

Regulatory Alert: FDA Releases New Import Strategy Document; FSVP “Educate While Regulate” Period Expected to End This Year, Agency May Begin Imposing Fines and Sanctions for FSVP Violations

Enforcement of FSVP Cornerstone of New Import Strategy, FDA Cracking Down on FSVP UNK Violations

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On February 25, 2019, U.S. Food and Drug Administration (FDA) released a document entitled “FDA Strategy for Imported Food” which outlines the agency’s enforcement priorities in upcoming years.

Please note that separately, **FDA indicated they will be taking enforcement action against customs brokers and other filers who file entries with UNK (unknown) as the FSVP importer after March. The agency has been receiving more than 900,000 UNK declarations per month. FDA has also indicated it may begin imposing fines and other sanctions for violations of the FSVP Rule this year.**

This regulatory alert summarizes the key points of the import strategy document.

Highlights of the import strategy document include:

1. Enforcement of the Foreign Supplier Verification Program (FSVP) Rule is a cornerstone of FDA’s strategy
2. FDA is working on a food safety systems recognition agreement with the European Union
3. FDA will be creating an accredited laboratory program for the testing of imported foods
4. FDA will be requiring import certifications for foods presented for entry under import alert
5. FDA will enforce the FSVP Rule
6. FDA may consider information from third party food safety standards (e.g. GFSI) in implementing FSVP

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In the import strategy document, FDA notes that the FSVP Rule has given the agency the opportunity to:

collect and analyze information from new sources . . . to form a more complete picture of the risk of imported food in a new era of smarter food safety. For example, information from the implementation of new oversight tools can help FDA identify which foreign facilities to inspect and which imported food shipments to test.

The agency states it will be “transparent by publishing non-confidential data about imported food, foreign suppliers of food, food importers, and FDA’s related oversight activities.”

FDA’s strategy employs several guiding principles:

1. Protecting public health is the first priority
2. Partnering with others to build prevention-based systems is the key to success
3. Maintaining scientific expertise and innovation as the foundations of FDA’s food safety work
4. Sustaining a level playing field for domestic and foreign food producers
5. Allocating resources according to risk is the most effective method for protecting public health, and data analytics is the key to prioritizing according to risk
6. Requiring measurement and ongoing refinement to ensure success
7. Establishing transparency as the standard

The agency’s strategy consists of four goals with several objectives:

1. Food offered for import meets U.S. food safety requirements
2. FDA border surveillance prevents entry of unsafe foods
3. Rapid and effective response to unsafe imported food
4. Effective and efficient food import program

Goal: Food Offered for Import Meets U.S. Food Safety Requirements

To meet this goal, FDA will:

- a. Optimize the use of foreign facility inspections and allocate resources to other oversight activities based on risk
- b. Hold foreign suppliers to U.S. food safety standards and importers to FSVP requirements
- c. Consider information from reliable third-party audits and other assurance programs aligned with U.S. food safety requirements as appropriate

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- d. Work cooperatively with domestic and foreign regulatory counterparts to establish agreements designed to leverage each other's food and facility oversight through data and information sharing
- e. Provide training and outreach to a variety of stakeholders (e.g. foreign industry, importers, brokers, regulatory counterparts) to increase compliance with U.S. food safety requirements

FSVP Implementation

FDA notes that the FSVP regulation provided FDA with a new tool to significantly enhance FDA's oversight of the inventory of foreign facilities and farms. FDA is building its inventory of FSVP importers and increasing its understanding of their connections through the supply chain with FDA-regulated foreign food facilities and farms. Through inspection of importers, domestic producers, and foreign suppliers, FDA will promote compliance with foreign supplier verification programs as well as supply chain requirements and will gather additional information to prevent unsafe food from entering the U.S. market.

FDA's strategy in implementing the FSVP regulation is stated to be:

1. Provide education and technical assistance to increase awareness of, and compliance with, foreign supplier verification programs
2. Deepen importer and foreign food facilities and farms inventory knowledge base to enable FDA to evaluate the extent of agency oversight of the foreign inventory through FSVP and to inform work plan determinations as to the type and frequency of inspection
3. **Deter noncompliance through strategic enforcement of the FSVP Rule and supply chain controls requirements (emphasis added)**

Third Party Audits

FDA notes that audits can provide valuable public health assurances if they are reliable and aligned with relevant FDA food safety requirements. The agency states that importers and manufacturers may request food safety assurance as part of contractual responsibilities of their suppliers. When these assurances are in alignment with U.S. food safety requirements, they are valuable and contribute to a body of information that can be taken into account with respect to allocation of oversight resources. **U.S. Food Imports LLC can assist you in obtaining these assurances.** For FDA there may be an opportunity to incorporate information from other assurance programs (emphasis added) aligned with U.S. food safety requirements into FDA's system of oversight.

Food Safety Systems Recognition

FDA has made systems recognition arrangements with New Zealand, Canada, and Australia and is working with the European Union on a mutual assessment. Whereas systems recognition is a regulatory partnership intended to help FDA redirect limited resources to higher risk areas, FDA may enter other types of arrangements that require assessments of foreign regulatory controls.

In addition to systems recognition and equivalence arrangements, FDA may enter arrangements with foreign regulatory authorities to conduct specific oversight and offer certain verifications (e.g. pre-export testing) to provide assurances of the safety of certain exported products. Through reliance on the food safety systems and information from regulatory counterparts with strong food safety systems, FDA can concentrate more resources on areas of higher risk.

Goal: Border Surveillance

FDA's surveillance effort at more than 300 active U.S. ports of entry, all points where shipments enter the U.S., remains an essential element of its strategy to ensure the safety of imported food.

FDA electronically screens every one of the millions of shipments of food offered for import into the U.S. every year. Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) is FDA's automated import screening tool. FDA uses PREDICT to identify higher-risk shipments of food offered for import. PREDICT screens all regulated shipments, taking into account multiple factors about each import shipment – everything from compliance history of the facility that produced the imported product to the level of risk associated with that product. With that current intelligence, PREDICT assigns a risk score every imported food shipment, identifying higher risk shipments for potential examination and expediting the clearance of lower-risk cargo.

FDA continues to assess opportunities to optimize import screening by incorporating new sources of intelligence with its current data. By optimizing import screening in this fashion, FDA is better able to identify and hold food offered for import when food poses a risk to public health.

Sampling and Testing

FDA intends to optimize use of physical examination and sampling of imported food. FDA intends to target the highest-risk products for sampling and testing.

Import Alerts and Import Certifications

Import alerts are used to provide information to field staff when the agency has reason to believe that future shipments of a product offered for entry may appear to violate FDA laws or regulations. After FDA detains a shipment that is listed on import alert, the importer has the opportunity to prove that the product it wants to import into the U.S. is safe.

FSMA gave FDA the authority to make a risk-based determination to require, as a condition of admissibility, that a food imported or offered for import into the U.S. be accompanied by a certification or other assurance that the food meets the applicable requirements of the Federal Food, Drug and Cosmetic Act (FD&C Act). The authority to mandate import certification for food, based on risk, is one of the tools FDA can use to help prevent potentially harmful food from reaching U.S. consumers. When FDA has determined that a food import is subject to such certification, FDA will require, as a condition of entry, a certification issued either by an accredited third-party certification body or by an agency or representative of the foreign government of the country from which the food at issue originated.

FDA will detain and refuse admission of food from a foreign facility, if FDA is refused inspection.

Laboratory Accreditation, Improving Testing Methodologies and Tools Used to Determine the Admissibility of Food

FDA intends to update and expand its analytical test method portfolio through identification and development of additional methods for testing of food offered for import; deploy new analytical tools to augment imported food screening capability and capacity and establish a program for laboratory accreditation to ensure that laboratories that test imported foods produce accurate and reliable results. FSMA directed FDA to create a laboratory accreditation program for imported food.

Maximizing the Benefit to Border Surveillance from State and Other Partnerships

Under certain circumstances, states conduct sampling and analyses of higher-risk imported foods – once they have entered commerce in their jurisdictions – and they share findings with FDA that may indicate significant food safety problems. FDA will continue to support collaborations and shared communications with state regulatory partners including:

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- Developing clearly defined criteria for FDA's acceptance of state food regulatory laboratory results to support agency action, thereby maximizing FDA's ability to leverage state's work to advance public health
- With input from state regulatory partners, develop and distribute best practices to prepare human and animal food testing laboratories for accreditation
- Support speed and accuracy of signal detection and response by encouraging foreign regulatory counterparts to participate in organizations and networks, such as GenomeTrakr, that provide platforms for sharing scientific evidence of food safety problems internationally

Goal: Rapid and Effective Response to Unsafe Imported Food

FDA intends to maximize the effectiveness of FDA response to an event involving imported food. This includes:

- Enhancing FDA decision making and coordination when responding to food safety problems caused by imported foods through greater access to information from foreign sources
- Enhance processes that allow foreign and domestic partners and stakeholders to notify FDA of food safety problems in a timely manner
- Further develop and refine processes to enable the use of agency authorities to prevent importation of unsafe food from facilities, including those with suspended registrations
- Exercising mandatory recall authority
- Using international arrangements to facilitate imported food safety investigations

Goal: Effective and Efficient Food Import Program

FDA intends to optimize resource allocation by developing a comprehensive global inventory of food facilities and farms and assessing the cumulative oversight applied to the global inventory. This includes developing an improved global inventory of human and animal food facilities and farms that intend to distribute food in the U.S. and developing a modeling framework that supports risk-based resource allocation decisions related to the strategic global oversight of human and animal facilities and farms.

FDA also seeks to ensure the effectiveness of import activities through performance assessment and continuous improvement by:

- Developing performance measures and outcome indicators for imported food safety

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- Publish meaningful data related to imported food, foreign food suppliers, and FSVP importers and other importers.

U.S. Food Imports LLC provides food importing solutions and foreign supplier verification services. Our proprietary FSMA Cloud® and FDA Cloud™ software ensures efficient FSVP compliance for you and your suppliers. Please contact Erik Lieberman at elieberman@usfoodimports.com or (202)765-1800 if you have questions or would like additional information.