

---

# The Trump Administration's Proposal to Reorganize the FDA

By Michael A. Walsh / Jun 25, 2018

The Trump Administration is [proposing](#) for the Food and Drug Administration (FDA) to get a makeover by removing food safety from FDA oversight and reorganizing all food safety functions into a single agency at the United State Department of Agriculture (USDA). According to the Government Office of Management and Budget (OMB)

Reorganization is one tool among many that this Administration is using to drive transformational change in Government. Meeting the needs of the American people, as well as the President's mandate for greater efficiency, effectiveness, and accountability, requires a range of transformational approaches to support reorganization.

For decades, the FDA and USDA have coordinated oversight of certain food safety requirements for areas where they have overlapping concurrent jurisdiction through a Memorandum of Understanding (MOU) and, more recently, a [formal agreement](#). In entering into the formal agreement in January 2018, Agriculture Secretary Perdue stated:

"Today, Commissioner Gottlieb and I signed a formal agreement to promote coordination and the streamlining of capacities and obligations on shared concerns and jurisdiction... Congress passed the Food Safety Modernization Act and assigned responsibilities to the USDA and the FDA. The USDA has the knowledge and expertise to support the FDA's work related to farming. We at the USDA have a motto: Do Right, and Feed Everyone. We believe this joint effort will help us move one step closer to that goal."

Notwithstanding the current coordination among the agencies, according to the OMB, for more than forty years federal oversight of food safety has been fragmented within different agencies resulting in "inconsistent oversight, ineffective coordination, and inefficient use of resources." As a result, food safety was elevated on OMB's list of high-risk issues in 2007 and now the OMB is recommending doing something about it.

For those who have wrestled with understanding where the FDA oversight ends and the USDA begins, OMB recites a familiar and convincing argument for taking action:

For example: while FSIS/[USDA] has regulatory responsibility for the safety of liquid eggs, FDA has regulatory responsibility for the safety of eggs while they are inside of their shells; FDA regulates cheese pizza, but if there is pepperoni on top, it falls under the jurisdiction of FSIS/[USDA]; FDA regulates closed-faced meat sandwiches, while FSIS/[USDA] regulates open-faced meat sandwiches.

The OMB proposal hopes to end oversight fragmentation and to house all of food safety in a newly minted "Federal Food Safety Agency." OMB summarizes the proposed reorganization as follows:

This proposal would address the current fragmented Federal oversight of food safety by reorganizing the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and the food safety functions of the U.S. Department of Health and Human Services' U.S. Food and Drug Administration (FDA) into a single agency within USDA. USDA demonstrates strong and effective leadership in food safety and maintains an expert understanding of food safety issues from the farm to the fork. This proposal would cover virtually all the foods Americans eat.

The FDA and USDA function in separate departments in the executive branch. Currently, the FDA is an office under the Department of Health and Human Services, which would be renamed under the proposal to the Department of Health and Public Welfare. The FDA currently oversees a number of Centers which regulate different industries under FDA's jurisdictional mandate. The Center which is largely responsible for oversight of food is the Center for Food Safety and Applied Nutrition (CFSAN) which is under the Office of Foods and Veterinary Medicine in the Office of the Commissioner of the FDA. There is logic to the reassignment of food safety under USDA, which is well equipped to tackle the oversight demanded under the new FSMA regime.

While there is no expectation that the Trump Administration's reorganization proposal will happen anytime soon, the good news for industry is that fully integrating USDA/FSIS with the food safety functions of FDA may bring a clearer set of rules and reliable oversight. Integration will not be easy and will require harmonization of a number of underlying legislative authorities and regulatory approaches, and reorganization would demand significant expertise and resources. Nonetheless, in this regard, the OMB stated

USDA is well poised to house the Federal Food Safety Agency. USDA is a strong leader in food safety; has a thorough understanding of food safety risks and issues all along the farm to fork continuum; and many agencies within USDA focus on food safety. *Id* at 34

If food is dropped from the FDA, the new FDA would be known as the "Federal Drug Administration" and would focus on drugs, devices, biologics, tobacco, dietary supplements and cosmetics. *Id* at 34. Among the unanswered questions is how extensive a new FDA's oversight of food ingredients and labeling would be and not all food will travel over to the USDA under the proposal. For example, even though dietary supplements are regulated as food, they would not travel over to USDA to be overseen as food. The FDA retention of dietary supplements would make sense because dietary supplements are more closely related to drugs than food in form, dosages (i.e. servings) and labeling, and manufacturing oversight more closely aligns with the oversight of the CDER than that of CFSAN. Nonetheless, dietary supplements are comprised of food and purported nutritional ingredients, and we may have OMB back in a few years suggesting that a pomegranate drink is regulated by the new Federal Food Safety Agency while the same drink with added caffeine is regulated by the FDA.

---

What would reorganization mean for the food industry?

For those currently under the oversight of the USDA, it will mean little to nothing. But for entities accustomed to FDA level oversight, a new day is dawning. When congress enacted the Food Safety Modernization Act (FSMA) in 2011 the then FDA Commissioner, and virtually every senior FDA official since, described FSMA as a paradigm shift. What they meant by “paradigm shift” is that instead of focusing on responding to incidents and outbreaks, FSMA put a burden on industry to prevent incidents and outbreaks. This means that manufacturers have compliance obligations and potential liability for the non-compliance of their suppliers irrespective of whether there is an incident or outbreak.

While the true potential impact of FSMA's paradigm shift has not come close to realization, internationally industry has largely shrugged off FSMA's massive new requirements. The food industry was not prepared to digest the full impact of FSMA and neither was the FDA. In fact, from the time of FSMA's passage, FDA has been ill-funded and ill-prepared to issue required enabling regulations. From the beginning, FDA failed to meet the deadlines set by Congress to create the regulations implementing FSMA. The FDA has been catching up and the regulations currently comprise more than 4,000 pages, and that is not counting the mountainous regulatory guidance. Fortunately for industry, the FDA is methodically and painstakingly creating a navigable passage to understand what is required and how to comply. Nonetheless, FDA does not have the resources to enforce these massive new regulations and is increasingly looking to the USDA and state health and food safety authorities to implement this paradigm shift.

Since the enactment of FSMA and creation of its implementing regulations, many have written and lectured that the new requirements are massive and will require a FTE who understands and ensures compliance with the regime. As the regulators continue to work to streamline compliance and enforcement, it is only a matter of time before enforcement gets underway in earnest. There is no doubt that the largest food industry companies have complied. But those companies who have not heeded the cries of a looming compliance and enforcement paradigm shift, the time to do so is now.