PREPARING FOR THE

FOOD SAFETY

MODERNIZATION ACT

BY CHARLES F. WOODHOUSE
This article discusses the Food Safety Modernization Act (FSMA) and the paradigm shift in how the risk of food-borne disease is controlled. This article also discusses the “Big Seven” Proposed Rules that are presently moving through their respective Comment Periods. We then conclude with some important points to aid working attorneys, whether in-house or in private practice, to guide their organizations or clients through the FSMA implementation process.

**Background on FSMA**

There are times when a symbolic act, such as the formal signing of legislation by a US president, is not simply a change in law or regulation, but is representative of a change in the paradigm we use to conceptualize an entire area of human endeavor. When President Obama signed FSMA on January 4, 2011, much more was accomplished than a simple update of the federal Food, Drug, and Cosmetic Act (FDCA).

The enactment of the FDCA, signed by President Roosevelt on June 25, 1938, was driven by the reaction to the sulfanilamide scandal of 1937. By contrast, the FSMA is driven by what current FDA Commissioner Margaret Hamburg calls the era of evidence-based “Regulatory Science.”

This is a paradigm shift, a change in culture, and a shift in how Americans will think about food safety in the years ahead.

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This is the agenda that FDA Commissioner Hamburg was already well on the way to formalizing at the time of the signing of the FSMA. By August 2011, she had published her “Strategic Plan” for the focus on Regulatory Science that is the hallmark of her tenure at FDA. Her definition of regulatory science is this—“Regulatory Science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products.”

This is particularly important as it defines the evidence-based and risk-based preventative controls that are at the heart of the FSMA.

Contrasting the reactive stance of the FDCA signed by President Roosevelt with the proactive stance of the FSMA signed by President Obama requires acknowledging that the “tools” that Margaret Hamburg will use to implement proactive public health policy did not exist in 1937. Before 2000, in the era of in vivo and in vitro biology, there existed only relatively primitive means to study food-borne pathogens, toxins, and natural and anthropogenic poisons. Today, in the era of genomics, molecular-level biology, and in silica synthetic biology, evolutionary changes in the virulence of food-borne pathogens can be anticipated and understood.


As a starting point for establishing evidence-based regulatory science as the driver for sound public policy decisions, Taylor confronts the fundamental and unasked questions: Do we have a food safety crisis, and is our food supply becoming more, or less, safe? Taylor’s opinion piece in the *New England Journal of Medicine* discusses the essay by Glenn Morris of the University of Florida, “How Safe Is Our Food,” in which Morris analyzes the two studies, by Elaine Scallan of the Colorado School of Public Health, covering established food-borne illness etiologies involving the 31 “major pathogens” and various “unspecified agents” of food-borne disease to which other episodes of acute gastroenteritis are attributed without the requirement for the establishment of a definitive etiology.

Taylor’s opinion piece captures the spirit of Margaret Hamburg’s program to develop regulatory science at FDA. In reality, the prevalence of food-borne illness in the United States is not clearly known. The CDC estimates for 2011 attribute 9.4 million annual illnesses to the 31 specified food pathogens, but these same estimates attribute 38.4 million illnesses to “unspecified agents.” That is, 80 percent of “attributed” food-borne illnesses are without established etiology. This degree of candor, acknowledging that “causality” has not been established for 80 percent of what is considered as food-borne illnesses, coming from a high-level federal executive, is truly refreshing and consistent with Margaret Hamburg’s commitment to regulatory science as the driver of public policy.

However, science alone does not determine the development of food safety culture. The influence of tort liability and product liability law on the behavior of the various stakeholders in the food production and distribution systems of the United States must also be recognized. In the decades to come, in courtrooms across America, juries will consider issues of causality and responsibility in legal actions brought by the victims of food-borne illness. The definitive establishment of the etiology of food-borne disease will have far-reaching impact on these state-law product liability decisions. Furthermore, the collective decisions of the nation’s tort and product liability bar to invest time and expenses in food-borne-illness-related product liability cases will have a significant impact on this process. The decreasing cost and increasing...
specificity of genomic tools will significantly increase the willingness of the tort bar to invest in product liability actions against the food industry. It may also increase the likelihood of settlements because insurance carriers will be more able to predict litigation outcomes. For additional discussion of insurance and tort liability issues, see Keane on contamination/recall policies and Marler on general product liability issues in contamination events.

An illustrative case is the extraordinary rapidity of the establishment of the etiology of the German enterohemorrhagic STEC E. coli outbreak of 2011. A close look at this case shows how the scientific and legal meanings of the term causality rapidly converge. For two generations, scientists have viewed causality through the lens of the famous criteria of Sir Austin Bradford-Hill. Similarly, the law, for three generations, has viewed causality through the prism of the writings of US Supreme Court Justice Benjamin Cardozo and his path-breaking articulation of the concept of Proximate Cause in Palsgraf v. Long Island Railroad. In the German outbreak, it required fewer than 90 days to definitively establish the etiology of the outbreak. A tangible demonstration of the convergence of Bradford-Hill’s “association or causation” and Cardozo’s “proximate cause” can be seen. The previous divergence in the understanding of causality by “science” and by “the law” is mitigated in the modern era of genomics.

In the FSMA, the impact of the emerging concept of regulatory science as the driver of the evidence-based analysis guides public policy decision-making at the FDA. At the heart of the FMSA is the concept of risk-based preventative controls (RBPCs) founded on evidence-based analysis. Consider also the profound legal implications of the scientific advances that enable the establishment of the definitive etiology of food-borne disease outbreaks and the precise attribution of responsibility for food-borne illness.

The “Big Seven” Proposed Rules

In the table below, reference information is provided to the most important Proposed Rules under FSMA. Reviewing each of these Proposed Rules, which occupy some 2,000 pages in the Federal Register, is beyond the scope of this article. At Michigan State University our MS Food Safety and LLM Food Law students cover these topics only partially in two full-semester courses: US Food Regulation and US Food Import Regulation. Most students also take a separate full-semester course, Canadian Food Regulation, which covers the new Safe Food for Canadians Act. The importance of a practicing food law lawyer needing to obtain university training beyond her or his law degree cannot be overemphasized. For further comments on food safety education, please see Professor Neal Fortin’s excellent discussion in Food, Cosmetics & Nutraceuticals News.

Preparing for FSMA

In this section, we discuss the role of the practicing food lawyer in preparing clients for the sweeping changes in the regulation of the US food supply that will be introduced over the next several years. We present some dozen comments on specific areas of food regulation where the impact of FSMA will change long-held patterns of practice and compliance and that may present significant challenges to manufacturers, importers, and distributors of human food and animal feeds.

A case in point is the increasingly important food import sector, where the two highest value import categories are fruits and vegetables and seafood, with US imports in 2013 of $24.3 billion and $17.8 billion respectively. Nearly 50 percent of major food safety regulatory problems, in both Europe and the United States, are in the aquatic food products (seafood and aquaculture) industries and in the produce industry. Thus, in the food import sector, everyone is awaiting the FDA’s release of the Proposed Rule on the Foreign Supplier Verification Program (FSVP). One major problem is that the Foreign Supplier Verification Program (FSVP) Proposed Rule and the VQIP are like a “pair of scissors.” The FDA has given us only the FSVP

THE BIG SEVEN FSMA RULES


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and not the VQIP, so this article cannot comment on the FSVP. Also, as far as the seafood industry is concerned, the FDA has failed to give any guidance on the hazard analysis and critical control points (HACCP) exemption in FSMA for seafood. It is fine for the FDA to say that seafood will remain in HACCP, but how will one qualify for VQIP if they do not prepare a RBPC? Many are unhappy facing the possibility that the FSVP Comment Period may end before the industry is permitted to review the VQIP Proposed Rule.

It is certain that these Big Seven rules, once completed with the additional release of the VQIP (making it the “Big Eight”), will make substantial changes to food import regulation and procedure and keeping up to date on these changes will present major challenges for food lawyers.

Major retail grocery and food service buyers are suddenly worried about FSMA compliance issues and are beginning to require extensive documentation from their suppliers. In recent months, food importers have started coming with questions, now that their retail grocery and food service customers are demanding detailed food safety packages including guarantees with very broad indemnification language. This is particularly evident in the produce sector (because of recent major food safety incidents), but increasingly buyers are setting extensive documentation requirements in other food categories as well.

Based upon this, our article offers a few comments on what attorneys should be thinking about and doing now to prepare clients for FSMA compliance:

1. Clients should retain counsel competent in drafting the required FSMA documents over the next several years. This is the time for attorneys to go back to school and study. Without recommending a specific program, note that at least three US research universities offer graduate certificate programs in food regulation. Of course, much of FSMA compliance requires a food science background. Lawyers with the requisite undergraduate science courses (biology, chemistry, physics, statistics, etc.) would be wise to complete one of the many MS food science programs offered by a number of US research universities. In choosing among these programs, students who are lawyers may prefer schools that specifically offer a choice of the “regulatory track” or the “food technology track.”

2. Think carefully about privilege issues, and counsel clients to be careful to compartmentalize the role of consultants because the client’s communications with consultants are not privileged. Serious food safety incidents can quickly develop into civil litigation, and even into criminal prosecution. Recently, several otherwise sophisticated clients have proposed “recall plans” that unnecessarily involve too many clerical employees and outsiders in their “crisis management” group. These companies believe that “sharing” information with lots of people is “good.” To the contrary, a properly designed recall plan must include strict compartmentalization of information and active protection of attorney-client privilege.

3. If a client is a food importer, this third point is very important. While waiting for the FSVP and VQIP Proposed Rules, attorneys should have already drafted for clients recall plan documents, a supplier questionnaire, and a required guarantee document package. The supplier questionnaire is essential for the timely gathering of the technical information that will be required in the RBPC Plan document that clients will soon be required to prepare. This applies, of course, to domestic suppliers as well, but the difficulties of obtaining information from overseas suppliers means a company that is not already doing this may be making a serious mistake.

4. Because the RBPC Proposed Rule enables a nearly complete understanding of what will be required to be determined, clients already should have been in contact with their domestic and foreign suppliers for full specifications and documentation on not only the basic food products themselves, but also all minor food ingredients, food additives, food allergens, processing aids, and food-contact materials (including all available MSDS or SDS data). Any success in limiting the scope of a recall will depend upon having this information on file in US offices and instantly available to FDA personnel.

5. As mentioned above, attorneys should be particularly attentive to guarantee and warranty agreements that clients are asked to sign from downstream customers. Very few practicing lawyers are familiar enough with food law in general, and the FSMA in particular, to competently produce such documents without making fundamental errors. In practice, many such documents contain language that violates product liability coverage terms and conditions and that clearly demonstrate inadequate knowledge of basic insurance law and procedure (including completely inappropriate choice of counsel provisions). Also, many such guarantees and warranties are routinely signed by sales executives who are not competent to review such complex documents. All food safety guarantee and warranty agreements must be reviewed by competent counsel. Clients should be warned not to permit sales executives to sign guarantee and warranty agreements that may bind the company to impossible promises.

6. Finally, three more points on recalls. First, it seems that few lawyers think to include language
that obligates the upstream supplier to timely notify your client when a recall event involving that supplier’s product initiates from another customer of that supplier. Secondly, very few documents (including recall insurance riders) adequately define and present the alternatives to recalls: market withdrawals and stock recoveries. Third, remember that many products entering US distribution channels will end up at retail in Canada. Be aware that there are many differences between US and Canadian food regulation—the differing lists of major allergens is but one small example.

7. If clients are importers, they already should have been in touch with each of their suppliers to plan for FSVP and VQIP compliance. This is an area where the “You snooze, you lose” rule applies. If clients are importers who are behind the FSMA implementation curve, they may well find themselves behind competitors who “get it” and are using FSMA compliance as a tool to expand their business.

8. The whistle-blower provisions of section 402 of the FSMA are cause for concern. Clients need to be carefully counseled on section 402 and on its relation to the Reportable Food Registry. This is an area of significant danger to clients. In February 2014, OSHA published its Interim Final Rule on Employee Retaliation Protection pursuant to section 402 of the Food Safety Modernization Act. Section 402 of FSMA and the OSHA Rule deserve careful attention.

9. In February 2014, FDA circulated the Designation of High-Risk Foods Statistical Model, which received strong and immediate industry reactions. Basically, the model takes a one-size-fits-all approach to the designation of risk. A number of industry associations are currently working to provide suggestions to FDA to make this model more flexible. For example, the current FDA stance could place a domestic producer with a perfect safety record in the highest-risk category because of a pattern of violations by foreign suppliers of the same product. The belief is that the insurance industry will not focus on such nuances in setting premiums once a product is designated high-risk by FDA.

10. As discussed above, the product liability provisions in the client’s CGL and contamination/recall policies must be carefully reviewed. Our recommendation is that clients pay attention to the issues raised in the excellent article on recall insurance by Vincent Keane cited earlier.

11. There are major questions raised by three provisions of FSMA: (1) the administrative detention authority given to FDA by Congress in section 207 of the FSMA; (2) the mandatory recall authority (MRA) granted in section 206 of FSMA; and (3) the facilities registration suspension authority granted in FSMA section 102(b). These three new powers granted to FDA under FSMA should be a source of significant concern to counsel to both food importers and to domestic food producers, distributors, and retailers. This author believes that these new powers will present significant problems in relation to Article 9, Security Interest Perfection in Secured Transactions. What will happen in circumstances under which FDA uses MRA or facility registration suspension authority against inventory in which an Article 9 security interest exists and upon which a secured lender relies? There is already a significant “case study” on Suspension of Facilities Registration in the Sunland events of late 2012.

12. Looking at these issues from the overseas supplier’s perspective—food exporters from around the world will be under great pressure to meet FSMA goals and requirements in the next several years. They will be forming stronger links with US importers who can help them. Attorneys should stress to clients that, in the new era of food safety, importers who sit passively and let the world change around them may wake up and find that they have been left behind.

Concluding Comments
We are entering a new era of food-borne illness reduction, but we will never eliminate risk in food products. Advances in food science have brought us to the point that risks can be measured and partially controlled. The new discipline of regulatory science has provided us with a cadre of lawyer-scientists who can understand the science and craft sophisticated risk-based controls to mitigate these risks to a greater extent than ever before in human history. But food science is a double-edged sword for the food industry. The same knowledge of food chemistry, microbiology, and toxicology that enables us to mitigate risk also permits the pinpoint establishment of the etiology of food-borne disease. Furthermore, the voluminous documentation required by FSMA creates a truly “target-rich” environment for the tort bar. In the Marler essay cited previously, one of America’s leading food-liability plaintiffs’ attorneys asks us if FSMA will let him close his practice. The answer is “Not quite yet.”

Endnotes
The endnotes for this article can be found at http://www.americanbar.org/publications/scitech_lawyer/web_exclusives/woodhouse_endnotes.