Food Safety Modernization Act (FSMA) Update

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What is it?

The U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4, 2011. Representing one of the most sweeping reforms of our food safety laws in more than 70 years, it aims to ensure the safety of the US food supply and thus public health by requiring domestic and foreign processors (exporting product to the US) to proactively manage food safety and food defense hazards associated with the manufacture and transport of FDA-regulated food products. Comprised of 41 sections, FSMA also grants the FDA the power to recall contaminated foods, increase inspections, demand accountability from food companies and oversee certain aspects of farming and packaging of fresh produce.

Main elements of FSMA include:

- New responsibilities for food companies
- New controls over imported food
- New powers for FDA
- New fees on food companies and importers

Who does it apply to?

Facilities which manufacture, process, pack, hold or transport FDA regulated food products designed for consumption by humans and animals will need to comply with all or parts of the proposed and final rules. Those regulated by the US Department of Agriculture's Food Safety and Inspection Service are currently required to meet the proposed Sanitary Transport rule. Businesses selling directly to consumers (e.g., food service and retail operations) and very small businesses (sales <$500K) are currently exempt from these rules.

Status

Thirty-four of the 41 sections of the Act were passed with little comment and industry review. Two of the originally proposed rules were finalized in September 2015 as described, and three more were finalized in November 2015. The remaining two proposed rules are still in a period of continuing industry and FDA comments and revisions, and are expected to publish in 2016.

When does compliance start?

The remaining proposed rules go into effect 60 days following their publication as Final Rules. Compliance for most affected businesses begins one year after the publications of the Final Rules, with an additional year for very small businesses to comply. FDA enforcement will mirror compliance.

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Final Rules

FSMA is supported by five rules designed to help the industry shift their focus from reacting to foodborne outbreaks to preventing them at key steps along the supply chain:

Final Rule	Summary *
Preventive Controls for Human Food (21 CFR 117)	Applies to facilities manufacturing and holding food for human consumption. Requires domestic and foreign facilities to implement current Good Manufacturing Practice (cGMP) (21 CFR 117.10) and undertake a thorough Hazard Analysis (21 CFR 117.130) to identify and control potential food safety hazards (biological, chemical or physical hazards which may be naturally occurring or introduced) in their product and process. Steps identified as preventive controls must be scientifically valid and have critical limits (as appropriate), be monitored, have corrections/corrective action, be verified and supported by records.
Preventive Controls for Animal Food (21 CFR 507)	Applies to domestic and foreign facilities that manufacture, process, pack or hold animal food including those who manufacture materials destined for feed (directly or for further processing) as byproducts of human food manufacture, including materials donated or sold. Requires facilities manufacturing animal food to implement modified cGMP and undertake a thorough Hazard Analysis to identify and control potential food safety hazards in their product and process. Steps identified as preventive controls must be scientifically valid and have critical limits (as appropriate), be monitored, have corrective action, be verified and supported by records. Sites producing byproducts of human food as animal food (or an ingredient for animal food) who comply with human food cGMP (21 CFR 117.110) do not need to comply with animal food cGMP (21 CRF 507) as long as the byproduct is not further processed, its identity properly communicated and it is held and transported to minimize potential food safety hazards to animals. If materials are further processed in-house, the site must follow human or animal cGMP for the materials.
Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (21 CFR 11, 16 & 112)	Requires science-based minimum standards at the farm and pack house levels to control the biological hazards associated with the consumption of minimally processed and ready to eat produce.
Foreign Supplier Verification Programs (21 CFR 1, 11 & 111)	Requires importers perform risk-based activities to verify that the finished goods they're importing are safe, non-adulterated, appropriately labeled and its manufacture follow other FSMA rules on a regular basis.
Accreditation of Third Party Auditors (21 CFR 1, 11 & 16)	Establishes a program for certification bodies and their auditors to conduct food safety audits and issue FDA certifications to foreign facilities and the foods they produce. The certifications may impact the entry of products into the US marketplace.

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Proposed Rules

Proposed Rule	Summary *
Protection Against Intentional Contamination	Applies to domestic and foreign facilities that manufacture, process, pack or hold human and animal food, requiring these firms address vulnerable processes to prevent acts on the food supply intended to cause large-scale public harm.
Sanitary Transport of Human & Animal Food	Applies to domestic and foreign ground transport carriers transporting food for humans & animals, raw materials ingredients regulated by FDA and USDA FSIS. Requires controls over general sanitation, temperature control and protection of food during transport to prevent adulteration (including spoilage).

* Brief summaries are addressed above. Please refer to the full text of the Act final and proposed rules on the FDA website.

What's the Difference Between Hazard Analysis and Critical Control Points (HACCP) and the FSMA Hazard Analysis and Risk-Based Preventive Controls Approach?

The Hazard Analysis and Risk-Based Preventive Controls Approach aligns with HACCP in the design, development, implementation and verification of the food safety plan required. The primary difference lies in the designation of the Preventive Controls. Under HACCP these would typically be restricted to steps in the process identified as Critical Control Points (CCPs) whereas under this new approach there is no such restriction. Thus, Preventive Controls will likely be Process Controls (i.e., CCP), Allergen Controls, Sanitation Controls, Supply Chain Controls or other types of controls, many of which are managed by sites outside the scope of the HACCP procedure but detailed in their prerequisite programs or GMP. This should encourage facilities to review their entire operation in a more holistic manner by managing all of the controls in place regardless of how they are classified (e.g., cGMPs, CPs or CCPs) and should allow facilities to better create food safety controls which reflect hazards within their operations.

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Verification	• ATP Testing Solutions, Charm Sciences Program • 3D TRASAR™ CIP: CIP Optimization Program provides 24/7 monitoring and actionable data
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