

Crisis Control Newsletter

Crisis Control Newsletter from RQA, Inc.—An XL Catlin Preferred Provider to Foodservice, Food Processing and Consumer Products Industries

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FSMA—Preventive Controls for Human Food

The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food rule is now final, and compliance dates for some businesses begin in September 2016.

This final rule is the product of an unprecedented level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local and tribal regulatory counterparts, academia and other stakeholders. This outreach began before the rule was proposed in January 2013.

In response to input received during the comment period and during hundreds of engagements that included public meetings, webinars, listening sessions, and visits to farms and food facilities across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective for industry, while still advancing the FDA's food safety goals.

The final rule has elements of both the original and supplemental proposals, in addition to new requirements that are the outgrowth of public input received during the comment period for both proposals. For example, flexibility has been built into key requirements, including control of the supply chain, and the definition of farms— which are exempt from these regulations— has significantly changed to reflect modern farming practices.

KEY REQUIREMENTS

1. Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes:
    - Hazard analysis
    - Preventive control
    - Oversight and management of preventive controls.
    - Monitoring
    - Corrective actions and corrections
    - Verification
2. The definition of a 'farm' is clarified to cover two types of farm operations. Operations defined as farms are not subject to the preventive controls rule.
    - Primary Production Farm
    - Secondary Activities Farm
3. Supply-chain program is more flexible, with separate compliance dates established.
4. Current Good Manufacturing Practices (CGMPs) are updated and clarified.

Compliance Dates

Compliance dates for businesses are staggered over several years after publication of the final rule:

Very small businesses

- (averaging less than $1 million per year (adjusted for inflation) in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale): Three years, except for records to support its status as a very small business (January 1, 2016).

Businesses subject to the Pasteurized Milk Ordinance

- (compliance dates extended to allow time for changes to the PMO safety standards that incorporate the requirements of this preventive controls rule): Three years

Small businesses

- (a business with fewer than 500 full-time equivalent employees): Two years

All other businesses: One year

Compliance dates after publication of the final rule for the requirements of the supply chain program:

Receiving facility is a small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule: Two years

Receiving facility is a small business and its supplier will be subject to the human preventive controls rule or the produce safety rule: Two years or six months after the supplier is required to comply with the applicable rule, whichever is later

Receiving facility is not a small or very small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule: 18 months

Receiving facility is not a small or very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule: Six months after the supplier is required to comply with the applicable rule

The FDA is developing several guidance documents to help with compliance of the key requirements. For more information visit:

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery#Key_Requirements

Food and Drug Administration Recalls (www.fda.gov)

Product: Salad and Slaw Kits
Incident: Possible Health Risk–Undeclared Allergen

A Kent, WA firm is recalling 29 cases of slaw kits and 13 cases of salad kits because it may contain undeclared peanut ingredients. The slaw and salad kits may potentially be packaged with sunflower seeds mixed with peanut pieces. The peanuts are not declared in the ingredient statement. People who have an allergy or severe sensitivity to peanuts run the risk of serious or life-threatening allergic reaction if they consume these products. Products were only sold to consumers directly from deli counter orders between August 5-7, 2015. Thirty-eight case were shipped to deli departments in Oregon and Washington. There have been no reported adverse reactions or illnesses to date. The firm initiated a recall after being contacted by a customer. Consumers who have purchased these items are urged to return them to the place of purchase for a full refund. Consumers with questions should contact the company.

Product: Hard Cider
Incident: Possible Health Risk–Re-Fermentation

A Cincinnati, OH firm announced it is voluntarily recalling of select (24/12 oz bottles), 12-packs and 6-packs of hard cider. The company received inquiries from consumers that had experienced broken bottles or bottle overflowing when opened. After conducting follow-up quality testing, the company determined that the affected cider is limited to two batches, produce on June 15 and 29, 2015. The firm is recalling the cases due to concerns that cider from these production runs appears to be showing signs of re-fermentation in the bottle, which could result in increased carbonation levels causing the bottles to over-flow when opened or burst under increased pressure. The impacted cases of cider were shipped to wholesalers in AL, AR, CO, IL, IN, IA, KY, LA, MI, MN, MS, MO, MT, NE, NM, MD, OH, SC, SD, TN, TX and WI. Consumers who have purchased any of these products are urged to dispose of or return them to the place of purchase for a full refund. Contact the company for more information.

United States Department of Agriculture Recalls (www.usda.gov)

Product: Steak and Chicken Pie Products
Incident: Possible Health Risk–Non-Inspection

A Chicago, IL establishment is recalling an undetermined amount of steak and chicken pie products distributed without the benefit of inspection. These products were also missing the ingredient statement and contained undeclared allergens including eggs, milk, and wheat. The 10 oz. individually wrapped steak and chicken pie items were produced between January 1, 2014 and August 14, 2015. These items were distributed to restaurants and retail establishments in Chicago, IL and New Buffalo, MI. The problem was discovered when an FSIS employee determined that product was being sold in a retail establishment in the Chicago area. FSIS and the company have not received any reports of illness due to consumption of these products. Consumers and media with questions about the recall should contact the firm directly for more information.

Product: Pork Product
Incident: Possible Health Risk–*Salmonella*

A Graham, WA establishment is recalling approximately 116,262 pounds of whole hogs that may be contaminated with *Salmonella*. The varying weights of whole hogs for barbeque were produced on various dates between April 18 and July 27, 2015. The product was shipped to various individuals, retail locations, institutions and distributors in Alaska and Washington. The Washington State Department of Health notified FSIS of an investigation of *Salmonella* illnesses. Trace-back investigation has identified 32 case-patients who consumed whole hogs from this establishment prior to illness onset and are part of a larger ill-ness investigation. Based on epidemiological evidence, 134 case-patients have been identified in Washington. Media and consumers with questions in regard to the recall should directly contact the company.

Consumer Product Safety Commission Recalls (www.cpsc.gov)

Product: Children's Nightlight
Incident: Possible Risk-Electrical Shock Hazard

A Conshohocken, PA importer is recalling approximately 359,000 units of night-lights (83,000 units in Canada). The recall involves white, orange and pink night-lights that automatically turn on in the dark and off in the light. The light has a dome-shaped plastic cover that gives the light its color and is attached to a white rectangular plastic base. The nightlight's plastic covering can detach and expose electrical components, posing an electrical shock hazard. The company has received one report from Austria where a child tried to remove the light from the electrical outlet when the colored plastic cover detached. The child received an electric shock and minor hand wounds. The product was manufactured in China and sold at a retailer nationwide and online from August 2013 through July 2015. Consumers should immediately stop using the recalled nightlight and return it for a full refund. Contact the company or visit their website for more information.

Product: Women's Sandals
Incident: Possible Risk-Fall Hazard

A New York, NY importer is recalling approximately 50,600 units of women's sandals from the spring 2015 collection (300 units in Canada) manufactured in China. The metal shank on the 10 styles of sandals can dislodge and break through the bottom of the outsole posing a fall hazard. The firm has received eight reports of metal shanks dislodging and breaking through the bottom of the outsole. No injuries have been reported. The sandals were sold at a retailer nationwide and online from February 2015 to July 2015. Consumers should immediately stop using the recalled shoes and return them for a full refund. Consumers with questions should contact the company directly or visit their website for additional information.

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