

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

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Principles for Implementing FSMA

Food safety depends primarily on the food industry, with top-level management commitment and working in a continuous improvement mode, to: (1) implement science- and risk-based preventive measures at all appropriate points across the farm-to-table spectrum, and (2) manage their operations and supply chains in a manner that provides documented assurances that appropriate preventive measures are being implemented as a matter of routine practice every day.

While FSMA reinforces industry's primary role and responsibility for food safety, it also builds on and strengthens FDA's oversight role in providing technical expertise, setting and fostering compliance with food safety standards, and responding to and learning from problems when they do occur. In fact, more so than ever before, FDA is called upon by FSMA to play a central leadership and operational role in the future global food safety system. Meeting this challenge—and successfully implementing FSMA's new prevention-oriented, systems approach to food safety—necessitates a new strategy for how FDA performs its food safety role and meets its new responsibilities.

FSMA (Food Safety Modernization Act) provides FDA for the first time an inspection frequency mandate for food and feed facilities, but FSMA's public health prevention framework demands transformative change in how FDA uses its inspection authority and traditional and enhanced enforcement tools to carry out its oversight responsibility and protect public health in the most efficient manner possible.

Inspection and Surveillance

FDA will significantly expand its inspection and surveillance tools to include a wider range of inspection, sampling, testing, and other data collection activities conducted through its own field force and through collaboration with partner agencies and the food industry. The types and purposes of inspection and surveillance will include:

- *Efficiently screening firms for food safety performance* to guide risk-based inspection priority, frequency, depth, and approach
- *Providing firms incentives for compliance* through enhanced presence in and targeted scrutiny of high-risk firms and products and reduced scrutiny of firms with records of demonstrated good performance
- *Assessing the compliance of individual firms* through a range of inspection and sampling techniques used in a strategic, risk-based way to maximize coverage of priority sectors and firms
- *Making in-depth assessments of individual firms* when needed to increase the incentive for compliance and determine the need for compliance or enforcement actions
- *Collecting data to inform understanding and analysis* of sector-wide hazards, practices, and preventive control deficiencies
- *Collecting data on compliance rates* to evaluate program performance and plan future efforts

Administrative and Judicial Tools

To achieve better public health outcomes, FDA will focus its industry oversight efforts on using a broad array of tools to ensure that firms are consistently implementing effective prevention systems that protect food safety, within their operations and through their supply chains; this will include developing legally sufficient evidence to prove specific rule violations when judicial enforcement is the right remedy, but FDA will focus primarily on assessing whether systems are working effectively to prevent problems and on taking immediate action to protect public health through voluntary corrective action or a range of administrative remedies.

Administrative Compliance Tools

FSMA's public health prevention focus and new administrative enforcement tools mean that FDA's primary tools for correcting preventive control deficiencies and resolving problems that put consumers at risk will be administrative compliance actions, rather than court enforcement cases, including:

- *Voluntary correction of problems at the facility level*, achieved immediately during the course of an inspection through communication with firm management by investigators and, as needed, Center technical staff
- *Voluntary correction achieved at the District level through deficiency letters*, issued within days after an inspection with Center back up, to document significant safety-related deficiencies and request correction within a specified period, with immediate inspection follow up to verify correction
- *Administrative detention* of product if needed to provide immediate public health protection or for other appropriate purposes.
- *Voluntary and mandatory recalls* to remove potentially hazardous food from the market
- *Administrative suspension of registration* when other administrative compliance measures have failed or are inadequate to achieve correction of significant deficiencies that put consumers at risk

Judicial Enforcement Tools

Enforcement includes judicial actions when necessary to complement non-judicial compliance actions and address matters for which there is no adequate administrative remedy, such as:

- *Seizure actions* that are needed to back up administrative detentions
- *Injunction actions* when suspension of registration or other measures are inadequate to prevent future non-compliance
- *Criminal prosecution* for falsifying records, lying to FDA, knowingly putting consumers at risk, or in other appropriate cases

Sources: FDA.gov

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

Product: Gouda
Incident: Possible Health Risk–*Listeria monocytogenes*

A Winchendon, MA firm is recalling 21 wheels of waxed Gouda, because it has the potential to be contaminated with *Listeria monocytogenes*, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. The wheels are coated in red wax and wrapped in saran wrap with various weights of whole wheels at 10-lbs and half wheels at 5-lbs. The product may have been cut and packaged at retail level for consumer size units. The waxed Gouda wheels were distributed in MA by wholesale distributors and further sold to retailers. So far no illnesses have been reported to date. The recall was the result of a routine sampling by the FDA which revealed that the finished products contained the bacteria. Consumers who have purchased the Gouda are urged not to consume them and to return them for a full refund.

Product: Smoked Atlantic Salmon
Incident: Possible Health Risk–*Listeria monocytogenes*

A Chicago, IL firm is recalling 1,878 pounds of sliced smoked Atlantic salmon due to possible contamination of *Listeria monocytogenes.* A single lot of 4-oz sliced smoked Atlantic salmon packages is the subject of this recall and is the result of one package of salmon that tested positive for *Listeria monocytogenes* by the Florida Department of Agriculture and Consumer Services. The packages of salmon are vacuum sealed and were sent to stores in New York, Massachusetts, Vermont, New Hampshire, Texas, Alabama, Florida, Georgia and South Carolina beginning on April 7, 2014. So far, no illnesses have been reported to date. Consumers should return products for a refund by mailing the product label or a copy of the receipt to the firm. Consumers should contact the company with any questions.

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

Product: Ribeye & Carcass Products
Incident: Possible Health Risk–*Contain Risk Materials*

A Jackson, MO establishment is recalling approximately 4,012 pounds of fresh beef products because the dorsal root ganglia may not have been completely removed, which is not compliant with agency regulations that require their removal in cattle 30 months of age and older. Products subject to recall include 40-lb. cases containing two, 20-lb. cryovac packages of bone-in ribeye and quartered beef carcasses stamped with a USDA mark of inspection. The products were produced and packaged on various dates between Sept. 2013 and April 2014. The ribeye roasts were distributed to a restaurant in NY and a distribution center in CT. The carcasses were distributed to an FSIS-inspected establishment in MO for further processing and distribution and to a restaurant in MO. FSIS discovered the problem during a review of company slaughter logs. FSIS has not received any reports of illness due to consumption of these products.

Product: Turkey Base Products
Incident: Possible Health Risk–*Undeclared Allergen*

A Broadview, IL establishment is recalling approximately 3,156 pounds of turkey base because of misbranding and an undeclared allergen. The turkey base which contains milk was misbranded as chicken base that does not include milk. The turkey base that was sold in 1-lb. tubs and labeled as chicken base was produced on March 19, 2014. After production, the products were shipped to food service distribution centers in PA, FL, OR, WI, IL and VA. The problem was discovered after one of the company's customers found tubs labeled as chicken base in cases labeled as containing turkey base. After a quality check, the company found that the turkey base had mistakenly been packaged into tubs labeled for chicken base. FSIS and the company have not received any reports of illness associate with consumption of these products. Consumers with questions in regard to the recall should contact the company.

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

Product: Bicycles
Incident: Possible Risk-*Fall Hazard*

A Ketchum, ID manufacturer is recalling approximately 2,000 units (481 units in Canada) of specific models of both men's and women's bicycles. The bikes were sold in black and white with blue, green, purple or teal accents. The steerer tube in the front bicycle fork could break during operation, as a result of which the front wheel can detach, posing a fall hazard. The bikes were manufactured in Cambodia an sold at authorized dealers nationwide at retail stores and online from August 2013-May 2014. The company has received one report of a fork breaking, no injuries have been reported. Consumers should stop using the recalled bicycles immediately and take them to an authorized dealer to receive a free replacement fork and have it installed at no cost. Consumers should contact the company directly or visit their website for more information.

Product: Throat Collars
Incident: Possible Risk-*Laceration Hazard*

A Montreal, Quebec, Canada manufacturer is recalling approximately 3,300 units of goalie throat collars (8,100 units in Canada). The recalled senior and junior goalie throat collars are black with white trim and were manufactured in China. A skate blade could penetrate the collar, posing a laceration hazard to the throat. The throat protectors have been decertified by the Bureau de normalisation du Québec (BNQ) for non-conformance to certification requirements. The recalled product was sold in stores nationwide from April 2012 through May 2014. So far there have not been any reports of product related injuries or complaints from consumers. Consumers should immediately stop using the recalled throat collars and contact their local hockey dealer to return the product for a full refund or replacement. Consumers with questions should contact the company or visit their website for additional information.

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