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# FDA should adopt risk-based approach to food safety: report

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The U.S. Food and Drug Administration's abilities to discover potential threats to food safety and prevent outbreaks of foodborne illness are hampered by impediments to efficient use of its limited resources and a piecemeal approach to gathering and using information on risks, says a new report by the Institute of Medicine and National Research Council.

To more proactively tackle food safety problems, FDA should implement a risk-based approach in which data and expertise are marshaled to pinpoint where along the production, distribution, and handling chains there is the greatest potential for contamination and other problems, the report says. The agency would then be able to direct appropriate amounts of its resources and attention to those high-risk areas and increase the chances of catching problems before they turn into widespread outbreaks, said the committee that wrote the report.

The report offers FDA a blueprint for developing a risk-based model. It also outlines several organizational steps the agency should take to improve the efficiency of its many food safety activities, such as increasing coordination with state and other federal agencies that share responsibility for protecting the nation's food supply. In addition, the report says Congress should consider amending the Federal Food, Drug, and Cosmetic Act to explicitly provide the authority FDA needs to fulfill its food safety mission.

"As recent illnesses traced to produce underscore, foodborne diseases cause significant suffering, so it's imperative that our food safety system

functions effectively at all levels," said committee chair Robert Wallace, professor, College of Public Health, University of Iowa, Iowa City. "FDA uses some risk assessment and management tactics, but the agency's approach is too often reactive and lacks a systematic focus on prevention. Our report's recommendations aim to help FDA achieve a comprehensive vision for proactively protecting against threats to the nation's food supply."

FDA is responsible for ensuring the safety of approximately 80 percent of the nation's food supply, including seafood, dairy products, and fruits and vegetables. Although it is not the sole organization overseeing food safety -- the U.S. Department of Agriculture handles meat, poultry, and egg products, and state and local agencies share in conducting food production facility inspections, surveillance, and investigations of outbreaks -- recent outbreaks of foodborne illness led to a congressional request for a review of gaps in FDA's food safety system.

The agency has been criticized for not adequately monitoring and inspecting food suppliers and distributors and for not taking a proactive approach to food safety overall. However, given that FDA is responsible for more than 150,000 food facilities, more than 1 million restaurants and other retail food establishments, and more than 2 million farms, as well as millions of tons of imports, it lacks the resources to sufficiently monitor the entire food supply, the committee noted.

A risk-based approach would give FDA's food safety officials the strategic vision needed to evaluate and plan for food safety concerns rather than tackling problems on a case-by-case basis, the report says. Without good information, agency officials cannot identify where its resources are needed most or determine which policy interventions are most effective. FDA has insufficient analytical expertise and infrastructure to gather, manage, and use data effectively. The agency should identify its data needs and review its policies for sharing data

with other agencies and organizations.

The federal government should establish a centralized food safety data center outside of the regulatory agencies to collect information and conduct rapid, sophisticated assessments of food safety risks and appropriate policy interventions. This center would go a long way toward developing much-needed capacity and would reduce interagency competition for resources, the committee said. It could also serve as an intermediate step toward consolidating food safety activities within a single agency, which many individuals and organizations have called for.

To enhance its efficiency, FDA should explore alternative approaches to regulating food safety, such as delegating food facility inspections to the states, the report says. FDA should establish national standards for the intensity and frequency of these facility reviews and help states and local municipalities bring their safety programs up to those standards. Once all programs are standardized, FDA should train and certify state inspectors with the goal of turning over the majority of inspections to them under the agency's supervision. This change would build on current practices in which roughly 60 percent of inspections are already conducted by state inspectors under contract with FDA. This integration and leveraging of resources would increase the quality of inspections and eliminate duplication of effort, the committee said.

Despite the dramatic developments in food production and distribution that have occurred over the years, the main statutory provisions under which FDA carries out its food safety responsibilities remain largely unchanged. Although various provisions give the agency broad discretion and flexibility through which it has been able to control potential problems, there are instances in which FDA lacks specific authority, which can make its actions vulnerable to court challenge. Congress should examine how the legislation could be revised to detail FDA's authorities in facility registration, preventive controls, risk-based

inspection, mandatory recall, reporting of adulteration, and banning of food imports if the public's health is at risk, among other areas.

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