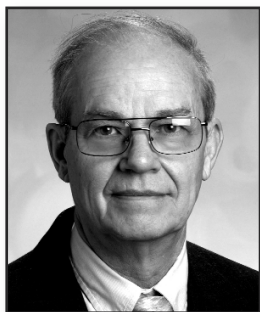


## New FDA Rule Makes Importers Responsible For The Safety Of Imported Food



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The two new food safety rules published by the US Food and Drug Administration (FDA) in the Federal Register on July 29, 2013 complement the two proposed rules the FDA issued in January 2013 (see our discussion of these rules at <http://agpolicy.org/articles13.html>, columns 650, 651, and 652). All four of these proposed rules have been developed by the FDA in accordance with the Food Safety and Modernization Act (FSMA), with more to come.

The first of these two newly proposed rules, Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) (<http://tinyurl.com/n3t54rd>), is the focus of this column. Next week we will examine the proposed rule on Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications. That proposed rule will describe the means by which third-parties will be able to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce.

The FSVP regulations would “would require importers to help ensure that food imported into the United States is produced in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under the hazard analysis and risk-based preventive controls and standards for produce safety sections of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), is not adulterated, and is not misbranded with respect to food allergen labeling.”

“In fiscal year 2011, nearly 10.5 million product lines of food (representing unique food products) were imported into the United States.... Human and animal food constitutes nearly 40 percent of all imported product lines regulated by FDA. About 15 percent of all food consumed in the United States is imported, including approximately 50 percent of fresh fruit and 20 percent of fresh vegetables.”

Rather than go through some of the details of the proposed rule, we want to offer some general impressions.

Given the occasional foodborne illness outbreaks that have resulted from imported foods and the melamine contamination of pet food (see our discussion in columns 352, 353, and 354), it is clear that Congress is not likely to

provide FDA with sufficient funds to hire enough inspectors to examine all of the food arriving at US ports of entry, nor does that make good sense. What the FSVP proposed rule does is turn the food safety paradigm on its head.

Instead of the cat and mouse game that expects port inspectors to find the unsafe food that is coming across the border, it makes sense to put that responsibility for the safety of imported food on the importers who have the necessary contacts with foreign producers and manufacturers. The foreign producers and manufacturers are certainly more likely to work with those who purchase their products than they are with FDA inspectors.

And the importers are more likely to take their responsibility for ensuring the safety of the products they import because their reputation is on the line; one serious mistake that their biggest customers could be looking for a new importer.

In a brochure, “Strengthening Oversight of Food Imports,” the FDA writes, “Importers would have to establish that the foods being imported to the United States have been produced in a manner consistent with US standards. In general it would require that importers:

- “Identify hazards associated with each food;
- “Conduct or obtain documentation of verification activities which could include onsite auditing, sampling, and testing, to provide adequate assurances that the identified hazards are being controlled; and
- “Take appropriate corrective action if hazards are not being adequately controlled.”

This shift in making the importers and their foreign food producers and processors responsible for meeting US food safety standards also shifts costs that traditionally have been borne the public at large to those providing the food. In this way, some of the costs differentials between US producers who have had to comply with US food safety standards and foreign producers and processors are equalized.

In addition, the whole focus of the FSMA shifts the costs of foodborne illnesses from treatment to prevention, potentially having a positive impact on healthcare costs in the US.

To accommodate small importers and small foreign producers, the FDA has modified the requirements in such way that these entities can participate in the market while at the same time assuring the public that the imported food they eat is safe.

“The understanding that the principal responsibility for food safety resides with industry forms the basis of our proposed regulations implementing not only the FSVP provisions but also the preventive controls and produce safety provisions of FSMA,” the FDA writes in its proposed rule on Foreign Supplier Verification Programs for Importers of Food for Humans and Animals. △

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