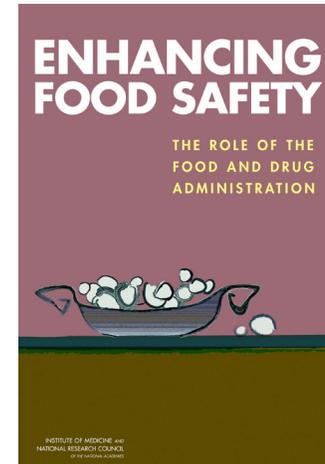


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Enhancing Food Safety

The Role of the Food and Drug Administration



In an increasingly complex world, there is a higher risk of foodborne disease. Approximately 76 million foodborne illnesses occur each year in the United States, causing more than 300,000 hospitalizations and 5,000 deaths. Foodborne diseases are caused by a variety of bacteria—such as *Escherichia coli* or *Salmonella*—viruses, parasites, or chemical residues. The severity of these diseases and the high rate of occurrence highlight the need to evaluate the current food safety system for its effectiveness at protecting the public's health. Providing safe food requires the effort of many partners. While food safety is regulated by several agencies, the U.S. Food and Drug Administration (FDA) oversees approximately 80 percent of the U.S. food supply, including all produce, seafood, and cheeses.

Food safety experts and the public have criticized the FDA's food safety system and questioned whether it properly safeguards Americans from foodborne diseases. Thus, Congress asked the Institute of Medicine (IOM) to examine the gaps in the current food safety system under the purview of the FDA and to identify the tools needed to improve food safety. Although the FDA recently created the Office of Foods to oversee and coordinate all food policy efforts within the agency, the FDA's approach to food safety continues to be reactive, lacking a systematic focus on prevention. The IOM committee's report, *Enhancing Food Safety: The Role of the Food and Drug Administration*, suggests that the FDA lacks a comprehensive vision for food safety and says it should change its approach in order to properly protect the nation's food.

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Adopting a Risk-Based Approach to Food Safety

While the committee commends the FDA for using some risk assessment and management tactics, it concludes that more changes need to take place. The agency should use a risk-based approach to evaluate food safety problems rather than its current reactive approach to food safety—which only addresses problems on a case-by-case basis and may fail to account for all the factors involved in making a decision. A risk-based approach allows decision makers to evaluate the system in a comprehensive way and to follow a systematic process for addressing and preventing problems. Components of a risk-based food safety system include:

- Strategic planning
- Public health risk ranking (ranking of hazards)
- Targeted information gathering (such as surveillance)
- Analyzing and selecting interventions
- Designing an intervention plan
- Monitoring and review

All levels of management should embrace this approach, and it should serve as the basis for food safety decision making, including, for example, prioritizing funding for surveillance and research. A risk-based approach is necessary to prevent the spread of foodborne illnesses and preserve the public's trust in the food safety system.

Implementing a Risk-Based Food Safety System

Training and hiring personnel with various expertise, such as risk management and analysis, is critical to implementing a risk-based system. Developing a comprehensive strategic plan that identifies public health goals and metrics to measure success is essential. In addition, the FDA should define the roles of all responsible parties,

including suppliers, farmers, retailers, consumers, and government agencies among others. The FDA also should develop a comprehensive, transparent strategy for choosing the level and intensity of policy interventions, which can range from setting standards to educating the public. If the FDA is going to continuously make improvements to public health, it needs to evaluate the effectiveness of these interventions and explore new interventions.

Importantly, a current shortcoming relates to the use of data, which drives the risk-based decision making approach. Currently, the FDA has limited analytical expertise and lacks the infrastructure to collect, analyze, interpret, manage, and share data, thus precluding the FDA from using data to support decision making. It is critical that the FDA evaluate its food safety data needs including surveillance, behavioral, economic, food production, and other data based on a risk approach. The FDA reports that sharing data among government agencies is difficult; therefore, the committee recommends that the FDA review the data sharing statutes and policies and develop plans to improve the sharing of data in a timelier manner by all federal, state, and local food safety agencies.

Integrating Food Safety Programs and Educating the Public

Food safety activities, such as inspections, surveillance, and outbreak investigations, are divided between the states and the federal government. The states are responsible for foods produced or sold within their borders and the federal government shares jurisdiction with the state and local governments for food transferred across state borders. However, these systems are not well integrated; a more integrated system would minimize duplication of food safety activities by leveraging the efforts of the state and local governments. In an effort to normalize and integrate food safety

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practices across the nation, the FDA should provide standards to states and localities and oversee their implementation.

Risk communication is an integral part of food safety management, especially during an emergency, when information needs to be conveyed clearly and in a timely fashion. The risk-based system will require integrating effective risk communication and food safety education. In order to accomplish this, the committee recommends that the FDA conduct research to improve its understanding of industry's, health professionals', and consumers' knowledge about food safety, paying particular attention to demographic groups that are most susceptible to food risks.

Enhancing the Efficiency of Inspections

The FDA's food safety inspection system—which monitors the way foods are manufactured, processed, packed, and stored—needs improvement. The inspection system is one area where the FDA could explore alternative regulatory approaches. The FDA's Office of Foods needs direct authority over the inspectors who work in the field, to minimize substantial delays in policy implementation that affect how inspections are conducted. Also, to increase efficiency, the FDA should streamline inspections to ensure that the amount of time and rigor used to inspect a facility is based on risks to the public's health and should set minimum

standards for the frequency and intensity of the inspections of all facilities. Since a number of food safety inspections already are conducted at the state and local levels, the committee recommends that, once their food safety programs and activities meet federal standards, the FDA conduct fewer inspections and instead delegate them to the states and localities. A small group of inspectors should remain within the FDA to audit inspections, provide specialty expertise, develop training material for inspectors, and conduct inspections in situations of special need.

Modernizing Legislation and Reorganizing the Food Safety System

The task of implementing a risk-based food safety system will not be easy. In order for the FDA to better ensure food safety, legislative and organizational changes are necessary. Most notably, Congress should consider taking legislative action to provide the FDA with the authority it needs to fulfill its food safety mission. Within the FDA, authority over field activities should shift from its Office of Regulatory Affairs to its Office of Foods. Such a change will ensure that responsibility lies with well-trained personnel with specialized expertise in food safety and risk-based principles of food safety management.

Recognizing that organizational reform will pose challenges, the committee recommends that



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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 safety of the U.S. food supply. The committee recommends establishing a centralized, risk-based analysis and data management center in order to improve efficiency and work toward a safer food supply. This center should include staff and support resources necessary to conduct rapid and sophisticated assessments of short- and long-term food safety risks and to ensure that the comprehensive data needs to support the risk-based system are met. This type of center will bring the FDA closer to establishing a single food safety agency.

Conclusion

Americans will continue to suffer from food illness, unless the FDA reevaluates their approach to food safety management. Shifting from a reactive approach to a risk-based approach allows the FDA to make decisions based on risk and prevent future foodborne disease, in turn protecting the public's health. Until the recommended changes are implemented, the FDA and the federal government will lack the process, capabilities, and structure needed to properly evaluate decisions that will ultimately ensure the safety of the nation's food. The recommendations in this report should provide a roadmap for the FDA to become more efficient and effective in carrying out its food safety mission in a rapidly changing world. 

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