

IN FOCUS

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Proposed Reorganization of U.S. Federal Food Safety Agencies

The Trump Administration is proposing to consolidate the federal government's primary food safety functions into a single federal agency based in the U.S. Department of Agriculture (USDA). This proposal is part of its broader effort to reorganize the U.S. federal government under its reform plan and reorganization proposals released in June 2018. Some in Congress—and also previous Administrations—have long pursued similar efforts to consolidate U.S. federal food safety functions.

Organization of the Food Safety System

Numerous federal, state, and local agencies share responsibilities for regulating the safety of the U.S. food supply. Federal responsibility for food safety rests primarily with USDA and the Food and Drug Administration (FDA). FDA, an agency of the Department of Health and Human Services (HHS), is responsible for ensuring the safety of all domestic and imported foods except meat and poultry. USDA's Food Safety and Inspection Service (FSIS) regulates meat, poultry, some egg products, and catfish.

At FDA, the Center for Food Safety and Applied Nutrition (CFSAN) oversees the safety of food and cosmetic products. CFSAN's primary responsibilities include the safety of most foods, food additives, infant formulas, medical foods, dietary supplements, and foods and ingredients developed through biotechnology; programs addressing health risks associated with foodborne, chemical, and biological contaminants; and food and nutrition labeling. CFSAN also collaborates with FDA's Office of Regulatory Affairs to conduct field activities, including facility inspections. FDA's authority extends beyond foods to also include pharmaceutical drugs, medical devices, biologics, animal drugs and feeds, veterinary devices, radiation-emitting products, and tobacco.

At USDA, FSIS conducts continual inspection at federally inspected facilities that slaughter meat and poultry. In these inspections, FSIS ensures that state inspection standards are at least equivalent to federal standards and that imported meat and poultry products are produced under standards equivalent to U.S. inspection standards. Other USDA agencies also play a role in U.S. food safety oversight. For example, USDA's Animal and Plant Health Inspection Service oversees animal and plant health, including preventing the introduction of foreign diseases and pests. USDA's Agricultural Marketing Service establishes quality and marketing grades and standards for a range of agricultural products. USDA's research agencies are also involved in food safety, providing federal funding and collaborating with universities and research institutions.

The first **text box** summarizes the primary U.S. food safety laws governing FDA and FSIS. The laws listed are among roughly 30 related to food safety, according to Government Accountability Office (GAO) estimates. GAO has also identified up to 15 federal agencies, including FDA and FSIS, as collectively responsible for ensuring the safety of food produced and sold in the United States. State and local food safety authorities collaborate with federal agencies on inspection and other food safety functions.

Primary U.S. Food Safety Laws

HHS's Food and Drug Administration (FDA)

- Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. §§341 et seq.), as amended by the FDA Food Safety Modernization Act (FSMA, 21 U.S.C. §§2201 et seq.)
- Fair Packaging and Labeling Act (15 U.S.C. §1454)
- Public Health Service Act (42 U.S.C. §§201 et seq.)
- Federal Import Milk Act (21 U.S.C. §§141-149)
- Federal Anti-Tampering Act (18 U.S.C. §1365)
- Pesticide Monitoring Improvements Act (21 U.S.C. §1401)

USDA's Food Safety and Inspection Service (FSIS)

- Federal Meat Inspection Act (FMIA, 21 U.S.C. §§601 et seq.)
- Poultry Products Inspection Act (PPIA, 21 U.S.C. §§451 et seq.)
- Egg Products Inspection Act (EPIA, 21 U.S.C. §§1031 et seq.)
- Agriculture Marketing Act (7 U.S.C. §§1621 et seq.)

Source: CRS Report RS22600, The Federal Food Safety System: A Primer.

Proposed Food Safety Reorganization

The Trump Administration's proposal to reorganize the U.S. federal government includes a proposal to consolidate FSIS and FDA's food safety functions into a single "Federal Food Safety Agency" to be housed at USDA. According to the Administration, this effort would address a "fragmented and illogical division of federal oversight" and would "merge approximately 5,000 full-time equivalent (FTE) employees and \$1.3 billion from FDA with about 9,200 FTEs and \$1 billion in resources in USDA." FDA would be renamed the "Federal Drug Administration" and its focus would be on drugs, devices, biologics, tobacco, dietary supplements, and cosmetics.

To the extent a reorganization would transfer an agency or entity vested by law in a particular department to a different department, additional legislation might be needed. These food safety laws specifically delegate authority to HHS in the case of FFDCA and FSMA and to USDA in the case of the FMIA, PPIA, and EPIA.

Previous Reorganization Efforts

The organization of the U.S. food safety system has been debated on and off since FDA was removed from USDA in the 1940s. Since then, a number of congressional and executive branch initiatives have raised the prospect of creating a single federal food safety agency. For example, in 1949, a presidential commission under the Truman Administration proposed transferring federal food safety activities to USDA. Years later, Congress passed the Wholesome Meat Act of 1967 and the Wholesome Poultry Products Act of 1968, substantially restructuring U.S. meat and poultry products inspection. Also during this time, a 1969 *White House Conference on Food, Nutrition and Health* report highlighted the divergence in food safety policy between USDA and the Department of Health, Education, and Welfare (which later became HHS), where FDA resided at that time. In the following years, there were a series of reports and congressional hearings adding to the debate over a single food safety agency. For example, in 1977, the Senate Committee on Governmental Affairs conducted its *Study on Federal Regulation*, recommending that USDA's food safety functions be transferred to FDA.

Committee Jurisdiction for Food Safety Issues

House: The Committee on Energy and Commerce claims general jurisdiction over all FDA-regulated products, including foods. The Committee on Agriculture asserts jurisdiction over USDA's inspection programs.

Senate: The Committee on Health, Education, Labor, and Pensions claims jurisdiction over all FDA-regulated products, including foods. The Committee on Agriculture, Nutrition, and Forestry asserts jurisdiction over USDA's inspection programs.

Congressional Appropriations Committees: The Agriculture subcommittees are responsible for funding and oversight of both FDA and USDA in the House and Senate.

Recent Congressional Efforts

Some in Congress have advocated for reforms to the nation's food safety system, particularly with respect to coordination and organization among federal agencies. Efforts to establish a single food safety agency were active from the 103rd Congress through the 111th Congress.

Although Congress passed comprehensive food safety legislation in 2010 (FSMA, P.L. 111-353)—representing the largest expansion and overhaul of FDA's food safety authorities since the 1930s—FSMA did not alter the existing food safety jurisdiction between FDA and USDA. While FSMA was being debated, however, Congress did consider options to reorganize and consolidate certain federal food safety functions. For example, in the 111th Congress, H.R. 875 (Food Safety Modernization Act of 2009) included provisions to consolidate certain food safety functions into a single federal agency, the Food Safety Administration, to be housed within HHS.

Following FSMA's enactment, some in Congress continued to be interested in establishing a single federal food safety agency. In the 114th Congress, the Safe Food Act of 2015 (H.R. 609/S. 287) proposed creating a single independent Food Safety Administration, which would be responsible for regulating food safety and related labeling, inspection, enforcement, and research functions of both domestically produced and imported foods. H.R. 609/S. 287 proposed transferring and consolidating the food safety authorities at FDA and USDA as well as portions of the National Marine Fisheries Service at Department of Commerce.

Recent Administration Efforts

The Obama Administration proposed to establish a single federal food agency as part of its FY2016 budget request, claiming that a single food safety agency would "provide focused, centralized leadership, a primary voice on food safety standards, and clear lines of responsibility and accountability that will enhance both prevention of and responses to outbreaks of foodborne illnesses." The proposal would not have created a new independent agency but would have instead transferred existing food safety functions into a new agency within HHS. The proposal was not included in the enacted appropriation.

Views Expressed by Outside Groups

Establishing a single food agency has the support of GAO and the National Academies of Sciences, Engineering, and Medicine and others within academia, as documented in myriad studies and reports. GAO's reports on food safety have regularly highlighted that the U.S. food safety system is fragmented across different departments and agencies that have overlapping responsibilities and that a single food safety agency would improve effectiveness and efficiency of food safety regulation.

While some view consolidation as a way to improve efficiency and effectiveness, others worry that it could unnecessarily compromise day-to-day food safety efforts. Some food safety advocates claim that USDA's principal purpose is supporting agribusiness and that food safety regulation and promotion should remain separate. Some also raise concerns about merging two agencies with distinctly different authorities, inspection regimes, and cultures. Others say it is unclear what this would mean for ongoing FSMA implementation at FDA and for both domestic and international food producers affected by the law's regulations. Others assert that any federal overhaul would be complex and costly, given the sheer number of federal agencies and different statutes involved, and could create new forms of fragmentation. Some also anticipate resistance by congressional committees that cover different agency jurisdiction, powers, and expertise. (Authorizing committees are identified in the second text box.)

Most consumer advocacy groups have opposed consolidating food safety operations within HHS, claiming that HHS does not have the necessary expertise or adequate resources to manage an expanded food safety function. Others point to differing legal authorities and inspection approaches. Others have claimed that USDA has a better record regarding food safety inspection and enforcement and worry that transferring these functions to HHS will lower meat and poultry inspection standards.

Creating a single food safety agency housed at USDA often raises concerns about the complexity of FDA's oversight authorities, which cover not only foods and beverages but other food-related responsibilities (e.g., safety of additives, biotechnology) and products. For example, under current law, dietary supplements are regulated as part of FDA's food safety responsibilities. The Trump Administration's proposal would keep supplements within the purview of the renamed "Federal Drug Administration," which is opposed by many within the industry.

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