Notes on Food Law: An Overview of the Food Safety Modernization Act

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Consumer interest in food has been steadily increasing in recent years. Fueled by popular books such as Omnivore's Dilemma by Michael Pollan,[1] and documentaries such as Food Inc.,[2] many consumers now seek information about where their food comes from and how it was produced. This has had a ripple effect across the food industry as businesses seek to capture the market trend, and it has created a variety of successful niche markets for agricultural producers and small businesses.[3] Important legal issues include those related to the regulation of food products, including the regulation of labeling and advertising.

A series of high profile and deadly outbreaks of food borne illness has also fueled increased consumer interest. In 2010, 500 million eggs produced in Iowa were recalled due to suspected Salmonella Enteritis contamination. In 2008-9 an outbreak of Salmonella Typhimurium in peanut products sickened 700 people in forty-six states and may have contributed to nine deaths. In 2008, there was the largest meat recall in U.S. history – 143 million pounds of beef – recalled because of the processing of "downer" cattle. And, in 2006 an E. coli outbreak associated with spinach sickened over 200 people, with 104 hospitalizations, and five deaths. Emphasizing how widely dispersed our food sources are, victims came from twenty-six different states and from Canada.[4]

While it is widely acknowledged that "[t]he combined efforts of the food industry and government regulatory agencies often are

1. Michael Pollan, the Omnivore's Dilemma: A Natural History of Four Meals 10 (2006).

2. King Corn (Mosaic Films, Inc. 2007).

3. *See*, Susan Schneider, Reconnecting Consumers And Producers: On The Path Toward A Sustainable Food And Agriculture Policy, 14 Drake J. Agric. L. 75 (2010).

4. The online national newspaper, Food Safety News, provides a complete accounting of food borne illness outbreaks. See, http://www.foodsafetynews.com/sections/foodborne-illness-outbreaks/ (last visited July 10, 2011). This newspaper is supported by the food safety firm, Marler Clark, based in Seattle, Washington (http://marlerclark.com).

credited with making the U.S. food supply among the safest in the world," a significant number of Americans become seriously ill as a result of the food they consume.[5] According to the Centers for Disease Control, each year, an estimated forty-eight million people in the United States become ill from contaminated food (one in six); 128,000 cases require hospitalization and 3,000 cases result in death.[6]

With these incidents in mind, Congress passed historic new food safety legislation, the Food Safety Modernization Act (FSMA), and President Obama signed the bill into law on January 4, 2011.[7] The new law is historic as the first major reform of the Food & Drug Administration's (FDA) food safety regime in seventy years. It shifts the FDA focus from reactive to preventative, expands FDA powers to inspect and recall, establishes risk-based priorities, and addresses major weaknesses in import safety assurances.[8] This note provides a brief overview of the new law.

The FSMA affects the FDA's authority and approach with respect to its food safety activities. Note that the FDA is responsible for ensuring the safety of essentially all domestic and imported foods *except for* most meats, poultry, and processed egg products.[9] The U.S. Department of Agriculture (USDA) has authority over meat, poultry and processed egg products.[10] The FSMA does not affect the USDA's authorities over these products. In many ways, however, it moves the FDA system closer to that already in place at USDA.

The structure of the FSMA changes can be understood by considering five areas of enhanced authority: a focus on preventing food borne illness; increased FDA inspection authorities; new requirements for imported products; food recall authority; and partnerships between the FDA, other food agencies, and private entities. The FSMA requires the FDA to promulgate more than a dozen new rules and to issue many industry guidances. Each will require collaboration with the industry, and most will require official notice and comment. Implementation is expected to occur over the next two years. An implementation report and timetable is found on the FDA Food Safety Modernization Act website.[11]

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5. Renee Johnson, Food Safety Issues for the 112th Congress, Congressional Research Service Report, R41629 (Feb. 10, 2010).

6. Center for Disease Control, Estimates of Foodborne Illness in the United States, http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html (last visited July 10, 2011).

7. Pub. L. No. 111-353, 124 Stat. 3885 (2011).

8. *See*, Michael R. Taylor, FDA Deputy Commissioner for Foods, *The FDA Food Safety Modernization Act: Putting Ideas into Action*, Presentation to the Food & Drug Law Institute Food Safety Conference, Jan. 27, 2011; available at http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofFoods/ucm241192.htm.

9. For an excellent overview of the different agencies involved in food regulation, see Renee Johnson, T*he Federal Food Safety System: A Primer*, Congressional Research Service Report, RS22600 (Jan. 11, 2011).

10. Federal Meat Inspection Act, 21 U.S.C. §§ 601 et seq.; Poultry Products Inspection Act, 21 U.S.C. §§ 451 et seq.; Egg Products Inspection Act, 21 U.S.C. §§ 1031 et seq.

11. FDA FSMA Implementation and Progress website, available at http://www.fda.gov/Food/FoodSafety/FSMA/ucm250568.htm (last visited July 10, 2011).

A Focus on Preventing Food Borne Illness

The FDA's approach has long been criticized as being too reactive. Much of its approach to food safety was focused on reacting to food borne illness outbreaks after they occurred. Under the FSMA, the FDA's focus shifts to more preventative controls.[12]

The FDA describes this shift and its new authorities with optimism. "For the first time, FDA will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply."[13] Indeed, the FDA describes three specific areas of preventative controls that are either authorized or required under the FSMA, 1) requiring "food facilities" to analyze their production and prepare food safety preventative control plans; 2) developing "science-based, minimum standards for the safe production and harvesting of fruits and vegetables;" and, (3) developing mitigation strategies to prevent the intentional contamination of the food supply.[14]

Food Safety Plans

Under the FSMA "facilities" will be required to develop food safety plans. These plans must evaluate production practices to determine where food safety hazards exist, identify and implement preventative controls to address these hazards, monitor how well these controls are working, and maintain records of food safety plan activities.[15] This part of the FSMA mirrors the "Hazard Analysis and Critical Control Point" (HACCP) system that has been in place in the meat industry since the 1990s[16] and more recently, for seafood and juice products.[17]

For purposes of these requirements, a "facility" is defined to include:

> [A]ny factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; other retail food establishments; nonprofit food estab-

12. The USDA already has a decidedly preventive approach called Hazard Analysis and Critical Control Point (HACCP), under which meat processers are required to have a food safety plan that acknowledges, tests, and corrects hazard points in the processing environment.

13. FDA, Food Modernization & Safety Act, Preventative Controls website, http://www.fda.gov/Food/FoodSafety/FSMA/ucm256826.htm (last visited July 20, 2011).

14. *Id.*

15. 21 U.S.C.A. § 350g (2011).

16. USDA, Food Safety and Inspection Service, HACCP and Pathogen Reduction website, http://www.fsis.usda.gov/science/Hazard_Analysis_&_Pathogen_Reduction/index.asp (last visited July 10, 2011).

17. *See,* FDA, Hazard Analysis and Critical Control Point (HACCP) website, http://www.fda.gov/food/foodsafety/hazardanalysiscriticalcontrolpointshaccp/default.htm (last visited July 10, 2011).

> lishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in section 123.3(k) of title 21, Code of Federal Regulations).[18]

Special provisions were included in the FSMA to assist smaller facilities. "Qualified facilities" are exempt from a number of the specific requirements, although they are required to document that they have identified hazards and established controls, document that they meet non-federal law requirements, and document that they meet the definition of a qualified facility.

"Qualified facilities" are defined as either 1) those that meet the FDA definition of a very small business or 2) those with a "limited annual monetary value of sales." The latter category applies to those businesses that have sold an average of less than $500,000 of food annually and that the majority of their sales were either direct sales to a consumer or to a restaurant or retail establishment within the state or within a 275 mile radius of where it was harvested or processed.[19]

Moreover, the FSMA specifically directs the FDA to clarify its regulations to provide expressly that the definition of "retail food establishments," a category of businesses that are exempted from the definition of food facility, includes the direct sale of food at farm stands, farmers' markets, and community sponsored agriculture programs.[20]

The FDA will be able to monitor industry compliance through a facility registration requirement, a requirement that existed prior to the FSMA, but that was amended and strengthened by the new law.[21] The FDA will now be able to suspend the registration of a facility if the Secretary determines that "food manufactured, processed, packed, received, or held by a facility . . . has a reasonable probability of causing serious adverse health consequences or death to humans or animals" if the facility "caused, or was otherwise responsible" or "knew of, or had reason to know of" the problem and "packed, received, or held such food."[22] The facility cannot import, export, or put food into commerce while its registration is suspended.[23] The FSMA includes provisions for a hearing on the suspension and the development of a "corrective action plan."[24]

Regulations for Agricultural Produce

Developing a preventative strategy for dealing with agricultural produce is challenging. However, given the severity of recent outbreaks associated with fresh produce, the problem could not be ignored. The FSMA directs the FDA to "establish science-based minimum standards for the safe production and harvesting" of certain fruits and

18. 21 U.S.C.A. § 350d(c)(1) (definition incorporated by reference, *see* 21 U.S.C.A. § 350g (o)(2) (2011).

19. 21 U.S.C. § 350g(l) (2011).

20. Food Safety Modernization Act, Pub. L. 111-353, Title I, § 102(c), 124 Stat. 3385, 3889 (2010).

21. 21 U.S.C.A. § 350d (2011).

22. 21 U.S.C.A. § 350d(b)(1) (2011).

23. 21 U.S.C.A. § 350d(4) (2011).

24. 21 U.S.C.A. § 350d(b)(2) (2011).

vegetables. Which fruits and vegetables (or mixes) will be regulated will be based on the Secretary's determination whether standards would "minimize the risk of serious adverse health consequences or death."[25] The FDA is directed to coordinate its efforts "with the Secretary of Agriculture and representatives of State departments of agriculture (including with regard to the national organic program established under the Organic Foods Production Act of 1990), and in consultation with the Secretary of Homeland Security."[26]

The produce provisions of the FSMA clearly target the large scale produce industry, although small operations are not automatically exempt from future regulation. There are specific provisions in place that evidence Congress' intent to protect small operations and direct market operations while also protecting consumer food safety.

> With respect to small businesses and very small businesses . . . that produce and harvest those types of fruits and vegetables that are raw agricultural commodities that the Secretary has determined are low risk and do not present a risk of serious adverse health consequences or death, the Secretary may determine not to include production and harvesting of such fruits and vegetables in such rulemaking, or may modify the applicable requirements of regulations promulgated pursuant to this section.[27]

The FSMA further requires that the regulations that are developed "provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruits and vegetables . . . including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities." The regulations cannot include any requirements that conflict with or duplicate the organic standards under the Organic Foods Production Act.[28]

Consumer input is required in promulgating the new rules, with "not less than 3 public meetings in diverse geographical areas of the United States" required.[29] Once the rules are promulgated, there will be a delay in the effective date for small businesses for either one year or two years, depending on the size of the business.[30] The new rules will not apply to produce that is produced by an individual for personal consumption."[31]

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25. 21 U.S.C.A. § 350h(a)(1)(A) (2011).

26. *Id*.

27. 21 U.S.C.A. § 350h(a)(1)(B) (2011).

28. 21 U.S.CA. § 350h(a)(3)(E) (2011).

29. 21 U.S.C.A. § 350h(a)(2) (2011).

30. 21 U.S.C.A. § 350h(b)(3) (2011).

31. 21 U.S.C.A. § 350h(g) (2011). Prior to passage of the FSMA, a number of internet sites warned, incorrectly, that the legislation would ban both farmers markets and backyard gardens.

Increased FDA Inspection Authorities

Inspection and compliance have always been a challenging task for FDA, and as our food system has expanded, that challenge has increased. As noted in a recent Congressional Research Service Report,

> [T]he FDA has oversight of more than 44,000 U.S. food manufacturers, plus well over 100,000 additional registered food facilities such as warehouses and grain elevators. In addition some 200,000 foreign facilities are registered with the agency. Various estimates of unannounced compliance inspections of domestic establishments by FDA officials range from once every five years to once every 10 years, on average, although the agency claims to visit about 6,000 so-called high risk facilities on an annual basis.[32]

New, more rigorous minimum inspection frequencies are mandated in the FSMA.[33] However, the FSMA directs the FDA to apply its inspection resources based specifically on a consideration of risk, designating some facilities to be "high-risk" and subject to greater scrutiny. The FSMA lists the factors to be used in the designation of high-risk status. These factors include the "known safety risks of the food manufactured, processed, packed, or held at the facility," the facility's "compliance history," including recalls and "violations of food safety standards," and the "rigor and effectiveness of the facility's hazard analysis and risk-based preventive controls."[34]

New Requirements for Imported Products

The FDA estimates that "15 percent of the U.S. food supply is imported, including 60 percent of fresh fruits and vegetables and 80 percent of seafood."[35] Given the complexity of the global food system, with complicated supply chains that are difficult to trace, the new requirements for imported foods could be considered to be the most significant aspect of the new authority.

Some of the highlights of the new import provisions include:

- A requirement that importers undertake supplier verification activities to ensure that the food that they are importing is safe;[36]
- A grant of authority to the FDA to refuse to admit food to the U.S. if the foreign facility or the country where it is located refuses to allow an FDA inspection when requested;[37]
- A grant of authority to the FDA to require that certain imported foods be

32. Renee Johnson, *The Federal Food Safety System: A Primer*, Congressional Research Service Report, RS22600, 2 (Jan. 11, 2011).

33. 21 U.S.C.A. § 350j(a)(2) (2011). It seems likely that federal budget cuts will impact the FDA's ability to implement the new inspection expectations contained in the FSMA.

34. 21 U.S.C.A. § 350j(a)(1) (2011).

35. FDA Food Safety Modernization Act, Food Safety Legislation Key Facts website, http://www.fda.gov/Food/FoodSafety/FSMA/ucm237934.htm (last visited July 10, 2011).

36. 21 U.S.C. § 384a (2011).

37. 21 U.S.C.A. § 384c (2011).

certified as being produced in compliance with U.S. food safety requirements;[38] and,

- The creation of a new voluntary certification program that would allow importers expedited review of their products.[39]

Included in the enhanced FDA authority with regard to imported foods are new provisions that seek to prevent the importation of intentionally adulterated food. The Secretary is directed to give the "highest priority" to increasing the number of inspections made of imported food products, with "the greatest priority given to inspections to detect the intentional adulteration of food." High priority is also to be given to improving the FDA information management systems and improving testing mechanisms for rapid detection of adulterated food. Moreover, the FDA authority to temporarily hold imported food at port is enhanced.[40]

Food Recall Authority

Prior to the passage of the FSMA, when a food borne illness outbreak was traced to a food product, the FDA would ask the manufacturer to issue a voluntary recall. While the FDA acknowledges that the food industry has been largely compliant with FDA's requests for voluntary recalls, timing issues can be critical. The delay of even several days can dramatically affect the amount of product that has already been consumed. Indeed, most recalls recover only a fraction of the amount of the food that is officially recalled.

The FSMA gives the FDA the authority to issue a mandatory recall of a food product if the responsible party does not voluntarily cease distribution and recall the food upon request. There is a provision for an informal hearing to challenge the FDA action and the possibility of restitution for recalls made in error.[41]

Partnerships

The FSMA emphasizes the importance of strengthening and coordinating collaboration among a variety of entities involved in promoting food safety. Federal, state, local, territorial, and tribal government agencies are encouraged to partner efforts in assuring food safety. The FSMA calls for improved training programs and authorizes grants for training, research, and inspection activities.[42] With respect to imported foods, the FSMA envisions both foreign governments and private certifiers being involved in verifying the safety of food products to be imported to the United States.[43]

38. 21 U.S.C.A. § 381(q) (2011).

39. 21 U.S.C.A. § 384b (2011).

40. 21 U.S.C.A. § 381 (2011).

41. 21 U.S.C.A. § 320l (2011).

42. 21 U.S.C.A. § 399b (2011) (note that the codification of this section may be in error; there is another § 399b, and the Public Law indicates that it should be § 399c).

43. *See, e.g.*, 21 U.S.C.A. §§ 384b, 384d (2011).

Conclusion

A number of different factors contribute to increasingly complex food safety issues in the future. Despite many calls for a more local food system, the complexity of global supply chains for processed food and an increasingly global food system for year-round supplies of fresh produce complicate the task of assuring a safe food supply. Moreover, local food may be susceptible to the same adulteration, but affect fewer consumers. Adding to the challenge, new pathogens are evolving, and many are resistant to our usual arsenal of antibiotics. The FSMA provides FDA with many of the tools that it needs to address these challenges. At this writing, however, a lingering question remains whether Congress will provide the FDA with the funds it needs to implement the new protections. One way or the other, food law, and in particular, food safety law, will be increasingly important going forward.

The University of Arkansas School of Law incorporates food law studies into its curriculum in a variety of ways. The student-edited *Journal of Food Law & Policy* publishes articles on food law topics and is the only law school journal focused in this area. In 2010, the name of the LL.M. Program was changed to Agricultural & Food Law, reflecting the increasing integration of agricultural and food law studies. Food law courses currently include *Food Law & Policy*, *Selected Issues in Food Law*, and *Food Safety and Litigation*. The note reflects a small part of this work.