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Food Safety Modernization Act: What Does it Mean for Importers?

This week we continue to discuss the Food Safety Modernization Act (FSMA), taking an in-depth look at the impact on importers. FSMA has a significant focus on improving the safety of imported food. The legislation raises the bar for entry of product into the country with additional minimum requirements and the ability to require certifications for certain types of imported food. New importer verification requirements place the accountability for the safety of food on importers. However, FSMA also allows the creation of a program to enable expedited entry for those who have proven compliance with U.S. laws and regulations.

Minimum Requirements for Entry

Several provisions in FSMA raise the standards for all registered facilities (domestic and foreign) and these will become an important hurdle when it comes to importing food into the U.S. Foreign facilities that produce, manufacture, hold, pack or distribute food will have to comply with registration requirements, increased U.S. FDA access to records, conducting hazard analysis and implementing preventive controls, performance standards, implementing product tracking systems and increased recordkeeping provisions, and implementing mitigation strategies for intentional adulteration. Additional information on the new requirements for registered facilities can be [found here](#). It will be important for importers to understand these new requirements for registered facilities as they will face additional accountability for ensuring the safety of food they import to the U.S. under FSMA.

Certification for Imported Food

Some aspects of the FSMA are already law and could impact the importation of food now. One new authority is that the FDA could now require that imported food be certified to ensure compliance with U.S. laws. Certifications can apply to a specific shipment of food or to a facility that manufactures, processes, packs, or holds food. The requirement for an article of food to be certified will be based on

the known safety risks associated with the food and the known safety risks associated with the country, territory, or region in which the article of food originated. Certification can be required if the food safety programs of the country, territory, or region of origin are found to be inadequate to ensure that food is as safe as a similar article of food that is manufactured, processed, packed or held in the U.S.

Certifications can be provided by a FDA designated agency or representative of the government of the country from which the food originates or a person or entity accredited as a third party auditor. Entry into the U.S. may be delayed until certification is obtained if it is determined that a food article or facility requires certification.

This new authority potentially gives FDA a great deal more leverage against imported high risk foods. How FDA defines high risk will be important. The definition of high risk will likely include those foods with a history of problems or countries that have consistently had problems controlling the safety of exported foods. Even though FDA has this authority today we believe that it will likely take a little while to gain full effect because FDA has to define the process for certification as well as take into account potential trade barrier issues, but we may see this being used fairly soon for selected foods.

Importer Accountability

Within two years, an importer verification program will be in place that will require importers to verify that product entering the U.S. is not adulterated or misbranded and has been produced in accordance with U.S. laws and regulations. FDA is required to issue regulations within the next year, but given the challenges of developing an importer verification program, firms should take a good look at the FSMA requirements and begin thinking about modifying existing programs or developing new programs to ensure the safety of food the imported into the U.S. If importers wait to begin designing and implementing the foreign supplier verification program until FDA issues the regulation, it will be very difficult to be in compliance one year later when the rule takes effect. Without a verification program in place, importers will not be able bring product into the United States.

In addition, under the mandatory recall provision, importers may be required to pay the FDA fees to cover the cost of a recall order if product they import is found to be adulterated or misbranded. Fees can include reimbursement for FDA costs for technical assistance, follow-up checks, and public notification.

The increased accountability on importers will result in importers putting increased pressure on foreign facilities and increased use of third party audits to ensure that food is produced in accordance with U.S.

laws and regulations. Exactly how the FDA will deem the adequacy of a third party auditor is yet to be determined, and this will be another area we will be watching carefully and providing regular updates on as clarity emerges.

Expedited Entry – “Green Lane”

The development of a “green lane” for imports may be the silver lining in what otherwise is some significant new requirements for importers. The concept of the green lane is to provide those importers who are “doing things right” with an expedited entry process for imported foods. Within one and a half years, FDA is required to establish a program that would provide expedited review of food from importers who participate in the voluntary program and import food from facilities that have been certified by a third party auditor. Specific requirements for participation will be outlined in a FDA guidance document. At this stage there are no details available but we believe this program will go beyond the basic compliance with the importer accountability requirements and possibly include components focused on best practices. Again an area to watch carefully as FDA embarks on the rule making and guidance writing process.

Importers who are eligible and volunteer to participate in the program will be able to expedite entry into the U.S. by gaining access to the “green lane.” To be eligible for expedited entry, importers will need to apply to the program and pay a fee to cover the administrative costs of participation. Importers can use third-party auditors to verify the facilities are producing food are in compliance with U.S. laws and regulations. At a minimum, the combination of a qualified importer and product from a certified facility will be necessary to expedite entry.

Importers should closely watch the development of the voluntary qualified importer program and the third party certification program to gain insight into the eligibility requirements for facilities to be certified for participation in the program. Watching the development of the programs and responding as specific requirements are known will put importers in the best position to ensure that they are eligible to participate in the program and will be able to immediately expedite product into the U.S.

Additional considerations

In addition to paying fees to cover recall orders and participate in the voluntary qualified importer program, the new legislation gives FDA the authority to collect fees to cover reinspection-related costs for any importer that requires a second visit from FDA following an inspection. Additional information on the new fees authorized by FSMA can be [found here](#).

Within 180 days, FDA may utilize administrative detention for food when there is a “reason to believe” that the food is adulterated or misbranded. This lowers the bar from the current requirement that administrative detention can only be utilized when there is “credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.” As a result of this provision, FDA will be able to take a more aggressive regulatory approach when importers fail to ensure the safety of the product they attempt to bring into the U.S.

FSMA also includes changes to the current prior notice. Within 180 days of enactment, importers will be required to disclose to FDA if the food offered for import was refused by any other country as part of the prior notice requirements.

Next Steps

While the certification requirement is already enacted, importers should closely monitor the implementation of the legislation. Much of the impact will depend on how FDA develops new regulations or programs and what resources are available to FDA for implementation. FDA has signaled that implementation of the legislation will be a collaborative process with industry. Importers should engage with FDA during the rule-making process to provide input on current best-practices and feasibility of proposed practices. Staying ahead of the changes will be important – as regulations and programs are developed, importers should be making changes to ensure they will be able to participate in the new programs and take advantage of the “green lane” as soon as possible.

A summary of key provisions in FSMA can be [found here](#). A summary of timelines related to the provisions below, please see our Food Safety Modernization Act Implementation Timeline.

Previous newsletters have covered provisions that went into effect upon enactment, key provisions that impact registered facilities and farms, and key provisions that impact the rest of the supply chain.