# Washington Report


## Removing 'Food' From FDA

Amid budget wrangling, lawmakers and White House envision a new agency for food safety | BY **TED AGRES**

The Obama administration's recent proposal to remove food safety-related components from FDA and USDA's Food Safety and Inspection Service (FSIS) and consolidate them into a single new agency is unlikely to gain traction anytime soon, experts say. The proposal is included in FDA's Fiscal 2016 budget request, which seeks $1.3 billion in appropriated federal funds for food safety activities beginning Oct. 1, 2015 (a 9 percent increase of $109.5 million) and $206.2 million from food industry user fees ($191.8 million of it new). The net food safety increase would come to about $301.2 million, 25 percent more than at present.

The proposed new food safety agency would, like FDA, remain situated within the Department of Health and Human Services (HHS), which also houses the CDC and other public health agencies. (USDA is an independent agency and not part of HHS.) The proposed agency would have primary responsibility for food safety inspections, enforcement, applied research, and outbreak response and mitigation.

"The new agency would be charged with pursuing a modern, science-based food safety regulatory regime drawing on best practices of both agencies," the White House said in a budget document. It would also serve as the central point for coordinating with state and local agencies and would "rationalize the food safety regulatory regime and allow the federal government to better allocate resources and responsibilities."

While details have not been revealed, the concept has drawn mixed reactions from food industry experts, trade associations, lawmakers, and consumer groups. Some call it a good idea, but challenging to implement; others think it should be abandoned; and still others applaud the concept, but say it doesn't go far enough.

"The concept of a single food agency has been wrestled with for decades. People want greater efficiencies and would like to have more clarity in the food inspection process," says Craig W. Henry, PhD, vice president of business development for the Americas, Decernis LLC. "There are good reasons why a single food agency should happen, but there are a multitude of reasons why it would be very, very difficult to execute," he tells *Food Quality & Safety* magazine.

There are, for example, political turf issues at FDA and USDA. Other concerns include possible budget cuts, job losses, and funding reductions to the states. Pending Food Safety Modernization Act (FSMA) regulations will likely need to be addressed because they specify what are likely to become outdated regulatory and inspection processes. "It will be a pain both domestically and for everybody around the world," Dr. Henry says.

David Acheson, MD, founder and CEO of The Acheson Group and a former FDA associate commissioner for foods, supports the idea of a single agency. "But you would need a group of people to sit down and figure out what it might look like and how to structure it effectively," he adds.

### Pizza the Poster Child

FDA has the lion's share of responsibility for food safety, overseeing about 80 percent of the nation's food products including produce, most seafood, dairy products, and shell eggs. FSIS oversees meat, poultry, processed eggs, and catfish. FSIS inspects manufacturers of packaged open-face meat or poultry sandwiches, while FDA inspects manufacturers of closed-face meat or poultry sandwiches. Manufactured frozen pizza has become the poster child of this fragmentation: A cheese pizza and its ingredients are regulated by FDA, but a pepperoni pizza is regulated by both agencies. The agencies differ in their inspection protocols: USDA inspectors are stationed at nearly every U.S. slaughterhouse, while FDA rarely inspects a facility unless a problem is reported or suspected. At ports of entry, FDA inspectors scrutinize less than 2 percent of shipments due to the sheer volume of imports.

This fragmented nature of the U.S. food safety system "has caused inconsistent oversight, ineffective coordination, and inefficient use of resources," concludes a recent report by the Government Accountability Office, the investigative arm of Congress. At least 30 laws related to food safety are administered by 15 federal agencies led by FDA and FSIS, but also involving the Environmental Protection Agency (pesticides and crops) and the National Oceanic and Atmospheric Administration (Seafood Inspection Program). While FDA and USDA coordinate some activities, "existing mech-

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anisms focus on specific issues and none provides for broad-based, centralized collaboration," the report says.

"I think it's a discussion worth having in terms of how we can best align the different components of government that are involved in food safety and what kind of an organizational structure would be necessary to best support that," outgoing FDA commissioner Margaret A. Hamburg, MD, told a House Appropriations subcommittee in March. Agriculture Secretary Tom Vilsack said Congress needs to give the Obama administration authority to reorganize the agencies. "This is a new way of thinking. The point of this is to get this [reorganization proposal] on the table so people can have a conversation about it," Vilsak told reporters at a USDA budget briefing in February.

But Senate Agriculture Committee Chairman Pat Roberts, R-KS, signaled early opposition. "In this tough economy, the last thing producers and consumers need is more red tape," Roberts said in a statement. Many agricultural and food industry groups have also expressed concern over the administration's proposal. Western Growers, an association representing half of the U.S. produce industry, believes the reorganization would pose a "major distraction" because key FSMA regulations are still being finalized. Similar sentiments were expressed by the National Milk Producers Federation and the National Cattleman's Beef Association.

On the other hand, many consumer advocacy groups support the consolidation effort. "Our current food systems are redundant and fragmented," says National Consumers League executive director Sally Greenberg. The administration's proposal to consolidate the responsibilities of FSIS and FDA "will ensure cohesive practices and superior response times in the event of an outbreak, ultimately keeping consumers and our food supply safer," she says.

But other groups think the proposal doesn't go far enough, and support the creation of an independent agency. HHS is a massive organization, says Christopher Waldrop, director of the Food Policy Institute at Consumer Federation of America. "A new food safety agency would be lost among the other priorities of the department, and would likely not receive the recognition or resources necessary for it to be effective," Waldrop says. And because FDA is also implementing FSMA, consolidation efforts "would seriously undermine FDA's implementation activities and hamper efforts to prevent consumers from becoming sick from contaminated food," he adds, supporting the establishment of a new independent food safety agency.

Along these lines, Democratic lawmakers Rep. Rosa DeLauro of Connecticut and Sen. Richard Durbin of Illinois have reintroduced legislation that would remove the food safety inspections, enforcement, labeling, and research responsibilities from FDA and USDA and merge them into a new independent agency to be called the Food Safety Administration. The lawmakers introduced the Safe Food Act of 2015 in the House (HR-609) and Senate (S-287) in January. The 90-page bill mirrors legislation that DeLauro and Durbin introduced four times previously in 1999, 2004, 2005, and 2007.

The Food Safety Administration would also have authority for mandatory recall of unsafe food; require risk assessments and preventive control plans to reduce adulteration; authorize enforcement actions to strengthen contaminant performance standards; improve foreign food import inspections; and require full food traceability to better identify sources of outbreaks.

As of publication time, the bill has attracted only 11 cosponsors in the House and three in the Senate—all of them Democrats—and is considered unlikely to gain traction this time around. "The bill was not written in a way to allow it to move forward," Dr. Acheson says. "It includes little detail on how the transfer and consolidation would work. In fact, details are turned over to an administrator to determine within 180 days after enactment. There is just no way this will happen and the resulting product be well thought out and practical," says Dr. Acheson. DeLauro and Durbin also support the Obama administration's HHS consolidation approach as being a step in the right direction.

## Budget Wrangling Begins

FDA's overall Fiscal 2016 budget request totals $4.9 billion, a 9 percent increase. "This is the largest FDA request in recent history. [It] will be tough to swallow," said House Appropriations Committee chairman Rep. Hal Rogers (R-KY) during an FDA budget hearing in March. Dr. Hamburg told him that not getting the requested funding will result in fragmented food safety efforts. "We do need real money to get the job done. If we make this investment, it will benefit all," she said.

Of the agency's $109.5 million requested increase for food safety, $32 million would go to build a national integrated food safety system. This includes grants and cooperative agreements for additional facility inspection training for about 1,000 state and local inspectors, especially to implement the new preventive controls rules in late 2016. An additional $25 million would go to train a cadre of more than 2,000 existing FDA inspectors, compliance officers, and other food safety staff. Yet another $25.5 million would be used to implement the Foreign Supplier Verification Program, including training of more than 400 current investigative and compliance personnel and the hiring of more staff.

"Why do we need this money? Because a lot of work must be done right now to ensure that the FSMA rules are implemented smoothly and effectively in late 2016 and 2017," said Michael R. Taylor, JD, FDA deputy commissioner for foods and veterinary medicine. "The bottom line is that without investment now, and sustained funding afterwards, there is the risk that the implementation of FSMA will be uneven or even delayed. This would be bad for everyone, including those who must meet the new standards and those who must enforce them," Taylor said in an online posting.

A significant portion of FDA's new funding would come from food industry user fees (increasing from $14.4 million to $206.2 million). These include a food facility registration and inspection fee to fund agency activities related to FSMA, and a food import fee. While drug and medical device manufacturers pay FDA user fees, they receive expedited product reviews in exchange. The food industry generally opposes user fees and Congress has consistently refused to appropriate them. A group of about 60 food industry associations signed a letter in February to leaders of the House and Senate appropriations committees urging lawmakers to appropriate all of FDA's funding and not saddle industry with additional burdens. ■

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