

# The Food Safety Modernization Act and Its Effects on Breweries

## Article #8 of Hopping on the Brewery Bandwagon Series

If you are active in the food and beverage industry, you are aware of the Food Safety Modernization Act (FSMA) and its implications on food and beverage companies. For those who have not heard, FSMA is probably one of the most significant changes to U.S. food law in decades. President Obama signed FSMA into law on January 4, 2011, which amended sections of the Food Drug & Cosmetic Act (FDCA). FSMA's aim is to shift the focus from responding to contamination to preventing it before adulterated and misbranded food even enter the marketplace for sale or consumption.

While FSMA is reassuring to consumers, it creates stricter regulations and higher safety standards for food and beverage companies. For example, under FSMA, food facilities must prepare and implement a food safety plan that includes preventive controls to minimize/ prevent known or reasonably foreseeable food safety hazards. Further, FSMA requires food facilities to update their registrations ever two years and mandates food facilities to provide email addresses on their registrations. These examples only begin to address the new hurdles that food facilities face under FSMA.

In addition to stricter regulations, FSMA has given the U.S. Food and Drug Administration (FDA) certain power that it did not possess before the law's enactment. Specifically, the FDA has mandatory recall authority, expanded administrative detention, and the ability to suspend a facility's registration if it determines there is a reasonable probability of death or serious illness to humans or animals.

Importantly, however, breweries (and other manufacturers of alcoholic beverages) are exempt from the majority of FSMA, including the onerous preventive control measures that are required of other food facilities. Generally, the Alcohol and Tobacco Tax and Trade Bureau (TTB) (formerly the Bureau of Alcohol, Tobacco and Firearms (ATF)) is responsible for monitoring the alcohol industry. Nonetheless, alcoholic beverages, including beer, meet the definition of "food" under FSMA and related provisions of the FDCA. Therefore, the FDA still maintains some jurisdiction over their regulation.

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## So Then How Are Breweries Affected by FSMA?

First, both foreign and domestic facilities that manufacture, process, package or hold alcohol beverages for human consumption within the U.S. are required to register with the FDA (this has been a requirement under the Bioterrorism Act since 2002), and now must update their registration in accordance with FSMA every two years.

Second, breweries are subject to more common inspections by the FDA, TTB or state agencies. In fact, FSMA requires the specific frequency by which inspections of food facilities occur. Nonetheless, breweries should not fear these inspections if they have proper record-keeping procedures in place and adhere to the good manufacturing practices in 21 CFR part 110.

Third, despite its current jurisdiction over the alcohol industry, if the TTB becomes aware of adulterated batches of beer (that is, beer that may cause a health risk to consumers), it has the authority to involve the FDA. Specifically, the TTB can recommend a subsequent FDA investigation and mandatory recall of the adulterated beer.

Lastly, brewers initially feared that the proposed FSMA rule on preventative controls for pet food and animal feed would impose regulations on spent grains (a byproduct of the brewing process commonly sold or given to farmers to feed livestock) that would make transfer to farmers burdensome and cost-prohibitive. However, less than a year ago, the FDA published revised rules that clearly indicate spent grains are exempt from this requirement. As such, brewers will not need to implement preventative controls except to ensure the products are held in the right type of storage container while waiting to be picked up by farmers, and that the container is properly labeled so, for example, the container is not mistaken for garbage. This revised rule will prevent the grains from being thrown away and further compounding landfills.

If you would like to know more about FSMA and the topics covered in this e-alert, please contact your Reinhart attorney or any member of the firm's Food & Beverage team.

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