



FSMA - Crawling, Walking or Running - September 2013

FDA's Food Safety Modernization Act (FSMA) was signed by President Obama 33 months ago. With this signing, there were strong statements regarding how FSMA would revolutionize the safety of the US food supply, reducing the number and frequency of food-borne illnesses, using the new "prevention" tools identified in FSMA. Against this backdrop of a promised safer food supply to US consumers, in the last few months there have been major outbreaks related to pomegranate seeds (Hepatitis "A" with 161 ill and 70 hospitalized) and Mexican lettuce (Cyclospora with 641 ill and 41 hospitalized). Specific to dairy products there are major recalls of Greek-style yogurt (mold with no illnesses identified) and artisanal cheese (listeria with 6 ill/hospitalized and 1 death). Predicting the progress and impact of FSMA and its regulations on the US dairy industry in near to medium term future is challenging but necessary if dairy companies and individual plants are to be prepared for the inevitable day when an FDA investigator (inspector) arrives and states they will be conducting a full-scale FSMA inspection of your dairy plant.

Of the many FSMA requirements and associated regulations published or required to be published by FDA (see table at end of article), "Preventive Controls" will have the most impact on day-to-day dairy plant operations. The comment period for the proposed "Preventive Controls" regulation closes on November 15, 2013. The "Preventive Controls" regulation, once finalized by FDA, will contain specific lists of written operational programs that have to be maintained as well as a complete overhaul of the food "Good Manufacturing Practices" which has been used by FDA field investigators to inspect all food processing plants for almost 30 years. The "Preventive Controls" regulation requires all dairy plants to have in-place, an operating HACCP program supported by written programs covering Supplier Management, Allergen Control, Product Traceability, Recall Plan, Food Defense, Employee Training (GMPs, HACCP, sanitation, allergens, environmental monitoring, food defense, food regulations, chemical use) and Processing Equipment Cleaning & Sanitizing. Dairy plants will have to provide records to FDA investigators showing these written programs are monitored, verified and written corrective action is applied when problems occur. This new "Preventive Controls" approach has been designated "HARPC" instead of "HACCP".

In addition, those dairy plant's that import dairy powders, cheese or butter need to understand the proposed Foreign Supplier Verification and Third Party Certification regulations (applies only to food processing plants outside the US) published July 26, 2013 with comments due November 26, 2013. These two regulations, once finalized, place the burden of ensuring the safety of imported dairy ingredients on the US importer. The result is FDA will take action against any dairy company that imports dairy ingredients which are adulterated (contaminated). In the past, FDA's approach was to block the importation of the product, with limited action against the importer. These two new FSMA regulations will result in the full weight of FSMA's fines/penalties, product detention, mandatory recall and criminal provisions applied to dairy importers. The biggest unanswered question for these two regulations is whether they are compliant with US obligations under the World Trade Organization treaty.

Just when we thought that FDA’s slow movement in publishing and finalizing the above FSMA regulations would allow all dairy companies time to adjust, on June 21st, a Federal judge out of California directed FDA to:

- Publish all proposed regulations* that have not yet been published by Nov. 30, 2013
- End the public comment period on all regulations* by March 31, 2014
- Publish all final regulations* no later than June 30, 2015

* Pending FSMA regulations including foreign supplier verification program, preventive controls for animal feed, protection against intentional adulteration, laboratory accreditation and sanitary transportation of food.

Another complication is how will the USDA Plant Survey Program and the National Conference on Interstate Shipments (NCIMS) programs interact/conflict with FDA’s efforts to enforce FSMA in dairy plants. It is likely that the USDA Plant Survey program will continue on without many, if any, changes as the result of FSMA. However, it is unclear for Grade “A” dairy plants operating within the NCIMS program, whether a duplication or conflict will result between FDA field investigators enforcing FSMA and state dairy inspectors enforcing the Grade “A” Pasteurized Milk Ordinance (PMO). Unfortunately, during the drafting of FSMA, congressional aids refused to specifically recognize that the Grade “A” PMO delivered safe dairy products for over 60 years, so no exemption was included in FSMA for Grade “A” dairy plants. The NCIMS Executive Board is planning to submit comments to FDA requesting recognition that the PMO delivers a similar level of dairy product safety (with a proven track record) to what the “Preventive Controls” might deliver, but how FDA addresses this request is uncertain.

In summary, FDA’s FSMA regulations and enforcement of the same are a moving target, with pressure on FDA from the industry to slow down while consumer groups, Congress and a federal judge want FDA to speed up. US dairy importers in many cases are unprepared or confused about their responsibilities related to FSMA. Whatever path is taken by FDA, it is important that US dairy companies and plants increase their food safety and training budgets for 2014 – 2016 to be prepared for FDA’s enforcement of FSMA’s “Preventive Controls”, “Foreign Supplier Verification” and “Third Party Certification” regulations.

For additional information on FSMA’s remaining regulations and their potential impact on dairy plants, register (Bhowdershelt@cfsrs.com or call 571-931-6763) for the ADPI-supported FSMA update webinar to be held Monday, September 16th starting at 1:30 pm CDT. Specific questions on FSMA can be forwarded to Allen Saylor (member of the ADPI Center of Excellence) at asaylor@cfsrs.com.

An overview of the FSMA milestones is summarized in the table below, listing of FDA’s FSMA accomplishments that have a direct impact on the dairy industry.

Nov. 26, 2013	Closing of Comment Period on FSVP & Third-party Auditing Program Proposed Regs.
Nov. 15, 2013	Closing of Comment Period on New GMPs, Preventive Controls & Product Safety Proposed Regs.
August 2013	Domestic and Foreign Facility Re-inspection, Recall, and Importer Re-inspection Fee Rates, FY 2014
July 26, 2013	Proposed Rule: Accreditation of Third-party Auditors
July 26, 2013	Proposed Rule: Foreign Supplier Verification Programs (FSVP) for Importers
May 30, 2013	Final Rule: Information Required in Prior Notice of Imported Food
April 2013	Analysis of FDA Food Defense Vulnerability Assessments and Identification of Activity Types
March 4, 2013	Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report

Feb. 2013	Criteria for Administrative Detention of Food for Human or Animal Consumption; Final Rule
Jan. 4, 2013	Proposed Rule for Preventive Controls: New GMPs & Risk-Based Preventive Controls
Dec. 2012	Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition)
Oct. 2012	Guidance for Industry: Updates to Food Product Categories in Food Facility Registrations
July 2012	Domestic and Foreign Facility Re-inspection, Recall, and Importer Re-inspection Fee Rates, FY 2013
Feb. 2012	Interim Final Rule: Establishment, Maintenance, and Availability of Records
	Guidance for Industry: Questions and Answers Maintenance of Records (Edition 5)
	Draft Guidance for Industry: FDA Records Access Authority Under FD & C Act
Oct. 26, 2011	Domestic and Foreign Facility Re-inspections, Recall, and Importer Re-inspection Fee Rates, FY 2012
Oct. 2011	SUPERCEDED Guidance for Industry: Administrative Detention of Foods
May 23, 2011	Preventive Controls for Registered Human Food and Animal Food/Feed Facilities
May 5, 2011	Administrative Detention of Food Interim Final Rule
	Prior Notice Interim Final Rule

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