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ARTICLES

FSMA: the Future of Food Litigation

Robert Shawn Hogue*

The Food Safety Modernization Act (“FSMA”) [Pub. L. No. 111-353, § 124 Stat. 3885, (2011)] ushered in the most sweeping changes to the food safety and regulatory system since Franklin Delano Roosevelt created the Food and Drug Administration (“FDA”) through the New Deal’s Food, Drug, and Cosmetic Act more than 70 years ago. FSMA continues to change the way food companies in the United States conduct their business, whether it be from the manufacturing to the transport of the product, or from farm to fork. FSMA also impacts international food companies exporting their products into the United States.

The way we eat today is changing. The era of globalization precipitated a new dynamic within the human experience. It used to be that one would only consume food that was grown and slaughtered within their community. The postwar period and the concept of a national economy expanded the distance and length of time for food to travel to the dinner table. Today our food is traveling farther to get from the farm to the same dinner table. The farm today is often

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overseas, but through innovation, technology, and the dedication of those working within the industry, the food remains wholesome for the most part. Still, while FSMA promised to make the food supply safer and bring our system into the 21st century, it has not yet achieved that goal. Why?

Today our food supply system is policed and governed by fifteen separate agencies all under the umbrella of the FDA, the United States Department of Agriculture ("USDA") and the Centers for Disease Control ("CDC"). Yes, fifteen separate agencies share overlapping jurisdiction over our food. As with any other governing bureaucracy, at times, it is the system itself which stands in the way of the goal.

The plethora of new FSMA regulations consists of an alphabet soup of acronyms, which is enough to make even the most seasoned regulatory attorney’s head spin. For example, Food Safety System Certification ("FSSC 22000"), Food Safety Service Providers ("FSSP"), Good Agriculture Practices ("GAP"), Good Agricultural Practices Audit ("GAP Shed/ Audit"), Global Food Safety Initiative ("GFSI"), Good Manufacturing Practices ("GMP"), and Hazard Analysis Critical Control Point ("HACCP"). Just to name a few. Still, the maxim _ignorantia juris non excusat_ (ignorance of the law excuses not) applies to the morass of administrative law, just as it does with other laws. Indeed, this is an arduous task. The same task is even more daunting for the foreign attorney trying to advise their client as to these regulatory issues.

An example of the challenges domestic regulatory compliance poses for international lawyers is manifested through the Foreign Supplier Verification Program ("FSVP") for Human and Animal Foods, Accredited Third-Party Certification ("ATPC"), and the Voluntary Qualified Importer Program ("VQIP"). These particular FSMA rules that affect international lawyers were “designed to enhance the security and safety of the supply chain for imported food,

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3 There are more than a hundred different mandates and requirements associated with FSMA compliance, and an acronym accompanies each one. See Food Safety and Modernization Act, Pub. L. No. 111-353, § 124 Stat. 3885, (2011).
which FDA has estimated makes up 15 percent of the U.S. food supply, including 50 percent of our fresh fruit, 20 percent of our fresh vegetables, and 80 percent of our seafood.\footnote{NEWS DESK, Industry bends FDA’s ear on import safety rules at public meetings, FOOD SAFETY NEWS (Sept. 3, 2016), http://www.foodsafetynews.com/2016/09/industry-bends-fdas-ear-on-import-safety-rules-at-public-meetings/#.V82q62a82EA.} According to the FDA’s website “[t]he final rule requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards.”\footnote{U.S. Food & Drug Admin., FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm (last updated Sept. 16, 2016).} The FDA first proposed this rule in July 2013, and it is scheduled for full implementation by the end of 2016.\footnote{Id.} The rule requires that foreign trading partners must implement these protocols, or face serious repercussions ranging from having their products quarantined to losing their ability to export their goods to the U.S. market.\footnote{See Ray Caron, FSMA’s Importing and Exporting Perishables Rule and its Global Impact, DELTATRAK (Aug. 19, 2014), http://www.deltatrak.com/about-us/blog/fsma-s-importing-and-exporting-perishables-rule-and-its-global-impact.}

It was in the spirit of enhancing a better understanding and demystifying FSMA that the Inter-American Law Review with the support of K&L Gates LLP undertook “The Food Safety Modernization Act: The Future of Food Litigation” symposium on February 6, 2015. The symposium was spearheaded by the leadership of the Inter-American Law Review collaborating with this author, Lindsey Lazopoulos Friedman, and Carol Lumpkin an Equity Shareholder at K&L Gates LLP—all alumni of the Inter-American Law Review. Bill Marler, the nation’s leading plaintiff’s food litigation attorney, was the keynote speaker.\footnote{In 1993, Marler represented 9-year-old Brianne Kiner in litigation against Jack in the Box following an E. coli O157:H7 outbreak, securing a $15.6 million settlement. He has been involved in litigation relating to most of the large foodborne illness outbreaks in the United States, representing individuals against large companies such as Chili’s, Kentucky Fried Chicken, Dole, and ConAgra. He is the founding partner of Marler Clark, Marler has been asked to speak to numerous}
teraction between: regulatory attorneys seeking a greater understanding of the rules, litigators interested in the opportunities and challenges FSMA poses, policymakers charged with the promulgation of these rules, and academics interested in how these rules will shape both the litigation and regulatory landscapes. The symposium was divided into three panel discussions that focused not only on FSMA’s impact, but also on important topics in meat safety as well.

As Americans want and expect greater transparency in farming/ranching, production, manufacturing, and labeling of meat products the majority of topics by this panel focused on these issues. The panel discussed what was being done to keep Americans safe from foodborne pathogens in a manner that is in compliance with a changing regulatory landscape as well as changing consumer concerns and demands. Mr. Marler observed that the efficacy of litigation as a mechanism to reduce foodborne illness has been questioned in the past, and some believe that greater transparency with the production, manufacturing, and labeling of meat products is key. Dr. Melvin Kramer the President of EHA Consulting Group, Inc, led this discussion, which also featured Daniel L. Engeljohn, Ph.D., the Assistant Administrator in the Office of Policy and Program Development at the United States Dairy Administration and Food Safety and Inspection Service (“FSIS”).

Bill Marler’s keynote focused on criminal liability of food companies and executives that negligently or recklessly ignore food safety warnings, or knowingly usurp rules and regulations resulting in foodborne illnesses. Suzan Onel, at the time, K&L Gates LLP’s Global Chair of the Food, Drugs, Medical Devices and Cosmetics practice group, asked probing questions of Mr. Marler on a broad range of topics during his Q&A. At the time of Mr. Marler’s keynote, there had not been significant usage of the criminal stick in the Food, Drug, and Cosmetic Act’s criminal statute9 to deter wrongdoing. Mr. Marler’s perspicacious speech and presentation could not have been timelier due to a growing trend to use this stick since 2015. A prime example of this is that in September 2015, a federal

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judge handed Stewart Parnell a sentence of 28 years for his part in the foodborne outbreak at the Peanut Company of America. His brother and food broker Michael Parnell received a 20-year sentence, and the plant’s quality assurance manager, Mary Wilkerson, received a five-year sentence. In February 2016, a criminal investigation was also launched concerning the Chipotle foodborne illness outbreaks across the country. The Department of Justice is continuing to investigate this outbreak along with others. In 2016, the Eighth Circuit also affirmed the criminal sentencing of two egg executives over a salmonella outbreak that got 56,000 people sick. A split panel affirmed U.S. District Judge Mark Bennett’s decision that Quality Egg LLC owner Austin “Jack” DeCoster and his son, Chief Operating Officer Peter DeCoster would spend three months in jail and each pay a $100,000.00 penalty.

On April 6, 2016, the Department announced that it would be expanding its efforts to prosecute executives at food companies that it deems responsible for food borne illness outbreaks. During a

10 “The former PCA chief executive was sentenced to 28 years for selling misbranded food, introducing adulterated food into interstate commerce, fraud, conspiracy and other charges related to knowingly allowing peanut butter contaminated with salmonella to enter the stream of commerce.” Dan Flynn, Parnell brothers finally in prison for deadly peanut butter outbreak, FOOD SAFETY NEWS (Feb. 17, 2016), http://www.foodsafetynews.com/2016/02/123674/#.V-1T1IfHDtl.

11 Id.


14 “Quality Egg admitted that workers knowingly shipped eggs with false processing and expiration dates to mislead state regulators and retail consumers about their age, and even bribed a U.S. Department of Agriculture inspector to approve the sales of the poor quality eggs.” Cracked Case: Eggs Executives Get Jail for Salmonella Outbreak, NBC NEWS (Apr. 13, 2015), http://www.nbcnew s.com/health/health-news/cracked-case-egg-executives-get-jail-salmonella-outbreak-n340916.

15 Principal Deputy Assistant Attorney General Benjamin C. Mizer Delivers Remarks at the Consumer Federation of America’s 39th Annual National Food Policy Conference, THE UNITED STATES DEPARTMENT OF JUSTICE (Apr. 6, 2016),
speech to the Consumer Federation of America, Assistant Attorney General Benjamin Mizner remarked, “when it comes to food safety, we have to rely on the companies who manufacture and distribute food to ensure that the food we buy is safe. In fact, most consumers give little thought to the safety of their food . . . .We simply don’t expect to get sick from the food at our favorite restaurant, or from the peanut butter or the eggs or the cantaloupes or the countless other products that we buy at the supermarket. That is why food safety is a priority for the Justice Department.”16 Today, federal prosecutors are using criminal prosecution to punish the bad actors, and deter further wrongdoing.17

Lindsey Lazopoulos Friedman’s panel discussion focused on the development of FSMA’s regulations and what attorneys needed to know. Her panel’s discussion concerned not only the impact that the regulations were having on the industry, but the projected effects of the proposed regulations as well. The panelists offered the perspective that the regulations are nothing new at all for the industry. For example, organizations like the California Leafy Greens Marketing Agreement that consist of 115 corporate members have been going beyond the requirements of FSMA for years.18 Panelists included Wesley Van Camp the Vice President and General Counsel of Tanimura & Antle, Jill Dunlop the Food Safety & Sustainability Manager at the Florida Fruit and Vegetable Association, Dr. Melvin Kramer, and Dr. Thomas Young the Senior Vice President of Marketing of the Florida based company Food Defend. During their discussion, the panelists explored how the enhanced regulations were impacting the fresh produce and raw food industry—an industry with slight profit margins and a product with a rapidly disappearing shelf life. The panelists discussed the scope of the Tester-Hagan


16 Id.


Amendment’s exemption for small farms and its impact on market trends.\textsuperscript{19} (This exemption continues to be a source of controversy given the fact that smaller farms are just as susceptible to foodborne illnesses as larger farms, and often they do not have the same controls in place to identify pathogens like listeria.) They also discussed the proposed rules on soil and manure intervals and water quality standards that have now been finalized in the Preventive Controls for Human Food rule.

Shawn Hogue’s panel discussion focused on the effects of the FDA’s regulatory authority on international commerce. Specifically, the preventative control rules that mandate foreign compliance for companies exporting their food products into the United States and the difficulty associated with implementing these foreign standards. The volume of new regulations and the degree of their complexity continue to pose a significant hardship on foreign companies. The panelists’ discussion also considered what some critics see as the broadening of the FDA’s authority akin to imperial oversight and an instrument of American political power. Discussion was also focused on the conflict of laws between free trade agreements such as the North American Free Trade Agreement (“NAFTA”) and FSMA’s regulations, which may put the U.S. at conflict with its obligations to the World Trade Organization (“WTO”). One needs to look no further than the dispute between Canada and the United States regarding Country of Origin Labeling (“COOL”) on meat products.\textsuperscript{20} Also, the panel discussed issues relating to human rights and working conditions on large farms run by

\textsuperscript{19} This exemption continues to be a source of controversy given the fact that smaller farms are just as susceptible to foodborne illnesses as larger farms, and often they do not have the same controls in place to identify pathogens like listeria.

\textsuperscript{20} US courts had upheld the labeling, but Congress repealed the COOL Act to comply with the rulings of the WTO that found the labeling scheme amounted to a non-tariff trade barrier prohibited by trade agreements. More specifically, “Congress included COOL repeal in the $1.4 trillion omnibus spending bill after the [WTO] ruled Canada and Mexico could begin imposing more than $1 billion in tariffs on U.S. products to punish it for the harm the labeling requirements were doing to them.” NEWS DESK, USDA Ends COOL Enforcement With President’s Signature on Omnibus Bill, FOOD SAFETY NEWS (Dec. 21, 2015), http://www.foodsafetynews.com/2015/12/usda-ends-cool-enforcement-with-presidents-signature-on-omnibus-bill/#.V83PiGa82EA.
multi-national corporations. Panelists included Jeffrey Bailey, then General Counsel and presently CEO of Bland Farms, Victor Garrido, the Director of Quality Assurance at Quirch Foods Company, and Jamie Renner, an Assistant Professor at Vermont Law School.

Carol Lumpkin offered very thoughtful comments in her closing remarks by encouraging the audience to consider the challenges not only of FSMA, but also the future of food litigation. She reminded the audience that despite the lack of forward momentum on the part of regulators, those in the industry and lawyers advising clients still had to make decisions on a day-to-day basis on compliance with the law. These future challenges are too extensive to detail in a single introduction, but below are some of the more salient ones that offer some food for thought:

- What will the FDA do about the de-criminalization of cannabis at the state level? Cannabis edibles are food and must comply with both state and federal, health, safety, and labeling requirements.

- The role of China’s food safety regime “the Chinese Food and Drug Administration” that was announced on June 30, 2013. This new agency in China hopes to not only make the food supply safer, but also minimize foreign interference with regulating their food supply. This is troubling considering that in November 2012 an audit by the USDA’s Food Safety Inspection Services (“FSIS”) announced that the agency-audit found China’s poultry not to be equivalent of that in the United States.

- The continuing role that criminal liability will play in the Department of Justice’s efforts to deter corporate malfeasance relating to foodborne illness outbreaks.

- The conflict between international treaty obligations that the United States is a party to
under regional trade agreements, and the FDA’s FSMA regulations.

These challenges continue to present themselves\(^\text{21}\) and 2016 was an active year for food litigators.

Genetically Modified Organisms (“GMO’s”) continue to pose real challenges for the industry and policy makers alike. As such, GMO’s remain, and will likely remain, a hot button issue both for consumers and the courts. Vermont is the only state that requires labels to identify products made with GMO’s. Critics of the law have complained that the labeling requirements are preempted under federal law,\(^\text{22}\) but Vermont originally had success in the lower courts defending the law. Since its success, the states of Connecticut and Maine have passed similar laws and have filed amicus briefs in support of Vermont’s law.\(^\text{23}\) The Second Circuit heard oral arguments on this issue in Grocery Manufacturers Association, et al. v. Sorrell, Docket Case No. 15-1504, in October of 2015.\(^\text{24}\) Leading the charge against Vermont has been the Grocery Manufacturers Association (“GMA”). The GMA argues the law stifles free expression because

\(^{21}\) Shortly after the symposium, the Supreme Court issued a landmark decision in Horne v. Department of Agriculture, 135 S. Ct. 2419 (2015). At issue was the question of whether a rule that required farmers to keep a portion of their crops off the market for the benefit of all raisin growers constituted a taking. The Court held that the plaintiff had standing to sue for violation of the United States Constitution’s takings clause because the National Raisin Reserve Act that required raisin growers to forfeit a certain percentage of their raisin crop back to the federal government in order for it to be sold on the open market for the benefit of all raisin growers infringed on the property rights of the individual grower.


it forces manufacturers to stifle free speech by forcing them to mark GMO products when there is no concrete evidence that GMO’s are unhealthy. This case may well be decided by what has already happened on the other side of the country. In California, the state Supreme Court issued a ruling in Quesada v. Herb Thyme Farms Inc., No. S216305, 2015 WL 7770635 (Cal. Dec. 3, 2015) that held that a consumer’s suit over “organic” herbs wasn’t preempted by the Organic Foods Production Act.

Also, the FDA’s definition of “natural,” continues to irk not only consumers and policy makers, but also federal judges. The courts continue to be tied up and confused by the meaning of the term “natural,” which the FDA has not provided guidance on despite the invitation by several federal judges for them to do so.25 The latest chapter in this ongoing saga comes from the West Coast as Del Monte Global Fresh currently finds itself in litigation concerning its claims about the amount of antioxidants within their canned fruit products. In Kosta et. al. v. Del Monte Foods Inc., the trial judge shot down the plaintiff’s motion for class certification.26 The trial judge found too much variation in class members’ experiences due to labeling; this case illustrates the conundrum judges face when deciding whether class actions against food companies are an appropriate vehicle for cases involving deceptive labeling.27 The case is currently pending in the U.S. Court of Appeals for the Ninth Circuit.

There was also the opportunity for the food industry to shape the realm of intellectual property this year. The case of Pepperidge Farm Inc., v. Trader Joe’s Co., Case No.: 3:15-cv-01774-AWT (D. Conn. 2016) concerned allegations that Trader Joe’s purposefully copied, manufactured and marketed a rectangular shaped cookie identical to the oval-shaped Milano cookies of Pepperidge Farm.28 Trader Joe’s also allegedly attempted to capitalize on consumers’ familiarity with the Milano brand of cookies by packaging

27 Id.
them in a fluted, paper tray similar to those used by Pepperidge Farm. The case promised to be a blockbuster, but it was settled in March. When *Fortune* reached out to Pepperidge Farm, the company simply said, “[w]e enforce and defend our valuable trademark rights and we want consumers to be sure of the source of their products. We have reached a mutually satisfactory resolution.” While one should celebrate alternative dispute resolution that does not involve litigation, it is disappointing that the courts did not ultimately decide this important question of law.

In closing, over the next five years, the courts will begin weighing in on the legality of FSMA’s regulations as they apply to business and international commerce. It is the opinion of this author that international governing bodies, like the WTO, and international arbitrators will not be as kind as U.S. federal judges have been. Nevertheless, in five years, maybe we will be able to give FSMA a grade that we were not able to give it in February 2015. At best, we could give it an incomplete, as the FDA at that time had not successfully implemented all of its provisions. Today, almost all the provisions have been finalized, and it will just be a matter of time before litigation ensues. It is my personal hope that a system of enforcement and law will develop that is not only equitable but also recognizable. The British legal philosopher H.L.A. Hart posited in *The Concept of Law* that any just legal system must be governed by a rule of recognition. The rule exists when any given member in a society can recognize what the rules of that society are. From this recognition, a reasonable individual can govern their behavior prospectively because they understand the rules, and what is expected of them.

At this time, FSMA and its enforcers do not offer this clarity, but this is not an anomaly within the realm of administrative law. Though, as courts begin weighing in on these issues domestically while at the same time the food industry here in the United States along with our international trading partners implement the regulations, maybe FSMA achieves the goal it set out to do. To modernize

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29 Id.
31 Id.
the food safety system at home by protecting the consumer—the same consumer whom already takes it for granted that their food is safe.