FOOD FOR THOUGHT

WHAT FOOD AND BEVERAGE COMPANIES NEED TO KNOW ABOUT FSMA ENFORCEMENT

A Miami-based distribution company imports food which caters to a diverse international clientele. While the company seeks to provide customers the culinary tour de force they've come to expect, some customers have fallen ill — and the distributor has become increasingly concerned about its foreign suppliers' commitment to product quality.

A popular seafood restaurant chain decides to open a new location in a bedroom community of a growing city, but discovers the space available will only be enough for the dining room. Warehousing must be done at another location, which is close to the harbor and more vulnerable to inclement weather. One bad storm could ruin thousands of dollars' worth of food and equipment.

These are examples of what the Food Safety Modernization Act (FSMA) aims to address. Signed into law in 2011, the FSMA is intended to ensure the safety of US food supply by preventing contamination incidents. The FSMA amended the Federal Food, Drug, and Cosmetic Act and instructed the Food and Drug Administration (FDA) to implement several regulations for the food industry to ensure that their products are safe. Many of these new regulations went into effect late 2015 and early 2016 and have only recently become enforceable.

THE FSMA'S INTENT

The goal of the FSMA was to ensure the safety of human and animal food. It was seen as an historic bill because it meant creating an entirely new food safety system, along with broad prevention mandates and accountability.

Under the FSMA, food producers are now required to identify possible hazards and take steps called "preventive controls" to prevent or minimize them. And introducing changes mandated by the FSMA is a public health imperative: According to the FDA, 48 million Americans — or one in six — suffer from foodborne illnesses each year. Of those, 128,000 are hospitalized and 3,000 die each year.

KEY PROVISIONS

A key element of the FSMA is the Foreign Supplier Verification Program (FSVP), which applies to importers of food into the US. Similar to the FSMA, the FSVP's aim is to minimize hazards and resulting foodborne illnesses.

Also included in the FSMA are Hazard Analysis and Risk Preventive Controls (HARPC), which require almost every food manufacturer, packer, bottler, and storage facility to identify food safety and adulteration risks to their products and processes and put controls in place to prevent exposure to those risks. Under HARPC, regulated businesses must verify that these controls are working, and design and implement corrective actions to address any deviations from the controls that might occur. Food and beverage companies are also required to create and maintain

written food safety plans that must be made available to the FDA upon request.

ENFORCEMENT STRATEGIES

Under the FSMA, the FDA has more authority to prevent adulterated or misbranded food from entering the marketplace. The law allows the agency to remove such food from distribution channels while it pursues legal or other enforcement actions.

The new law also gives the FDA greater authority to access records. In addition to records tied to a particular food that could pose a health hazard, the agency can now also inspect records related to any other food it believes is likely to be affected in a similar manner. The FDA also now has the power to deny US entry to food producers that do not allow it to inspect any facilities that are used to manufacture, process, pack, or hold food products.

To enforce the FSMA, the FDA can suspend registration of a food and beverage facility, during which time it cannot be used. For the company that depends on a suspended facility, that could mean lost revenue as it temporarily changes its supply chain to accommodate the suspension.

The FSMA also expands the FDA's ability to administratively detain food. Under the old standard, the agency needed credible evidence of serious adverse health consequences or death; under the FSMA, the FDA needs only a reason to believe food is adulterated or misbranded.

Meanwhile, whole genome sequencing allows the FDA to better pinpoint the source of a foodborne illness and stop it. Over time, this improved accuracy could help the FDA reduce foodborne illnesses and deaths, both in the US and abroad. This new approach also makes it difficult for businesses whose products are found to be the source of illnesses to deny responsibility.

YOUR RISK MITIGATION STRATEGY

To comply with the FSMA, organizations should focus on three areas:

1. **Registration:** FDA registration triggers compliance with HARPC, but not every location owned or operated by a food and beverage company must be registered with the FDA. Businesses should ensure that only those facilities that manufacture, process, pack, or hold food for consumption by humans or animals in the US are registered.
2. **Suppliers:** Food and beverage companies should establish and maintain aggressive supplier approval and management programs to ensure good manufacturing practices are being employed. These programs should show that suppliers are ensuring the safety of products intended for US consumers. Once you have the program in place, continue auditing and improving it.
3. **Insurance:** Food and beverage companies should build effective insurance programs that include recall, product contamination, general liability, and property insurance. Businesses should also verify that their foreign suppliers have adequate insurance coverage.

Companies that import food into the US should also take steps to ensure compliance with the FSVP. Among other actions, such companies should:

- Perform a hazard analysis for each type of food and determining whether it requires a control.
- Evaluate risks posed by the food and the performance of foreign suppliers.
- Provide names, electronic mailing addresses, and unique facility identifiers for their suppliers when filing for entry with US Customs and Border Protection.
- Verify supplier activities through annual onsite audits, food sampling and testing, and reviews of relevant food safety records.

This briefing was prepared by Marsh's Food & Beverage Practice, in conjunction with Marsh Risk Consulting and Keller and Heckman LLP.

For more information on this topic, contact your local Marsh representative or:

GREG BENEFIELD
Food & Beverage Segment Leader
+1 615 340 2449
Greg.Benefield@marsh.com