FDA Proposes New Food Safety Standards

The U.S. Food and Drug Administration proposed two new food safety rules that will help prevent foodborne illness. The proposed rules implement the landmark, bipartisan FDA Food Safety Modernization Act (FSMA) and are available for public comment for 120 days from January 4, 2013. The FDA encourages Americans to review and comment on these important proposed rules.

The proposed rules build on significant strides made during the Obama Administration, including the first egg safety rule protecting consumers from Salmonella and stepped up testing for E. coli in beef as well as existing voluntary industry guidelines for food safety, which many producers, growers and others currently follow.

The rules follow extensive outreach by the FDA to the produce industry, the consumer community, other government agencies and the international community. Since January 2011, FDA staff have toured farms and facilities nationwide and participated in hundreds of meetings and presentations with global regulatory partners, industry stakeholders, consumer groups, farmers, state and local officials, and the research community.

“The FDA Food Safety Modernization Act (FSMA) is a common sense law that shifts the food safety focus from reactive to preventive,” said Health and Human Services Secretary Kathleen Sebelius. “With the support of industry, consumer groups, and the bipartisan leadership in Congress, we are establishing a science-based, flexible system to better prevent foodborne illness and protect American families.”

The burden of foodborne illness in the United States is substantial. One in six Americans suffer from a foodborne illness every year. Of those, nearly 130,000 are hospitalized and 3,000 die from their illness. Preventing foodborne illnesses will improve public health, reduce medical costs, and avoid the costly disruptions of the food system caused by illness outbreaks and large-scale recalls.

These two FSMA rules are part of an integrated reform effort that focuses on prevention and addresses the safety of foods produced domestically and imported, with additional rules to be published shortly.

The first rule proposed would require makers of food to be sold in the United States, whether produced at a foreign- or domestic-based facility, to develop a formal plan for preventing their food products from causing foodborne illness. The rule would also require them to have plans for correcting any problems that arise. The FDA seeks public comment on this proposal. The FDA is proposing that many food manufacturers be in compliance with the new preventive controls rules one year after the final rules are published in the Federal Register but small and very small businesses would be given additional time.

The FDA also seeks public comment on the second proposed rule, which proposes enforceable safety standards for the production and harvesting of produce on farms. This rule proposes science- and risk-based standards for the safe production and harvesting of fruits and vegetables.

The FDA is proposing that larger farms be in compliance with most of the produce safety requirements 26 months after the final rule is published in the Federal Register. Small and very small farms would have additional time to comply, and all farms would have additional time to comply with certain requirements related to water quality.

“The FDA knows that food safety, from farm to fork, requires partnership with industry, consumers, local, state and tribal governments, and our international trading partners,” said FDA Commissioner Margaret A. Hamburg, M.D. “Our proposed rules reflect the input we have received from these stakeholders and we look forward to working with the public as they review the proposed rules.”

Before issuing the two rules, the FDA conducted extensive outreach that included five federal public meetings and regional, state, and local meetings in 14 states across the country as well as making hundreds of presentations to ensure that the rules would be flexible enough to cover the diverse industries to be affected. The FDA also visited farms and facilities of varying sizes.

“We know one-size-fits-all rules won’t work,” said Michael R. Taylor, the FDA’s deputy commissioner for foods and veterinary medicine. “We’ve worked to develop proposed regulations that can be both effective and practical across today’s diverse food system.”

Additional rules to follow soon include new responsibilities for importers to verify that food products grown or processed overseas are as safe as domestically produced food and accreditation standards to strengthen the quality of third party food safety audits overseas. Improving oversight of imported food is an important goal of FSMA. Approximately 15 percent of the food consumed in the United States is imported, with much higher proportions in certain higher risk categories, such as produce. The FDA will also propose a preventive controls rule for animal food facilities, similar to the preventive controls rule proposed today for human food.
**Food and Drug Administration Recalls** (www.fda.gov)

**Product:** Salad Products  
**Incident:** Possible Health Risk—Listeria monocytogenes

A Salinas, CA firm has initiated a precautionary recall of 110 cases of Romaine 10 oz. bag salad products. The product is being recalled out of an abundance of caution following a single random finished package test conducted by the Food and Drug Administration (FDA) which tested positive for Listeria monocytogenes. Listeria monocytogenes can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. There have been no complaints or illnesses reported in association with this recall. The company is cooperating with the FDA and California Department of Public Health (CDPH) regarding the recall. Customers that may have purchased this product are urged not to consume the product and should dispose of it. Consumers with further questions should contact the company for more details.

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

**Product:** Smoked Salmon  
**Incident:** Possible Health Risk—Listeria monocytogenes

A Seattle, WA firm is recalling 371 cases of ready-to-eat cold smoked salmon products because of possible contamination by Listeria monocytogenes. Listeria monocytogenes can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. The recalled salmon was a product of Chile. It was sold in 3 and 4 oz. packages and distributed to various retailers and distribution centers in WA, OR, CA, AZ, TX, CO, MA, NH, CT, RI, NJ, and NY from November 20 through December 12, 2012. The company has notified the retailers and distributors who may have received the affected product. There have been no complaints or illnesses reported in association with this recall. The potential for contamination was noted after internal testing by the company revealed the presence of Listeria monocytogenes in samples of the product. Consumers should discard any open packages and return unopened packages for a full refund.

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

**Product:** Breaded Chicken Products  
**Incident:** Possible Health Risk—Foreign Materials

A Duluth, GA establishment is recalling approximately 35,800 pounds of breaded chicken products because they may contain pieces of plastic. The products subject to recall include cases containing twelve, 12-oz. cartons of fully cooked chicken nuggets, fully cooked gluten/soy free chicken patties, and 10-lb. bulk cases of fully cooked chicken nuggets. The nuggets and patties subject to recall bear the USDA mark of inspection and were produced on March 15, 2012 and Sept. 6, 2011. The products were produced for a separate federally-inspected establishment and distributed to retail stores nationwide. The problem was discovered as a result of consumer complaints about finding pieces of plastic in the products. The plastic pieces may have originated from the plastic bag the products were held in prior to production. There have not been any reports received about an injury or illness at this time. Contact the company with any questions.

**Product:** Mortadella  
**Incident:** Possible Health Risk—Undeclared Allergen

A South Chesterfield, VA establishment is recalling approximately 2,650 pounds of mortadella because the product contains pistachio nuts, a known allergen, which is not declared on the label. The products subject to recall include cases containing two, 6-8 lb. bulk deli packages of mortadella which were shipped to retailers in NJ and NY. Also included in the recall are cases containing two, 5-7 lb. bulk deli packages of mortadella shipped to distributors in FL and IL. Both products were produced on Nov. 10, 2012. The problem was discovered by the company, who notified FSIS. The company produces mortadella with and without pistachios. This problem occurred when the label for the product without pistachios was incorrectly placed on product containing pistachios. FSIS and the company have received no reports of adverse reactions at this time. Consumers and media should contact the company with questions.

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

**Product:** Gas Fireplace Inserts  
**Incident:** Possible Risk-Electrical Shock and Burn

The CPSC and Health Canada in cooperation with a Gorham, ME manufacturer have announced a voluntary recall of 1,200 units (50 units in Canada) of gas fireplace inserts. The recall involves four models of fireplace inserts that fit into existing vented fireplaces providing a variety of fireplace effects fueled by natural gas or liquid propane. The inserts are cast iron or steel and have a glass front, ceramic fiber logs, a gas burner and an electrical cord. The fireplace insert’s electrical wiring can come into contact with the metal raking plate on the insert, posing electrical shock and burn hazards to consumers. These inserts were manufactured in the United States and sold at independent specialty fireplace and stove stores nationwide and in Canada from June 2010 through September 2012. Consumers should immediately stop using and unplug the recalled gas fireplace inserts and contact the store of purchase for a free repair.

**Product:** Stroller  
**Incident:** Possible Risk-Fall

The CPSC and Health Canada in cooperation with a Richmond, VA firm have announced a voluntary recall of 8,400 units (2,200 units in Canada) of strollers. The recall involves a specific model stroller manufactured in China between May 15 and August 20, 2012. The strollers have charcoal-colored metal frames with black, silver, red or green fabric stroller seats and canopies. The stroller frame can fail to lock in place and collapse while in use, posing a fall hazard to children in the stroller. The company has received six reports of incidents with the stroller’s frame failing to lock. No injuries have been reported. The strollers were sold at juvenile product stores nationwide and online from July 2012 through October 2012. Consumers should immediately stop using the recalled strollers and contact the company for a free replacement stroller frame. Consumers and media should contact the company with any questions.

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