

# The ‘Teeth’ of FDA’s Food Safety Law

**T**he Food Safety Modernization Act (FSMA), signed into law by President Obama in January, has been called “historic” because it puts the focus of the Food and Drug Administration (FDA) on prevention—working to ensure that unsafe foods are not distributed in the first place.

FDA Commissioner Margaret A. Hamburg says the law directs the agency to oversee food safety in a way that applies “the best available science and good common sense to prevent the problems that can make people sick.”

What lends the new law additional importance is that it provides FDA with new enforcement and inspection authorities.

“These new authorities are critical for the law’s success,” said Michael R. Taylor, FDA’s deputy commissioner for foods. “They give the food companies strong additional incentives for keeping their products safe, and that helps us achieve the new law’s goal, which is to protect consumers from unsafe food.”

Foodborne outbreaks are a significant public health burden that increases the cost of the nation’s health care and, as Taylor has emphasized, many of them can be prevented. And keeping foodborne outbreaks from



**FDA has new authorities to inspect food-producing facilities and enforce safeguards mandated by the Food Safety Modernization Act.**

happening in the first place is what FDA intends to do by implementing the following key provisions:

### Preventive Measures

- **Expanded administrative detention:** The law gives FDA more authority to prevent the release into the marketplace of adulterated or misbranded food, including potentially harmful food.

Food adulteration can be caused by many factors, including bacterial or chemical contamination, filth or decomposition, the presence of an unsafe food additive, being prepared, packed or held under insanitary conditions, and leaving valuable materials out of the product or substituting other, inferior materials.

Misbranding food can be caused by ways that include not declaring certain ingredients or major food allergens, and not complying with nutrition information content on labeling.

This tool allows FDA to effectively remove the food from distribution channels while the agency pursues legal or other enforcement actions.

- **Records inspection:** The law expands FDA's authority to gain access to records about potentially hazardous foods. In addition to examining the records tied to a particular food that could pose a health hazard, the agency can now inspect records related to any other food it believes is likely to be affected in a similar manner.
- **Authority to deny entry:** Under FSMA, if a food producer in another country does not permit FDA to inspect its facility, FDA can refuse to allow food from that facility into the United States.

### Enforcement Measures

The new law also strengthens FDA's enforcement tools in the event that potentially unsafe food has already

entered the marketplace.

- **Suspension of registration:** The law authorizes FDA to suspend the registration of a facility under certain circumstances if the food it manufactured, processed, packed, received or held presents a serious health hazard. A facility with a suspended registration will not be able to legally offer food for sale in the United States until FDA lifts the suspension.

- **Mandatory recall:** Before FSMA, FDA had to rely on a firm's voluntary decision to remove food from the marketplace that could be hazardous to humans or animals. Under the new law, the agency can order a recall if the company does not cease distribution itself and recall its product. If there is reason to believe that the food is adulterated or misbranded and that use of the product could result in serious illness or death, FDA can order that distribution be halted and all implicated products recalled. Additionally, FDA has launched a new search engine ([www.fda.gov/Safety/Recalls](http://www.fda.gov/Safety/Recalls)) where consumers can quickly and easily check on new and recent recalls.

FDA is also directed by the law to upgrade its ability to track both domestic and imported foods. To do this, FDA will establish pilot projects to test how to rapidly identify recipients of food—this is critical information FDA needs to rapidly find the source of a foodborne outbreak and to understand its scope.

"Product tracing doesn't prevent an outbreak, as it's more about response," says Bill Correll at FDA's Center for Food Safety and Applied Nutrition. "However, it can prevent further illnesses during an outbreak when FDA can determine the source, contain further exposure and get the product recalled and out of distribution and consumer households."

### Positive Feedback

The new FDA authorities have been widely acclaimed by consumer advocates as well as industry.

Caroline Smith DeWaal, the veteran food safety director of the Center for Science in the Public Interest, has hailed FSMA as a far-reaching improvement over previous food safety laws. "The bill contains important provisions for prevention, standard setting and enhanced enforcement. It will significantly reinforce the FDA's food safety program," she predicts, "and help the agency advance in its public health mission."

Kathy Means, vice president of the Produce Marketing Association, said that members of her organization "regard FSMA as a law that takes a good, comprehensive look at food safety. It sets the expectations for food safety measures by the industry, and it sets the priorities for the FDA—all of which is important for keeping our food safe."

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