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UPDATE

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IN THIS ISSUE







Food: The Three Rs of the FDLI Conference

By Deborah C. Attwood

In school, you learn the three "Rs" — reading, (w)riting, and (a)rithmetic. At this year's FDLI conference, another trio of Rs emerged as common themes — risk, resources, and right-to-know. Risk-based regulation, particularly epitomized by the Food Safety Modernization Act (FSMA), the continuing need for additional resources to protect the US food supply, and the growth of the consumer right-to-know movement—none of these themes were new to the conference attendees, but they featured in almost every presentation relating to food.

As Liz Dickinson, FDA's Chief Counsel, noted in her speech, FDA regulates many products that Americans use in their daily lives with the simple expectation that these products will be safe. When it turns out that these products have caused or may cause harm, FDA often ends up on the front pages for failure to do something, whether it is failure to regulate, failure to enforce, failure to warn. But FDA does not have unlimited resources, and decisions must be made about where to allocate money and manpower. Risk-based regulation is a scientifically-supported and common sense method to ensure that resources are directed to the areas that present the highest risk of harm, and thus where the greatest benefit can be achieved. Yet even as it implements these risk management policies, FDA must ensure that it is appropriately communicating with the public about those areas the agency considers to be low risk, and perhaps more importantly, *why* the agency considers them low risk. More than ever, the public is proactively seeking information about their food, what it is made of, and how it is made. While no one would deny consumers the right to know what they are eating, in the absence of guidance from FDA people will turn to other sources that may not provide

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science-based or reliable information. This article will discuss the three Rs—risk, resources, and right-to-know—in the context of specific topics discussed during the food program presented at this year's FDLI conference.

The Risk Paradigm

In the breakout session *FDA's Involvement in the Oversight of GMO Crops*, Karil Kochenderfer described a "risk paradigm" of three key concepts: risk assessment, risk management, and risk communication. With risk assessment, or said a different way, hazard identification, the important precept to bear in mind is that no product is risk-free. Every time a food is consumed, it presents a potential hazard—from physical hazards, such as choking, to chemical and biological contamination. Yet another important principle to bear in mind is that a hazard represents only potential harm—how the hazard is managed so that harm becomes more or less likely to occur is an equally important consideration. Hazard identification is an essential component of the risk paradigm presented by different food products because only once the hazards are identified can appropriate procedures and systems be developed and implemented to control the hazard. Yet it is only the first step. Hazard identification occurs so that policies can be established to manage the risk that a hazard will cause harm. Without proper hazard identification, any management system may not achieve the desired goals, resulting in wasted resources for no benefit. But taken out of the context of risk management, hazard identification often becomes meaningless. Under the guise of keeping consumers informed, websites with laundry lists of potential hazards in our everyday products serve only to scaremonger, without providing useful guidance on where true risks lie. This is where risk communication becomes essential, so that the appropriate frame of reference is established for a proper discussion regarding where limited resources can and should be allocated so as to achieve the most benefit. Fundamentally, proper communication to the public is essential to create understanding and confidence that a product is safe to eat.

FSMA

Risk assessment and management are key to FDA's mission and particularly to its implementation of FSMA. Speakers called FSMA a "game-changer," through which FDA can utilize its strength in science-based decision making and data-driven analyses to determine comparative risks and establish a compliance and enforcement program that deploys the agency's resources efficiently and effectively. The continuing implementation of FSMA presents FDA with a case study in whether risk-based regulation implemented throughout the food industry and across almost all commodities can be successful. Dr. Susan Mayne, Director of the Center for Food Safety and Applied Nutrition (CFSAN), made clear that FDA expects to publish its final rules as required by the schedule established in the Consent Decree filed in the District Court of Northern California in February of 2014. Consequently, we can expect to see final rules on the Hazard Analysis and Risk-Based Preventive Controls (HARPC) for both human and animal food by the end of this August, with the produce safety, third party accreditation, and Foreign Supplier Verification Program (FSVP) final rules following just two months later. These foundational regulations aim to establish a flexible regulatory framework through which industry will work to identify potential hazards and develop and implement science- and risk-based preventive measures so as to provide on-going assurances as to the safety of food from farm to table.

Even as FDA works to complete the final rules, the agency also is working on its Phase II implementation. This will entail a significant education and outreach program, most notably with development of commodity- and sector-specific guidance documents for industry. There will be guidance and training for FDA personnel, particularly inspectors, so that the compliance and enforcement programs are applied consistently across the board. Importantly, FDA also is developing performance/public health metrics through which the agency can measure the success of its programs. These metrics will help the agency determine whether its programs are working effectively and also where it may be possible to free up resources for reallocation to areas of greater concern.

These metrics are very important from an agency-management perspective. Risk-based regulation is becoming FDA's programmatic approach due, in part, to the likely reality that the agency will not receive significant additional financial resources. Consequently, the agency continually needs to make rational cost-benefit based determinations regarding resource allocation. Some types of product present a greater risk of harm as compared to others and it makes sense, therefore, to devote more resources to those commodities for which greater investment is likely to result in lessened risk of harm. Performance metrics are essential to that deliberative process.

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Performance metrics are important tools not only for FDA's internal processes, but also for the external perception of the success of FSMA implementation. Ultimately, consumers expect their food to be safe. FDA has faced continued criticism that it is not doing enough to protect the food supply, particularly in relation to imported foods. It simply is not sufficient for FDA to put in place a model regulatory system that makes food safer if the successes of that system are not properly communicated to the public. FSMA's risk-based regulatory framework is supported by science and well-understood within the regulated community. Yet these massive efforts by FDA and industry to keep the vast majority of food safe for consumption mean very little when all the public sees are the attention-getting recalls and food poisoning outbreaks, or reads factoids such as FDA having the resources to inspect only 1% of food that is imported into the country. FDA must ensure that the performance metrics are not only helpful for continued FSMA implementation but also can be used as evidence of improvements in the safety of the food supply due to FSMA.

Finally, even with FDA's continued attention to risk-based resource allocation, agency leadership continues to press for additional resources from Congress. In a recent editorial, Dr. Michael Taylor, Deputy Commissioner for Foods, pressed the case for a budget increase for 2016, primarily for FSMA implementation, of $109.5 million more than provided in 2015.[1] In her FDLI presentation, Dr. Mayne also reemphasized the need for additional resources. It is clear that FDA leadership is concerned that the agency does not have the resources, both financial and personnel, needed to properly implement FSMA's broad mandate and scope, even when the agency is targeting its programs and resources on those commodities of highest risk and concern. Dr. Mayne noted the need for FDA to recruit new personnel to ensure continued institutional knowledge and to do more to retain talent, a need reemphasized by Dr. Jennifer McEntire, the Grocery Manufacturers Association's Vice President of Science Operations. Given the current climate, however, it appears more likely that FSMA implementation will need to continue apace utilizing, as best possible, FDA's existing resources, in partnership with other stakeholders such as the U.S. Department of Agriculture and state-level officials.

GRAS and Chemicals in Food

Industry and FDA have been under significant scrutiny recently regarding the presence of "chemicals" in food, particularly in relation to the marketing of additives on the basis of industry self-determinations that a substance is generally recognized as safe (GRAS), and thus exempt from the need for premarket approval. The GRAS concept was first applied to food with the Food Additives Amendment Act of 1958, which exempted a substance from the definition of a "food additive" and the need for formal premarket approval by FDA if it is "generally recognized, among experts qualified by scientific training and experience to evaluate safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use."[2]

To establish that a substance is GRAS requires the same quality and quantity of scientific data as is required to obtain FDA's approval of a food additive regulation. A GRAS determination should be based on published data, while unpublished studies and other data also may be used to support the determination.[3] The GRAS exemption is, therefore, a risk management tool, operating on the principle that provided there are sufficient scientific data publicly available to demonstrate to experts in the field that a given hazard (the additive, or any constituents or impurities) presents a sufficiently low risk, it is not necessary to obtain clearance from FDA prior to marketing the product.[4]

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In 1972, FDA established a voluntary GRAS affirmation petition process through which manufacturers could request FDA's review and approval of a GRAS determination. Because the petition process was highly inefficient, FDA proposed in 1997 a new program under which a company could notify FDA of its determination that a particular use of a substance has been determined to be GRAS.[5] FDA began accepting petitions in 1998, but never finalized the proposed rule. In February 2014, the Center for Food Safety (CFS) sued FDA, alleging that the GRAS Notification program could not operate under only a proposed rule, and arguing that FDA was required to return to the GRAS petition process.

A return to the GRAS petition process would have provided very little benefit. GRAS substances are subject to the same evidentiary and safety standard as those substances submitted to the agency for preapproval. From FDA's perspective, the petition process was time- and resource-intensive, in part because it required rulemaking.[6] Moreover, due to FDA's long delay in reviewing petitions, companies were discouraged from going to the agency. By contrast, there are now nearly 600 GRAS Notifications listed on FDA's online inventory, along with the publicly releasable information and data provided by the notifier.[7] This efficient and transparent process encourages disclosure of GRAS determinations, making substantial amounts of information available to consumers. Recognizing the benefits of the GRAS Notification process, FDA settled with CFS in October, 2014, agreeing to finalize the 1997 rule by August 2016. Consequently, although in his presentation Stuart Pape called it "unfinished business," eventually the final rule should be one item that FDA can check off its list.

Even as it works to finalize the GRAS Notification rule, FDA is working on other issues relating to chemicals in food. In particular, Dr. Mayne indicated during her speech that the agency is working on an overhaul of the food ingredients program, with pre- and post-market "enhancements" under consideration. Dr. Mayne did not provide any detail regarding these enhancements, although some speculation is possible. Items that we know FDA is working on include guidance on conflicts of interest (COI) for consulting scientific experts on GRAS notifications and updating the industry guidance "Toxicological Principles for the Safety Assessment of Food Ingredients," more commonly known as the Redbook.

Concerns regarding the potential for conflicts of interest were raised in a 2010 report by the Government Accountability Office (GAO).[8] Companies may rely upon the opinion of a panel of scientific experts to support the general recognition component of the exemption. GAO noted that there is no guidance on conflicts of interest for companies to use to help ensure that participants on expert panels are independent in their determinations of GRAS status. In response to this criticism, FDA has reported that it is developing guidance on how to address potential conflicts in the GRAS evaluation process.

With regard to the Redbook, FDA is in the beginning stages of the process to update the guidance to reflect current science. FDA held a public meeting and opened a docket to receive comments and feedback from stakeholders on the update. Notably, FDA is considering expanding the scope of the Redbook to include chemical safety assessments for all areas over which the CFSAN has statutory authority (e.g., food additives, food contact substances, dietary supplement ingredients, food contaminants, and cosmetics).[9]

Finally, Dr. Mayne also noted that FDA is continuing work on two significant chemical contamination issues, namely the presence of arsenic in food and advice on consumption of fish that may contain lower levels of mercury. The issue of arsenic in rice is an excellent example of the complexity of the risk paradigm in foods.[10] Arsenic is a chemical element, naturally present in the environment from both natural and human sources. There are two types of arsenic compounds that may be present in soil and ground water—organic and inorganic—resulting in the presence of low levels of arsenic in certain foods, such as rice, fruit juices, and juice concentrates. Long-term exposures to high levels of *inorganic* arsenic are associated with higher rates of skin, bladder, and lung cancers, as well as heart disease. The questions of whether exposure to low levels of arsenic presents a hazard, and how best to manage that hazard, are very difficult to answer. In September 2013, FDA released the analytical results of over 1000 new samples of rice and rice products, as part the agency's effort to understand and manage possible arsenic-related risks associated with the consumption of these foods. FDA found that the arsenic levels found in the testing were too low to cause immediate or short-term adverse health effects, so the agency is now focusing on risk-management for long-term exposures.[11] Risk communication on this topic also is complex, particularly given

that FDA does not have answers to all the questions. Consumers read that there is arsenic present in rice and juice and understandably are concerned about the potential health impacts, particularly for children. In the absence of definitive guidance from FDA, other groups step in to fill the void.[12] While these organizations are responding to consumer demand for advice on what is safe, it is unclear whether the information provided has been produced or reviewed by scientists with relevant knowledge and experience, or those who work in risk management. Consequently, consumers receive a barrage of information from a variety of sources, with little guidance on what is reputable and reliable.

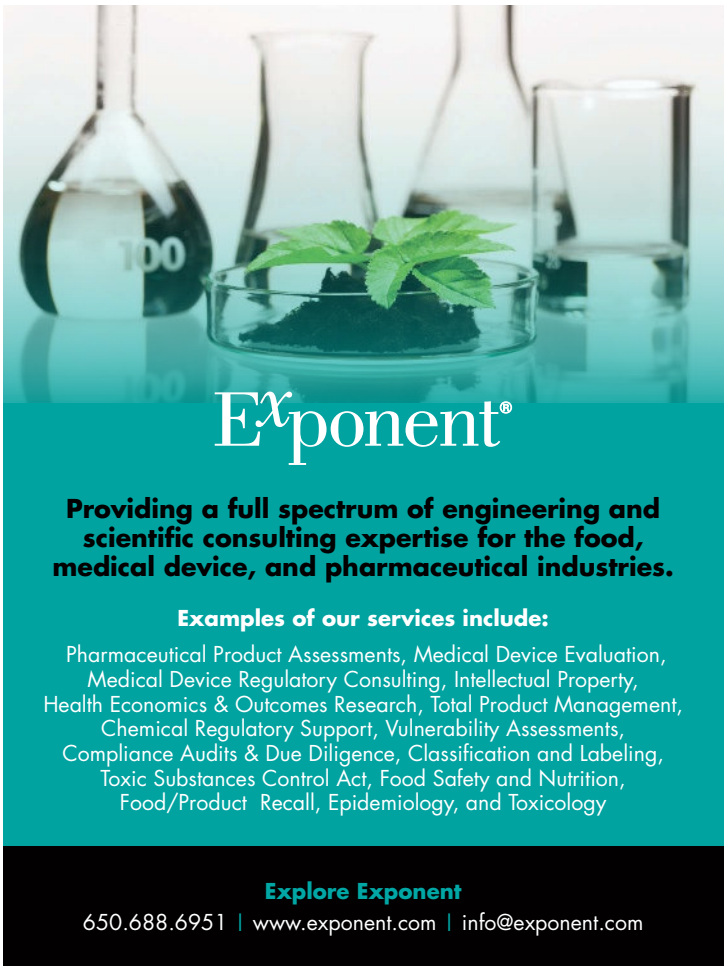
The Right-to-Know Movement

Speakers paid much attention, as has been the case for several years, to FSMA. Yet a few panelists raised what arguably is becoming more important on a day-to-day basis, to industry; namely, the impact of the right-to-know movement on risk evaluation and management. The rise of consumer rights advocacy is being increasingly felt throughout the entire FDA-regulated community, with particular impacts on the food sector. Foods produced from genetically modified (GM) ingredients and labeling of a product as "natural" or "all natural" are two high profile and resource-consuming issues of particular note.

GM Foods

Foods that are made using GM ingredients may be the poster child for the difficulty of relating risk management with risk communication. As Ms. Kochendorfer stated, there is a global consensus that GM crops, and the foods made from them, are as safe as the conventional versions. GM crops can provide significant benefits, including protection against plant diseases or pests and higher nutrient content. Yet there is still a very vocal minority who continue to argue that GM foods have not been demonstrated to be safe, despite substantial scientific evidence to the contrary.[13] Unfortunately, it appears that the scientific case for the safety of GM foods has become disassociated from the perception of these products in the marketplace.

One reason for the continued distrust of GM foods may relate to the absence of mandatory premarket approval by FDA. FDA currently has a voluntary program to assess the safety of GM plants, a process through which many GM products have been evaluated.[14] Gregory Jaffe, Director of the Biotechnology Project at the Center for Science in the Public Interest, argued that FDA's voluntary consultation process may not provide sufficient assurances for consumers that the products are safe. FDA should instead implement a mandatory premarket approval process through which the FDA is required to conclude whether the product is safe.[15] Another rationale for the vigorous opposition to GM foods may be because the first GM crops, herbicide-tolerant corn and soy, became inextricably linked to "big Ag."[16] As a result, all other GM foods are considered, by default, to be big business benefiting at the expense of the consumer, or small/organic farmer.



Regardless of the cause, antipathy to GM foods has led to consumer demand for "GM-free" foods or labeling of foods that contain GM ingredients. Industry has poured massive resources into fighting state-level GM labeling initiatives while simultaneously investing in determining whether foods are GM-free (a complex process) and establishing supply chains for GM-free ingredients so that products can transition to being GM-free. These resources arguably could have been better spent in improving safety programs, such as those required by FSMA.

Natural

Class action litigation by consumer advocacy groups and plaintiffs has exploded in recent years, particularly in relation to products for which "natural" claims, such as "100% natural" and "all natural," are made. The question in all of these cases is whether use of these phrases is false or misleading, with allegations that certain types of ingredient are not natural (e.g. xanthum gum) or are so highly processed as to no longer be natural. Many of these cases have been filed in the U.S. District Court for the Northern District of California, which has now earned the nickname of the "Food Court." Lawsuits have targeted major brand owners and retailers, resulting in a stream of expensive settlements as companies seek to avoid even more costly and time-consuming litigation.

The underlying principle of these suits is that the consumer has a right to know that the food she is consuming is "natural." Yet the problem is that "natural" can be used as a stand-in for a multitude of concerns regarding what is used in food, including GM ingredients, preservatives, colors, and highly refined ingredients. A 2014 Consumer Reports survey found that about two-thirds of consumers believe "natural" means that a processed food has no artificial ingredients, pesticides, or genetically modified organisms, while more than 80% believe that it should mean those things.[17] The litigation boom also is fueled, in part, by FDA's refusal to define the term "natural." In a 1993 Final Rule, FDA declined to either define "natural" or prohibit its use;[18] stating that "there are many facets of this issue that the agency will have to carefully consider . . . [b]ecause of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for "natural" . . . [and] will maintain its current policy regarding the use of 'natural,' as meaning that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food."[19] This current policy leaves substantial room for interpretation, room that consumer groups and plaintiffs' attorneys are seeking to fill. Mr. Pape called the absence of a "natural" definition by FDA another item of "unfinished business"; until this business is completed, industry can expect the flood of litigation to continue, consuming resources under the banner of "right-to-know."

Conclusion

Risk, resources, and right-to-know—these are three issues that will continue to occupy food-related government agencies and industry for the foreseeable future. Every day seems to bring a new issue that raises questions of whether a product presents a hazard, whether the risk of that hazard causing harm is being appropriately managed, and how to best communicate with the public over the risk that product presents to them. Significant attention continues to be paid to laws and regulations that address how to identify and manage hazards; however, I believe that it is risk communication, and particularly the need to counter the non-science based allegations against safe products, that will prove to be the more difficult problem to solve. I have not presumed to present any solution in this article, but I believe that the marriage of science and public relations is needed in order to best inform and guide consumers.

1. "The Future is Now for the Food Safety Modernization Act," Food Safety News, March 17, 2015, available at http://www.foodsafetynews.com/2015/03/the-future-is-now-for-the-food-safety-modernization-act/#.VUeNpflVhBc.
2. 21 U.S.C. §321.
3. 21 C.F.R. §170.30.
4. In 1958, FDA published a list of GRAS substances, which was eventually incorporated into 21 C.F.R. Part 182.
5. A GRAS Notification requires the same type and quality of data as was required for a GRAS petition. FDA does not affirm a GRAS determination under the Notification program; instead, FDA concludes that it either has no questions regarding the GRAS determination, or that the notice does not provide a sufficient basis for a GRAS determination.
6. Presentation by Dr. Antonia Mattia, Director, Division of Biotechnology and GRAS Notice Review, Center for Food Safety and Applied Nutrition, at the Food and Drug Law Institute, February 5, 2013, available at http://www.fdli.org/docs/default-document-library/mattia.pdf?sfvrsn=0.
7. FDA's online inventory of GRAS Notifications is available at http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices.
8. U.S. Government Accountability Office Report to Congressional Requesters, "FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)," February 2012,

available at http://www.gao.gov/new.items/d10246.pdf.

9. The public meeting was held on December 9, 2014, and the transcript is available at http://www.fda.gov/downloads/Food/NewsEvents/Workshops-MeetingsConferences/UCM441507.pdf. The docket, FDA-2014-N-1497, closed on May 11, 2015.
10. FDA, "Arsenic in Rice and Rice Products," available at http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm367263.htm.
11. "FDA Statement on Testing and Analysis of Arsenic in Rice and Rice Products," September 6, 2013, available at http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm367263.htm.
12. One example is the Consumer Reports consumption guidelines for rice and other grains "How much arsenic is in your rice?" Consumer Reports, November 2014, available at http://www.consumerreports.org/cro/magazine/2015/01/how-much-arsenic-is-in-your-rice/index.htm.
13. In a recent article in the Washington Post, author Tamar Haspel stated that "Most GMO opponents aren't anti-science; they're anti-GMO, and therefore see the large body of science that contradicts their ideas as tainted by association with industry, flawed methodologically, done by biased scientists or otherwise dismissible. They are, in fact, pro-science — toward science that confirms their beliefs." Haspel, T. "The GMO debate: 5 things to stop arguing," Washington Post, October 27, 2014.
14. "Consultation Procedures under FDA's 1992 Statement of Policy - Foods Derived from New Plant Varieties," (June 1996; revised October 1997), available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm096126.htm.
15. Yet, given that there has been significant agitation recently regarding the safety of some food additives that are cleared by FDA, the value of a mandatory program is questionable.
16. *See* Haspel, T., *supra*, at note 13.
17. http://www.consumerreports.org/cro/news/2014/06/say-no-to-natural-on-food-labels/index.htm.
18. 58 Fed. Reg. 2302, 2397 (January 6, 1993).
19. *Id.*, at 2407.

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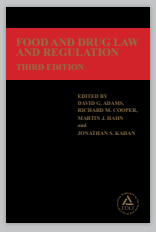

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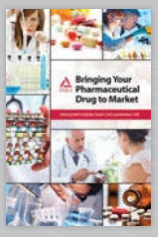

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