Technical Paper

Food safety and compliance

Processes for improving food safety and recall effectiveness.

The FDA defines recalls as “actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm’s own initiative, by FDA request, or by FDA order under statutory authority.” Furthermore, the FDA breaks out recalls into the following classifications:

Class I recall: A case in which there is a reasonable probability that the use will cause serious adverse health consequences or death. An example would be E. coli contamination of meat.

Class II recall: A situation in which the consumption of a product may cause temporary adverse health consequences or where the probability of serious health consequences is highly unlikely. One example might be an undisclosed food dye that is known to cause mild allergic reaction in some individuals.

Class III recall: A case where there is an error, but consumption of a product is not likely to cause adverse health consequences. An example would be an underweight product.[7]

Five processes that impact recall readiness.

To be prepared for a recall, you need to have a framework in place that is built around these five processes.

Regardless of which classification a recall is designated, there are well-defined processes for dealing with it that include prevention, identification, notification, removal and replenishment. If you're unable to prevent a recall, the first and most critical step is to identify the affected products. You next need to notify everyone who's affected; make sure the affected products are removed from the shelves; and then get replacement products onto the shelves as soon as possible.

After prevention, timely, factual identification of affected products is the most critical of these processes. The faster you can identify and isolate contaminants, the less potential for consumer harm you face, and the lower the possible costs to your supply chain stakeholders. This challenge is made even more acute in today's fast-paced and efficient supply chains, which can see ingredients distributed across multiple products, retailer channels, and geographies in a matter of hours.

Coming next week: Building a technology framework for improved recall effectiveness

5 "Egg Contamination and Recalls," The New York Times (http://topics.nytimes.com/top/reference/timestopics/subjects/e/eggs/contamination_and_recalls/index.html), September 23, 2010.
6 Food Safety Modernization Act (FSMA), Frequently Asked Questions, US Food and Drug Administration (www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm), March 15, 2012.
7 Recalls, Market Withdrawals, & Safety Alerts; Background and Definitions; US Food and Drug Administration (www.fda.gov/Safety/Recalls/ucm165546.htm); June 24, 2009.