

## Why GAO Did This Study

Numerous outbreaks of foodborne illnesses in past years continue to draw public attention to the safety of the nation's food supply. Prompt responses from government entities and the food industry can play a vital role in stopping the spread of illnesses and deaths, but unwarranted recalls of food products can trigger serious economic losses for the food industry. In response to congressional direction regarding the FDA Food Safety Modernization Act, GAO (1) examined government entities having the authority to order product recalls and how FDA implements its authority; (2) examined the challenges FDA faces, if any, in advising the public about food recalls or outbreaks of foodborne illness and how the agency has addressed these challenges; and (3) identified mechanisms that may compensate the food industry for erroneously ordered food recalls or erroneous food-related advisories. GAO reviewed documents from FDA and other government entities and FDA data and interviewed stakeholders from the food industry and consumer organizations, government officials, and experts in food safety or food law.

## What GAO Recommends

GAO recommends, among other things, that FDA issue regulations or industry guidance to clarify its ordered food recall process and implement recommendations from others to address FDA communication challenges in advising the public about food recalls and outbreaks. The agency neither agreed nor disagreed with GAO's recommendations but cited ongoing agency actions that are to address most recommendations.

View [GAO-12-589](#). For more information, contact Lisa Shames at (202) 512-3841 or [shamesl@gao.gov](mailto:shamesl@gao.gov).

## FOOD SAFETY

### FDA's Food Advisory and Recall Process Needs Strengthening

## What GAO Found

Several government entities, including federal agencies such as the Food and Drug Administration (FDA) and the Consumer Product Safety Commission, and some states such as Texas, have the authority to order product recalls. Generally, FDA is to follow the same process for implementing its food recall authority as other federal agencies use to order recalls of other products, including (1) determining that available evidence of a threat meets a standard of proof to order a recall, (2) offering a company the opportunity to voluntarily recall a product before a recall order is issued, and (3) providing the company with an opportunity to challenge a recall decision. FDA has internal procedures describing the steps it will take to order a food recall, although these procedures are not yet public and the agency has not issued regulations or industry guidance to clarify its ordered food recall process.

FDA faces a number of communication challenges when advising the public about food recalls or outbreaks of foodborne illness, ranging from balancing technical accuracy with timeliness of communications to coordinating messages with other agencies to meeting the needs of diverse public audiences. The agency has taken steps to begin meeting these challenges but has yet to fully address recommendations from GAO and others to fashion a comprehensive food recall communication policy and related implementation plans. Specifically, FDA has not (1) adopted a recommendation from its Advisory Committee on Risk Communication to create a policy for emerging events to more comprehensively address several of its communication challenges; (2) created plans recommended by the Institute of Medicine and National Research Council to help address coordination challenges surrounding its communications; or (3) fully implemented a recommendation from GAO's past work to determine jointly with the Department of Agriculture what, if any, additional approaches are needed for advising consumers about recalls. When GAO asked FDA officials how they had responded to these recommendations, they provided information on some actions they are taking. However, FDA's stated actions do not fully implement these recommendations. As a result of not implementing them, FDA may be missing opportunities to more comprehensively address its communications challenges.

Various government mechanisms—each with advantages and disadvantages described by individuals GAO interviewed—might be available to compensate food producers in case of an erroneously ordered food recall or erroneous food-related advisory, but GAO found no examples of such mechanisms that have been used to provide compensation. The mechanisms include a dedicated federal government program or federal government-subsidized insurance, among others. For example, individuals GAO interviewed said that a potential advantage of a dedicated program would be assurance to industry that a mechanism would be available, but a potential disadvantage may be that in lean budget times, funding for such a program may be difficult to obtain. Individuals GAO interviewed identified several factors that may come into play when deciding to establish any compensation mechanism, such as defining what constitutes an error or mitigating the potential for unintended consequences.