



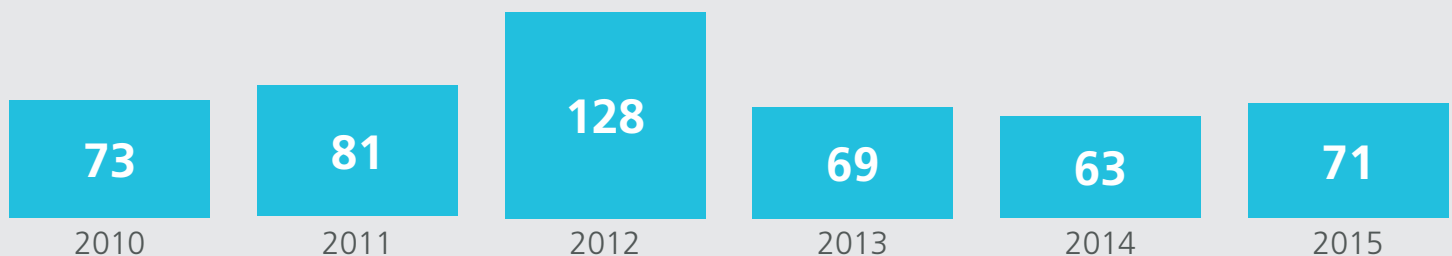
New food safety rules increase regulatory complexity for produce stakeholders worldwide

Recalls are a significant issue within the fruit and vegetable industry. Over the last five years, there have been nearly 500 produce recalls, affecting more than 440 companies and accounting for 14 percent of FDA food recalls. And the regulatory environment is only growing more complex.

Under the new Food Safety Modernization Act (FSMA), food manufacturers must maintain a written food safety plan, identify potential hazards, and implement preventative measures to control them. They are also required to monitor those controls closely and maintain records of regular monitoring practices. The Produce Safety Rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. These rules govern water quality, domesticated and wild animals, worker health and training, and much more.

FSMA affects not only domestic growers, but also companies that import produce into the U.S. Under the Foreign Supplier Verification Rule, importers must perform certain risk-based activities to verify that their products have been produced in a manner that meets applicable U.S. safety standards. Those operating in this increasingly strict regulatory environment, recall readiness is more important than ever.

Number of Produce Recalls by Year



Top 3 Causes of Recalls from 2010-2015



Crisis Prevention & Preparation

Of course, the best case scenario for any company is to prevent a crisis from ever happening. While there are no foolproof methods, following best practices can help minimize the possibility.

Companies should evaluate their procedures and how they stack up against all regulations, including FSMA. It's also crucial to examine the entire supply chain to prevent any weak link from causing a costly recall.

While crisis prevention is critical, companies should also take steps to mitigate their risk in the event a recall does occur. Developing a recall plan that designates an internal recall coordinator and testing that plan regularly can ensure any recall is managed as smoothly as possible. Companies should consider investing in recall insurance to safeguard against the potentially detrimental financial damage a recall can cause. Finally, they should have an understanding of how their partners, suppliers, and vendors execute recalls.

Managing an Event

Organizations that take swift action in putting their recall plan into effect are best positioned to mitigate risk and prevent irreparable brand damage.

To do that, companies must understand the regulatory environment, effectively communicate the recall to those affected, choose the right remedy, and close out the recall as quickly as possible.

Companies must alert distributors, wholesalers, retailers, customers, and other stakeholders in order to ensure affected product is no longer sold. Depending on the level of severity, a news release may also be required to notify the public. Sample press releases are available for specific recall causes, including salmonella and undeclared allergens. The FDA classifies recalls in three categories, based on the level of danger they present:

- **Class I:** Dangerous or defective products that predictably could cause serious health problems or death. Examples include: food found to contain botulinum toxin and food with undeclared allergens.
- **Class II:** Products that might cause a temporary health problem, or pose only a slight threat of a serious nature.
- **Class III:** Products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws.

Once a recall has been announced, it is important to have an effective means of responding to consumer questions, including a well-staffed contact center and a dedicated website. A third party may be required to assist with this, depending on the scope of the issue. Customers should be advised of what action they should take and informed of what the remedy will be, such as a reimbursement or refund.

As affected product is removed from the market, effectiveness checks should be performed to validate the process and ensure data is accurately collected for regulatory reporting. Companies must also consider how they will handle, document, and sustainably dispose of any returned product so it is never combined with unaffected product, inadvertently reentering the marketplace.

Potential Consequences

Mismanaging a recall can have serious consequences for a company's brand and bottom line, including:

- Regulatory fines
- Civil lawsuits
- Criminal prosecutions
- Loss of customer trust and loyalty
- Charge backs and other fees incurred from retailers

With so much at stake, it is important that companies understand the most common causes of recalls within their industry, keep up-to-date with the changing regulatory environment, and prepare for the likelihood of a recall by developing a comprehensive plan.

