



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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Good Manufacturing Practices

Since the publication in 1906 of Upton Sinclair's book, "The Jungle", the food manufacturing industry has gone through many changes...for the better. We have seen the evolution of quality and safety policies and systems and the progression of regulations to ensure that manufacturers take proactive measures to be sure that products are safe and free of defects and adulterants. In order to make certain that manufacturers guard against the contamination of food in their processes, many countries have adopted their own set of Good Manufacturing Practices (GMPs). GMPs describe the methods, equipment, facilities, and controls for producing processed food. As the minimum sanitary and processing requirements for producing safe and wholesome food, they are an important part of regulatory control over the safety of the food supply.

Today, we have more sophisticated technologies, methods, and processes in manufacturing that help us identify and address issues before defective or dangerous products make it to the marketplace. In a study commissioned by the FDA to elicit expert review of current food safety issues and preventative controls to address these issues, it was found that "deficient employee training," "contamination of raw materials," "poor plant and equipment sanitation," and "poor plant design and construction" were ranked as the top four food safety problems faced by food manufacturers today. The most frequently mentioned preventive controls included:

- *Training* -- Ongoing and targeted training on issues ranging from allergen control, cleaning and sanitation procedures, incoming ingredient receipt protocol, and monitoring for employees, management, as well as suppliers,
- *Audits* -- Periodic audits and inspections of facility and raw material suppliers either in-house or by third-party firms,
- *Documentation* -- Documentation of training activities, raw material handling policies and activities, cleaning and sanitation, receiving records, and use of sign-off logs, and
- *Validation/Evaluation* -- Evaluation of training effectiveness and establishment of accountability; validation of cleaning through testing

Most GMP requirements are very general and open-ended, allowing each manufacturer to decide individually how to best implement the necessary controls. This provides much flexibility, but also requires that the manufacturer interpret the requirements in a manner which makes sense for each individual business.

Sources: *World Food Program, GMP Handbook, FDA, CFIA*

By: Carol Kozlowski, CPIM, Manager of Crisis Management for Insurance Services, RQA, Inc.

Failure to Meet GMPs

GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors. This in turn, protects the consumer from purchasing a product that can be harmful or even dangerous. Furthermore, actual contamination need not have taken place; food can be deemed adulterated if it was merely held under unsanitary conditions likely to result in contamination. Failure of firms to comply with GMP regulations can result in very serious consequences including recall, seizure, fines, and jail time.

A few examples of failure to meet GMPs are as follows:

- Dead rodents, rodent excrement and bird feathers were found in a peanut manufacturing facility. The FDA inspections noted unsanitary conditions including cockroaches, mold and leaking roofs. Plant operations were ordered stopped and a recall was ordered of all products manufactured and shipped from the plant. The business filed for bankruptcy about 1 month after the recall.
- U.S. Marshals, acting on the request from FDA, seized more than \$1 million of food from a rodent-infested food processor and warehouse in Tennessee. A Nashville distributor of bulk restaurant foods, had received a warning letter from the agency in May 2009, citing numerous deviations from good manufacturing practices.
- FDA issued a warning to a seafood company in Florida, concerning serious violations of federal seafood processing and GMP regulations. The agency said its inspection revealed deviations from federal HACCP and GMP requirements that caused the firm's ready-to-eat seafood products, including cooked crabmeat and refrigerated canned pasteurized crabmeat, to be adulterated because they were prepared, packed or held under insanitary conditions

It is the responsibility of all food manufacturers that GMPs are designed to ensure an effective overall approach to food quality and safety by setting appropriate standards and practices.

Sources: <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/AllBusiness/FDAWarningLetters>

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

Product: Breakfast Cereal

Incident: Uncharacteristic Off-Flavor/Smell—Packaging

A Battle Creek, MI firm has issued a voluntary recall of four breakfast cereals distributed nationwide. The recall was issued due to an uncharacteristic off-flavor and smell coming from the wax liner of the package. The problem was discovered after 50 consumers complained to the firm about the off taste and odor, including several who reported experiencing ill effects after eating one of the products. While potential for serious health problems is low, consumers were asked not to eat the recalled products. Some consumers may experience a sensitivity to the smell and experience temporary symptoms, including nausea and diarrhea. Consumers that have any of the recalled products should discard them or return them to the place of purchase. Those with questions or who would like a replacement product should contact the company's Consumer Response Center.

Product: Sweet Potato & Chicken Dry Dog Food

Incident: Possible Health Risk – *Salmonella*

A Pacoima, CA firm is recalling Sweet Potato & Chicken Dry Dog Food that was originally manufactured on Dec. 17, 2009. This product has the potential to be contaminated with salmonella. *Salmonella* can affect animals and there is also a risk to humans that handle contaminated pet products. Consumers exhibiting symptoms of salmonella including nausea, vomiting, diarrhea or bloody diarrhea, abdominal cramping and fever after having contact with this product should contact their healthcare providers. Pets with *Salmonella* may be lethargic and have diarrhea or bloody diarrhea, fever and vomiting. If your pet has consumed the recalled product and has any of these symptoms, contact your veterinarian. Recalled products were distributed in the states of AK, AZ, AR, CA, CO, HI, ID, IL, IA, KS, LA, MN, MS, MO, MN, NV, NM, ND, OK, OR, SD, TX, UT, WA, WI, WY. Consumers who have purchased this dog food should return it to the place of purchase for a full refund.

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

Product: Pasta Product with Meatballs

Incident: Possible Health Risk – Under-processing

A Paris, TX establishment is recalling approximately 15,000,000 pounds of canned pasta products due to possible under-processing. The company states that a cooker malfunctioned at one of the company's plants in Texas and left the meat undercooked. These products were manufactured between December 2008 and June 2010 and were distributed nationwide. The problem was discovered through a routine warehouse inspection by the company and its subsequent investigation. There has been no reports of illnesses from consumption of these products. Recalled products should be safely discarded and not consumed. Consumers and media with questions regarding this recall should contact the company.

Product: Frozen Chicken Meals

Incident: Possible Health Risk – *Salmonella*

A Bluffs, IA establishment announced that they are recalling all 13 oz packages of Cheesy Chicken and Rice frozen meals distributed nationwide, regardless of production date. The company was informed by the U.S. Centers for Disease Control and Prevention (CDC) of an investigation involving 29 people in 14 states who have been diagnosed with salmonellosis linked to *Salmonella* serotype Chester. Eight of the case patients reported eating this product in April and May 2010. The last reported illness was reported on May 22, 2010. The investigation is on-going, and has not yet definitively identified a food vehicle(s). Recalled products should be safely discarded and not consumed. Consumers and media with questions about the recall should contact the company.

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

Product: Mint Mouthwash

Incident: Hazard – Child-Resistant Closure Failure

A Cincinnati, OH firm in cooperation with the CPSC is recalling about 35,000 bottles of mint mouthwash sold at retailers nationwide from January 2010 to June 2010. The product was manufactured in the USA. The recall involves 1 liter size bottles that may have malfunctioning child-resistant closures. The mouthwash also contains ethyl alcohol which can be toxic and can cause serious injury or death if ingested by children. So far no incidents or injuries have been reported. Consumers should keep this product out of the reach of children and may contact the company for a full refund or replacement coupon. Adult consumers can continue to use the product as directed. For additional information, consumers are asked to contact the company or visit the company's website.

Product: Children's Belts

Incident: Hazard – Excessive Levels of Lead

A Minneapolis, MN retailer in cooperation with the CPSC is recalling approximately 105,150 boy's and girl's belts. These belts that were manufactured in China and sold nationwide from December 2008 through December 2009. The belt buckles contain excessive levels of lead, violating the federal lead paint standard. So far the retailer has not received any incident reports or reports of injuries. Consumers should immediately stop using the recalled belts and return them to the store to receive a full refund. For more information, consumers can contact the company or visit the company's website.

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

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