FDA Meeting FSMA Food Safety Goals

Six months after President Obama signed the landmark FDA Food Safety Modernization Act (FSMA) into law, the Food and Drug Administration continues to move forward in its efforts to protect the nation's food supply.

According to the Centers for Disease Control and Prevention, 48 million Americans get sick and 3,000 die each year from foodborne diseases. A recent outbreak of a virulent strain of *E.coli* in Europe, which killed dozens of people and made thousands sick, has raised new concerns about food safety here.

But the food safety act gave FDA a mandate to implement a system that is based on science and addresses food safety hazards from farm to table. The agency has already strengthened a number of protections, including making it easier for consumers to learn about recalled foods and providing safety guidelines for commercial fisherman and fish processors.

After the legislation became law, FDA had 180 days—on or before July 3—to meet other specific goals. And, in accordance with that deadline, the agency has taken two new actions, one to prevent the smuggling of food into this country, and another to make sure that all new ingredients in dietary supplements are safe for consumers.

The law "requires the agency to build a new food safety system," says Michael R. Taylor, FDA's deputy commissioner for foods. "This new system will better leverage the resources of federal agencies and it will make industry a major partner in safeguarding the health of U.S. consumers."

Preventing entry of smuggled food

The new anti-smuggling strategy was developed by FDA, the Department of Health and Human Services (HHS) and the Department of Homeland Security (DHS). Within DHS, FDA is working with Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE).

The goal is to better identify and prevent the entry of smuggled foods that could be dangerous to both national security and consumer safety. Food may be smuggled for many reasons, including for economic gain, to evade import taxes, evade routine inspection that could raise safety concerns, or for more dangerous reasons, including plots to intentionally harm the American public.

FDA will be working closely with CBP to identify import shipments that could conceal undeclared foods.

The law defines smuggled food as "any food that a person introduces into the United States through fraudulent means or with the intent

"This new (food safety) system will better leverage the resources of federal agencies … in safeguarding the health of U.S. consumers."

A U.S. Customs and Border Protection official inspects an imported shipment.

to defraud or mislead." And while this could be interpreted to apply to a food item concealed in someone's luggage, the agencies will be focusing on imported foods that pose a significant public health risk.

Dietary supplements

FDA has a history of taking legal action against supplement makers who include hidden or deceptively labeled ingredients in their products. These could potentially be dangerous to consumers, especially those using medications or with a health condition.

This time the agency is issuing a draft of a guidance document for the dietary supplements industry stipulating that manufacturers must notify the agency in advance when adding a new ingredient with an unknown safety profile to their products. The manufacturers must also provide evidence that the ingredient is safe for consumers.

If the notice from a supplement firm is deemed inadequate because the new ingredient is an anabolic steroid or a material with the same chemical qualities, FDA is required to alert the Drug Enforcement Administration.

Food processing facilities

In addition to the actions listed above, FDA now has the authority to prevent the distribution of unsafe food by suspending the registration of the processing facility. Food producing firms must be registered with FDA to market their products in the U.S.

The registration could be suspended if the food processor not only fails to produce safe foods, but also takes no measures to keep those foods from reaching consumers. In addition to preventing their distribution, the processor of unsafe foods would be expected to investigate what went wrong and take steps to prevent a recurrence. If this is not done, FDA will step in.

One of the food-safety law's major provisions is a requirement that food facilities have a written preventive controls plan that spells out potential safety problems and the steps that would be taken to prevent or minimize the likelihood of these hazards occurring.

Other actions

Also now in effect is a rule, issued on May 4, that allows FDA to detain for up to 30 days food products it believes may be adulterated or misbranded. Such foods would be kept out of the marketplace until the agency determines whether there is a need for further enforcement actions, such as seizure or an injunction to prevent the suspect products from being distributed.

The food safety law set another goal that was to be met by July 3: the issuance of the Fish and Fishery Products Hazards and Control Guidance, This document, popularly known as The Hazards Guide, was issued in April, well ahead of the deadline. The guide provides commercial fisherman and processors the latest scientific information on contaminants and the controls needed to eliminate them.

FDA delivered the first tangible product of the historic food safety reform legislation on April 4: a new web-based search engine that makes it easier and quicker to learn about product recalls. At the same time, the agency redesigned its web page dedicated to the food safety act: *www.fda.gov/FSMA*.

Find this and other Consumer Updates at *www.fda.gov/ForConsumers/ConsumerUpdates*

Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*