

Following are questions and answers on the topics covered in David Elder's interview on FSMA import provisions.

GENERAL

WHAT ARE THE KEY AREAS THAT THE IMPORTER WILL NOTICE THAT WILL BE DIFFERENT UNDER FSMA?

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. Among other things, importers will need to verify that their suppliers are in compliance with reasonably appropriate risk-based preventive controls that provide the same level of public health protection as those required under FSMA.

WHAT IS THE FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP) AND HOW WILL IT WORK?

The FSVP requires importers to conduct risk-based foreign supplier verification activities to verify that imported food is not, among other things, adulterated and that it was produced in compliance with FDA's preventive controls requirements and produce safety standards, where applicable.

WHO IS SUBJECT TO THE FOREIGN SUPPLIER VERIFICATION PROGRAM?

When the foreign supplier verification program's requirements take effect, they will apply to all importers, unless there's an exemption. The law defines "importer" as: (A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or (B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.

WHAT FOOD DOES THE PROGRAM'S REQUIREMENTS APPLY TO?

The requirements of the foreign supplier verification program will apply to all food imported by the importer or agent of the importer, unless there's an exemption.

EXPEDITED IMPORTS

WHAT IS THE VOLUNTARY QUALIFIED IMPORTER PROGRAM (VQIP) AND WON'T THIS FORCE FDA TO RELY HEAVILY ON INSPECTIONS BY FOREIGN GOVERNMENTS?

Section 302 of the statute requires FDA to establish a voluntary, user-fee funded voluntary qualified importer program (VQIP) to expedite entry into the United States of imported food from eligible, qualified importers. To be eligible to participate in VQIP, an importer must offer food for importation from a facility that has a certification by an accredited third party. FDA will qualify eligible importers to participate in VQIP based on risk considerations. The new law directs FDA to issue guidance on participation in and compliance with VQIP.

COMPLIANCE

DOES FDA HAVE NEW COMPLIANCE TOOLS FOR IMPORTS?

Yes. First, we will increase the number of foreign inspections we do. FDA can deny entry to an import if a foreign facility refuses an FDA inspection it can require certification for high-risk foods; and prior notice submissions will need to include, as an additional element, any country to which the food has been refused entry.