



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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Health Hazard Evaluation—Food and Beverages Importance to Successful Recall Management

A health hazard evaluation is an important part of successful recall management. It is a risk-based approach to determine if there is a risk to consumer health and safety and how great that risk may be. A health hazard evaluation is not just aimed at the general population, but also other sub-populations at risk, such as the very young, the elderly, people with compromised immune systems and pregnant women.

The conclusion of the health hazard evaluation identifies the predicted severity and probability of the health hazard associated with the product, which then assists the recalling firm and the relevant regulatory agency in determining the recall's appropriate class, depth and communication strategy.

The **class** is determined by the degree of health hazard presented by the product: Class I (high risk), Class II (moderate risk) and Class III (low or no risk). Class I is generally assigned to products when there is high risk that eating, drinking or exposure to the product will likely cause significant harm/injury, illness or death.

The **depth** is the level in the distribution chain to which the company will contact in order to retrieve the recalled product, such as wholesale level, user level, retail level and consumer level. The depth is based on the recall class.

The **communication strategy** is the plan for notifying the appropriate level(s) in the supply chain, which varies by class and depth. For all Class I recalls, it is extremely important to warn consumers of the product's risk. The communication strategy should include issuing a joint press release on the agency's web site and through news and specialized media, having a dedicated toll free number and posting the press release and other information on the company web-site. Other communication methods to consider are creating a video news release to complement the written press release, social media, point-of-purchase posters and paid advertising via national, regional or local television, radio and newspapers. Also, If higher risk sub-populations are involved, communication through more precise and targeted means may be required, such as directly to day care centers, hospitals, nursing homes, schools, physicians and specific magazines, web-sites and organizations.

Companies suspecting their products may cause harm to consumers should complete a health hazard evaluation to determine the consumer health and safety risk. The health hazard assessment will assist in assigning the class, determining the depth and developing the communication strategy.

Components

A health hazard evaluation helps achieve the ultimate goal of all recalls, to protect consumer health and safety.

A health hazard evaluation should include considering the following:

Current Affects:

- Has a disease or injury already occurred from using the product?

Product Use Profile:

- Who is expected to use the product?
- Are sub-populations at higher risk?
- Are there existing conditions that could increase the risk or chance of hazard?

Impact:

- What are the immediate or long term consequences?
- What type of disease or injury could occur?
- What is the severity of the disease or injury?

Probability/Likelihood:

- How likely is the hazard in all populations?

“NOTE: A recall decision does not depend solely on the health risk of the product. Defective products and misbranded products, where no health hazard exists, are still in violation of the law and should be recalled.”

Sources/References:

- Canadian Food Inspection Agency, <http://www.inspection.gc.ca/english/corpaffr/recarapp/recafse.shtml>
- ¹Food and Drug Administration's (FDA) Guidance for Industry: Product Recalls, Including Removals and Corrections, <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>
- United States Department of Agriculture Food Safety and Inspection Service Glossary, available at: <http://www.fsis.usda.gov/help/glossary-r/index.asp>
- 21CFR7, Sec. 7.41 Health Hazard Evaluation and Recall Classification, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7&showFR=1&subpartNode=21:1.0.1.1.5.3>


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

Product: Alfalfa and Spicy Sprouts
Incident: Possible Health Risk– *Salmonella*

An Urbana, IL firm has issued a voluntary recall of their 4 oz Spicy Sprouts and all package sizes of their Alfalfa Sprouts from November 1 thru December 21st because they have the potential to be contaminated with *Salmonella*. These products were distributed thru various distributors in Illinois, Indiana, and Missouri and could have ended up in restaurants and supermarkets near those areas. The mutual goal of the FDA and the company is to pinpoint the source of the contamination and stop the spread of *Salmonella*. Those infected with *Salmonella* often experience fever, diarrhea, nausea, vomiting and abdominal pain. There have been 51 confirmed cases of *Salmonella* in Illinois and around that same number in 15 other states. The illnesses were reported after individuals reported eating alfalfa sprouts at a restaurant in Illinois. Consumers that have any of the recalled products should return it for full credit or destroy it in a sealed container. Those with questions should contact the company directly.

Product: String Cheese
Incident: Risk–*Listeria monocytogenes* & *S. aureus*

A Los Angeles, CA company is recalling a brand of string cheese sold in 17.63-oz / 500-g clear plastic packages because it has the potential to be contaminated with *Listeria monocytogenes* and *Staphylococcus aureus*. Food contaminated with either of these bacteria can cause headache, nausea, vomiting, stomach cramps and diarrhea. The recall was the result of a routine sampling program by the FDA which revealed that the finished products contained the bacteria. The company has ceased production and distribution of the product as they continue the investigation as to what caused the problem. There have not been any reports of illnesses associated with this product. No other products or batches from this company and/or product that may have been distributed were affected by this recall. Consumers who have purchased these products should return them for a full refund. Consumers with further questions can contact the company for more details.


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

Product: Ground Beef Products
Incident: Possible Health Risk–*E. Coli O157:H7*

A Hawthorne, CA establishment is recalling approximately 34,373 pounds of organic ground beef products because they may be contaminated with *E. coli* O157:H7. The organic beef products were sold in 16-ounce packages in both organic ground beef bricks and patties. These products were produced on December 7 and 16, 2010 and were shipped to retail establishments in CA, NJ, NY, NC, WI and WA. The problem was discovered through company microbiological sampling which confirmed a positive result for *E. coli* O157:H7. *E. coli* O157:H7 is a potentially deadly bacterium that can cause bloody diarrhea, dehydration, and in the most severe cases, kidney failure. FSIS and the company have not received any reports of illness due to consumption of these products. Anyone concerned about an illness should contact a physician. Consumers and media with questions regarding this recall should contact the company.

Product: Chicken Mushroom Pies
Incident: Possible Health Risk–*Mislabeling*

A Los Angeles, CA establishment is recalling approximately 600 pounds of frozen chicken mushroom pies because they contain monosodium glutamate (MSG) which is not declared on the label. MSG is not a classified allergen, but can cause a brief reaction in people with a sensitivity to MSG. The products were produced between September 2010 and December 2010 and sold in 6-lb. cases with each case containing 12 individual packages. The individual packages indicate that they contain two pies that are 4-ounces each. These products were shipped to distribution centers for further retail sales in CA and NY. The problem was discovered by FSIS during a routine inspection. FSIS has not received any reports of adverse reactions due to consumption of these products. Individuals concerned about a reaction should contact a physician. Consumers and media with questions about the recall should contact the company.


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

Product: Handlebar Stems
Incident: Hazard– *Fall*

A Bloomington, MN importer is voluntarily recalling about 6,500 units of handlebar stems manufactured in Taiwan. The recall involves threadless and quill handlebar stems sold as individual aftermarket units after April 1, 2010. The handlebar stems are black and have a word painted on the extension. They also have a hash mark on the inside of the stem bar clamp area. The handlebar stems can crack or break, posing a fall hazard to the rider. They were sold at bicycle retailers and websites between April 2010 through October 2010. The firm has received one report of a handlebar stem breaking that resulted in minor injuries. Consumers should immediately stop riding bicycles containing these handlebar stems and contact a dealer for a free inspection and a handlebar stem replacement or ask for a full refund. For additional information, consumers are asked to contact the company or visit the company's website.

Product: Backpacks
Incident: Hazard–*Suffocation*

A Salt Lake City, UT importer/manufacture in cooperation with the CPSC and Health Canada is recalling approximately 3,500 units of backpacks. These backpacks were manufactured in China and sold at specialty outdoor and ski shops nationwide from January 2010 through December 2010. These backpacks have an air intake system that the company states extracts air from the snow, allowing the victim of an avalanche to breathe while buried under the snow. The air intake tubing can crack under cold temperatures, causing the unit not to function as intended, posing a suffocation hazard. The company has received one report of the air intake tubing cracking. No injuries have been reported. Consumers should immediately stop using these recalled backpacks and contact the company to receive a free replacement product or a full refund. For more information contact the company or visit the company's website.

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