

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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Process Changes May Affect Food Safety

The manufacturing process for a food substance may evolve and some of these changes in a manufacturing process may be considered significant. FDA's guidance provides their current thinking regarding considerations for assessing the impact of a significant manufacturing process change on the safety and regulatory status of a food substance. In addition, the guidance provides relevant recommendations for assessing the effect of a significant manufacturing process change on the safety and regulatory status of food substances, including those that are the subject of a food additive or color additive regulation, a food contact substance notification, or a generally recognized as safe (GRAS) determination.

Irrespective of a company's conclusion about whether a change affects the safety or regulatory status of the food substance, it is recommended to consult with the FDA. It is prudent practice for companies to do so, particularly when the manufacturing process change involves emerging technologies, such as nanotechnology. Food substances may be used in a wide array of products manufactured, distributed and sold at retail by a large number of firms. The consequences (to consumers and to the food industry) of broadly distributing a food substance that is later recognized to present a safety concern have the potential to be significant.

These are some factors companies should consider when determining whether a significant change in manufacturing process for a food substance may affect its safety or compliance to regulations:

- Affects the identity of the food substance;
- Affects the safety of the use of the food substance;
- Affects the regulatory status of the use of the food substance;
- Warrants a regulatory submission to FDA.

An assessment of the safety of a food substance generally involves an evaluation of information about its safety and functionality including all studies and tests of a food additive on animals and humans and all studies and tests of a food additive for identity, stability, purity, potency, performance, and usefulness (21 CFR 171.1(h)(4)) which generally include the manufacturing process as part of the information describing the identity of a food substance.

As FDA stated in the preamble to the proposed rule for the GRAS notification program, "The published results of a particular safety study may not be sufficient to demonstrate the common knowledge element if the study raises safety questions that require additional data to be resolved" (62 FR at 18943). Similarly, if fundamental questions exist regarding such a study's basic ability to resolve or address relevant safety questions, that study is likely to be insufficient to demonstrate general recognition of safety.

Assessing Effects of Process Changes

Whenever there has been a significant manufacturing process change, it is recommended that a company assess the effect of such change on the safety and regulatory status of the marketed product. This applies to:

1. *The use of food substances that are the subject of a food additive or color additive regulation*
2. *The use of food contact substances for which there is an effective Food Contact Notification*
3. *The use of food substances that are affirmed or identified as GRAS in 21 CFR*
4. *Use of a food substance for which there is an existing determination that a use of a food substance is GRAS*

Steps that a company should take to determine the effect of process changes on the four areas mentioned above are:

- Determine what changes have been made to the identity as a result of the change in manufacturing process, including its physicochemical structure and properties, purity, and impurities;
- Take into account any impact of the change in identity, conduct a safety assessment for its use, including characteristic properties such as physicochemical structure and properties, purity, impurities, bioavailability, or toxicity;
- Consult with the FDA about the company's conclusions about the impact of the significant manufacturing change on the safety and regulatory status of the use of the food substance;
- Make an appropriate regulatory submission to FDA as circumstances warrant.
- Consider whether:
    - the use of the food substance is authorized under a food additive or color additive regulation
    - the substance would be within the scope of an effective FCN
    - the use of the substance is within the scope of a GRAS affirmation or identification as GRAS in FDA's regulations
    - the GRAS status of the use of the food substance would be affected .

Companies need to consider the impact in all area when making processing changes.
Source: FDA.gov

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

Product: Roma Tomatoes
Incident: Possible Health Risk–*Salmonella*

A Tracy, CA firm is recalling specific lots of Roma tomatoes because they may be contaminated with *Salmonella* as a result of routine testing. *Salmonella* is an organism which can cause serious and sometimes fatal infections in young children, elderly people and others with weakened immune systems. These lots of Roma tomatoes were shipped whole to retailers in CA, NV, and WA. They were also used in salad kits shipped to retailers in CA and AZ. The product was also sold at deli counters at retailers in CA, NV and AZ. So far, no illnesses or customer complaints have been reported to date. These Roma tomatoes should not be consumed. Consumers should return the tomatoes to the place of purchase for a full refund. Consumers with questions should directly contact the company for more details.

Product: Ground Black Pepper
Incident: Possible Health Risk– *Salmonella*

A Bayonne, NJ firm is recalling 16,443 cases of 3.53 oz. plastic jars of ground black pepper because it has the potential to be contaminated with Salmonella. The recalled product was distributed to a specific retailer nationwide with the exception of Alaska and Hawaii. So far, no illnesses have been reported to date. The recall was initiated as the result of sampling by the FDA which revealed that the finished products contained the bacteria. Consumers should immediately dispose of the recalled products if they have them in their possession. Consumers with questions should directly contact the company for more details.

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

Product: Beef Jerky Products
Incident: Possible Health Risk–*Noninspection*

An Albuquerque, NM establishment is recalling an undetermined amount of beef jerky products because they were produced without the benefit of inspection. In addition, the beef jerky products contain wheat and anchovies, known allergens that are not declared on the product label. The vacuum packed plastic bags of jerky products were sold primarily over the internet. The products were packed mostly in 4 oz. bags but may have also been packed in bags of other sizes. There are no identifying dates or codes on any packaging, therefore all products produced prior to September 12, 2014 are being recalled. The problem was discovered during an ongoing investigation into the establishment. FSIS and the firm have not received any reports of illness due to consumption of these products. Media and consumers with questions about the recall should contact the company directly for more information.

Product: Pork Sausage Product
Incident: Possible Health Risk–*Undeclared Allergen*

A Woodinville, WA establishment is recalling approximately 4,820 pounds of pork sausage products due to misbranding and an undeclared allergen. The products contain milk, a known allergen, which is not declared on the product label. Included in the recall are 1 lb. and 5 lb. packages of pork products. The products were cooked in a Redmond, WA restaurant and sold to the general public. The products were produced using bread crumbs that came from a vendor who listed wheat, soy and milk on the label. The label for the sausage products did not list milk as an ingredient. The products were produced on March 17, 24 2014, May 5, 2014, June 2, 30, 2014, July 15, 29, 2014, August 26, 2014 and September 8, 2014. The problem was discovered by an FSIS inspector who saw that the products were incorrectly labeled. FSIS has not received any reports of illness due to the consumption of these products.

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

Product: Stroller Activity Trays
Incident: Possible Risk-*Strangulation Hazard*

A San Diego, CA importer is recalling approximately 770 units of snack and activity trays with connectors for strollers (90 units in Canada). The three-piece units include a black plastic tray with a cup holder, a left connector and a right connector. The opening between the recalled tray and stroller seat bottom allows an unharnessed child's body to pass through but could trap a child's head, posing a strangulation hazard. The company has not received any reports of injuries related to the use of this product. The trays were manufactured in Taiwan and sold at juvenile product stores nationwide and online from May 2011 through June 2012. Consumers should immediately remove the recalled trays and connectors from strollers and contact the company to receive a free replacement tray and connectors. Consumers with questions should contact the company directly or visit their website for more information.

Product: Children's Swing
Incident: Possible Risk-*Fall Hazard*

A Conshohocken, PA importer is recalling approximately 2,000 units of children's swings (300 units in Canada). The swing is intended for indoor and outdoor use by children ages 3-7. It is made of green polyester fabric and hangs from a plastic suspension fitting attached to steel hooks. The suspension fittings can break causing a child to fall from the swing, posing a risk of serious injury. There have been four reports worldwide of the suspension fittings breaking in use. In one incident a child fell and sustained a fractured leg. No incidents have been reported in the US. The swings were manufactured in Vietnam and sold at a specific retailer nationwide and online from June 2014 to August 2014. Consumers should immediately take down the swing to prevent use by children and return it to the retailer for a full refund. Consumers should contact the company directly or visit their website for additional information.

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