

## MEMORANDUM

**From:** Joseph A. Levitt  
Maile Gradison Hermida  
Elizabeth Barr Fawell  
Mary B. Lancaster

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**Re:** **FDA Releases Strategy for the Safety of Imported Food**

The U.S. Food and Drug Administration (FDA) recently released the “FDA Strategy for the Safety of Imported Food” (the Strategy), which outlines the agency’s approach to ensuring the safety of the ever-rising volume of imported foods. <sup>1/</sup> The Strategy sets out four food safety goals: 1) preventing food safety problems in the foreign supply chain prior to entry; 2) detecting and refusing entry of unsafe foods at the border; 3) quickly responding to unsafe imported food; and 4) developing and publishing metrics to monitor FDA progress. This memorandum provides an overview of the agency’s strategy, explains the guiding principles behind this strategy, and summarizes the methods the agency plans to use to accomplish its four goals.

### Strategy and Guiding Principles

The U.S. imports about 15 percent of its overall food supply – 32 percent of fresh vegetables, 55 percent of fresh fruit, and 94 percent of seafood – from more than 200 countries or territories representing about 125,000 international food facilities and farms. The same U.S. food safety requirements apply to all food consumed in the United States, regardless of where it was produced.

FDA has developed what it calls “a multilayered safety net” for imported food, specifying distinct roles for manufacturers, importers, third-party auditors, foreign regulatory bodies, FDA, and other stakeholders. FDA aims to use the new requirements under the FDA Food Safety Modernization Act (FSMA) regulations to collect and analyze information from these sources to form a more complete picture of the risk of imported food. The agency also plans to use data analysis to allocate resources in a more targeted way, identifying areas of greater risk where supplemental training or focused outreach efforts can be most beneficial.

FDA identifies seven guiding principles for its strategy:

1. Protecting public health is the first priority.

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<sup>1/</sup> FDA Strategy for the Safety of Imported Food (Mar. 2019), available at: <https://www.fda.gov/downloads/Food/GuidanceRegulation/ImportsExports/Importing/UCM631864.pdf>.

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.

### **FDA's Goals and Objectives**

FDA's imported food safety goals fall into three categories: (1) preventing food safety problems in the foreign supply chain prior to entry into the United States, (2) effectively detecting and refusing entry of unsafe foods at the border, and (3) rapidly responding when FDA learns of unsafe imported foods. An overarching fourth goal is to create an effective and efficient food import program, with metrics to measure progress. The strategy outlines several methods the agency plans to use to accomplish these goals including strategies for each objective, as summarized below.

#### *Goal 1. Food Offered for Import Meets U.S. Food Safety Requirements*

To ensure the safety of food imports, FDA will pursue objectives related to verification, enhanced compliance, and increased data and information sharing. Specifically, FDA will optimize the use of foreign inspections and ensure importer use of verified foreign suppliers through implementation of the Foreign Supplier Verification Programs (FSVP) regulation. FDA seeks to strengthen the capacity of foreign suppliers to produce safe food by increasing awareness of and training on food safety requirements and incentivizing importers to use verified suppliers of safe food through the Voluntary Qualified Importer Program (VQIP). The agency also intends to work cooperatively with domestic and foreign regulatory counterparts to establish data and information sharing agreements designed to leverage each other's food and facility oversight.

#### *Goal 2. FDA Border Surveillance Prevents Entry of Unsafe Foods*

The agency will continue to enhance and refine the import screening and entry review processes at the 300 plus U.S. ports of entry by improving testing methodologies and tools used to determine admissibility of food offered for import and optimizing the use of physical examinations and sampling of imported foods. FDA also plans to strategically use import alerts and import certifications (one of the new tools under FSMA). 2/

#### *Goal 3. Rapid and Effective Response to Unsafe Imported Food*

FDA will take steps to enhance the efficiency and effectiveness of imported food safety recalls, such as by using information-sharing opportunities with regulatory counterparts with strong food safety systems. When appropriate, FDA will exercise the mandatory recall authority granted to the agency by FSMA.

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2/ Note that the Strategy does not provide any examples of the situations when FDA would use its import certification authority.

*Goal 4. Effective and Efficient Food Import Program*

Longer term, the agency hopes to develop a comprehensive global inventory of food facilities and farms that intend to distribute food in the United States, which will allow FDA to assess the cumulative oversight applied to the imported food inventory. The global inventory will also assist in accountability – FDA intends to publish performance measures and outcome metrics, as well as non-confidential data about imported food, foreign suppliers, and imports.

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We will continue to monitor developments involving FDA's import strategy. Please contact us if you have any questions.