

Crisis Control Newsletter

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

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FSMA Produce Safety—Proposed Rule

On January 4, 2013, FDA released for public comment its proposed rule, Section 105 of the Food Safety Modernization Act (FSMA), that directs the FDA to establish science-based minimum standards for the safe growing, harvesting, packing and holding produce on domestic and foreign farms.

This rule considers both the commodity and the practices associated with growing, harvesting, packing and holding produce as well as how produce will be used and consumed after it leaves the farm. The proposed produce rule provides growers flexibility in their approach to on-farm food safety, so that food safety practices being taken by farmers can be appropriate for the scale of production and type of agricultural practices being used.

The proposed rule sets science-based standards for the safe production and harvesting of fruits and vegetables that the Agency determines minimize the risk of serious adverse health consequences or death. FDA proposes to set standards associated with identified routes of microbial contamination of produce, including: (1) agricultural water; (2) biological soil amendments of animal origin (3) health and hygiene (4) animals in the growing area and (5) equipment, tools and buildings. The proposed rule includes additional provisions related to sprouts. Sprouts present a unique risk because the warm, moist, and nutrient-rich conditions required to produce sprouts are the same conditions that are also ideal for the growth of pathogens. The proposed rule would require treating seed before sprouting, testing spent sprout irrigation water (or sprouts, in some cases) for pathogens and monitoring the growing environment *for Listeria species* or *Listeria monocytogenes*.

The proposed produce rule covers most fruits and vegetables while they are in their raw or natural (unprocessed) state. It would not apply to raw agricultural commodities that are rarely consumed raw, those produced for personal or on-farm consumption, and (with certain documentation) those destined for commercial processing, such as canning, that will adequately reduce microorganisms of public health concern.

Some farms would not be covered by the rule, or would be eligible for a partial exemption based on factors including the monetary value of their food sales and to whom they sell. The partial exemption would still subject eligible farms to certain modified requirements, and could be withdrawn in certain circumstances.

The proposed rule would provide that farms may establish alternatives to certain requirements related to water and biological soil amendments of animal origin if the alternative is scientifically established to provide the same amount of protection as the requirement in the proposed rule without increasing the risk of adulteration.

The proposed rule would require certain records, for example, to document that certain of the standards are being met. However, it would not require duplication of records already kept for other purposes.

FDA is proposing that the requirements be effective 60 days after a **final rule** is published in the Federal Register. Recognizing that small and very small businesses may need more time to comply with the requirements, compliance dates would be phased in based on business size.

Highlights of Proposed Rule

Agricultural Water. Water used for produce production presents different microbial quality demands depending on its use. Water can be a carrier of many different microorganisms of public health concern. The proposed rule would require that all agricultural water be safe and of adequate sanitary quality for its intended use. "Agricultural water" would be defined in part as water that is intended to, or likely to, contact covered produce or food-contact surfaces. The proposed rule would require that, at the beginning of the growing season, the agricultural water system components under a farm's control be inspected to identify conditions that are reasonably likely to introduce pathogens to produce or food-contact surfaces. FDA is proposing that specific criteria for the quality of agricultural water be established for water that is used for certain purposes, with proposed requirements for periodic analytical testing.

Biological Soil Amendments of Animal Origin. Biological soil amendments of animal origin, such as composted manure, may contain pathogens of public health concern. To address this, the rule proposes three types of measures to reduce the risk: types of treatment, methods of application, and time intervals between the application of a biological soil amendment of animal original and crop harvest. The proposed rule also has provisions pertaining to the handling and storage of biological soil amendments of animal origin.

Health and Hygiene. Bacteria, viruses, and parasites are frequently transmitted from person to person and from person to food, particularly through the fecal-oral route. The proposed rule would require that farm personnel use hygienic practices, including hand washing and maintaining adequate personal cleanliness.

Domesticated and Wild Animals. Pathogens can be introduced into fruit and vegetable production systems via animal feces. Where there is a reasonable probability that animals will contaminate produce, the rule proposes certain requirements, such as an adequate waiting period between grazing of domesticated animals and harvesting produce from that growing area. Similarly, for working animals used where a produce crop has been planted, farms would be required to take measures to prevent pathogens from being introduced onto the produce. In addition, farms would be required to monitor for significant wild animal intrusion events both immediately before harvest, and, as needed during the growing season, and not harvest produce that is visibly contaminated with animal excreta.

Equipment, tools and buildings. Among other things, the proposed rule also would set standards for certain equipment and tools, buildings, and sanitation used for produce operations on farms.

Training. The proposed rule would require training for farm personnel who handle the produce or food-contact surfaces, and for supervisors.

Source: FDA.gov

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

Product: Donuts
Incident: Possible Health Risk–Undeclared Allergens

A Middlebury, IN firm is recalling all its donut varieties and cinnamon caramel donut holes because they may contain undeclared egg. They are also recalling their Nutty Crunch variety sold in 8oz pouches because they contain undeclared peanuts. People who have allergies to egg, or peanut run the risk of serious or life-threatening allergic reaction if they consume these products. The donut products are packaged in brown 6 and 12 count boxes, while the donut holes are packaged in 1.05-lb. boxes. These products were produced on or before Jan. 13th, 2014 and were sold in their retail store and distributed to retail stores in Northern Indiana. The donuts containing undeclared peanuts were packaged in 8 oz. pouches and were sold in their retail store and distributed to retail stores in PA, IL, KS, MI, OH, WI, IN, MN, MO, VA; and to a distributer in PA or purchased on their website. No illnesses have been reported to date.

Product: Mixed Nut Candy
Incident: Possible Health Risk–Undeclared Allergen

A Dalton, WI, firm along with it's manufacturing partner is recalling mixed nut candy packaged in 4oz. green and yellow plastic bags, because it contains undeclared peanuts. This affects all products with a sell by date of June 1st 2014 or before. 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. The candy was distributed to distributers in WI and NJ. No illnesses have been reported to date in connection with this problem. The recall was initiated during an FDA inspection of the manufacturer which found the undeclared peanut allergen in the product. Subsequent investigation indicates the problem was caused by a temporary breakdown in the company's production and packaging process. Current product will be labeled to declare peanuts. This product is no longer manufactured with peanuts as of January 15th 2014.

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

Product: Meat Products
Incident: Possible Health Risk–Non-Inspection

A Petaluma, CA establishment is recalling approximately 42,103 pounds of various meat products because they were produced without the benefit of federal inspection, making them unfit for human food consumption. Included in the recall are beef carcasses sold in 20, 30, 50 and 60-lb. boxes such as beef feet, beef oxtail, beef hearts, beef liver, beef cheeks, beef tripe, beef tongue and book tripe. The products were produced Jan. 8, 2014, and shipped to distribution centers and retail establishments in California. The problem was discovered as a result of an ongoing investigation. FSIS believes the company produced product without full ante-mortem inspection as per federal regulations. FSIS has received no reports of illness due to consumption of these products. Anyone concerned about an illness should contact a health care provider. Consumers and media who have questions about the recall should contact the Quality Control manager.

Product: Beef Franks
Incident: Possible Health Risk–Undeclared Allergen

A Mandan, N.D., establishment, is recalling approximately 2,664 pounds of beef franks due to misbranding and an undeclared allergen. The products were formulated with non-fat dry milk, a known allergen, which is not declared on the product label. The products subject to recall include 16-oz. packages of Beef Franks and 12-lb. cases containing 12 packages of individual 16-oz. packages of Beef Franks. The products were produced on Nov. 23 and Dec. 13, 2013, with use-by dates of February 21 and March 13, 2014 respectively. The products were sold to retail establishments in Montana, North Dakota and Washington State. The problem was discovered by the company during an internal label review. The problem occurred when the newly designed label included an incorrect ingredient statement. FSIS and the company have received no reports of adverse reactions due to consumption of these products.

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

Product: Oscillating Fan Heaters
Incident: Possible Risk-Fire & Burn Hazards

A Hoffman Estates distributor/importer is recalling approximately 42,500 units of oscillating fan heaters. The heaters are gray and white, measure about 12 inches tall by 9 inches wide, have two dials at the top for temperature and fan speed and a red on-off button on the front base. Broken motor mounts can cause the units to overheat, catch fire and ignite nearby items, posing a fire and burn hazard to consumers. The company has received seven reports of the fan heaters smoking or catching fire, including two reports of injuries. The fan heaters were manufactured in China and sold at a retailer chains nationwide from September 2013 through November 2013. Consumers should immediately turn off and unplug the recalled fan heaters and return them to the retailer for a full refund. Consumers and media should contact the company directly or visit their website for more information.

Product: Card Table & Chair Sets
Incident: Possible Risk-Finger Amputation and Falls

A Bentonville, AR importer is recalling approximately 73,400 units of card table sets with a black padded metal folding table and four black padded metal folding chairs. The chairs can collapse unexpectedly, posing a fall hazard and a risk of finger injury, including finger amputation. The company has received 10 reports of injuries from collapsing chairs. Injury reports include one finger amputation, three fingertip amputations, sprained or fractured fingers and one report of a sore back. The card table sets were manufactured in China and Taiwan and sold exclusively at a retailer nationwide and online from May 2013 through November 2013. Consumers should immediately stop using the recalled card table and chair sets and return the entire set to the retailer for a full refund. Consumers and media should contact the company directly or visit their website for more information.

Crisis Control is a newsletter jointly published by RQA, Inc. & Catlin Group.

For more information about these topics and more, please contact:

Carol Kozlowski, CPIM
Manager of Crisis Management, RQA, Inc.
Phone: 708-364-7060 x129
Email: c.kozlowski@rqa-inc.com

RQA-Inc.com

London, UK:
David Burke: david.burke@catlin.com
Ian Bailey: ian.bailey@catlin.com
John Naughton: john.naughton@catlin.com
Andrew Kyle: andrew.kyle@catlin.com

Email: CrisisManagement@catlin.com

Catlin.com