Foreign Exporters Study Food Safety Law

FDA Commissioner Margaret Hamburg meets with China's Vice Minister Pu Changcheng, who's with the country's food regulatory agency, during a 2010 trip to Beijing. Ensuring the safety of products coming into the U.S. from abroad is one of Hamburg's top priorities.

The Food and Drug Administration's international program has logged nearly 75,000 hits to its Web pages on the new food safety law, as foreign companies that export food to the United States scramble to learn how the law affects them.

"A lot of our foreign offices are being deluged with questions," says Mary Lou Valdez, FDA's associate commissioner for international programs. "The China office has done significant outreach with Chinese officials and exporters."

Valdez says FDA translated seven documents about the FDA Food Safety Modernization Act (*www.fda.gov/InternationalPrograms/FDAPublicationsinForeignLanguages/ucm241468.htm*) into 11 languages that use eight different alphabets. Excluding English, they include the five remaining, official United Nations languages—Arabic, Chinese, French, Russian, Spanish—and six languages that represent the top countries from which the United States imports food—Italian, Japanese, Korean, Portuguese, Thai, and Hindi.

President Obama signed the food safety act into law on Jan. 4. It enables FDA to more effectively guard against foodborne illness by focusing on prevention, as opposed to reacting to contamination and other food safety problems after they happen.

"For imported foods, the primary difference under the new law is that, for the first time, importers will be specifically required to have a program to verify that the food products they are bringing into this country are safe," says David Elder, director of FDA's Office of Regulatory Operations.

Increased Authority

Because a high percentage of some foods—such as seafood and fresh fruit—served in U.S. households and restaurants are imported, the law gives FDA important new authority to hold imported foods to the same standards as domestic foods. This authority includes:

- **Importer accountability**—For the first time, importers have an explicit responsibility to verify that their foreign suppliers have adequate controls in place to ensure that the food they produce is safe.
- **Third-party certification**—It establishes a program through which qualified third parties can certify that foreign food facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports.
- **Certification for high-risk foods**—FDA has the authority to require that imported foods that are at high risk of contamination have a credible third-party certification or other assurance of compliance as a condition of entry into the U.S. The "third party" could be a private company or a governmental entity.
- **Voluntary qualified importer program**—FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from program-certified facilities.
- **Authority to deny entry**—FDA can refuse entry into the U.S. of food from a foreign facility if the agency is denied inspection access by the facility or the country in which the facility is located.

Inspections Abroad

The law also directs FDA to develop a plan to expand the technical, scientific, and regulatory food safety capabilities of foreign governments and their industries. Part of the plan includes training foreign governments and food producers on U.S. food safety requirements.

Elder says resident investigators in FDA's foreign offices have already gotten a jump on the requirements.

"FDA's foreign offices have already exceeded our operational expectations," he says. "Investigative staff in-country have conducted many routine and directed inspections to support FDA's foreign inspection program. They have already been working closely with the host country inspectors to help them better understand what our requirements are."

And the foreign inspection program is bearing fruit, Elder says. Last year, a food producer in China—the site of FDA's first foreign office—refused to allow an FDA investigator to perform an inspection.

"That resulted in FDA's first ever import alert (*www.accessdata.fda.gov/cms_ia/importalert_521.html*) based on a foreign firm's refusal to permit an FDA inspection," Elder says.

In addition, Elder says investigators in FDA's 11 foreign offices have obtained and shared local information that resulted in better identifying the products coming into the U.S. that might not meet strict FDA standards.

"Their efforts to build productive working relationships with, and provide training and technical assistance to, regulatory officials in foreign countries will serve us well in the long term by supporting awareness, collaboration, and product safety," Elder says.

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