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Foreign Food In Flux

New U.S. Food Import Safety Standards Stir Up Food For Thought

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A FREEBORN & PETERS FOOD INDUSTRY TEAM WHITE PAPER

ABOUT THIS WHITE PAPER:

This paper provides food industry executives with an overview of what is currently known about the new FSMA regulations and how these regulations may affect their businesses. As timelines and comment periods evolve in 2012 and 2013, there will be new insights and guidance, and we will provide updates as new information becomes available.

When President Obama signed the Food Safety Modernization Act (FSMA) into law in January 2011, he ushered in the most sweeping changes to food safety regulation since President Franklin Delano Roosevelt signed into law the Federal Food, Drug and Cosmetic Act of 1938.

In 2012 and 2013, the food import provisions of the FSMA come to the fore, affecting food coming into the United States from abroad.

For U.S. businesses that import food from abroad, and for foreign companies that export food to the U.S., there is a clarion call for affected companies to participate in the evolving process, understand the effects of proposed regulations and possibly realign and retool their various operations to achieve compliance and profitability.

At issue are three dramatic changes to the way the United States imports food:

- The Foreign Supplier Verification Program and related provisions;
- The Voluntary Qualified Importer Program; and
- Other FSMA provisions that affect importers.

In Food We Trust

THE FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP)

At the heart of the FSMA regulations is the belief that the food coming in to the United States must be safe. The **Foreign Supplier Verification Program** (FSVP) and related provisions of the FSMA aim to do just that, taking effect over the course of the next two years. However, many observers believe the scheduled roll-out of proposed regulations is not entirely logical and may create challenges for the FDA and food industry both here at home and abroad.

The three key provisions of the FSVP are:

1. BASIC REQUIREMENT

Under **FSMA Section 301**, food importers must verify that their foreign suppliers have adequate preventive controls in place, including measures that provide the same level of protection as those newly required for domestic facilities.

But how? To satisfy this requirement, importers may be required to do any or all of the following:

- Monitor records for shipments
- Conduct lot-by-lot compliance certification
- Conduct annual on-site inspections
- Check the hazard analysis and risk-based preventive control plan of the foreign supplier
- Periodically test and sample food shipments

By when? At the time of writing, the FDA plans to publish a guidance document and regulations relating to the FSVP in early 2012. The program is scheduled to take effect on January 4, 2013.

FSMA Section 103 requires every food facility to implement a written plan to evaluate and prevent hazards, monitor controls, maintain records and correct problems that may arise.

2. MANDATORY PREVENTIVE CONTROLS FOR FOOD FACILITIES

It is anticipated that the FSVP will incorporate key aspects of the mandatory preventative controls required for domestic food facilities. **FSMA Section 103** mandates that every food facility implement a written plan to:

- Evaluate the hazards that could affect food safety
- Indicate how the facility will monitor these controls to ensure they are working
- Detail what preventive controls will be put in place to minimize or prevent the hazards
- Maintain routine records of the monitoring
- Determine what actions the facility will take to correct problems that may arise

The new controls do not apply to certain facilities – particularly those processing seafood, juice and low-acid canned fruits – that are already complying with the Hazard Analysis & Critical Control Point (HACCP) standards for these types of foods.

By when? This requirement is scheduled to take effect on July 4, 2012. By that date, the FDA is required to establish relevant standards and publish a guidance document on preventive controls.

3. MANDATORY SAFETY STANDARDS FOR PRODUCE

It is anticipated that the FSVP will incorporate key aspects of the produce safety standards that the FDA is developing for domestic facilities. **FSMA Section 105** directs the FDA to develop its product safety standards.

Establishing and implementing these produce safety standards is a high priority for the FDA. As part of this task, the FDA will establish science-based minimum standards for the safe production and harvesting of certain fruits and vegetables. These standards must consider factors such as:

- Soil amendments
- Hygiene
- Packaging
- Temperature controls
- Animals in the growing area
- Water

By when? At the time of writing, the FDA is scheduled to publish a proposed rule on produce safety standards in early 2012, and the rule will not take effect until sometime in 2013 - one year after the close of the comment period.

Entering the Green Lane

THE VOLUNTARY QUALIFIED IMPORTER PROGRAM (VQIP)

Think of it like an express lane. The FSMA seeks to help importers speed up review and entry of foods and created the **Voluntary Qualified Importer Program (VQIP)** to do just that. But here's the catch: only importers offering food from facilities that have been certified as safe are eligible for the program. That sounds reasonable enough but the FDA has yet to establish a host of details for how the certification will work.

According to the FSMA, the FDA will review importer applications based on a variety of factors, including:

- The known safety risks of the food to be imported
- The compliance history of foreign suppliers used by the importer
- The capability of the regulatory system of the country of export to ensure compliance with the U.S. food safety standards for a designated food
- An importer's compliance with the FSVP
- An importer's recordkeeping, testing, inspections and audits of facilities, traceability of articles of food, temperature controls and sourcing practices
- The potential risk for intentional adulteration of the food

At the time of writing, the FDA plans to publish a guidance document in early 2012 and formally establish the program by July 4, 2012, one of the chief concerns relates to third-party auditors for these foreign facilities.

Under **FSMA Section 307**, qualified third-parties can certify that foreign food facilities comply with U.S. food safety standards. According to legislation, the FDA must develop model standards by July 4, 2012, and recognize accreditation bodies by January 4, 2013.

FDA IS HUNGRY FOR CORPORATE COMMENTS

The FDA is seeking industry input and taking these comments seriously if your company is affected by these new regulations:

- Pay attention to the draft regulations
- Work with counsel and industry associations to make your mark on these regulations by submitting comments
- Act quickly as the comment periods are sometimes rapid

Your company will have to live with the new FSMA regulations for many years to come. Take the time now to participate in shaping these new requirements.

A Mélange of Other Provisions

INSPECTION, RISK & NOTICE

At this stage, several other FSMA provisions are being unveiled that will affect how food companies do business.

The first of these – **Inspection of Foreign Food Facilities (FSMA Sections 306 and 201)** – is the FSMA's ambitious plan for the FDA to inspect at least 600 foreign facilities within one year of the law's enactment and to double those inspections every year for the next five years. If a foreign food facility denies access to the FDA, the agency can prevent food from that facility from entering the United States.

Next, under the **Certification for High-Risk Foods (FSMA Section 303)** provision, the FDA now has the authority to require that certain high-risk imported foods have enhanced certification. Specifically, the provision asks that these foods be accompanied by a "credible third-party certification or other assurance of compliance."

As with the foreign facility inspection provisions, if a facility does not provide this assurance, the FDA has the authority to ban the imports from U.S. entry.

Finally, under the **Prior Notice of Certain Food Shipments (FSMA Section 304)** provision, importers must inform the FDA of any food that has been refused entry by another country.

Build a Better Future

USING FSMA TO YOUR ADVANTAGE

It is clear that Congress had good intentions in passing the Food Safety Modernization Act: the spate of food-related outbreaks that occurred throughout 2011 confirmed the need for a more effective approach.

However, when we talk with industry players, it is apparent that they have mixed feelings about the legislation and the emerging regulations. They agree that strong food safety standards are a modern necessity but they worry that compliance with the emerging rules may be unnecessarily burdensome, particularly when many already employ food practices that likely exceed government mandates.

Uncertainty about the future is never a corporation's best friend and until the specific guidelines are outlined, tried and tested, the transition to a safer and more proactive way of protecting our nation's health will be viewed with cautious, even skeptical, eyes. To understand how this could play out, it may be helpful to draw parallels with another initiative - the so-called "Total Quality Management" movement - which came to the fore in the United States in the 1990s, particularly among manufacturers of durable goods, and which emphasized "quality first".

For years, many U.S. corporations believed that high quality and low costs were necessarily in conflict. But Japanese firms, especially auto manufacturers, such as Toyota, showed these were in fact entirely compatible, indeed mutually reinforcing, objectives. Now the vast majority of companies understand they don't have to choose between low costs and high quality standards, but instead their striving for one goal can assist in attaining the other. Freeborn believes that growers, producers, processors and others could see a very similar outcome with respect to food safety. It is quite possible that a proactive approach to FSMA will lower, and not increase, costs. For example, a well-structured food safety regime would give greater control over inventory, reduce spoilage and limit expensive product recalls. Leaders in the food industry should not see regulations as a burden, but instead use them to establish competitive advantage and to steal a march over those who are not ready to adapt.

The members of the Food Industry Team are working today with food companies seeking to change their positions in the marketplace and to ensure that they are beneficiaries of the coming new order. We encourage you to reach out to us and discuss how you can build a better future for your organization.

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John Shapiro is a Partner in the Litigation Practice Group and a member of the Food Industry Team. He focuses his practice on solving clients' complex business issues and disputes; counseling clients on litigation, employment and business issues; and providing general corporate advice. His litigation experience includes handling cases involving a wide-array of business issues in federal and state courts, in arbitration and before administrative agencies, including disputes concerning international and domestic supply chains, breaches of contract, corporate governance, non-compete and non-disclosure agreements, theft of trade secrets, ownership and protection of intellectual property, fraud, wages and hours, discrimination and other employment-related laws. In addition, John serves as General Counsel of Inspiration Corporation, a Chicago-based nonprofit that assists people affected by poverty and that operates Inspiration Kitchens, a 13-week restaurant skills training program, conducted in two for-public restaurants and a catering business, that is designed to provide participants with the tools they need to secure and retain jobs in the food service industry.

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Freeborn & Peters offers clients the unique combination of business insight and legal acumen to address the complex challenges facing the food industry.

The Freeborn & Peters Food Industry Team

America's food industry faces many challenges: a rapidly modernizing food safety regime; a complex network of suppliers and buyers with many risks and potential liabilities; stagnant domestic demand and intense price competition.

Our Food Industry Team helps food companies address these challenges. It also guides them as they build towards a better future: protecting investments in brands, innovation and facilities; structuring profitable ventures and M&A transactions; securing new financing; and taking advantage of foreign market opportunities.

The Team's partners bring many years of experience, gained at multiple points in the industry and across different legal disciplines, including regulation, litigation, corporate law and government affairs.

We combine legal know-how with business insight derived from careful attention to clients' needs and an ongoing focus on the food industry's specific opportunities and challenges.

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Freeborn & Peters LLP is a full-service law firm headquartered in Chicago, with international capabilities. Freeborn is always looking ahead and seeking to find better ways to serve its clients. It takes a proactive approach to ensure its clients are more informed, prepared and able to achieve greater success – not just now, but also in the future. While Freeborn serves clients across a broad range of sectors, it has also pioneered an interdisciplinary approach that serves the specific needs of targeted industries, including food, private equity and venture capital, transportation, and insurance and reinsurance. Freeborn is a firm that genuinely lives up to its core values of integrity, caring, effectiveness, teamwork and commitment, and embodies them through high standards of client service and responsive action. Its lawyers build close and lasting relationships with clients and are driven to help them achieve their legal and business objectives.

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