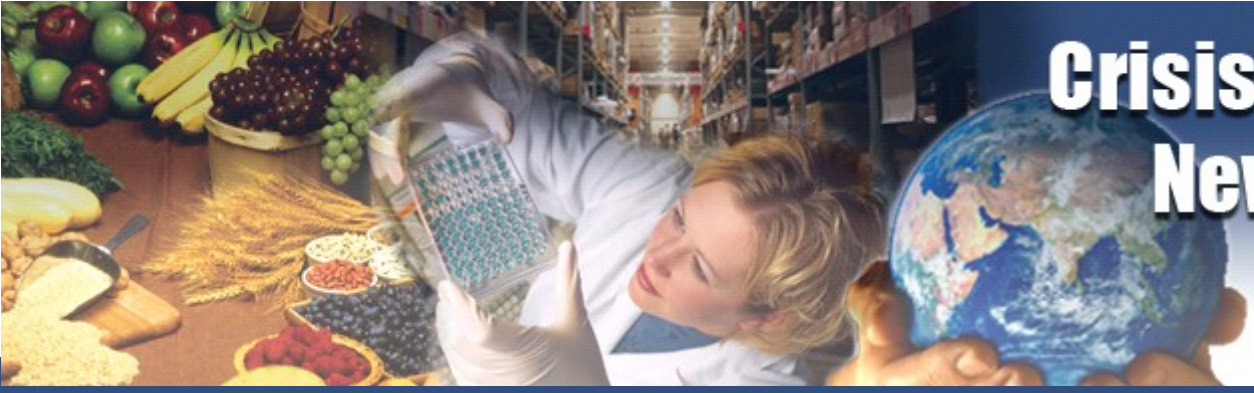

Crisis Control Newsletter

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

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Corrective And Preventative Action—CAPA

No business wants to have problems, but problems are inevitable. Most businesses work to prevent problems through rigorous quality programs, supplier partnership programs, and testing performed throughout the production process.

When a problem arises, it is important to take swift and effective corrective actions. Corrective and preventative action, CAPA, is part of an overall total quality management system (QMS). The CAPA model is a tool that supports the process of continuous improvement in a company's quality system. CAPA focuses on a systematic approach to identity and investigate an issue and develop corrective measures to prevent such issues from recurrence. In addition, preventative action is a proactive approach to determine potential or likely issues or nonconformances and implement measures to ensure that they do not occur. Preventative action is a form of risk avoidance.

The ISO 9001:2000 standard requires to establish, document, implement and maintain:

8.5.2 Corrective action

A documented procedure is established to define requirements for:

- reviewing nonconformities (including customer complaints),
- determining the causes of nonconformities,
- evaluating the need for action to ensure that nonconformities do not recur,
- determining and implementing action needed,
- records of the results of action taken, and
- reviewing the effectiveness of the corrective action taken.

8.5.3 Preventive action

A documented procedure is established to define requirements for:

- determining potential nonconformities and their causes,
- evaluating the need for action to prevent occurrence of nonconformities,
- determining and implementing action needed,
- records of results of action taken, and
- reviewing the effectiveness of the preventive action taken.

Any implemented changes should be reviewed with respect to their impact on the issue and monitored to make sure that an issue can finally be closed out. Documentation of the complete corrective and/or preventative action from identification through close out is essential to meeting regulatory compliance.

Sources: ISO 9100, FDA, ASQ

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

Root Cause Analysis

Stop putting out fires and extinguish the problem at the source. Don't put a bandage on a problem, fix the reason for the problem. We've heard many of these expressions. While there are many tools, techniques and methodologies that offer help in root cause analysis, none will be valuable or effective if they are not used properly.

It is essential to have the right team in place to collect data and do the investigation necessary to determine what factors to consider and what factors to eliminate from the analysis. Communication needs to be crystal clear in all matters to make sure that the right questions are asked during investigation in order to obtain the correct root cause. In order to implement a solid and successful corrective action plan, it is essential to determine the correct root cause. Implementing corrective actions on the wrong root cause will not solve the problem and may create others.

The first step in root cause analysis is to clearly define what is the actual problem or clearly determine what is the nonconformance. Answering the wrong problem won't resolve the situation.

Once the correct problem is determined, gather whatever facts can be obtained about the issue or those that may be related to the issue.

Perform a comprehensive investigation to eliminate factors that are not pertinent to the issue in order to focus on those causes which, if corrected, will eliminate the problem and keep it from reoccurring. It is also important to understand contributory factors that will have an impact on obtaining the true root cause.

Have confidence in the determination of the root cause(s) before executing corrective action measures.

Ensure that corrective action measures are implemented as planned then monitor the effectiveness of the corrective action plan so that the problem does not resurface.

If the problem reoccurs, check the results of the investigation to determine if there might be additional causes that were missed. Also review the corrective actions that were implemented to verify and make certain that they were followed as intended.

Continuous improvement and risk mitigation in any organization depends on precise root cause determination and well-founded and monitored corrective action plans.

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

Product: Dry Dog Food
Incident: Possible Health Risk– *Excess Vitamin D*

A Wilton, CT firm has issued a voluntary recall of certain production runs of dry dog food. These packages may contain possible excessive levels of Vitamin D that can affect the health of some dogs. While Vitamin D is a beneficial component of these foods, the Company believes that these products may have levels of Vitamin D that are beyond formula specifications. If was discovered that the ingredient supplier had made a scheduling error and produced a Vitamin D supplement immediately prior to preparing the ingredients for the food. There have been 36 cases nationwide of dogs reported with symptoms consistent with elevated Vitamin D levels while feeding on these products. Symptoms include lethargy or unusually frequent water consumption and urination. If your pet has consumed these products and shows signs of these symptoms, please consult a veterinarian. All recalled products should be returned to the place of purchase for a full refund. Consumers and media with questions should contact the company.

Product: Chocolate Covered Raisins
Incident: Possible Health Risk–*Undeclared Allergen*

A Glendale, CA company is voluntarily recalling a single production code of their 10 oz bags of chocolate covered raisins. Products produced with this code may contain an allergen not listed on the bag's ingredient label, specifically peanuts. People who have allergies or severe sensitivity to peanuts run the risk of serious or life-threatening allergic reaction if they consume these products. There have been 3 reports of complaints received to date. While this product is labeled with a precautionary statement "made on equipment that also processes peanuts," the product should not, but may contain some peanuts that are not declared on the label. Consumers allergic to peanuts, should not consume these products. Consumers who have purchased these products should contact the company for a full refund and discard any remaining packages. Those with further questions should contact the company for instructions.

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

Product: Beef Stick Products
Incident: Possible Health Risk–*Foreign Materials*

A Milwaukee, WI establishment is recalling approximately 2,740 pounds of beef stick products because they may contain foreign materials. Each 8-ounce packages of the beef stick products are vacuum packaged and have a "Use By" date of March 1, 2012. The beef stick products were produced on August 31, 2010, packaged on September 1, 2010, and shipped to distribution centers and retail stores nationwide. The problem was discovered after a retail chain reported consumer complaints about finding hard plastic and/or pieces of glass in the product. FSIS has not received any consumer complaints or reports of injury due to consumption of these products. Anyone concerned about an injury from consumption of these products should contact a physician. Consumers and media with questions regarding this recall should contact the company.

Product: Spicy Vegetable Potstickers
Incident: Possible Health Risk–*Mislabeling*

A Los Angeles, CA establishment is recalling approximately 1,608 pounds of spicy vegetable potstickers due to a mislabeling of individual pouches that were packed with chicken potstickers. The products subject to recall include 5-lbs. boxes of 10-ounce cartons of spicy vegetable potstickers. The products were produced on September 13, 2010 and were distributed to a retail establishment in Texas. Each package bears a "Use By" date of Sept 13, 2011. The problem was discovered by a consumer complaint to the establishment. There have not been any reports of adverse reactions due to consumption of these products. Those with further questions should contact the company for instructions.

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

Product: Infant Boy Shoes
Incident: Hazard– *Choking*

A Grand Rapids importer is voluntarily recalling about 2,300 units of infant boy shoes manufactured in China. These infant boy casual shoes with bungee laces and toggles were sold at a major retail chain nationwide from July 2010 through September 2010. The shoe lace toggles can detach, posing a choking hazard to young children. The firm has not received any reports of incidents or injuries due to the use of this product. The brown leather shoes were sold in infant sizes 5 to 10 and have the brand imprinted on the bottom of the shoe. Consumers should immediately take the recalled shoes away from children. They should also remove and discard the toggles to eliminate the hazard or return the product to any one of the retailers for a full refund. For additional information, consumers are asked to contact the company or visit the company's website.

Product: Trampolines
Incident: Hazard-*Fall*

A Santa Fe Springs, CA distributor in cooperation with the CPSC is recalling approximately 160,000 trampolines. Incorrectly assembled trampolines can allow the top rails and legs to bend or break during normal use, resulting in partial collapse of the trampoline. This poses a fall hazard to consumers. The recall involves 12', 13', and 14' units with certain models numbers and come in 3 colors. These trampolines were manufactured in China and sold at retailers and on the internet nationwide from January 2007 through September 2010. There have been 247 reports of top rails bending or breaking during normal use and four injuries reported due to the bending and breaking of the trampolines. Consumers should immediately stop using the recalled products and contact the company for instructions on how to inspect for damage and request replacement parts. For more information, consumers may contact the company.

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