheap and fertile land, made their living as farmers. More farmers meant more saleable agricultural commodities, and the result was that commodity markets in the United States were chronically oversupplied.²⁰³ At the same time, however, the sheer number of farmers relative to the population as a whole gave the agricultural sector considerable voting power, meaning that farmers' interests were often overrepresented in Congress.²⁰⁴

The second reason is a matter of coordination in economic markets. Economists have recognized that “[i]n most free market economies or sectors, there will develop a balance between the component of economic activity coordinated by markets and situations where coordination works best within the firm.”²⁰⁵ Simply by way of their market power, large firms often have the ability to set the price for a good within a particular sector; they may also have considerable influence over the quality level or other characteristics of that good.²⁰⁶ This market power creates stability and facilitates the orderly marketing of that commodity, because large firms are typically well established, and therefore farmers will usually know in advance the price they can expect to receive for their goods.

However, in the 1930s, when Congress passed the AAA, large national and international agricultural commodity firms did not exist. Instead, prices for agricultural commodities were determined by a broad and diverse network of farmers scattered across the country—most of whom were selling only locally or regionally. In the 1920s, some farmers successfully organized cooperatives to control commodity supply, establish pooled prices, and negotiate with handlers only on a collective basis.²⁰⁷ However, any sort of national cooperative effort by individual farmers to collectively influence commodity prices would prove very difficult, if not impossible. Therefore, “[i]t is likely that the resulting balance of public marketing machinery was influenced by this ‘more atomistic’ nature of traders in the American experience. Here the alternative to a public system of

²⁰³ Padberg & Hall, *supra* note 135, at 73–74.

²⁰⁴ *Id.* at 74 (“The politics of this situation favored the agricultural interests more than in any government in history. The participative nature of government . . . and the overbalancing of voters in farming was unprecedented.”).

²⁰⁵ *Id.* at 74–75.

²⁰⁶ *Id.* at 74.

²⁰⁷ *Zuber v. Allen*, 396 U.S. 168, 173 (1969).

grades and standards was not a functional private one, but chaos.”²⁰⁸ And indeed, “[t]he drop in commodity prices during the depression years destroyed the equilibrium of the 1920s and utter chaos ensued.”²⁰⁹ Recognizing that cooperatives could no longer assure farmers a fair price for their commodities, Congress authorized the Secretary of Agriculture to approve industry-led marketing orders and agreements to allow a large network of small “firms”—that is, individual farmers—to organize for their own benefit where they would not otherwise have been able to do so. In sum, marketing orders were part of the larger New Deal effort to shift the balance of economic power from the large aggregators in favor of the small, independent grower.²¹⁰ Seen in that light, marketing orders and agreements are as much a vehicle for participative democracy as they are a method of control over commodity prices in any given industry.

Given that historical background, the resulting statutory scheme is designed to benefit farmers. Marketing orders—after approval by the Secretary of Agriculture and a two-thirds vote among affected producers—require “agricultural producers in a designated region to take various actions to promote orderly marketing, such as influencing supply and quality and pooling funds for promotion and research.”²¹¹ Although similar to a marketing order, a marketing agreement is voluntary and only applies to entities that have signed the agreement.²¹² Either way, the Secretary has wide discretion to approve either type of agreement so long as the procedural requirements have been followed. The only limitation is a required finding that the order or agreement “effectuate[s] the declared policy”

²⁰⁸ Padberg & Hall, *supra* note 135, at 74.

²⁰⁹ *Zuber*, 396 U.S. at 174.

²¹⁰ Bensing, *supra* note 203, at 8. *See also*, *Bailey Farm Dairy Co. v. Anderson*, 157 F.2d 87, 90 (8th Cir. 1946) (noting that the purpose of the marketing order is to benefit the commodity producer). For a more detailed discussion of the AMAA, *See* 9 NEIL E. HARL, *AGRICULTURAL LAW* §§ 70.01–07 (1993 & Supp. 1994).

²¹¹ U.S. Dep’t of Agric., Econ. Research Serv., *Farm and Commodity Policy: Glossary*, <http://www.ers.usda.gov/Briefing/FarmPolicy/glossary.htm#m> (last updated Sept. 21, 2009); *see also* 7 U.S.C. § 608c.

²¹² 7 U.S.C. § 608b (2010). *See also* STEPHEN A. NEFF & GERALD E. PLATO, U.S. DEP’T OF AGRIC., ECON. RESEARCH SERV., AER-707, *FEDERAL MARKETING ORDERS AND FEDERAL RESEARCH AND PROMOTION PROGRAMS: BACKGROUND FOR 1995 FARM LEGISLATION* 15 (May 1995), *available at* <http://www.ers.usda.gov/Publications/aer707/aer707a.pdf>. *See also* 9 NEIL E. HARL, *AGRICULTURAL LAW* §§ 70.01–70.07 (1993 & Supp. 1994) (discussing the Agricultural Marketing Agreement Act and Marketing Orders and Marketing Agreements).

of the AMAA²¹³—which, generally, is to “establish . . . such orderly marketing conditions for agricultural commodities” as will benefit farmers and consumers.²¹⁴

4. *The Proposed National Leafy Greens Marketing Agreement*

In 2009, the NLGMA Proponent Group submitted a petition to the Department of Agriculture asking the Secretary to use his authority under the Agricultural Marketing Agreement Act of 1937 to establish a national leafy greens marketing agreement (NLGMA) applicable to leafy greens handlers across the United States.²¹⁵ Western Growers Association, a non-profit trade association that represents more than ninety percent of the leafy greens growers and handlers in California and Arizona, took a lead role in the NLGMA’s creation and promotion by helping to draft the Agreement’s language and testifying at many of the hearings on the proposal that were subsequently conducted by AMS throughout the United States.²¹⁶

Given Western Growers’ involvement, it’s not surprising that many structural features of the proposed NLGMA are similar to those included in the California and Arizona marketing agreements. The NLGMA comprises three different committees: administrative, technical review, and market review. The Administrative Committee, composed of producer and handler representatives from five different zones across the country, is responsible for the overall administration of the proposed NLGMA and, most important, has the power to “create operational rules and regulations, adopt metrics (after notice and comment), receive and investigate complaints, recommend amendments and collaborate with state entities.”²¹⁷ The Technical Review Board, which includes food safety experts, USDA and FDA

²¹³ See, e.g., *Queensboro Farm Prods., Inc. v. Wickard*, 137 F.2d 969 (2d Cir. 1943) (Secretary of Agriculture is given broad discretion in administering AMAA). See also H.R. REP. NO. 73–6, at 490–91 (1933) (noting that the Secretary’s powers to enter into agreements under the AMAA are “sufficiently flexible to enable him to adapt . . . to changes in our economic situation at home and abroad” but that they are “restrained by the requirement that such agreements may be entered into only for the purpose of effectuating the declared policy of gradually establishing and maintaining such balance between production and consumption as will reestablish for agricultural commodities their pre-war purchasing power”).

²¹⁴ See 7 U.S.C. § 602(1), (4).

²¹⁵ NLGMA Proponent’s Group Brief, *supra* note 170, at 2.

²¹⁶ *Giclas Testimony*, *supra* note 189, at 1.

²¹⁷ DRAFT National Leafy Greens Marketing Agreement, Executive Summary of Key Provisions at 5, <http://www.nlgma.org/documents/041009NLGMASummaryDraft.pdf> (last visited Apr. 24, 2011).

officials, and industry representatives, is responsible for “developing and recommending the ‘metrics’ for a national program” while also accounting for regional growing variances and differences in the size and scale of farming operations.²¹⁸ Finally, the Market Review Board includes representatives from food service companies, retail grocers, consumers, and academics, and will be called upon to provide advice on “retail, food service, and consumer issues that should be addressed to maximize [consumer confidence through] market acceptance and recognition of the program.”²¹⁹

Perhaps the most notable part of the NLGMA is who may become a signatory and who may not.²²⁰ Per the statutory language of the AMAA, only “handlers” of agricultural commodities are eligible to become signatories to the NLGMA.²²¹ Notably, however, retailers and leafy greens brokers may not become signatories, and neither may the farmers who grow the leafy greens at issue:

Producer is synonymous with grower and means any person engaged in a proprietary capacity in the production of leafy green vegetables for sale or delivery to a signatory of the agreement. Producers are NOT eligible to become signatories but because the agreement will impact growers who supply signatory handlers, they are given seats on the Marketing Committee to provide input and direction into the program.²²²

²¹⁸ *Id.* at 4. While these as-yet-unspecified metrics will likely use FDA’s GAP Guide as a starting point, the technical review board has the authority to start from a clean slate if it desires. *See* NLGMA Q&A, *infra* note 223 (“The [Technical Review Board] has license to begin with any set of industry metrics or other guidance in whole or part and may modify them to meet the needs of signatories or adopt them as is.”).

²¹⁹ DRAFT LEAFY GREENS MARKETING AGREEMENT DEFINITIONS, *supra* note 88, at § 970.31.

²²⁰ Signatories to the NLGMA agree to both announced and unannounced audits by USDA inspectors to ensure compliance with the GAP metrics promulgated by the technical review board, and they also agree to pay an assessment (not to exceed \$.05 per carton of leafy greens handled) to fund the NLGMA. *Id.* at § 970.66 (Verification Audits); § 970.56 (Assessments).

²²¹ *See* 7 U.S.C. § 608b (“[T]he Secretary of Agriculture shall have the power . . . to enter into marketing agreements with processors, producers, associations of producers, and others engaged in the handling of any agricultural commodity or product thereof”) (emphasis added). However, the proposed NLGMA broadly defines “handlers” to include anyone who receives, acquires, ships, distributes, or imports leafy greens. DRAFT LEAFY GREENS MARKETING AGREEMENT DEFINITIONS, *supra* note 88, at §§ 970.11 and 970.12.

²²² Q&A Session for NLGMA Proponent Group Presentation at the National Leafy Greens Marketing Agreement Webinar (Aug. 19. 2009) [hereinafter NLGMA Q&A], available at <http://www.nlgma.org/documents/090819QA.pdf> (emphasis in original).

The distinction drawn between producers and handlers in the NLGMA is important because it raises questions about the permissible scope of marketing agreements, as discussed below.

***F. The Failure of Public-Private Partnerships
in Food Safety Regulation—Why the Proposed NLGMA
Cannot Adequately Ensure the Safety of Leafy Greens***

***1. The Idea of Marketing Agreements as a Market Control Device is
Not Consistent with Modern Food Industry Structure***

As a general matter, commentators have argued that marketing agreements—at least as they are needed to provide a semi-democratic means of collective organization—have been reduced to a historical anachronism by the rapid consolidation in the food industry during the past fifty years.²²³ As mentioned above, when Congress passed the AAA in the 1930s, large national and international agricultural commodity firms did not exist. Today, however, the economic and political landscape in which farmers operate is very different. Farmers today account for only about five percent of the rural population, and their voting power has diminished accordingly.²²⁴ Further, unlike 100 years ago, agriculture is now big business. As noted in Part II.A, the leafy greens industry is highly concentrated, both in terms of unprocessed agricultural commodities—with most sourced from California and Arizona, and processed agricultural commodities—with just four firms controlling eighty-six percent of the bagged salad market in 2006. The result is that issues historically addressed by marketing orders and agreements—that is, quality or quantity control requirements, pack or container requirements, or grade size and maturity standards—“are not likely very important or necessary because the large firms have their own, often superior, handling methods and product definitions.”²²⁵ So it is too with safety requirements. As we have seen, the very largest processors and retailers of leafy greens have already established strict super-metrics for bacterial contamination, and these metrics have influenced the market for leafy greens.

However, just because the largest processors and retailers are able to corner the market for safety simply by way of market power does

²²³ See Padberg & Hall, *supra* note 135, at 86–87 (arguing that marketing orders that regulate quality characteristics are “out of tune with the future”).

²²⁴ *Id.* at 76.

²²⁵ *Id.* at 82.

not mean that it is desirable for them to do so. As we will see, the second objection to marketing agreements—and the NLGMA in particular—is that they can be used merely as a vehicle in an intra-industry fight to control safety standards in the absence of government regulation.

2. *The NLGMA Is an Attempt to Create a Safety “Baseline” in the Absence of Government Regulation*

It is worth asking *why* Western Growers and other large leafy greens trade groups have pushed for a national agreement when, as mentioned above, the California and Arizona marketing agreements effectively cover ninety percent of the leafy greens sold at retail. One reason is surely that the Proponent Group sees ninety percent buy-in as incomplete, and the NLGMA is an attempt to corral the remaining ten percent of the leafy greens handlers, who are scattered throughout the Midwest and the East Coast. The Proponent Group has framed this as an accessibility problem: because their retail buyers expect them to adhere to the “strictest set of food safety rules” at all facilities, large handlers cannot source from growers in regions not subject to the California and Arizona marketing agreements.²²⁶ Standardized safety metrics would therefore “facilitate commerce by allowing engaged handlers broader access to products than available today by allowing their suppliers to demonstrate they are following. . . accepted practices.”²²⁷

But this collective buy-in seems to be only a precursor for the main reason driving a national leafy greens marketing agreement: the recent proliferation of private retailer super-metrics. As the Proponent Group puts it, “a standardized and agreed upon set of practices . . . can be utilized to push back on and help extinguish the diverse market driven specifications and independent audits that plague growers and handlers across the country.”²²⁸ There are two reasons why major leafy greens handlers might take issue with this so-called plague of independent and diverse safety efforts—one fairly cynical and the other less so. The less cynical reason is the need to standardize costs and “establish

²²⁶ *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, 11 (Sept. 24, 2009) (testimony of Drew McDonald, Vice President of National Quality Systems, Taylor Farms), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5079859>.

²²⁷ *Giclas Testimony*, *supra* note 189, at 2.

²²⁸ *Id.*

consistency in leafy green production and handling practices through the industry supply chain.”²²⁹ That seems fair, considering that retail super-metrics may duplicate, conflict with, or go beyond the self-imposed standards of leafy greens handlers, thereby increasing compliance costs without necessarily increasing end-product safety. To the extent that a single set of leafy greens safety metrics reduces the fixed safety costs associated with processing leafy greens, both the industry and consumers stand to benefit.

But the more cynical reason for handler pushback against retail super-metrics is competitive in nature—or more precisely, anticompetitive. In particular, leafy greens handlers worry that standards developed by retail distributors “are focused on protecting the retailer’s brand and not necessarily on protecting the grower and handler brands.”²³⁰ Furthermore, increasingly exacting and expensive-to-comply-with retailer safety standards could lead to increasingly individualized supply chains for each retailer, thereby shrinking the overall number of handlers who can supply the largest produce buyers and reducing market competition.²³¹

The language about brand protection, however, is what really helps to explain why handlers are using collective efforts such as marketing agreements to fight retailers over safety standards. Recall the idea that food safety is much more about *consumer perceptions* than it is about the actual safety of a food. One commentator has compared the recent proliferation of private safety standards to “an ‘arms race’ to prove who is providing the safest food and hopefully capitalize on a perception of related consumer preferences.”²³² Because consumers cannot tell if food is actually safe, they have to use proxies, and one fairly reliable proxy for food safety is a brand name. But as noted above, because many growers and handlers trade in raw agricultural commodities and do not sell directly to consumers, they simply cannot establish a retail brand. They can only hope to raise the safety

²²⁹ NATIONAL LEAFY GREENS MARKETING AGREEMENT, *supra* note 133, § 3.

²³⁰ *Id.* § 6.

²³¹ *See id.* (“[T]he retailer programs probably will not take into account the cost to a small producer or handler to implement the programs. In fact, with each large retailer developing its own standards, small handlers or growers will potentially be unable to compete for business delivering leafy green products to one of these retailers.”).

²³² STARMER & KULICK, *supra* note 146, at 6 (quoting MECHEL PAGGI, AN ASSESSMENT OF FOOD SAFETY POLICIES AND PROGRAMS FOR FRUITS AND VEGETABLES: FOOD-BORNE ILLNESS PREVENTION AND SECURITY 2 (2008)) (paper presented at the meeting of the North American Agrifood Market Integration Consortia Annual Workshop in Austin, Texas) (internal quotation marks omitted).

stature of leafy greens *as a whole*, and doing so requires collective action from the *entire* leafy greens industry.

This “arms race” might not be a problem if all industry players were competing to create the strictest standards for the safety of leafy greens, or a race to the top, but two points suggest that might not be the case. First, recall that food safety is primarily based on perceptions because of the informational asymmetry that exists between food companies and consumers: food companies know what food safety standards they employ, but the public often has no way to obtain this information. As a result, food companies have little incentive—other than perhaps the often-distant threat of tort litigation—to raise safety standards above industry minimums. Second, there is currently no mandatory baseline for safety in the leafy greens industry. As noted above, the FDA has imposed only nonbinding guidance for ensuring the safety of leafy greens. From an industry perspective, a mandatory safety baseline can often be advantageous because it allows an individual firm to say confidently to the public that, if nothing else, its product is “safe,” at least as that term is contemplated by regulators. Firms may go beyond that standard if they want to say that their product is “safer.” For example, automakers put airbags and anti-lock brakes in their products, as mandated by regulation, but voluntarily fit their cars with electric nannies such as blind spot assistance cameras²³³ and even pre-crash systems that tighten seatbelts and automatically apply the brakes when the car senses an imminent collision²³⁴ to distinguish their products on the basis of safety. And as Volvo can attest, consistently exceeding the mandatory safety baseline and leveraging that effort via brand distinction can help sell products. But in the leafy greens industry, the lack of brand differentiation among those who handle leafy greens, plus the lack of a safety baseline, raises the worrisome specter of an anticompetitive race to the bottom—a fight for control over an industry baseline of safety, in the absence of government regulation, rather than a fight to establish the most stringent safety standards.

²³³ Christopher Diken, *Volvo Invents BLIS: Blind Spot Info System, Actual Happiness Still Not Attainable*, AUTOBLOG (Aug. 4, 2004, 9:13 AM), <http://www.autoblog.com/2004/08/04/volvo-invents-blis-blind-spot-info-system-actual-happiness/>.

²³⁴ Brian Gill, *What's the Difference Between Pre-Collision and Advanced Pre-Collision? Are They the Same System?*, LEXUS DRIVERS, <http://drivers.lexus.com/lexusdrivers/magazine/content.do#:pub-share/magazine/html/Vehicle-Insider/Ask-Lexus-Collision.html> (last visited Apr. 24, 2011).

There is evidence to suggest this is precisely the unstated goal behind the NLGMA. As the proponent group has put it:

The market will always have the opportunity to go beyond any statutory or industry implemented program *The proponents however do not believe that the marketplace should allow for differentiation based on product safety.* . . . A single standard builds efficiencies and reduces costs throughout the chain so there is a strong return on investment inherent in collaborating to achieve a national standard.²³⁵

As noted above, super-metrics are so named because they go above and beyond many of the growing field requirements already in place under the California and Arizona leafy greens agreements. So why adhere to an agreement that seeks to uniformly impose the lower standards of the previously enacted marketing agreements on a national scale? One commentator has framed the issue this way:

[B]y setting the safety standards lower, and ceding the more stringent requirements to the then market-leader, Fresh Express, the [NLGMA would have] the effect of leveling the playing field for the rest of the market, and so ensuring that all would bear similar costs in meeting improved, but still lower, safety requirements. While a good public-relations maneuver, this was, in fact, a strongly anticompetitive move that created a set of largely voluntary safety requirements that were less stringent than what would have likely resulted if market participants had been forced to compete in an open market on the basis of improved safety and innovation. This can easily be seen if one looks at the requirements that were in the process of being imposed by major buyers of fresh produce, using their own economic leverage as a means of requiring a safer product.²³⁶

This point is only bolstered by the position taken on the NLGMA by Chiquita Brands International, the parent company of Fresh Express, the largest brand name in the leafy greens business. Its post-hearing brief, which opposes the proposed NLGMA for many of the reasons discussed *infra*, is laden with language suggesting an anticompetitive, “safety baseline” rationale for the NLGMA. In objecting to the fact that the NLGMA is not harmonized with global food safety standards, Chiquita writes, “[f]or such companies already certified to a [Global Food Safety Initiative] recognized standard, the Proposed NLGMA audits of fields and manufacturing will be redundant and will not

²³⁵ NLGMA Q&A, *supra* note 223 (emphasis added).

²³⁶ Stearns, *supra* note 132, at 264–65.

provide any additional level of food safety assurance.”²³⁷ And perhaps even more telling is its objection to the assessment costs to be leveled on growers: “As a Company that consistently exceeds the standards contained in the Proposed NLGMA, the proposed assessments . . . seems excessive.”²³⁸

Collusion among industry participants is not necessarily always a bad thing—after all, that is what the AMAA authorized producers to do. But collusion to achieve price control, which is what the AMAA contemplates, is a world away from collusion to achieve *safety*. Collusion to achieve safety is clearly outside the contemplated scope of the Agricultural Marketing Agreement Act of 1937.

3. *Reversing the AMAA: NLGMA’s Attempt to Regulate Producers for the Benefit of Handlers*

Economics aside, the question from a legal perspective is whether the NLGMA effectuates the declared policy of the AMAA, for in the end, that is the inquiry that the Secretary of Agriculture must make. As this Article discusses next, while the NLGMA may fit within the technical, narrow language of the marketing agreement provision, the statutory scheme taken as a whole, as well as prior marketing orders approved by the Secretary that regulate food safety, suggest that the NLGMA is in fact beyond the intended scope of the AMAA and would therefore be *ultra vires* if approved by the Secretary.

a. *The AMAA Is Intended to Regulate Handlers for the Benefit of Producers*

The statutory language of the AMAA and the legislative history surrounding it do not directly answer two questions: Who does the AMAA regulate? And who is to benefit from that regulation? At least in the context of the marketing agreement provision 7 U.S.C. § 608b, the answer is not immediately clear—in no small part because marketing agreements have been, in the words of one commentator, a “[s]tatutory [d]ead [e]nd.”²³⁹ Though the Secretary has approved

²³⁷ *Brief on Behalf of Chiquita Brands International, Inc., and Its Wholly-Owned Subsidiary Fresh Express Incorporated: Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, 5 No. AO-FV-09-0138 (Jan. 27, 2010), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5082265>.

²³⁸ *Id.* at 7.

²³⁹ Bensing, *supra* note 203, at 9.

hundreds of marketing orders since the AAA's passage in 1933, "with the exception of a single marketing agreement program for peanuts, handlers have never been willing to voluntarily enter into marketing agreements. . . ." ²⁴⁰ Instead, most marketing agreements are the result of a marketing order: "Where a marketing order is in effect, however, the USDA will request handlers to sign marketing agreements which simply restate their obligations under the order."²⁴¹ Therefore, the reported cases that have interpreted the AMAA's provisions have done so in the context of marketing orders.

Despite the indeterminate holdings in the various cases, the answer to the question of who is to benefit from marketing orders and agreements seems reasonably clear: mainly farmers, as well as consumers. The best evidence for this statement is the AMAA's declaration of policy, which gives the Secretary the power to establish orderly marketing conditions "as will provide, *in the interests of producers and consumers,*" an orderly supply of agricultural commodities.²⁴² Courts looking to the AMAA's legislative history and context have reached similar conclusions.²⁴³

As to whom the AMAA is to regulate the answer is not quite as clear, though the answer is very likely to be handlers only. The statutory language of § 608b governs marketing agreements and provides the Secretary the authority to enter into agreements with "processors, producers, associations of producers, and others engaged in the handling of any agricultural commodity or product thereof."²⁴⁴ The provision on marketing orders, § 608c, permits the Secretary to issue orders applicable to "processors, associations of producers, and others engaged in the handling of any agricultural commodity or product thereof" but notably omits the word "producer" as is included

²⁴⁰ *Id.* at 9 (citations omitted).

²⁴¹ *Id.*

²⁴² 7 U.S.C. § 602(4) (emphasis added).

²⁴³ *See, e.g.,* Glickman v. Wileman Bros. & Elliot, Inc., 521 U.S. 457, 461 (1997) (purpose of AMAA is "[to] establish and maintain orderly marketing conditions and fair prices for agricultural commodities"); United States v. Borden Co., 308 U.S. 188, 199 (1939) (purpose of AMAA is to maintain orderly marketing conditions to insure farmers of purchasing power); Waddington Milk Co. v. Wickard, 140 F.2d 97, 101 (2d Cir. 1944) ("here was . . . a regulative measure to improve marketing conditions not for the consumer, but for the producers . . . it was the impairment of 'the purchasing power of farmers' and the destruction of the value of 'agricultural which support the national credit structure' towards which the legislative attention was directed.").

²⁴⁴ 7 U.S.C. § 608b(a) (emphasis added).

in § 608b.²⁴⁵ Complicating matters somewhat is § 608c(13)(A) and (B), which explicitly exempt from marketing orders, respectively, “any person who sells agricultural commodities or products thereof at retail in his capacity as such retailer” and “any producer in his capacity as a producer.”²⁴⁶ This statutory scheme has led one court to say flatly: “Although it protects producers, the AMAA regulates handlers only.”²⁴⁷

Keep in mind, courts that have reached this conclusion spoke in the context of marketing orders. Notably, the language in § 608c(13)(B) does *not* have anything to say about whether this provision applies to marketing agreements, though because the statute very clearly delineates the two terms throughout, it is fair to assume that Congress could have said “no order *or agreement*” if it had wanted to be more restrictive.²⁴⁸ Indeed, courts have subsequently narrowed the language of § 608c(13)(B) by holding that producers who also handle agricultural commodities do not fit within the § 608c(13)(B) exception.²⁴⁹

So does the marketing agreement provision also intend to exempt producers in their capacity as producers from regulation? We are left with the language of § 608b and its rather unfortunate comma

²⁴⁵ 7 U.S.C. § 608c(1).

²⁴⁶ *Id.* at § 608c(13)(A)–(B).

²⁴⁷ *Lamers Dairy, Inc., v. U.S. Dep’t of Agric.*, 379 F.3d 466, 469 (7th Cir. 2004). *See also* *Koretov v. Vilsack*, 601 F. Supp. 2d 238, 240 (D.D.C. 2009), overruled on other grounds, 614 F.3d 532 (D.C. Cir. 2010) (“Marketing orders regulate the activities of processors, associations of producers, and others engaged in the handling of certain agricultural commodities . . . They do not regulate farmers in their capacity as producers (or growers).”).

²⁴⁸ *Compare* 7 U.S.C. § 608c(13)(B) (“No order issued under this chapter shall be applicable to any producer in his capacity as a producer.”), *with* 7 U.S.C. § 608c(5)(G) (“No marketing *agreement or order* applicable to milk and its products . . . shall prohibit or in any manner limit, in the case of the products of milk, the marketing in that area of any milk or product thereof produced in any production area in the United States.” (emphasis added)).

²⁴⁹ *See, e.g.,* *Lion Raisins v. United States*, 416 F.3d 1356, 1360 (Fed. Cir. 2005) (“Although producers are not directly bound by the statute . . . all persons seeking to market California raisins out-of-state are deemed handlers and must comply with the Order.”); *United States v. United Dairy Farms Co-op. Ass’n*, 611 F.2d 488, 491 n.7 (3d Cir.1979) (“producers who also function as handlers . . . are subject to regulation under [the milk marketing order].”); *Ideal Farms, Inc. v. Benson*, 288 F.2d 608, 614 (3d Cir.1961), *cert. denied*, 372 U.S. 965 (1963) (“Other provisions of this section of the Act explicitly recognize that a person or business entity may be engaged in the milk business in more than one capacity and that a producer is exempt from regulation only in his capacity as a producer.”); *Freeman v. Vance*, 319 F.2d 841, 842 (5th Cir.1963) (same).

placement between “producers” and “and others engaged in the handling of any agricultural commodity” Does the language “engaged in the *handling* of any agricultural commodity” modify the entire preceding list, or does it refer to only the “and others” immediately preceding? Using the statutory interpretation canon *reddendo singula singulis*,²⁵⁰ the answer is likely the former. Reading on, we see that the word “handling” is used again in § 608b(a)—this time in the context of a clause that is essentially a statutory hook that brings the provision within Congress’ power to regulate interstate commerce.²⁵¹ If this interstate commerce clause only modified the phrase “others engaged in the handling of any agricultural commodity or product thereof,” then it would follow that the Secretary could enter into agreements with “processors, producers, [and] associations of producers” that did *not* operate in interstate commerce.²⁵² Giving § 608b(a) this strained interpretation severely insults Congress’ collective ability to understand the basic constitutional limits of its authority. Therefore, it is likely that Congress intended marketing agreements, like marketing orders, to regulate *only* processors, producers, and associations of producers *that handle* the product at issue.

In any case, the idea that marketing agreements regulate *handlers* for the benefit of *growers* is bolstered by Congress’ statutory scheme for the approval of marketing orders with and without marketing agreements. For example, 7 U.S.C. § 608c(8), “orders with marketing agreement,” conditions the issuance of marketing orders upon two things: first, at least fifty percent of the handlers of the regulated commodity must enter into a marketing agreement per § 608b, and second, the Secretary must then determine that at least two-thirds of the producers, either by number or by volume of product within the production area, approve of the order.²⁵³

Furthermore, Congress provided a way for producers to regulate handlers even over their objection. Section 608c(9), “[o]rders with or without marketing agreement,” allows the Secretary to issue a

²⁵⁰ “The different portions of a sentence . . . are to be referred respectively to the other portions or sentences to which we can see they respectively relate, even if strict grammatical construction should demand otherwise.” HENRY CAMPBELL BLACK, HANDBOOK ON THE CONSTRUCTION AND INTERPRETATION OF THE LAWS 226 (2nd ed. 1911).

²⁵¹ 7 U.S.C. § 608b (“[O]nly with respect to such handling as is in the current of interstate or foreign commerce or which directly burdens, obstructs, or affects interstate or foreign commerce in such commodity or product thereof.”).

²⁵² *See id.*

²⁵³ *See* 7 U.S.C. § 608c.

marketing order, “notwithstanding the refusal or failure of handlers. . . of more than [fifty percent] of the volume of the commodity or product thereof” to sign a marketing agreement, if the Secretary finds that (1) the order is favored by two-thirds of the producers of the regulated commodity, and (2) that issuance of the order is the “only practical means of advancing the interests of the producers of such commodity . . .”²⁵⁴ To sum up the marketing order statutory scheme: handlers cannot enact marketing orders without a two-thirds approval of producers, but producers can impose mandatory marketing orders on a minority of handlers, given a two-thirds majority of producer approval and a finding by the Secretary that the order will further the *producers’*—not the handlers’—interests. If there were ever a statutory scheme designed to regulate handlers for the benefit of producers, this would be it.

Finally, the idea that marketing orders and agreements regulate handlers for the benefit of growers is also supported by the structure of mandatory marketing orders that have included food safety controls. For example, the almonds marketing order clearly distinguishes between almond growers and handlers, emphasizing that growers who do nothing more than sell or deliver almonds to handlers are not handlers themselves.²⁵⁵ Handlers have requirements for almonds that come into their processing plants (they must conduct random quality control sampling and dispose of inedible kernels)²⁵⁶ and they have requirements for outgoing almonds (they must use either on-site or audit-based verification processes to ensure that

²⁵⁴ *See id.*

²⁵⁵ *See* 7 C.F.R. § 981.12 (2010) (“Grower is synonymous with producer and means any person engaging, in a proprietary capacity, in the commercial production of almonds.”); *id.* § 981.13 (“Handler means any person handling almonds during any crop year, except that such term shall not include either a grower who sells only almonds of his own production at retail at a roadside stand operated by him, or a person receiving almonds from growers and other persons and delivering these almonds to a handler.”); *Id.* § 981.16 (“To handle means to use almonds commercially of own production or to sell, consign, transport, ship . . . or in any other way to put almonds grown in the area of production into any channel of trade for human consumption worldwide *However, sales or deliveries by a grower to handlers, hullers or other processors within the area of production shall not, in itself, be considered as handling by a grower.*” (emphasis added)). *See also* 72 Fed. Reg. 15,022 (Mar. 30, 2007) (“The rule only affects those who meet the definition of ‘handler’ in § 981.13 of the order . . .”).

²⁵⁶ 7 C.F.R. § 981.442(a).

almonds have been treated for harmful *Salmonella* bacteria),²⁵⁷ but the marketing order imposes no on-field metrics aimed specifically at growers. This is true even though one of the two *Salmonella* outbreaks identified by Congress as the impetus for the order was traced back to an almond orchard, not the processing facility.²⁵⁸ Nevertheless, the order makes handlers, not growers, bear the direct burden and cost of implementing technology in their processing plants.²⁵⁹

b. Turning the Table: The NLGMA Regulates Producers for the Benefit of Handlers

It is very important to answer the question of who the AMAA regulates, as well as for the benefit of whom, because certain aspects of the proposed NLGMA do not regulate handlers—they regulate growers, regardless of whether these growers actually handle leafy greens. The NLGMA document at least gives lip service to the fact that AMAA implicitly limits regulation to handlers of leafy greens, noting in the Act’s definition section that the term “handle determines who is able to become a signatory to the marketing agreement. The marketing agreement will directly regulate ‘handlers’ . . . and so how handle is defined becomes a foundational issue for the agreement.”²⁶⁰ Though the NLGMA broadly defines the term *handler* to include anyone who receives, acquires, sells, processes, ships, distributes, or

²⁵⁷ 7 C.F.R. § 981.442(b) (“[H]andlers shall subject their almonds to a treatment process or processes prior to shipment to reduce potential *Salmonella* bacteria contamination in accordance with the provisions of this section.”); *id.* § 981.442(b)(4) (“[H]andlers shall utilize either an on-site verification program (traditional), or an audit-based verification program to ensure that their almonds have been subjected to a treatment process to reduce *Salmonella* bacteria prior to shipment. Each handler may decide which verification program would be the most cost-effective for his or her operation.”).

²⁵⁸ Almonds Grown in California; Outgoing Quality Control Requirements, 72 Fed. Reg. 15, 021, 15,022 (Mar. 30, 2007).

²⁵⁹ The process must deliver “a lethal treatment for *Salmonella* in almonds to achieve a minimum 4-log reduction” of the bacteria. *Id.* at 15,025. The pistachio marketing order imposes a similar scheme for reducing aflatoxin levels in pistachios. See 7 C.F.R. § 983.14(a)-(c) (2010) (defining “handler” as anyone who receives, hulls, dries, or “[f]urther prepar[es]” pistachios for marketing or packaging); *id.* § 983.14(d) (noting that transporting pistachios from the orchard to the processing facility is not considered “handling”); *id.* § 981.150(d) (imposing mandatory aflatoxin sampling and testing procedures on handlers).

²⁶⁰ DRAFT National Leafy Greens Marketing Agreement, Executive Summary of Key Provisions at 1, <http://www.nlgma.org/documents/041009NLGMASummaryDraft.pdf> (last visited Apr. 21, 2011).

imports leafy greens,²⁶¹ it also defines producer separately. “Producer is synonymous with grower and means any person engaged in a proprietary capacity in the production of leafy green vegetables for sale or delivery to a signatory of this agreement.”²⁶² The emphasized language suggests that the NLGMA drafters clearly contemplated that producers and handlers could be separate entities—a statement bolstered by the fact that the proponents have made it explicitly clear that “[p]roducers are NOT eligible to become signatories to the agreement”²⁶³ However, the agreement does allow growers to sit in their capacity as growers on the Administrative Committee that governs the agreement,²⁶⁴ this was done “to reflect the fact that even though growers are not *directly* regulated by the proposed national marketing agreement which is for ‘handlers’ of leafy greens—they are impacted and need to have a voice in the process.”²⁶⁵

In reality, producers are more than impacted by the NLGMA—they are *regulated* in their capacity as growers, even though the AMAA contemplates that they should not be. This is because many of the proposed NLGMA metrics—and in particular, the good agricultural practice (GAP) metrics—regulate at the growing field level, which is the very heart of a producer’s job. Though precise GAP audit metrics have not yet been set, an NLGMA summary document clarifies their intended scope:

[The USDA will conduct] GAP audits of *all producers including producers outside the production area who provide leafy greens to signatory handlers*. These audits will cover good agricultural practices related to the following areas: water quality, soil amendments, machine harvest, hand harvest (including direct contact with soil during harvest), transfer of human pathogens by field workers, field sanitation, equipment-facilitated cross contamination, flooding, water usage to prevent dehydration, and

²⁶¹ DRAFT LEAFY GREENS MARKETING AGREEMENT DEFINITIONS, *supra* note 88, at § 970.10.

²⁶² Leafy Green Vegetables Handled in the United States, Hearing on Proposed Marketing Agreement No. 970, 74 Fed. Reg. 45,565, 45,568 § 970.20 (Sept. 3, 2009) (emphasis added).

²⁶³ NLGMA Q&A, *supra* note 223 (emphasis added).

²⁶⁴ Draft Leafy Greens Marketing Agreement, *supra* note 87, at § 970.40 (“A majority of the producer members of the Committee *shall not otherwise be engaged in the handling of leafy green vegetables* or the manufacturing of fresh-cut, packaged leafy green products”) (emphasis added).

²⁶⁵ NLGMA Q&A, *supra* note 223 (emphasis added).

production location concerns, including climatic conditions and environment, and encroachment by animals and urban settings.²⁶⁶

At the same time, the NLGMA does propose good handling practices (GHPs) and good manufacturing practices for handlers, processors, and manufacturers of leafy greens, including post-harvesting process controls such as cooling, reuse of field containers, and the condition and sanitation of transport vehicles; handling and manufacturing processes such as wash water, wash system capacity, employee handling hygiene, and finished product packaging; and distribution handling processes such as temperature measurement of product and the condition and sanitization of cooling facilities. However, the thrust of the NLGMA is regulation of microbial contamination at the field level. That much is evident from the Proponent Group's post-hearing brief to the Secretary of Agriculture in support of the NLGMA, which notes that "there are two potential mechanisms of foodborne pathogen transmission from domestic animals or wildlife to leafy greens and both of these routes are addressed by the NLGMA."²⁶⁷ It is true that these two mechanisms—direct transmission of bacteria through runoff of fecal matter and indirect transmission through soil, sediment, and bioaerosols—are the main methods of bacterial contamination *on the growing fields*, but the NLGMA does not address the fact that the contamination risk can be exacerbated by the processing methods used by the fresh-cut industry, as discussed above. Aside from standard sanitary practices such as employee hygiene, wash water controls, and temperature regulation that most processors likely already have in place, the NLGMA as proposed contains no requirements for Hazard Analysis and Critical Control Point (HACCP)-style programs that identify and address especially high-risk areas in the processing plant, or even any references to the FDA's guidance for the vegetable processing industry. Rather, the crux of the agreement focuses on growing fields, which are controlled by producers—not all of whom are also *handlers* of leafy greens.

This comprehensive regulation of growing fields would not be so worrisome if the proposed NLGMA were actually voluntary, as the

²⁶⁶ NATIONAL LEAFY GREENS MARKETING AGREEMENT, *supra* note 133, § 8 (emphasis added).

²⁶⁷ NLGMA Proponent Group Brief, *supra* note 170, at 4.

Proponent Group continually stresses.²⁶⁸ In reality, though, it is not. That is because, as noted above, the leafy greens industry is driven by a highly centralized, top-down food supply chain that is controlled by the largest retailers and processors of leafy green vegetables. Handlers of leafy green vegetables have every incentive to sign up for the NLGMA since the agreement gives them considerable say in the process of creating the governing metrics.²⁶⁹ And because the handler industry recognizes the need for collective action to preempt the proliferation of retail super-metrics, once major handlers sign on, the dominoes will likely start to fall accordingly.

The result is that growers who want to continue to sell their leafy greens to handlers will have no choice but to comply with the handler-mandated NLGMA GAP metrics, particularly in areas such as California and Arizona, “where a few handlers dominate the market, and growers have little choice of buyers for their product.”²⁷⁰ This fact is further illustrated by the ninety-nine percent participation rate in the CLGMA.²⁷¹ This concern has been raised not only by growers—some of whom have already lost handler accounts due to

²⁶⁸ See, e.g., *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, 4 (Oct. 6, 2009) (testimony of Tom Stenzel, President & CEO, United Fresh Produce Ass’n), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5080123> (“A NLGMA [is] 100% voluntary—no individual grower or handler has to participate. For those who fear that retailers will demand it, a [sic] NLGMA will no more raise nor reduce the likelihood that retailers will want compliance that you follow GAPs.”).

²⁶⁹ For example, the proposed Administrative Committee, which is to establish the “terms and conditions” of the NLGMA, consists of 23 seats—13 for handlers, 6 for producers, and 4 for other non-handler members. DRAFT LEAFY GREENS MARKETING AGREEMENT, *supra* note 88, at § 970.40(a).

²⁷⁰ *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, (Oct. 22, 2009) (testimony of Roland McReynolds), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5080471>. See also Jane Palmer, *New Food Safety Rules Threaten Small Organic Farms*, SAN JOSE MERCURY NEWS, May 23, 2010, http://www.mercurynews.com/breaking-news/ci_15148280?nclick_check=1 (quoting one California-based grower as saying that she follows the CLGMA because “if I don’t comply, then I won’t have anybody to sell to”).

²⁷¹ In fact, one of the Proponent Group’s witnesses admitted at the ALJ hearing that a marketing agreement and order would have the same effect. “[I]f we look at the results from the California Leafy Greens, what is it, 99 percent participation of that order [sic]? What’s the difference between 99 percent and having everyone participating between the agreement and the order? So it’s a very small difference in the effect.” *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, Docket No. AO-FE-09-0138, 315 (Sept. 22, 2009), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5080510>.

their decision not to follow California LGMA standards²⁷²—but also by some small handlers of locally and organically grown leafy greens, who fear that their grower-suppliers either would not or could not comply with NLGMA requirements due to cost and scale restraints.²⁷³

Furthermore, the proposed NLGMA adds another form of market compulsion: an “official certification mark” that would be licensed for use by all handlers in compliance with the NLGMA’s provisions.²⁷⁴ Though the Proponent Group has clarified that this mark is to be placed only on bills of lading or packing boxes shipped to retailers and not on any packaging that consumers will see,²⁷⁵ the implicit notion behind the mark is clear: leafy greens sourced by unmarked handlers are less safe than those of NLGMA signatories. The use of this certification mark is perhaps the clearest indication that the NLGMA is intended by proponents as a collective attempt to corner the safety market in the leafy greens industry, thereby stealing the thunder of retailer efforts. It also belies the notion that the NLGMA is intended to be a voluntary agreement.

1. The NLGMA Makes Food Safety a Subset of Food Quality

In the debate over the leafy greens marketing agreement, it is easy to lose sight of what this debate is ultimately about. As noted above, the Secretary may approve any marketing agreement if it, as applicable here, “provides, in the interests of producers and consumers, an orderly flow of the supply [of leafy greens] to market throughout its normal marketing season to avoid unreasonable

²⁷² See Palmer, *supra* note 271 (noting that one small organic farmer who declined to follow the CLGMA regulations “has lost his Canadian accounts as the nation’s government prohibits imports of leafy produce from farmers who have not signed on to the marketing agreement. The cost, 5 percent of his income, is not borne easily in today’s economy”).

²⁷³ As one small handler recounted in his testimony before the USDA: “As one mid-size farmer on the Central Coast of California said to me last Monday, ‘what am I going to do? Aside from my home ranch I have 11 other properties that I lease for production. That is a total of 12 separate water sources. How can I afford to test 12 separate water sources with any regularity?’” *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, 3 (Sept. 24, 2009) (testimony of Bu Nygrens, Co-Owner & Purchasing Manager, Veritable Vegetables), <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5079869>.

²⁷⁴ DRAFT LEAFY GREENS MARKETING AGREEMENT, *supra* note 88, at § 970.69.

²⁷⁵ See NLGMA Proponent Group Brief, *supra* note 170, at 15 (“[N]othing in the proposed rule contemplates that the certification mark would appear on consumer packaging.”).

fluctuations in supplies and prices.”²⁷⁶ This orderly marketing business is a pretty long way from what started this whole debate: the *safety*—or lack thereof—of leafy greens. And that raises the critical question of *who* is best positioned to address that issue. The question is important because both industry and federal agencies in this debate define the word *safety* in different ways—and not always in the same way that the public defines it. This idea will be discussed later in this section.

But first, the *who* of marketing agreements. Once approved by the Secretary of Agriculture, marketing agreements are administered by Agricultural Marketing Service (AMS), a division of the USDA. It is important to repeat at the outset that the USDA’s role is merely supervisory: the industry writes its own metrics, the Secretary stamps his approval, and USDA inspectors or USDA-approved state authorities enforce the industry-created rules. If this does not exactly sound like a model setup for safety regulation, that is because it is not meant to be—and in fact, the USDA has explicitly acknowledged the FDA’s primacy in the area of fruit and vegetable food safety.²⁷⁷ AMS’s role within USDA is even more specialized. The mission of AMS, as its director has told Congress, “is to facilitate the strategic marketing of agricultural products in the domestic and international marketplace. AMS is not a food safety agency. The agency, through programs such as marketing orders and agreements, assists handlers and producers in verifying various product quality control efforts.”²⁷⁸ Reduced to two words, AMS’s purview is this: *product quality*.

Given AMS’s—and ultimately USDA’s—limited jurisdiction over produce safety, the question is how the term *safety* should be defined. Is food safety one of many attributes, such as size, variety, and color wrapped up in the concept of food quality, or is food safety something altogether separate—an end to be achieved of itself? The proponents of the NLGMA clearly believe it is the former:

The industry believes that a national marketing agreement promulgated by USDA is the best available instrument for protecting the quality and hence, the marketability of fresh leafy green vegetables by promoting the use of scientifically-based

²⁷⁶ 7 U.S.C. § 602(4) (2010).

²⁷⁷ *Pegg Testimony*, *supra* note 75, at 2 (“As you know, the Food and Drug Administration is the Federal agency with primary responsibility for food safety of fruits and vegetables.”).

²⁷⁸ *Id.*

GAPs, GHPs, and GMPs in a standardized manner to reduce physical, chemical, and microbial contamination events.²⁷⁹

Hence:

USDA is the most appropriate federal agency to oversee a national food quality enhancement program because it has significant expertise and experience in the design and delivery of programs that involve inspection for product quality and verification of production practices. . . . Both the leafy green industry and the USDA have a good working relationship with the FDA on food quality programs that include food safety issues.²⁸⁰

And if there was any question as to whether the proponent group views AMS as the proper sub-agency to regulate the safety of leafy greens: “Proof of use of best practices is essential to the marketability of fresh produce. Growers that demonstrate the use of GAPs, GHPs, and GMPs will undoubtedly have *better marketing opportunities* than those who cannot demonstrate that they have a food safety and quality management program in place.”²⁸¹ Fair point, that last one: “We would know whether our lettuce was tainted if only we had a quality management program!” does not exactly make for a catchy advertising tagline.

In any event, AMS appears to agree with the NLGMA proponents—safety is an element of *quality*, and therefore making food safer makes it a higher quality product, which makes it easier to sell to consumers, which—ostensibly—helps maintain an orderly flow of the commodity. Quite the chain of reasoning. AMS considers “the absence of harmful pathogens or toxins to be a characteristic of *higher quality* products,” Administrator Pegg told Congress in 2007.²⁸² In its inspection standards regulations for fruits, vegetables, and specialty crops, USDA defines quality as “the combination of the inherent properties or attributes of a product which determines its *relative degree of excellence*.”²⁸³ The italicized language in the two quotes above suggests that the USDA views food safety not only as a subset of food quality, but as something that is subject to degrees.

²⁷⁹ *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, 2 (Sept. 22, 2009) [hereinafter *Pezzini Testimony*] (testimony of Joe Pezzini, Chief Operating Officer, Ocean Mist Farms), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC 5079700>.

²⁸⁰ *Id.* (emphasis added).

²⁸¹ *Id.* at 4 (emphasis added).

²⁸² *Pegg Testimony*, *supra* note 75, at 5 (emphasis added).

²⁸³ 7 C.F.R. § 51.2(p) (2010) (emphasis added).

But safe and safety as adjectives are not relative terms, nor should they be defined that way. The dictionary supports this (“Safety: the quality or condition of being safe; freedom from danger, injury or damage; security”),²⁸⁴ and so does common usage (in baseball, a base runner is either safe or out). Certainly, some activities or positions can be *perceived* as safer than others. Eating leafy greens with a fork is safer than eating them with a butcher knife, and by the same token, the perception of food safety—that is, how food is marketed to consumers—can also be subject to degrees. That is because, as mentioned above, the informational asymmetry in the food industry leaves consumers guessing as to whether their leafy greens are contaminated with harmful pathogens. They can deal only in probabilities or risks. So leafy greens with an NLGMA stamp of approval might be perceived as safer (i.e., *less likely* to be contaminated by pathogens and therefore “Grade A” leafy greens) than those not run through NLGMA metrics (i.e., *more likely* to be contaminated and therefore “Grade B” greens). But as to the actual safety of the greens themselves, there is no Grade B. Food is either Grade A (not contaminated and therefore safe) or Grade F (contaminated and therefore unsafe).

In the end, to equate food safety with food quality and therefore subject it to degrees is to seriously undermine the historical notion in the United States of food safety as a public good. Put another way:

[Food safety] is a critical issue that rises above other characteristics like size, variety, or appearance. The issue of whether minimum safety practices were followed is not something that should be subject to efforts to distinguish between competing brands. It is unfair to ask consumers to determine which products were produced with which food safety standards—and it is unacceptable to make the penalty for buying the wrong brand an increased risk of illness.²⁸⁵

The notion of food safety as a public good to be achieved as an end in itself is supported by the structure of our system of laws. As common law developed in England, it split into two branches: torts, which remedied violations by individuals against other individuals,

²⁸⁴ WEBSTER’S NEW WORLD COLLEGE DICTIONARY 1181 (3d ed. 1997).

²⁸⁵ *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, (Sept. 23, 2009) (testimony of Patty Lovera, Assistant Director, Food & Water Watch), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5079736>.

and criminal law, which remedied an individual's violations against the state or society as a whole.²⁸⁶ In the late nineteenth century, faced with the development of an industrialized food regime, U.S. lawmakers decided that "provision of foods that threaten the integrity of our food supply should be treated as a crime against society."²⁸⁷ This notion can be seen in the Federal Food, Drug, and Cosmetic Act's strict liability criminal penalties for violating its misbranding provisions, which can include fines and even imprisonment. The FFDCFA, of course, is administered not by the USDA, but by the FDA, which as mentioned above is a consumer protection agency dedicated to safety as opposed to maximizing production and rural economic development.

In any case, the point of the foregoing discussion should be abundantly clear: food safety is far too important a goal to be reduced to the vagaries of "quality" and "orderly marketing." And because of their collusive nature, marketing agreements have the potential to undermine the deliberative process contemplated by more formal types of rulemaking. A marketing agreement results in private standards promulgated by industry groups that are subject to change at any time,²⁸⁸ and that may or may not take into consideration the needs of minority groups such as small scale or organic growers and handlers within the industry²⁸⁹ or the public at large.²⁹⁰

²⁸⁶ Lyon, *supra* note 42, at 745.

²⁸⁷ *Id.*

²⁸⁸ See NLGMA Q&A, *supra* note 223 (noting that "an industry program is much more flexible, adaptable and can be changed more easily than a government rule").

²⁸⁹ See, e.g., Community Alliance with Family Farmers, *Policy: Leafy Green Marketing Agreement*, available at <http://www.caff.org/policy/leafygreen.shtml> (last visited Apr. 24, 2011) (listing several links to position papers opposing the marketing agreement's potential impact on small farms). Examples of the disparate impact in proposed leafy green marketing agreements include testing requirements as these costs would comprise a large percent of the operations total budget, and setback requirements which would be spread over fewer acres of potential production. See Community Alliance with Family Farmers, *Comments to Joint Assembly and Senate Committees on Agriculture*, Feb. 27, 2007, at 5, available at <http://www.caff.org/policy/CAFFCommentsonFoodSafety.pdf>. Part of the justification for this opposition is the contention that the potential for more widespread damage from a foodborne illness and thus the necessity for expensive investment in technological solutions arise from production factors inherent only (or with greater frequency) in larger-scale operations. Accordingly, only large operations should bear the burden of mandatory investment in technological solutions. See Cohen, *supra* note 36, at 38-39. The FDA Food Safety Modernization Act incorporates this concept, exempting from some rules small business with limited sales. See H.R. 2751, 111th Cong., § 103 (2011) (to be codified at 21 U.S.C. § 418(k)).

²⁹⁰ Consumers Union, the nonprofit publisher of *Consumer Reports* magazine, opposes the NLGMA on grounds that it would "allow the leafy green industry to develop its own

Perhaps worst of all, the NLGMA might create the *perception* that leafy greens are safe without actually making them so, if the metrics are not strong enough or policed with sufficient rigor.²⁹¹ In any case, the NLGMA certainly will not be enforced with the power of recall now granted to the FDA. Instead, the ultimate penalty for failing to comply with the NLGMA metrics is not a fine, or removal of the greens from the market, but the loss of the privilege of using the NLGMA mark of certification, which does not even appear on consumer packaging to start with.²⁹² Suffice to say that this likely is not the leafy greens regulation that the public would want if they had a say in the process, and they ought to be given a chance to voice their concerns on the front end through a deliberative, open forum such as the kind provided by notice-and-comment regulation. This point garners additional force when one considers that the Supreme Court has ruled that consumers do not have standing to challenge the Secretary's promulgation of marketing orders and agreements.²⁹³

2. *Agency Capture and Skirting Responsibility—Why Government Regulation Is a Better Solution*

From an industry perspective, the weak-kneed regulation and enforcement scheme provided by the USDA and AMS under the proposed NLGMA is likely precisely the goal. And that raises the third strike against marketing agreements: agency capture. As one commentator has noted in the context of food safety regulation, “[i]n the subtlest sense, capture exists any time an agency moves too far toward accommodating a single interest while moving away from its statutory mission. Such capture may provide a measure of public

safety standards virtually all by itself, with only a minor tip of the hat to public input.” *Leafy Green Vegetables in the United States: Hearing on Proposed Marketing Agreement No. 970 Before the U.S. Dep’t of Agric.*, Sept. 23, 2009 (testimony of Elisa Odabashian at 1), available at <http://www.ams.usda.gov/AMsv1.0/getfile?dDocName=STELPRDC5079744>.

²⁹¹ In July 2009, a CLGMA signatory recalled 22,000 cases of lettuce shipped to 29 states after a random sample by the Wisconsin Department of Agriculture tested positive for salmonella. *See* Rusk, *supra* note 113.

²⁹² *See* notes 275–276 *supra* and accompanying text.

²⁹³ *Block v. Community Nutrition Institute*, 467 U.S. 340, 352 (1984) (“The Act contemplates a cooperative venture among the Secretary, producers, and handlers; consumer participation is not provided for or desired under the complex scheme enacted by Congress. Consumer suits would undermine the congressional preference for administrative remedies and provide a mechanism for disrupting administration of the congressional scheme.”).

good, but regulators' care is balanced more for industry benefit than for the public's."²⁹⁴ According to AMS, that is exactly what marketing orders and agreements do—they “balance the availability of quality product with the need for adequate returns to producers and the demands of consumers.”²⁹⁵ It is notable that AMS's most robust audit programs—the Qualified Through Verification and the GAP and GHP Audit Verification Program—were created at industry request.²⁹⁶ And “[as] the demand for verification of GAP, GHP, and GMP has increased, commodity groups have approached USDA for assistance with the development of commodity specific audit programs.”²⁹⁷ That is because the industry believes that USDA will be more responsive than FDA in responding to their needs. This is not to say that the NLGMA proponents naively believe that the NLGMA can preempt FDA regulation altogether.²⁹⁸ Rather, a USDA-approved NLGMA allows the major players in the leafy greens industry to continue to do what they have always tried to do: retain control of the rules to which they are bound.²⁹⁹ As the Proponent Group has put it:

If there is a clear signal from USDA early, through the approval of a [sic] NLGMA, proponents anticipate that US FDA will be a collaborator in the development of audit metrics for the program. This would allow the FDA to recognize this industry program as meeting their requirements and expectations.³⁰⁰

And perhaps that is the bottom line—an NLGMA designed to improve safety with costs imposed on the grower community and controlled exclusively by industry, under the supervision of a friendly USDA regime, rather than mandatory FDA regulations that take control over safety metrics outside of industry hands. As discussed

²⁹⁴ Fortin, *supra* note 32, at 582.

²⁹⁵ Agric. Mktg. Serv., *Marketing Orders and Agreements*, U.S. DEP'T OF AGRIC., <http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateA&navID=MarketingOrders&leftNav=MarketingOrders&page=MarketingOrders&acct=AMSPW> (last visited Apr. 24, 2011).

²⁹⁶ *Souza Testimony*, *supra* note 158, at 2.

²⁹⁷ *Id.* at 3.

²⁹⁸ See *Stenzel Testimony*, *supra* note 269, at 2 (“I think it’s wise for all of us to realize that mandatory GAPs for all leafy greens are not far away A NLGMA will not forestall nor replace these eventual FDA regulations However, it can be helpful now in gaining grower/handler input and consensus on what the rules ought to be, and subsequently in demonstrating compliance with those rules.”).

²⁹⁹ See *Bensing*, *supra* note 203, at 42 (questioning continued appropriateness of “giving industry leaders the authority to administer a program that regulates their competitors and themselves”).

³⁰⁰ NLGMA Q&A, *supra* note 223.

below, the FDA Food Safety Modernization Act passed by Congress in December 2010 cuts through this administrative maneuvering and specifically authorizes FDA, rather than USDA, to issue regulations relating to leafy green safety at both the field level³⁰¹ and further along the food supply chain.³⁰² This may foreclose any chance of a NLGMA. However, leafy greens are not the only commodity potentially subject to a marketing agreement or order and the arguments surrounding this questionable approach to food safety regulation may resurface in another context. As discussed in the next section, shell egg safety presents another example of multiagency jurisdiction and a compelling case for food safety reform.

III SHELL EGGS: CONSOLIDATION, INDUSTRIALIZATION, AND REGULATORY RECALCITRANCE

The Centers for Disease Control and Prevention (CDC) has recognized *Salmonella Enteritidis* (SE) contamination in eggs and the associated public health implications since 1988.³⁰³ Eggs may become contaminated during egg formation in the ovary or via subsequent contact with contaminated materials that penetrate the egg shell.³⁰⁴ There are numerous programs, administered by several agencies, directed at preventing SE infections.³⁰⁵ Recent government estimates from the FDA and USDA estimate that of the forty-seven billion eggs consumed as shell eggs, 2.3 million are SE-positive,³⁰⁶ resulting in more than one million illnesses and several hundred deaths per year.³⁰⁷

³⁰¹ See H.R. 2751, 111th Cong. § 104 (2011) (to be codified at 21 U.S.C. § 118).

³⁰² See H.R. 2751 § 102 (to be codified at 21 U.S.C. § 117).

³⁰³ GAO EGG SAFETY, *supra* note 40 at 1. See also FDA SE Final Rule, *supra* note 65, at 33,031.

³⁰⁴ FDA SE Final Rule, *supra* note 65, at 33,032.

³⁰⁵ Among the programs are the continuous inspection of egg processing facilities and mandatory pasteurization of processed egg products, administered by the USDA Food Safety Inspection Service (FSIS), 9 C.F.R. Part 590 (2010); the Agricultural Marketing Service's (AMS) oversight and inspections to prevent cracked, dirty, and otherwise unfit eggs from being sold on the shell egg market, 7 C.F.R. Part 57; the Animal and Plant Health Inspection Service's (APHIS) voluntary breeding program to reduce the incidence of SE in laying hens, 9 C.F.R. Part 145 and 147; and the FDA's mandatory food safety labeling warning, 21 C.F.R. § 101.17(h). For a more detailed discussion of the regulatory morass, see Eskin, *supra* note 80, at 441.

³⁰⁶ FDA SE Final Rule, *supra* note 65, at 33,032.

³⁰⁷ The government estimated 1,203,650 illnesses and 494 deaths in 2001, and 1,376,514 illnesses and 427 deaths in 2004. *Id.* at 33,031.

A. *Shell Egg Production Background*

From 1999 through 2009, egg production in the United States increased from eighty-four to ninety-one billion eggs per year³⁰⁸—a rather modest increase relative to other agricultural products such as leafy greens,³⁰⁹ or commodities such as corn³¹⁰ and soybeans.³¹¹ What is remarkable, however, is that the vast majority of the production increase occurred in one state—Iowa. This was not always the case. In 1993, Iowa was the ninth largest egg producer.³¹² Egg production more than doubled in Iowa from 1999 through 2009, and increased fourfold between 1993 and 2009.³¹³ By 2001, Iowa surpassed Ohio, formerly number one, and now almost doubles Ohio’s annual production.³¹⁴

Iowa’s rapid ascent to the top coincides with tremendous structural change in the nature of egg production. In 1987, there were approximately 2500 egg-producing farms.³¹⁵ By 2009, 205 industrial-scale operations produced ninety-five percent of the nation’s eggs.³¹⁶ And of these 205, sixty-two had operations with more than one million animals and twelve had more than five million.³¹⁷ This massive structural change in the industry coincided with the movement of egg production from other states to Iowa.

³⁰⁸ See U.S. Dep’t of Agric., Nat’l Agric. Statistics Serv., *Egg Production, 1996–2006* (May 2007), http://www.nass.usda.gov/Charts_and_Maps/Poultry/eggprd.asp.

³⁰⁹ See *supra* notes 84–105 and accompanying text (discussing growth in leafy green production).

³¹⁰ See Nat’l Corn Growers Ass’n, *Corn Production Trends, 2009*, available at <http://www.ncga.com/corn-production-trends> (stating that corn production increased from 9,430,612 million bushels in 1999 to 13,130,632 bushels in 2009).

³¹¹ See The American Soybean Association, *Soy Stats@*, U.S. Soybean Production 1984–2009, 2010, available at http://soystats.com/2010/page_09.htm (stating that soybean production increased from 2654 million bushels in 1999 to 3361 million bushels in 2009).

³¹² Iowa produced 3328 million eggs in 1993. See Nat’l Agric. Statistics Serv., *Chickens and Eggs Annual Summary*, available at <http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1509>.

³¹³ Iowa produced 6745 million eggs in 1999 and 14,475 million in 2009. Statistics compiled from annual statistical summaries, Nat’l Agric. Statistics Serv., *Chickens and Eggs Annual Summary* (1995–2011), available at <http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1509>.

³¹⁴ See *id.* In 2009, Ohio produced 7392 million eggs, compared to Iowa’s production of 14,475 million. NAT’L AGRIC. STATISTICS SERV. CHICKEN AND EGGS 2009 SUMMARY 3 (Feb. 2010) available at <http://usda.mannlib.cornell.edu/usda/nass/ChickEgg/2010s/2010/ChickEgg-02-25-2010.pdf>.

³¹⁵ American Egg Board, *Egg Industry Fact Sheet*, available at <http://www.aeb.org/egg-industry/industry-facts/egg-industry-facts-sheet>.

³¹⁶ *Id.* The largest 205 operations all have more than 75,000 laying hens. *Id.*

³¹⁷ *Id.*

This raises the question: Why Iowa? What competitive advantage does Iowa have over others? Corn is one answer—Iowa is consistently one of the top corn-producing states. There is an abundant supply of the yellow gold—a primary component of chicken feed—in Iowa.³¹⁸ But another contributing factor has a more cynical bent. Might this be an example of the proverbial race to the bottom to attract an industry with significant environmental externalities and a history of low-wage employees? And unlike California,³¹⁹ Iowa has little chance of a robust animal welfare movement taking off that could potentially increase production costs.

The summer 2010 shell egg recall is illustrative. The largest known SE outbreak in history³²⁰ was found in shell eggs traced back to two facilities—Wright County Egg, in Galt, Iowa, and Hillandale Farms of Iowa, Inc.³²¹ From May 1 to November 30, at least 1939 people fell ill after consuming eggs sold under the brand names of Lucerne, Albertson, Mountain Dairy, Ralph's, Boomsma's, Sunshine, Hillandale, Trafficanda, Farm Fresh, Shoreland, Lund, Dutch Farms, and Kemps, among others.³²² In mid-August, both Wright County Egg and Hillandale Farms voluntarily implemented a nationwide recall covering more than 500 million eggs.³²³

Unfortunately, this was not an isolated event for Austin J. DeCoster, the owner of both facilities distributing the tainted eggs. In fact, *The New York Times* reported that egg operations owned by Mr. DeCoster were the primary source of some of the first major SE

³¹⁸ See U.S. Dep't of Agric., *2010 Corn for Grain Harvested*, NASS.USDA.GOV, available at http://www.nass.usda.gov/Charts_and_Maps/graphics/cornacm.pdf (last visited Apr. 24, 2011) (indicating that Iowa was the largest corn producer in the United States for 2010).

³¹⁹ California Prevention of Farm Animal Cruelty Act, CAL. HEALTH & SAF. CODE §§ 25990 et seq. (2008) (commonly referred to as "Proposition 2," prohibiting, starting January 1, 2015, the confinement of farm animals in a manner that does not allow them to turn around freely, lie down, stand up, and fully extend their limbs/wings).

³²⁰ F.D.A., *Frequently Asked Questions and Answers: FDA's Investigations into the Salmonella Enteritidis Outbreak Involving the Recall of Shell Eggs*, U.S. DEP'T OF HEALTH & HUMAN SERV. (Aug. 27, 2010), <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm223723.htm>.

³²¹ *Id.*

³²² F.D.A., *Salmonella Enteritidis Outbreak in Shell Eggs*, U.S. DEP'T OF HEALTH & HUMAN SERV. (Nov. 30, 2010), <http://www.fda.gov/food/newsevents/whatsnewinfood/ucm222684.htm>.

³²³ *Id.*

outbreaks involving eggs in the 1980s.³²⁴ Due to repeated problems with SE contamination with DeCoster operations, the state of New York banned the sale of eggs from his farms.³²⁵ Maine and Maryland forced his farms to undertake a rigorous SE testing program as a condition of future sales.³²⁶ After state testing of DeCoster operations revealed widespread contamination,³²⁷ Maryland imposed a quarantine whereby DeCoster could only sell his eggs to processing plants that would pasteurize them.³²⁸ DeCoster violated the order, selling shell eggs to a local store and received a sentence of probation and a small fine.³²⁹ DeCoster sold his Maryland farms in 1993 to focus his efforts in Iowa—a state that had no SE testing requirements.³³⁰ And now, Iowa leads the nation in egg production.

In the wake of the egg recall and the national attention focused on Iowa's farm policies, the Editorial Board of *The Des Moines Register* rejected calls for a state *Salmonella* testing program similar to Maine's, stating that "oversight of this country's food supply is a federal responsibility . . . [that] needs uniform standards that apply to all states."³³¹ The problem with individual state standards, according to the editors, is that "eventually state lawmakers would loosen regulations to attract producers and jobs. Companies would gravitate to states with the least-stringent regulations—creating a sort of 'race

³²⁴ See William Neuman, *An Iowa Egg Farmer and a History of Salmonella*, N.Y. TIMES, Sept. 21, 2010, <http://www.nytimes.com/2010/09/22/business/22eggs.html>. The first *Salmonella* outbreak identified by public health officials involved runny scrambled eggs served at a nursing home in New Hampshire. *Id.* The eggs were from a former DeCoster farm, which he later repurchased. *Id.* Five years later, in 1987, another outbreak in a hospital traced the eggs to another DeCoster-owned farm in Maryland, followed by two more outbreaks the next year traced to the same farm. *Id.*

³²⁵ *Id.*

³²⁶ *Id.* Pennsylvania also established a nationally recognized *Salmonella* prevention program. See Pennsylvania Dep't of Agric., *Pennsylvania Egg Quality Assurance Program*, http://www.portal.state.pa.us/portal/server.pt/gateway/PTARGS_0_2_24476_10297_0_43/http%3B/10.41.0.36/AgWebsite/ProgramDetail.aspx?name=Pennsylvania-Egg-Quality-Assurance-Program-%28PEQAP%29&navid=12&parentnavid=0&palid=56& (last visited Apr. 24, 2011).

³²⁷ Neuman, *supra* note 325.

³²⁸ *Id.*

³²⁹ *Id.* (DeCoster complained about the cost of testing for *Salmonella*, insisting there was little risk associated with egg production/consumption.). The Maryland state veterinarian noted that DeCoster refused to acknowledge that he was causing a problem. *Id.*

³³⁰ *Id.*

³³¹ The Register's Editorial, *Cracking Down on Eggs is a Federal Job*, DES MOINES REGISTER (Sept. 18, 2010), <http://www.truthabouttrade.org/news/latest-news/16666-cracking-down-on-eggs-is-federal-job->.

to the bottom' in food safety standards."³³² Apparently, the editors failed to the look in mirror—Iowa ran that race and the prize was the DeCoster facilities, similar industrial-scale operations, and the honor of receiving the Centers for Disease Control's attention during the summer of 2010.

B. Testing Regimes and Jurisdictional Limits

As one digs deeper into the 2010 *Salmonella* outbreak, the importance of a rigorous testing regime becomes clear. But testing is only part of the solution; what to do with the test results and which agency has jurisdiction to order remedial actions remain key issues that, unfortunately, contributed to the latest SE contamination at a DeCoster facility.

The FFDCA generally does not require pre-approval of food products, and thus the FDA does not inspect food production facilities—including shell egg operations—on a regular schedule absent a reported problem.³³³ Accordingly, prior to its 2010 implementation of the new SE testing program³³⁴ the FDA almost never inspected shell egg production facilities.³³⁵ On the other hand, USDA's FSIS, under the Egg Products Inspection Act, must conduct daily, continuous inspections of egg product facilities.³³⁶ Moreover, USDA AMS inspectors are present in those facilities that elect to participate in the agency's grading program for shell eggs.

The Wright County Egg facility tested positive for *Salmonella* 426 times from 2008 to 2010—seventy-three of the samples were for *Salmonella Enteritidis*, the strain that caused the illnesses.³³⁷ As part

³³² *Id.*

³³³ GAO EGG SAFETY, *supra* note 40, at 15.

³³⁴ See FDA SE Final Rule, *supra* note 65. After implementation of the new rule, FDA officials are inspecting the nation's six hundred largest egg production facilities. Layton, *supra* note 41; see also, FDA, *FDA Begins Inspections under the Egg Safety Rule* (Sept. 28, 2010), <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/EggSafety/ucm227619.htm> (intending to complete inspections within 15 months).

³³⁵ Layton, *supra* note 41.

³³⁶ *Id.* This is a classic example of the failure of risk-based prevention. Egg products are pasteurized and yet subject to continuous inspection. Shell eggs generally are not pasteurized but are almost never inspected. *Id.*

³³⁷ Letter from Representatives Henry A. Waxman and Bart Stupak to Austin DeCoster (Sept. 14, 2010) (on file with the author) (requesting additional documents in advance of DeCoster's testimony).

of their routine inspection and grading functions, USDA officials in the Wright County Egg packing houses noted serious sanitation issues on their daily reports, but allegedly failed to share their concerns with FDA.³³⁸ In other words, USDA inspectors continued to grade and approve the shipment of eggs contaminated with SE because it was FDA's responsibility to oversee the "safety" aspect of shell eggs, while USDA's jurisdiction extended only to the grading of eggs for "quality" purposes. The information was not passed to FDA because "the conditions at the egg plant packing facilities were routine,"³³⁹ and the USDA officials were "focused on grading eggs. They are not necessarily focused on all of the other issues that the FDA had, and all the responsibilities FDA had."³⁴⁰

Fortunately, new federal rules require all but the smallest shell egg producers—those under 3000 laying hens—to implement an SE prevention plan.³⁴¹ In addition to monitoring pullets for SE,³⁴² producers must conduct environmental testing for SE at regular intervals.³⁴³ A positive test requires the producer to conduct tests on the shell eggs themselves.³⁴⁴ Facilities with eggs testing positive for SE must process the eggs to eliminate the bacteria—pasteurization as egg product—or divert to nonfood uses for the life of the poultry flock.³⁴⁵ FDA inspections of the DeCoster facility in August 2010—after the CDC identification of the source of the SE contaminated eggs—noted that the operation has "serious deviations" from the FDA's SE prevention rules.³⁴⁶ Part of the mandatory SE prevention

³³⁸ Layton, *supra* note 41. See also Alicia Mundy & Bill Tomson, *Egg Inspectors Failed to Raise Alarms*, WALL ST. J. (Sept. 10, 2010), <http://online.wsj.com/article/SB10001424052748703960004575482091768513872.html>.

³³⁹ Mundy & Tomson, *supra* note 339.

³⁴⁰ *Id.* (quoting USDA Secretary Vilsack).

³⁴¹ FDA SE Final Rule, *supra* note 65 (codified at 21 C.F.R. § 118).

³⁴² 21 C.F.R. § 118.4 (2010). USDA's APHIS operates the National Poultry Improvement Plan that certifies poultry breeding stock and hatcheries as free from diseases, including SE. See *Helping You, The Poultry Breeder, Prevent Disease*, NAT'L POULTRY INVOLVEMENT PLAN (U.S. Dep't of Agric./Animal & Plant Health Inspection Serv.), Jan. 2006, available at http://www.aphis.usda.gov/publications/animal_health/content/printable_version/npip-helping_you.pdf. A pullet is a chicken less than twenty weeks old. See FDA SE Final Rule, *supra* note 65, at 33,030.

³⁴³ Producers must test for SE when hens are 40–45 weeks old and 4–6 weeks after molting. 21 C.F.R. § 118.6 (2010).

³⁴⁴ 21 C.F.R. § 118.10.

³⁴⁵ 21 C.F.R. § 118.6(2). There are, however, some exceptions to reinstate a flock for shell egg sales. *Id.*

³⁴⁶ Warning Letter from John W. Thorsky, District Director, F.D.A. to Mr. Austin J. Decoster, Owner, Quality Egg LLC (Oct. 15, 2010) [hereinafter FDA Warning Letter to

plan under the FDA regulations would have required SE testing of the shell eggs after the seventy-three positive tests, but the FDA's rules did not take effect until July 9, 2010,³⁴⁷ and the agency did not inspect the facility until after the outbreak.³⁴⁸

Perhaps an earlier roll-out and full implementation of the FDA's new regulations would have prevented the outbreak and saved almost two thousand people the misery³⁴⁹ and expense of contracting this foodborne illness. FDA estimated that full implementation of the SE prevention regulations will "prevent approximately 79,170 cases of SE per year."³⁵⁰ On the other hand, the FDA does not have the resources to be at every egg production facility to ensure compliance, and the new SE prevention rules maintain the multiagency food safety regime for eggs. Therefore, improved coordination and information sharing with USDA quality inspectors will be essential to minimize the chance of future SE outbreaks.

IV LESSONS LEARNED? A COMPARATIVE LOOK AT THE IMPACT OF THE FDA FOOD SAFETY MODERNIZATION ACT ON LEAFY GREENS AND SHELL EGGS SAFETY

Thus far, this Article has discussed the development over the previous century of the bifurcated and patchwork food safety system and analyzed two major foodborne illness outbreaks in the first decade of this millennium—leafy greens and shell eggs. The last few days of 2010 witnessed Congress passing what some are calling the most important food safety legislation since the Federal Food, Drug, and Cosmetic Act in 1938. Although the actual impact of the FDA

Mr. Austin J. Decoster] *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm229805.htm>.

³⁴⁷ See FDA SE Final Rule, *supra* note 65, at 33,034.

³⁴⁸ See FDA Warning Letter to Mr. Austin J. Decoster, *supra* note 347. As a postscript, on November 30, 2010, FDA permitted Wright County Egg to resume sales of shell eggs to consumers from one of its six locations, based on the agency's confirmation that the company had taken the necessary remedial measures to eliminate SE. See News Release, U.S. Food & Drug Admin., FDA Permits Wright County Egg to Begin Shipping Shell Eggs to Consumers (Nov. 30, 2010), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm235179.htm>.

³⁴⁹ See Layton, *supra* note 41 (discussing the excruciating pain experienced by one SE victim).

³⁵⁰ See FDA SE Final Rule, *supra* note 65, at 33,081 (summarizing costs and benefits of the SE prevention program).

Food Safety Modernization Act (FSMA) remains to be seen, at this point many of the key issues identified above remain unresolved. Responsibility for food safety remains divided across multiple federal agencies with accompanying historical approaches to food safety that may be suboptimal. The question of whether safety is a subset of quality for marketing purposes as opposed to an independent end to accomplish as a public good itself is an open question within the marketing agreement context. Finally, to the extent that agencies such as the USDA's AMS persist in implementing marketing agreements to control safety, the voice of minority producers and consumers remain threatened. Despite the criticism discussed briefly below, the authors remain optimistic that the FSMA will meet its objectives and that Congress will provide the FDA the necessary funding to implement its wide-ranging programs.

A. Balkanization and Institutional Bias

FDA's new *Salmonella* testing regime may correct some of the jurisdictional issues regarding authority for mandating testing in the event of an SE positive environmental test, but the regime does not resolve the balkanization of responsibility and silo approach of the USDA graders, evidenced by their failure to communicate potential health hazards to the FDA or other authorities. Perhaps part of this rests in the fee-for-service relationship between the USDA egg graders and the egg production facility. Facilities agree to subject themselves to the grading service—it enhances marketability of their eggs—but must pay for the USDA inspectors. If the inspectors, who generally are members of the local community, raise alarm bells that would jeopardize the ability to sell the eggs in the more lucrative shell as opposed to egg product market, there would be no eggs to grade and thus no paycheck. A reputation of aggressive enforcement could motivate marginal facilities to abandon egg grading and the accompanying USDA quality shield. Perhaps this goes back further to the fundamental purpose and mission of the agency. USDA's purpose is to promote agricultural production while FDA's mission is to protect consumers, whether from adulterated food, unsafe drugs, or unreliable medical devices. In all aspects, FDA's mission is for the benefit of the end user of the product—the consumer—as opposed to USDA's focus on the product and producer or processor. It is these underlying preferences that may lead to silo reporting, jurisdictional squabbles, and a generalized reluctance to disappoint long-term agency constituents.

B. For Eggs, Unlike Leafy Greens, Safety Is Not a Characteristic of Quality

USDA's shell egg grading and certification program is administered by the Agricultural Marketing Service, the same agency responsible for the proposed National Leafy Green Marketing Order designed to enhance the safety of leafy greens. Ironically, the agency notes that its grading services ensure that the shell eggs meet the "requirements for quality, weight, condition or other factors."³⁵¹ But as noted above, USDA graders—working as part of a fee-for-service arrangement with the egg packing facility—are not focused on safety, but rather grading eggs according to their quality. Safety is left to the FDA. But for an agency so willing to relegate safety responsibilities to another in the shell egg context, it is interesting that the USDA's AMS is willing to stretch statutory language to regulate safety in another product—leafy greens—under the guise of quality. In common parlance, a food product should be safe to eat, whether it is perceived as high quality, such as grass-fed Kobe beef, or low quality, such as meat used for dog food. But from a regulatory perspective, the issue is clear: quality and safety are distinct concepts delegated to separate agencies. It is precisely this bifurcation of responsibilities that has engendered the calls for consolidation of food safety responsibilities and the jurisdictional authority for the agency responsible for food to oversee the entire food supply chain—from farm to fork.

C. The FDA Food Safety Modernization Act: Initial Impact Assessment

The FDA Food Safety Modernization Act is an important piece of legislation that will close some of the gaps in the existing food safety system. Key additions and revisions to the existing food safety framework include:

The ability of FDA to mandate food safety measures at the farm level for fruit and vegetable production—previously outside FDA's

³⁵¹ Agric. Mktg. Serv., *Grading, Certification and Verification*, U.S. DEP'T OF AGRIC., <http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=GradingCertificationandVerification&leftNav=GradingCertificationandVerification&page=PYShellEggGradingandCertification1&acct=poultrygrd> (last modified July 19, 2006).

jurisdiction as agricultural production was the exclusive purview of the USDA with very limited exceptions;³⁵²

FDA authority to create a system of Hazard Analysis and Critical Control Points (HACCPs) in all food-processing facilities—a safety system previously limited to shellfish, juice and low-acid canned foods;³⁵³

Development of regulations for the safe transportation of food;³⁵⁴

Enumeration of factors upon which the agency should use to identify high-risk facilities and mandatory schedules for inspection by the FDA;³⁵⁵

Authorization for FDA officials to inspect and copy all operational records relating to any article of food that the agency “reasonably believes” “will cause serious adverse health consequences . . . to humans or animals” from all facilities in the supply chain, with the exception of farms and restaurants;³⁵⁶

Notwithstanding the previous limitation, during an active investigation of a foodborne illness outbreak, in coordination with state and local food safety agencies, the FDA may request farms to identify potential immediate recipients of any food subject to the investigation;³⁵⁷

FDA authority to issue a regulation outlining specific record keeping requirements for designated “high risk” foods;³⁵⁸

Protections for employees for providing information to the federal government or state attorney general regarding violations of the FFDCa;³⁵⁹ and, perhaps most important,³⁶⁰

Provide FDA with mandatory recall authority based on a “reasonable probability” that a food is adulterated or misbranded and the exposure or use “will cause serious adverse health consequences” to humans or animals.³⁶¹

³⁵² H.R. 2751, 111th Cong. § 105 (2011) (to be codified at 21 U.S.C. § 419).

³⁵³ H.R. 2751 § 103 (to be codified at 21 U.S.C. § 418).

³⁵⁴ H.R. 2751 § 111 (directing development of regulations to implement 21 U.S.C. § 416(b)).

³⁵⁵ H.R. 2751 § 201 (to be codified at 21 U.S.C. § 421).

³⁵⁶ H.R. 2751 § 101 (to be codified at 21 U.S.C. § 350(c)(a)(2)).

³⁵⁷ H.R. 2751 § 204(f).

³⁵⁸ H.R. 2751 § 204(d).

³⁵⁹ H.R. 2751 § 402 (to be codified at 21 U.S.C. § 1012).

³⁶⁰ See Michael T. Roberts, *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*, 59 FOOD & DRUG L. REV. 563, 580–83 (2004) (discussing why the FDA should have mandatory recall authority).

³⁶¹ H.R. 2751 § 206 (to be codified at 21 U.S.C. § 423).

Congress also included a few specific carve-outs in the FSMA to protect certain industries. For example, section 114 of the Act specifically prohibits FDA from issuing guidance or regulations for raw oyster post-harvest processing unless certain criteria are met, including extensive reporting to Congress. In October 2009, the FDA considered implementing postharvest processing requirements for raw oysters to reduce the presence of the bacteria *Vibrio vulnificus*.³⁶² As part of a revised seafood HACCP program,³⁶³ Gulf of Mexico oysters harvested during warm summer months would have to undergo post-harvest processing to reduce the potentially deadly bacteria.³⁶⁴ In the face of intense political pressure from the industry, however, the agency withdrew its proposal.³⁶⁵ The FSMA appears to further insulate the oyster industry from this unpopular food safety measure.

The FSMA included two other exceptions with potentially broad applicability: the small farm and direct marketing exemptions. After intense lobbying by small farm and local food advocates,³⁶⁶ the Senate passed the Tester-Hagan Amendment to the original bill as a compromise to minimize the financial impact of compliance with many of the new statute's provisions. Specifically, Congress exempted small farms that had less than \$500,000 in total sales engaged in direct-farm marketing, so long as fifty percent of total farm sales were in direct sales to consumers or restaurants in the same state or within a 275-mile radius.³⁶⁷ Congress included a similar exemption for these entities from the HACCP requirements.³⁶⁸

³⁶² See Letter from Donald W. Kraemer, Deputy Director, Office for Food Safety, U.S. Food & Drug Administration, to the Interstate Shellfish Sanitation Conference (Oct. 16, 2009), available at <http://www.fda.gov/NewsEvents/Speeches/ucm187015.htm>. See also Michael Taylor, Senior Advisor the Comm'r, Food & Drug Admin., Remarks at the Interstate Shellfish Sanitation Conference Biennial Meeting (Oct. 17, 2009), available at <http://www.fda.gov/NewsEvents/Speeches/ucm187012.htm>.

³⁶³ 21 C.F.R. pts. 123, 1240 (2010).

³⁶⁴ See Letter from Donald W. Kraemer, *supra* note 363.

³⁶⁵ For a thorough discussion of the FDA's reversal regarding oyster post-harvest processing, see Endres & Tarr, *supra* note 65, at 115–16.

³⁶⁶ See Bonnie Azab Powell, *Tester Amendment Protecting Local Food Production Now Attached to Food-Safety Fill*, GRIST, Nov. 18, 2010, <http://www.grist.org/article/fod-2010-11-18-Tester-amendment-protects-local-food>.

³⁶⁷ H.R. 2751, 111th Cong. § 105 (2011) (to be codified at 21 U.S.C. § 419(f) (Exemption for Direct Farm Marketing)).

³⁶⁸ H.R. 2751 § 103 (to be codified at 21 U.S.C. § 418(l) (Modified Requirements for Qualified Facilities)).

With respect to leafy greens and shell eggs, a few potential impacts from the FSMA stand out. First, the HACCP rules in section 103 of the statute would apply to both leafy greens and shell egg processing facilities. Second, FDA's authority under section 105 of the FSMA to impose farm-level food safety rules for fresh produce would apply to leafy green production. The ability of the FDA to impose specific food safety rules at the farm level appears to preempt the need for a nationwide leafy greens marketing agreement sanctioned by the AMS. Moreover, in light of FDA's explicit jurisdiction to issue farm-level food safety rules, any marketing agreement in conflict with the FDA regulations would face a preemption challenge.³⁶⁹ More likely, the industry proponents of the NLGMA would attempt to incorporate elements of their plan into any future FDA rule.

Unlike with leafy greens, the FDA is unlikely to alter its current shell eggs safety measures in response to the FSMA. The agency, through the FFDCA and Public Health Service Act, already had substantial jurisdiction over shell egg production, and the FDA's new SE prevention rule already requires a HACCP-like food safety plan. Moreover, Congress specifically noted in the FSMA that the new law does not alter or limit the USDA's authority under the Egg Products Inspection Act.³⁷⁰

Finally, section 204 of the FSMA directs FDA to coordinate with the food industry to develop pilot programs to explore methods to more rapidly and effectively identify foodborne illness outbreaks.³⁷¹ The pilot projects must include at least three different types of foods that in the last five years have been subject to significant outbreaks—certainly shell eggs and leafy greens qualify.³⁷²

Although it is too early to assess the full impact of the FSMA on the leafy greens or shell egg industry, much less offer an evaluation of the Act's impact on the overall food safety system, there is much optimism that the FDA's enhanced authority will break down some of the traditional jurisdictional barriers between food production and food processing, resulting in an improved food safety system. However, the FSMA did not significantly redistribute authority from USDA to FDA;

³⁶⁹ *But see* H.R. 2751 § 403(1) (noting that the FDMA does not alter the USDA's jurisdiction regarding voluntary inspection of non-amenable species under the Agricultural Marketing Act of 1946).

³⁷⁰ H.R. 2751 § 403(4)(C).

³⁷¹ H.R. 2751 § 204.

³⁷² *Id.*

it merely extended FDA's jurisdiction, leaving in place two large and occasionally divergent agencies responsible for food safety. Moreover, significant governance issues, as discussed below, persist, which Congress and/or the agencies should address in the near future.

D. Minority Representation: The Voice of Consumers and Small-Scale Producers in Food Safety Regulation

Although this subtopic is worthy of a separate article, at this stage a brief mention is necessary as this theme occurs at several levels in the current food safety debate. As highlighted in the criticisms of the proposed NLGMA, many of the disease prevention measures impact production at the farm level, yet growers may not sign onto the proposed marketing agreement. More important, those growers participating in the negotiation process—such as the Proponent Group—represent the largest industrial-scale growers, not the small, independent farmer.³⁷³ Moreover, consumers of leafy greens have no ability to challenge the marketing agreement in the courts, thereby excluding the recipient of the purported safety measures from a substantial role in the process.³⁷⁴ And yet the USDA, the so-called “People’s Department,”³⁷⁵ generally supported the NLGMA process. Perhaps the tide, however, is starting to turn. USDA’s “Know Your Farmer, Know Your Food” campaign acknowledges the role of small-scale farming and consumer demand for fresh local food.³⁷⁶ And the Tester-Hagan Amendment to the FSMA established important exemptions for small scale, local food producers.³⁷⁷ But a real transformation of the current industrial-scale food supply chain into one that accounts for the unique characteristics of the small scale food producer will not occur without the sustained vocal support of the consuming public.

³⁷³ See *supra* notes 269–270 and accompanying text.

³⁷⁴ See *supra* note 294 and accompanying text.

³⁷⁵ See PHILLIP MATTERA, U.S. DEP’T OF AGRIC., INC.: HOW AGRIBUSINESS HAS HIJACKED REGULATORY POLICY AT THE U.S. DEPARTMENT OF AGRICULTURE 4 (July 23, 2004), available at <http://www.nffc.net/Issues/Corporate%20Control/USDA%20INC.pdf> (noting that President Lincoln first envisioned the USDA as the “People’s Agency”).

³⁷⁶ See Letter to Honorable Tom Vilsack, *supra* note 10 and accompanying text; see also U.S. Dep’t of Agric., *Know Your Farmer, Know Your Food*, USDA.GOV, <http://www.usda.gov/wps/portal/usda/knowyourfarmer?navid=KNOWYOURFARMER> (last visited Apr. 24, 2011).

³⁷⁷ See *supra* notes 367–68 and accompanying text.

V CONCLUSION

Facilitating a fundamental transformation of the nation's food supply system to incorporate scale-appropriate food safety measures that accommodate a diverse food chain should be the next focus of federal government action. The current regulatory framework described above illustrates the disconnect of the various food safety regulatory agencies from their constituent consumers, and the century-long balancing act between maximizing low-cost production and safe food presents a significant challenge to the agencies, but one that the consuming public over the last fifty years largely ignored. The recent widespread foodborne illness outbreaks, coupled with the public and media's growing interest in local food systems, however, has shifted attention to the role of the agencies and the potential conflicting missions. While mere consumer demand and calls for reform may not revolutionize the current multinational food supply system, political pressure on agencies responsible for food safety and Congress in the upcoming farm bill negotiations can reshape organizational values and policy priorities, resulting in real change to the food system and, to the extent it changes the economics of diverse farming operations, revive the vibrancy of rural communities.