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FSMA – A High Level Overview for Importers Of Food to the USA

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The Food Safety Modernization Act (FSMA) was signed into law in January 2011. FSMA pertains only to food regulated by the US Food and Drug Administration (FDA) and represents the greatest changes to US food safety regulations in over 75 years. Stephen Ostroff, M.D., the FDA's new Deputy Commissioner for Foods and Veterinary Medicine (FVM) recently highlighted the complexities of working in a food system, especially with the United States being such a major global importer and exporter of food. Food is sourced from an estimated 200 countries into the United States, thus it is imperative that FSMA is both understood and adopted by the entire US food supply chain, both domestic and imported.

FSMA is all about moving from a reactive regulatory system to a preventive one. There are many new regulations now published that require both domestic and foreign entities in the supply chain that are importing human and animal food into the United States, to focus on risk based preventive controls. The preventive approach in FSMA has been translated down to 7 major new regulations (with publication dates listed below in the table). Compliance dates vary depending on the size of the business and can be accessed at www.achesongroup.com.

It should be noted, however, that FSMA does not impact everyone in the supply chain. There is very little impact on retailers and food service operations today, if any at all.

FSMA Rule	Publication Date
Preventive Controls for Human Food	Sept. 17, 2015
Preventive Controls for Animal Food	Sept. 17, 2015
Produce Safety	Nov. 27, 2015
Foreign Supplier Verification Program	Nov. 27, 2015
Third Party Audit	Nov. 27, 2015
Sanitary Transportation	Apr. 6, 2016
Intentional Adulteration (Food Defense)	May 27, 2016

The key sections that apply to US importers, and therefore affecting foreign firms based outside of the United States are marked with an asterisk (*) below:

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***Preventive Controls for Human Food**: Requires that food facilities have Food Safety Plans (FSP) that set forth how they will identify and minimize hazards. There are some exemptions *e.g.,* FDA facilities under Seafood or Juice Hazard Analysis Critical Control Point (HACCP) plans. This is a key rule for foreign facilities exporting human food into the US. For companies that currently have Global Food Safety Initiative (GFSI) recognized certification, the Food Safety Plan can be built on the current HACCP plans for the facility as this is a very good starting point. However, a GFSI recognized audit and/or a HACCP plan on its own does not cover all aspects of FSMA. The Current Good Manufacturing Practices (cGMPs) have also been updated in this rule.

***Preventive Controls for Animal Food**: Establishes Current Good Manufacturing Practices and preventive controls for food for animals. This is a new requirement but very similar to the preventive controls rule for Human Food.

***Produce Safety**: Establishes science-based standards for growing, harvesting, packing and holding produce on domestic and foreign farms. There are key requirements for biological soil amendments of animal origin; water testing; worker health and hygiene; cleaning and sanitation of equipment and tools; and controlling and managing encroachment by domesticated and wild animals.

***Foreign Supplier Verification Program**: US Importers will be required to verify that food brought into the United States has been produced in a manner that provides the same level of public health protection as that required of U.S. food producers.

Third Party Certification: Establishes a program for the accreditation of third-party auditors to conduct food safety audits and issue certifications of foreign facilities producing food for humans or animals.

Note: An importer bringing high risk product into the US will have a relatively expedited service with this certification if they register for **VQIP (Voluntary Qualified Importer Program).** If a company has been audited by a "FSMA accredited" third party, then that's one key element of the VQIP program to help prevent border delays (the delay may be due to inspection or other documentation issues). VQIP runs from Oct 1 –Sept 31st and the application window for the following fiscal year runs from Jan 1 to May 31st. Fees are published on the Federal register in August and must be paid before Oct 1st. Further information on VQIP can be accessed at www.achesongroup.com.

***Sanitary Transportation**: Requires those who transport food to use sanitary practices to ensure food safety. This relates to moving food in the US by road or rail if you are a shipper, receiver, loader and /or carrier. It does not apply if the food is shipped through the United States and does not enter US distribution.

***Intentional Adulteration (Food Defense)**: Requires domestic and foreign facilities to address vulnerable processes in their operations to prevent acts intended to cause large-scale public harm.

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Generally, firms importing food into the US will have to ensure that foreign facilities [outside of the United States] are able to provide the same level of food safety assurance to the FDA as expected from domestic facilities. A manufacturer or processor importing raw materials or ingredients into the US will need to ensure that they have a robust supply chain program that can handle the associated complexities that often come as a result of implementation *e.g.,* short shelf life, seasonal challenges, documentation or process records. Foreign facilities will need to be fully aware of the FSMA requirements and expectations to avoid severe delays at the border. Testing for allergens may be one component of verifying that the imported product is not adulterated or misbranded. Other verification activities may also be used as part of the process including batch processing records or indicator organism or pathogen programs.

When FSMA was signed, the FDA assumed new immediate authority in a number of key areas including inspection of records, suspension of FDA registration, detention of food, authority to require import certificates for high risk foods and mandatory recalls. It is important to note that the FDA has already made one (or perhaps more) visits to FDA registered companies that are based outside of the US [and export directly or indirectly to the US]. These visits were conducted to assess the operation from a FSMA compliance perspective. These new FDA powers or authority will apply to both domestic and international supply chains for FDA registered product.

Whether it involves looking for residual allergens as part of operational sanitation (sometimes known as mid-shift cleaning programs) or screening for potential pathogens (or their respective indicators) as part of a company's environmental monitoring program. If you haven't demonstrated compliance to FSMA and documented it, then it hasn't been done.

In a nutshell, the biggest change to the US global food supply system [with respect to existing food safety systems that companies have used for years] is that the US importer will need to formally verify that the foreign supplier (*e.g.,* manufacturer / processor) has **a Food Safety Plan** for the Preventive Control rules. These include key components such as a robust **recall** plan; a fully implemented **supply chain** program, an effective **sanitation/hygiene** program; **an environmental monitoring program** (if you have ready to eat exposed food that is not further processed once in the final package) and a thorough review of **allergen management practices** and controls. There are many more details in each FSMA rule and the FDA has published further guidance and clarification where needed, as well as extending compliance dates for special circumstances.

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Neogen is a leader in developing and marketing diagnostic test kits that provide food safety solutions. Its products are unsurpassed in terms of ease of use, convenience and speed. Neogen's comprehensive line of rapid food safety diagnostics includes:

Food Allergens

Neogen offers food allergen test kits to detect almond, egg, gliadin (gluten), hazelnut, crustacea, total milk, mustard, peanut, sesame, shellfish, soy, and walnut residues. Neogen provides allergen test kits in multiple formats for validation, verification and finished product and environmental (contact surface), testing.

Foodborne Pathogens

Neogen provides multiple different pathogen detection systems. Neogen's revolutionary new ANSR™ system is the quickest and easiest testing method to definitively detect pathogen DNA in food and environmental samples — providing results in as little as 10 minutes. Reveal® 2.0 tests for pathogens are fast and easy immunological lateral flow devices, which can be used at nearly any facility.

General Microbiology

Neogen's Soleris® system rapid detects microbial contamination by monitoring the color differences produced by changing pH or CO_2. Using Soleris, time to results for general microbiological assays are reduced by up to 60%. Neogen offers NEO-GRID® and ISO-GRID® disposable filter membrane system and culture media for rapid and easy enumeration of bacteria in liquids.

Natural Toxins (including mycotoxins)

Neogen's new Reveal® Q+ fully quantitative lateral flow test for mycotoxins are quick and easy, with results in just minutes. Agri-Screen® and Veratox® mycotoxin tests kits provide screening and quantitative ELISA-based test for aflatoxin, DON, fumonisin, zearalenone, ochratoxin, and T-2/HT-2.

Sanitation

Neogen's AccuPoint® Advanced sanitation verification system quickly and easily measures ATP collected from food contact surfaces or liquids as a verification of sanitation programs. DataManager software allows for complete data traceability and data analysis.

About The Acheson Group, TAG

The Acheson Group (TAG) brings clients practical food safety solutions. Food companies today worry about operational efficiency and risk control, brand reputation and complying with current and new regulations.

TAG brings a unique suite of services that provides deep industry expertise and a global perspective focused on assessing and managing operational risk, reputational risk and regulatory risk.
Our team is comprised of noted industry leaders with global experience in food safety and defense.
Our clients span farm to fork and include technology companies looking to assist all sectors of the food industry.

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