



The regulatory environment facing the dairy industry is growing increasingly complex

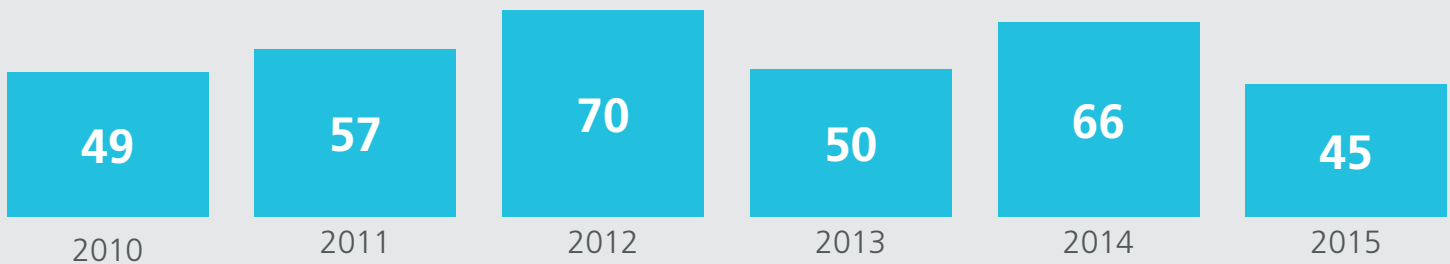
Recalls are a significant issue within the dairy industry. Over the last five years, there have been more than 300 recalls of dairy products, affecting more than 300 companies and accounting for 10 percent of FDA food recalls. And the regulatory environment is only growing more complex.

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. In addition, many dairy producers may be affected by FSMA's Intentional Adulteration Rule, which requires a documented plan to address potential terrorist attacks against the food supply. Bulk liquids are considered to be particularly vulnerable to such threats.

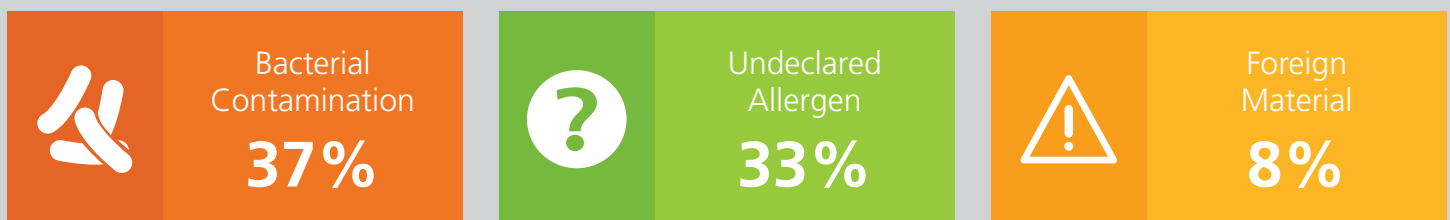
But it isn't just guidelines within the U.S. As the market grows increasingly more global, companies operating in multiple countries face a complex patchwork of regulations. One main reason for this is the varying levels of dairy consumption around the world. Such regional differences, along with an increasingly strict regulatory environment, make recall readiness more important than ever.

<sup>1</sup>foodsafetymagazine.com

### Number of Dairy 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.

