

A report to congressional requesters.

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What GAO Found

Since 2015, the Food and Drug Administration (FDA) has issued nine rules (regulations) that establish a framework for preventing foodborne illness under the FDA Food Safety Modernization Act (FSMA) enacted in 2011. Separately, FDA has completed most but not all requirements that GAO identified in the law.

The nine rules are significant because they help clarify the specific actions that industry must take at different points in the global supply chain to prevent contamination of human and animal food. For example, one rule sets standards for businesses that grow, harvest, pack, or hold fruits and vegetables. Another rule addresses hazards that could cause illness, death, or economic disruption of the U.S. food supply.

In addition to issuing the rules, FDA has completed 41 of 46 requirements GAO identified in FSMA. For example, FDA has issued guides that are intended to describe in plain language what businesses need to do to comply with rules, and conducted various studies FSMA required. The requirements FDA has not completed are to

- issue guidance on hazard analysis and preventive controls for human food;
- issue guidance to protect against the intentional adulteration, or tampering, of food;
- report on the progress of implementing a national food emergency response laboratory network;
- publish updated good agricultural practices for fruits and vegetables; and
- establish a system to improve FDA's capacity to track and trace food that is in the U.S.

FDA officials cited competing priorities and an October 2024 agency reorganization as reasons for not fully completing these requirements. In March 2025, FDA officials told GAO they intend to establish the system FSMA requires to help track and trace food by July 2028. However, they did not provide specific time frames for completing the other requirements. Doing so, and then taking action to complete them, would help ensure that industry and others have the information they need to effectively implement FSMA's preventive framework.

FDA's efforts to assess how the nine rules are helping to prevent foodborne illness have largely focused on monitoring industry compliance with three rules. This includes overseeing hazards that could affect food safety. However, FDA has not developed a performance management process to guide the agency's efforts to assess the results of the nine rules.

Key practices for federal performance management emphasize the need for agencies to define what they are trying to achieve, collect relevant information, and use that information to assess how well they are performing and identify how they could improve. FDA officials said the agency prioritized implementing the rules over assessing the results. But developing a performance management process would better position FDA to assess the results of the rules, with the ultimate goal of helping prevent foodborne illness.

Why GAO Did This Study

Each year, foodborne illnesses sicken millions of Americans and cause thousands of deaths. In 2011, Congress enacted FSMA, which shifted the focus of FDA's food safety program from reacting to, to preventing those illnesses. FDA helps ensure the safety of 80 percent of the U.S. food supply, including fruits and vegetables, processed foods, dairy products, and most seafood.

GAO was asked to review FDA's efforts to implement FSMA's preventive framework. This report examines the extent to which FDA has (1) issued rules and completed requirements included in selected sections of FSMA and (2) assessed how the rules are contributing to preventing foodborne illness.

GAO focused on sections of FSMA that provide a foundation for creating a modern, risk-based framework for food safety. GAO compared FDA's efforts with requirements in FSMA and key practices for federal performance management, which GAO developed based on federal laws, guidance, and past GAO work. GAO also interviewed agency officials and 17 selected stakeholders, representing industry associations, consumer advocacy groups, and state and local regulators.

What GAO Recommends

GAO is making seven recommendations, including that FDA take steps to complete requirements included in FSMA, such as issuing guidance, and develop and implement a performance management process to assess whether FDA's rules have helped prevent foodborne illness. The Department of Health and Human Services concurred with the recommendations.