

The nutraceutical industry faces a complex patchwork of regulations



For products meant to benefit customer health, a recall can be detrimental – especially if the event catches media attention. Over the last five years, there have been 274 recalls of nutraceutical products, affecting 250 companies and accounting for eight percent of FDA food recalls.

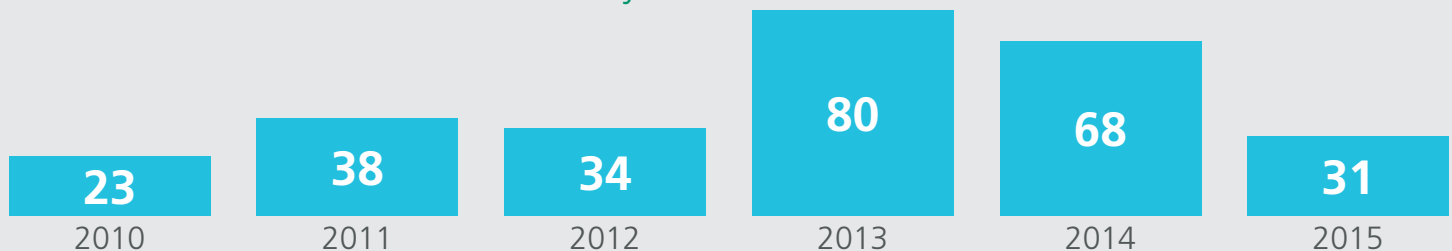
The nutraceutical industry experienced fewer recall events than many others regulated by the FDA over the past five years. Despite this, the amount of product affected during this time period was relatively high by comparison, at over 85.5 million units.

The regulatory environment surrounding the nutraceutical industry is complex, with multiple laws governing it in the United States (U.S.) alone. The most notable is the Dietary Supplement Health and Education Act of 1994 (DSHEA), which states:

1. Manufacturers and distributors are prohibited from marketing products that are adulterated or misbranded, and are responsible for evaluating the safety and labeling of their products prior to market to ensure all DSHEA and FDA requirements are met.
2. The FDA is responsible for taking action against adulterated or misbranded product after it reaches the market.

But it isn't just guidelines within the U.S. As the market grows increasingly more global, companies face a complex patchwork of regulations. Some countries have an explicit set of regulations for the industry, others include nutraceutical products under food regulation, and some require animal and/or human clinical studies. As the nutraceutical industry's regulatory environment grows increasingly complex, recall readiness is more important than ever.

Number of Nutraceutical Recalls by Year



Top 4 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. 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 copies of recall plans from partners, suppliers, and vendors on hand at all times.

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 bacterial infections 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.
- **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.

Companies must also consider how they will handle returned product so it is never combined with unaffected product, inadvertently reentering the marketplace. Once products are returned, documenting and disposing of them in a sustainable and compliant manner is critical to effective recall management. Only then can companies close out the recall with regulatory bodies.

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.

