Food Safety Modernization Act

On November 30, 2010 the U.S. Senate passed the Food and Drug Administration (FDA) Food Safety Modernization Act by a large majority (73-25). This comes in the wake of a stream of high profile recalls, both domestic and foreign, over the past few years. This gives the FDA greater power than in the past to protect the nation’s food supply.

Previously, the FDA could only recommend that a company recall products that may be contaminated but could not force a company to recall such products. Michael Pollan and Eric Schlosser cite in the New York Times how the new bill gives the FDA powers to “test widely for dangerous pathogens and to recall contaminated food...[and] require more frequent inspections of large-scale, high-risk food-production plants.”

One of the major changes that this Act brings about is a change from a reactive approach to food safety to now a more proactive approach to limit or mitigate the exposure of contaminated food to the public. It also sets up a system to allow FDA to trace-back food so that we can find out where the contaminated food came from and quickly stop it from reaching grocery store shelves.

Other key elements of the Act include:

- Requirement for facilities to identify, evaluate, and address hazards and prevent adulteration via a food safety plan.
- Expanding FDA access to a registered facility’s records in a food emergency.
- Allowing FDA to enable qualified 3rd parties to certify that foreign food facilities comply with U.S. food safety standards.
- Requirement for importers to verify the safety of foreign suppliers and imported food. Allows FDA to require certification for high-risk foods, and to deny entry to a food that lacks certification or that is from a foreign facility that has refused U.S. inspectors.
- An increase in the number of FDA inspections at all food facilities.
- Enhancing food-borne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on food-borne illnesses.
- Enhancing tracking and tracing of high-risk foods and directs the Secretary to establish a pilot project to test and evaluate new methods for rapidly and effectively tracking and tracing food in the event of a food-borne illness outbreak.
- FDA authority to initiate a mandatory recall of a food product when a company fails to voluntarily recall the contaminated product upon FDA’s request.
- FDA authority to suspend a food facility’s registration if there is a reasonable probability that food from the facility will cause serious adverse health consequences or death.

Sources: FDA, Washington Post, New York Times, Chicago Sun Times

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

Brief History of Key FDA Regulations

Back in the late 1800’s there was widespread adulteration of food and poor, unsanitary conditions in food processing plants. On June 30, 1906, President Theodore Roosevelt signed into law both the Pure Food and Drug Act and the Meat Inspection Act. Passage of these two Acts laid the foundation for modern U.S. food regulation. New regulations were added throughout time and rose out of needs and concerns of the public about the safety of our food supply and the public’s demand to know what is in the food they consume.

- 1938—Food, Drug and Cosmetic Act
  Among other requirements, included the pre-marketing approval proof of the safety of drugs.
- 1958—Food Additives Amendment
  New additives to food must prove safe before approved by FDA to market.
- 1960—Color Additives Amendment & Delaney Clause
  Color additives could not be used to deceive consumers or to conceal inferiorities in products.
- 1973—Low Acid Food Processing
  Protects consumers from harmful microorganisms (such as Clostridium Botulinum) that must be destroyed or inhibited to avoid germination.
- 1982—Tamper Resistant Packaging & Federal Anti-Tampering Act
  Requires that most over the counter drugs be packaged in tamper resistant packaging. Makes tampering with a consumer product a felony.
- 1990—Nutritional Labeling and Education Act (NLEA)
  Requires packaged foods label to contain a nutritional panel and ingredient statement.
- 2002—Bio-Terrorism Act
  Designed to protect the food supply from acts of bio-terrorism. FDA can use information required by this Act to assist in control of food safety concerns. The Act requires registration of food facilities, prior notice of imported food, establishment and maintenance of records, and administration detention of foods that pose a threat of serious health or even death to humans or animals.
- 2009—Reportable Food Registry
  Registered food facilities that manufacture, process, pack or hold food for human or animal consumption in the U.S. are required to report when there is a reasonable probability that use or exposure to an article of food will cause serious adverse health consequences or death.
### Food and Drug Administration Recalls (www.fda.gov)

<table>
<thead>
<tr>
<th>Incident</th>
<th>Product</th>
<th>Possible Health Risk</th>
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<tbody>
<tr>
<td>-</td>
<td>Cilantro</td>
<td>Salmonella</td>
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A Wheeling, IL company has issued a voluntary recall of 23 its products because they contain a certain lot of fresh cilantro that may be contaminated with *Salmonella*. This lot of cilantro was distributed by a Lompoc, CA company and then sent to a produce supplier. The recalled products were distributed nationwide and the number of products affected total 43,814 lb. *Salmonella* is a common foodborne pathogen that can cause severe illnesses, including fever, abdominal cramps and diarrhea. If these symptoms persist for more than a few days, please consult a physician. Consumers that have recently purchased any of the recalled products should not consume them and should return them to the store of purchase for a full refund or replacement. Consumers and media with questions should contact the company directly.

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<th>Incident</th>
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<tbody>
<tr>
<td>-</td>
<td>Potato Chips</td>
<td>Undeclared Allergen</td>
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A Hanover, PA company is voluntarily recalling a single day’s production of a certain brand of potato chips because of a labeling issue. The recalled products produced on this date are the result of a seasoning containing a milk allergen. The potato chip bags do not display a milk allergen warning. The product in question was produced at the company’s Jeffersonville, IN plant. Overall 18 cases containing ten 12-oz bags of this product have been affected. These chips were distributed throughout the Midwest in OH, IN, MI, WI, and IL. There have not been any reports of allergic reactions or illnesses associated with this product. Consumers allergic to milk or dairy products, should not consume these potato chips. Consumers who have purchased these products should return them to the place of purchase for a full refund. Consumers with further questions should contact the company for more details.

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

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<tbody>
<tr>
<td>-</td>
<td>Appetizer Products</td>
<td><em>Listeria monocytogenes</em></td>
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An East Haven, CT establishment is recalling approximately 57 pounds of meat and cheese roll appetizer products that may be contaminated with *Listeria monocytogenes*. These 8-ounce packages of mozzarella & prosciutto antipasto products were produced on Nov. 15, 2010 and distributed to warehouses and retail outlets in Boston and Springfield, MA as well as Westport, CT. The problem was discovered through microbiological sampling by FSIS personnel. So far there have not been any reports of illnesses associated with the consumption of this product. Consumption of food contaminated with *Listeria monocytogenes* can cause listeriosis, an uncommon but potentially fatal disease. Listeriosis can cause high fever, severe headache, neck stiffness and nausea. Anyone concerned about an illness should contact a physician. Consumers and media with questions regarding this recall should contact the company.

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<tr>
<td>-</td>
<td>Fully Cooked Ready-To-Eat Turkey Breast</td>
<td><em>Listeria monocytogenes</em></td>
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A New Braunfels, TX establishment is recalling approximately 2,609 pounds of fully cooked, ready-to-eat smoked turkey breast products that may be contaminated with *Listeria monocytogenes*. The affected products come in 1-lb. and 4 to 6-lb. packages and were produced on August 4, 2010. These products were distributed nationwide, including catalog and internet sales. The problem was discovered through a microbiological sampling by FSIS. Consumption of food contaminated with *Listeria monocytogenes* can cause listeriosis, an uncommon but potentially fatal disease. Listeriosis can cause high fever, severe headache, neck stiffness and nausea. Anyone concerned about an illness should contact a physician. Consumers and media with questions regarding this recall should contact the company.

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

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<th>Hazard</th>
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<tr>
<td>-</td>
<td>Pogo Sticks</td>
<td>Risk of Serious Injury</td>
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A Bud Lake, NJ distributor is voluntarily recalling about 3,100 silver and blue pogo sticks manufactured in February 2010 in China. The aluminum rivets on the pogo stick’s frame tubes can break and cause the support clamp to detach and release the spring, posing fall and laceration hazards to consumers. So far the company has received three reports of incidents with the pogo sticks, including two reports of injuries to the consumers’ inner thigh and hands requiring medical attention. The recalled products were sold at a specific retailer nationwide from April 2010 through October 2010. Consumers should immediately stop using the recalled pogo sticks and return them to any of the retailer locations to receive a full refund. For additional information, consumers are asked to contact the company or visit the company’s website.

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<td>Stainless Steel Carafes</td>
<td>Burn</td>
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A Morris Plains, NJ importer in cooperation with the CPSC is recalling approximately 36,000 units of 1-liter stainless steel carafes. The insulated carafe has a chrome-plated plastic top with a black plastic base and is lined with glass. These stainless steel carafes were manufactured in China and sold at a specific retailer nationwide from September 2010 through October 2010. The handle on the carafe can come loose from the body and cause liquid to spill, posing a burn hazard to consumers. There have not been any reports of injuries associated with the use of this product. Consumers should immediately stop using the recalled carafe and return it to the retailer where it was purchased for a full refund. For more information, consumers can contact the company or visit the company’s website.

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