INSTITUTE OF MEDICINE RELEASES REPORT ON FDA’S ROLE IN ENHANCING FOOD SAFETY

On June 8, an Institute of Medicine (IOM) committee released its long-awaited report and recommendations on the role of the U.S. Food and Drug Administration (FDA) in enhancing food safety.1 The IOM committee was convened at the request of Congress in 2008 to examine the gaps in the current food safety system under the purview of FDA and to identify the tools needed to improve food safety.

Most significantly, the Report recommends that FDA implement a risk-based approach to tackling food safety problems, in which data and expertise would be marshaled to pinpoint where along the production, distribution, and handling chains there is the greatest potential for contamination and other problems. The Report offers FDA a “blueprint” for developing such a risk-based model. Additionally, the Report outlines several steps that FDA should take to improve the efficiency of its food safety activities, such as increasing coordination with state and other federal agencies that share responsibility for protecting the nation’s food supply. The Report also recommends that Congress consider amending the Federal Food, Drug, and Cosmetic Act (FDCA) to explicitly provide the authority FDA needs to fulfill its food safety mission. Many of the Report’s recommendations would be addressed by the food safety reform legislation currently pending in Congress.2

In a public briefing held on June 8, the day of the Report’s release, committee chairman Robert Wallace noted that while many of the enhancements recommended in the Report are directed at FDA, the Report does implicate other federal agencies, state and local governments, and the private sector. Wallace stated that organizational changes will be “necessary” in both the government and the private sector in order to fully address the deficiencies in the food safety system.

COMMITTEE CONCLUSIONS

As part of the committee’s investigation, they reviewed FDA’s 2007 Food Protection Plan (FPP), a roadmap developed to align with the agency’s strategic plan for ensuring food safety. The committee also worked to identify additional tools and capacities to improve food safety. The committee’s main conclusions are as follows:

- The FPP lacks sufficient detail on which to base policy decisions on prevention and risk.
- FDA currently lacks a comprehensive, systematic vision for a risk-based food safety system, which would include attributes such as strategic planning, transparency, and formalized prioritization processes.

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1 Institute of Medicine, Enhancing Food Safety: The Role of the Food and Drug Administration (2010) (hereinafter “Food Safety Report” or “Report”).
2 Click here for our client alert describing H.R. 2749, which the House of Representatives passed on July 30, 2009. Click here for our client alert describing S. 510, which was reported out of the Senate HELP committee on November 18, 2009, and awaits consideration by the full Senate.
FDA has not adequately assessed its data needs and lacks a systematic means by which to collect, analyze, manage, and share data.

- Food safety activities of state and local governments are not fully integrated with the role of the federal government such that duplication is minimized.
- FDA's food programs lack direct authority over the work of inspectors, which affects inspection efficiency.
- FDA’s risk-based food safety management system needs to incorporate effective risk communication and food safety education for consumers and those who could impact public health through their professions, such as public health officials.
- The provisions of the FDCA relevant to ensuring the safety of 80% of the nation’s food have remained unchanged since 1938, resulting in deficiencies that leave FDA vulnerable to court challenges and reluctant to take action when needed.
- Greater integration and organizational changes at FDA would be needed to ensure the agency’s success in ensuring food safety through the development of a risk-based food safety management system.

Committee Recommendations

The Food Safety Report makes multiple recommendations under nine main headings. Below, we provide these headings, as well as key examples of the types of recommendations included under each.

- **Implementing a Risk-Based Approach to Food Safety**
  The committee details six steps that it believes should constitute the basis for a comprehensive risk-based food safety system. These are: (1) strategic planning; (2) public health risk ranking; (3) targeted information gathering and consideration of other factors; (4) analysis and selection of intervention(s); (5) design of an intervention plan; and (6) monitoring and review. The Report further specifies the sub-components of each of these steps and encourages FDA to develop internal operating guidelines, to identify metrics, and to identify expertise needed to implement this approach.

- **Sharing the Responsibility for Food Safety**
  The committee recommends that FDA develop a plan to improve collaborative efforts between the agency, the states, the private sector, third parties (such as independent auditors), and other countries’ governments in order to better ensure food safety.

- **Creating a Data Surveillance Infrastructure**
  The committee asserts that FDA data collection should be driven by the recommended risk-based approach to food safety and should support agency decisionmaking. The Report makes numerous recommendations as to how FDA should improve its data collection and analytical capabilities, such as by establishing an analytic unit with resources and expertise needed to support risk-based decisionmaking.

- **Creating a Research Infrastructure**
  The committee recommends that FDA should have a food safety research portfolio that supports the recommended risk-based approach. The Report urges FDA to examine the relevance and allocation of its research resources by using public health risk ranking and prioritization.
Integrating Federal, State, and Local Food Safety Programs
The committee recommends that FDA harness the surveillance, inspection, and analytic systems and resources of state and local governments to develop a fully integrated food safety program.

Enhancing the Efficiency of Inspections
The committee recommends that FDA develop an inspection system in which inspection frequency and intensity are based on risk, with minimum standards for the frequency and intensity of inspections for all facilities. The Report also urges FDA to consider conducting fewer inspections by itself and to increase the delegation of inspections to states and localities. The Report notes that FDA should “fully consider” the implications of accepting inspection data from third-party auditors. If FDA intends to rely on these parties to inspect facilities for compliance with food safety regulatory requirements, the agency should set minimum standards for such auditors and audits, with oversight and implementation being assigned to an accreditation and standards body.

Improving Food Safety and Risk Communication
The committee recommends that FDA play a “leadership role” in coordinating the education of the food industry, the public, healthcare professionals, and public health officials at all levels of government. The Report further recommends that FDA continue its efforts to develop a single source of authoritative information on food safety practices, foodborne illnesses and risks, and crisis communications.

Modernizing Legislation
The committee states that Congress should consider amending the FDCA to provide explicitly and in detail the authorities that FDA needs to fulfill its food safety mission. The Report flags the following as the “most critical areas” in which Congress should enact amendments: (1) mandatory reregistration of food facilities and FDA authority to suspend registrations for violations that threaten the public health; (2) mandatory preventive controls for all food facilities; (3) FDA authority to issue enforceable performance standards; (4) mandatory adoption by FDA of a risk-based approach to inspection frequency and intensity; (5) expansion of FDA’s access to records; (6) FDA authority to mandate recalls; and (7) FDA authority to identify countries with inadequate food safety systems and to ban all imports from such countries.

Realizing the Vision of an Efficient Food Safety System
The committee recommends that FDA’s Office of Foods have complete authority over and responsibility for all field activities for FDA-regulated foods, including inspection, sampling, and testing. The Report further urges that the federal government move toward the establishment of a single food safety agency to unify the efforts of all agencies and departments with major responsibility for the safety of the U.S. food supply. It emphasizes the importance of an “integrated, unimpeded, and centralized approach to risk-based analysis and data management,” regardless of how the food safety system specifically evolves.

Covington & Burling LLP will closely monitor developments on this issue and would be pleased to answer questions regarding the potential impact of the Report’s recommendations on industry interests.
If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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