



## Voluntary Market Withdrawals and Recalls – Guidance for Craft Brewers

While craft brewers strive to manufacture and ship the highest quality beer, which is in compliance with Alcohol and Tobacco Tax and Trade Bureau (TTB) and state regulations, it is possible for a product to enter the market that is mislabeled or could cause adverse health effects.

Brewers have the responsibility to consumers to protect their health and well-being. This is of upmost importance to Brewers Association (BA) membership. When there is potential for adverse health effects, brewers must take steps to ensure that consumers are kept safe. A voluntary market withdrawal or recall involves removing products from distributor inventories and store shelves and effectively notifying consumers of the risk.

[Good Manufacturing Practices](#) (GMPs), Hazard Analysis and Critical Control Points (HACCP) plans, and food safety plans can be used to ensure quality and food safety during the manufacturing process; however, mistakes can and do occur. When such mistakes occur, it is the brewer's responsibility to ensure removal of the product from the market before harm is caused to the consumer. These events can be planned for through contingency and crisis management strategies, which facilitate the speed with which a recall or market withdrawal can be completed.

The U.S. Food and Drug Administration (FDA), under the mandate of the Food Safety Modernization Act (FSMA), is responsible for the regulation and food safety standards for most of the U.S. food supply. Recalls are [classified according to their potential seriousness](#). The FDA now has authority to force a recall and shut down operations at breweries or other food-production plants if it deems that there is a significant threat to public health.

As the main regulating body in the beer industry, the TTB also has an interest in voluntary market withdrawals and recalls. Brewers must notify the TTB immediately if a voluntary market withdrawal or recall is imminent, and the FDA should be given a courtesy call. The TTB may also communicate with the FDA about beer recalls and market withdrawals, and either organization may notify the other about a given recall.

Any brewer initiating a recall must notify the TTB, and file a Notice of Intent (NOI) before destroying recalled beer for which they intend to take a federal excise tax credit. Prior to filing the NOI, a brewer must provide a complete and final submission to the TTB Office of Market Compliance containing a description of the problem, including:

- The scope of the problem
- A detailed analysis of the health hazard (including an analysis of the root cause)
- Actions taken to date and the level of effectiveness of the recall (the percentage of recovery and where recovered from, i.e.: in wholesaler control and retail, and amount confirmed purchased by consumers).

As part of the “actions taken to date,” a copy of the press release published for consumers, communications to wholesalers and retailers, and a statement confirming which agencies have been notified should also be submitted. See TTB industry circular *2017-4, Voluntary Alcohol Beverage Recalls* for more recall information.

Contamination, adulteration and misbranding comprise the major reasons for which a brewer’s products can be recalled. Some examples of these include:

- Misbranded or mislabeled beer
- Foreign object inclusion such as plastic, glass or metal fragments
- Chemical contamination
- Allergens or other toxins in the beer
- Package over-pressurization.

Only in rare cases will FDA request a recall. The responsible, and more likely scenario, is that a brewery discovers a problem and withdraws a product on its own. Even though a brewer may initiate a voluntary market withdrawal for a product for being out of specification, or for freshness or flavor issues, a recall is required if one of the following situations occurs:

- A manufacturer or distributor discovers a food safety issue and contacts FDA directly
- Inspection of a manufacturing facility by FDA reveals a potential cause for recall
- A beer, or brewer fails testing carried out through FDA
- In the case of illness associated with a specific product, individual state health departments will contact the Centers for Disease Control and Prevention (CDC), which in turn contacts FDA.

The more likely scenario is a voluntary market withdrawal which occurs when a product has a quality issue that does not violate food safety regulations that require a recall. In this case a brewery would remove the product from the market voluntarily. This type of withdrawal would not be subject to FDA legal action. For example, a product removed from the market that does not meet brand specifications (sour, for instance) or a removal due to tampering without evidence of manufacturing or distribution problems, would be examples of voluntary market withdrawals.

---

## The bottom line

Voluntary market withdrawals and recalls are expensive and can be stigmatizing for the affected brewery. It is in the brewer’s best interest to do everything possible to prevent them through good brewery management practices. If a situation does arise where a voluntary market withdrawal or recall is warranted, a brewer should act quickly to maintain and regain consumer confidence during these types of events by communicating openly and honestly and working hard to remove product. The best practice to ensure this rapid and efficient recovery of out of specification or potentially harmful products is to have a recall plan in place and to practice the activity regularly.

## Some things a brewery can do to make a voluntary market withdrawal of recall less painful:

Follow the Brewers Association [Date and Lot Coding Best Practice](#).

- Keep a library of packaged beer and test them for flavor, pressure, pH, etc. after a period of time or over a period of time.
- Put together an internal consumer safety team to identify potential areas that could cause a voluntary market withdrawal or recall scenario.
- Reference the BA's [Food Safety Plan for Craft Brewers](#) and [Good Manufacturing Practices for Craft Brewers](#) resources.
- Develop a recall plan and practice the plan with mock recalls.
- At a minimum, implement a basic microbiological screening program.