

GAO Highlights

Highlights of [GAO-16-425](#), a report to the Committee on Health, Education, Labor, and Pensions, U.S. Senate

Why GAO Did This Study

The safety and quality of the U.S. food supply are governed by a complex system involving more than 3,000 federal as well as nonfederal agencies at the state, local, tribal, and territorial levels. In 2011, FSMA mandated that FDA take steps that would better integrate its food safety oversight with that of nonfederal agencies. These steps relate to three new FSMA-mandated rules on produce, human food, and animal food. Among other things, FSMA required FDA to coordinate with nonfederal agencies in the areas of rule development, rule implementation, and regulator training.

GAO was asked to review FDA's coordination with nonfederal agencies on food safety, particularly in relation to FSMA. This report examines—for the rules on produce, human food, and animal food—the extent to which FDA has (1) met its regulatory consultation responsibilities in developing the rules, (2) developed plans to coordinate implementation of the rules, and (3) developed and administered plans for training regulators on the rules. GAO reviewed documentation; analyzed comments from nonfederal agencies on FDA rulemaking; and interviewed officials from FDA, associations of nonfederal officials, and industry, public interest, and other groups.

What GAO Recommends

GAO recommends that FDA (1) make certain that its tribal consultation policy explicitly provides for early tribal consultation and (2) develop a timetable for finalizing the policy. GAO provided a draft of this report to FDA. FDA agreed with these recommendations.

View [GAO-16-425](#). For more information, contact Steve D. Morris at (202) 512-3841 or morris@gao.gov.

May 2016

FOOD SAFETY

FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed

What GAO Found

The Food and Drug Administration (FDA) took numerous steps to ensure meaningful and timely input from nonfederal officials during development of the FDA Food Safety Modernization Act (FSMA)-mandated rules on produce, human food, and animal food but did not fully meet its tribal consultation responsibilities. Among other things, FDA—an agency within the Department of Health and Human Services (HHS)—held 13 public meetings and offered extended comment periods on the rules. However, FDA did not consult with Indian tribes before publication of the proposed rules, as directed by the HHS tribal consultation policy. Under that policy, each HHS agency is to establish its own tribal consultation policy, which should include an accountable process to ensure meaningful and timely input by tribal officials. FDA has begun to develop such a policy and issued a draft in late February 2016. FDA's draft policy, however, does not explicitly provide for early consultation on all rules with tribal implications. Without early consultation, tribes are unable to provide input at a time when it is most likely to have a meaningful impact on FDA's decision making. Moreover, FDA has not established a timetable to guide the policy's finalization, without which FDA risks continued delays.

FDA has begun to develop plans to ensure compliance with the FSMA-mandated rules through coordinated implementation with nonfederal agencies and is working to overcome related challenges. For example, according to FDA, insufficient data exist on businesses subject to the rules, making it difficult to assign inspection responsibilities, among other things. In response, FDA is taking steps, such as exploring new data sources. In addition, associations of nonfederal officials that GAO interviewed stated that nonfederal agencies have varying legal authorities and regulatory structures. For example, they stated that most nonfederal agencies lack authority to oversee produce, which is needed for coordinated implementation. In response, FDA is taking steps such as funding the National Association of State Departments of Agriculture's development of a model produce rule that states can adopt. Associations suggested that FDA consider opportunities to improve coordinated implementation, including establishing a system to share information on industry compliance and a process to answer questions from regulators on the rules. According to FDA, it is taking steps to implement these and other suggestions. For example, FDA is developing a new system to allow regulators to access information housed in existing FDA information systems before, during, and after an inspection.

FDA has developed, and begun to administer, a plan for training regulators on the human and animal food rules. As of February 2016, FDA had begun to develop, but not to administer, a plan for training regulators on the produce rule. FDA is working to overcome challenges related to regulator training. For example, one challenge relates to the thousands of regulators who must be trained. FDA plans to, among other things, use a phased training strategy, administering training in 2016 to regulators in areas with the highest concentrations of large businesses, for which compliance is due first; in 2017 to regulators in areas with the highest concentrations of small businesses, for which compliance is due later; and in 2018 to regulators in areas with the highest concentrations of very small businesses, for which compliance is due last.