UNDERSTANDING THE FDA'S MANDATED RECALL AUTHORITY AND INSURANCE IMPLICATIONS

CONTACT

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ABOUT THE AUTHOR

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In November 2018, the U.S. Food and Drug Administration (FDA) released new guidance on how and why they will utilize their statutory power to mandate recalls. The new guidance expands upon the original January 2011 Food Safety Modernization Act (FSMA) which was signed into law by President Obama.

ABOUT THE FOOD SAFETY MODERNIZATION ACT (FSMA)

The purpose of the FSMA's mandated recall authority is based on the notion that unsafe products should be identified expeditiously, and corrective actions should be taken swiftly by the manufacturing facilities producing or distributing the adulterated goods.

The overall goal of the Act is to give "teeth" to the FDA's authority in the event that a manufacturer does not proactively recall adulterated food, animal feed and/or dietary products. According to the FDA, the average recall occurs within four calendar days of the problem being identified. While most manufacturers are aware of the severe implications of releasing an adulterated item into the chain of commerce and immediate actions are taken, the FDA's authority under FSMA allows them to address the outliers who do not proactively recall adulterated products.

The primary driver of the FSMA legislation was the need to address the increasing globalization of the food supply chain and the impact of foodborne illnesses on the health of the public.[1]

Notable features and enhancements of this legislation include:

- **Prevention Controls:** Proactive approach to food safety vs. a reactive approach
- **Inspection & Compliance** : Application of federal resources to respond in a risk-based manner
- **Response :** Enacts the ability for the FDA to mandate food recalls
- **Enhanced Partnerships :** Establishes clear and consistent goals on federal, state, local and foreign levels by strengthening coordination

This article from the FDA's website shares more details on the FDA's key authorities and mandates under FSMA.

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NEW GUIDANCE ON MANDATORY FOOD RECALLS

The advisory document containing new guidance from the FDA stipulates that certain criteria must be met before the FDA can exercise its mandatory recall authority. First, there must be reasonable probability that a consumable product is adulterated or misbranded. In addition, the FDA must have reasonable probability that use or exposure to this product will cause serious adverse health consequences in or death to humans or animals.

After the criteria for a mandatory recall has been met, the FDA must first give the party responsible for the product an opportunity to discontinue distribution and recall the product. The FDA does this by sending notification of this opportunity in writing to the responsible party. If the responsible party fails to comply, the FDA may order the party to cease distribution, order the responsible party to notify others to cease distribution, and give the party the chance for an informal hearing which is held no more than two days after the FDA issues the order.

Upon completion of these steps, the FDA Commissioner may mandate a recall if it is determined that removal of the product is necessary.

In the event of a mandatory recall, the FDA will ensure a press release is published with details on the recall. It may also issue additional alerts and announcements as appropriate to ensure impacted consumers and retailers are notified. The FDA's publication will include the name of the food subject to recall, a description of risks associated with the food, and information about similar products that are not affected by the recall.[2]

HOW THE FDA EXERCISES THEIR RECALL AUTHORITY

Per the FDA's published guidance, below are examples of circumstances that could result in the FDA exercising its mandatory Class 1 recall authority: [2]

- Peanut butter, alfalfa sprouts, and deli products found to be contaminated with salmonella
- Under-processed canned chili that contains clostridium botulinum toxin
- Smoked salmon and pumpkin seeds found to be contaminated with listeria monocytogenes
- Products containing undeclared allergens such as milk, peanuts or eggs
- Baby food that poses a choking hazard
- Horse feed contaminated with elevated levels of monensin
- Pet foods contaminated with elevated levels of melamine and cyanuric acid, or contaminated with salmonella or listeria monocytogenes
- Sheep feed containing elevated levels of copper

Below are three times that the FDA has used its mandatory recall authority:

- 2013 – Kasel Associates Industries failed to recall all of their pet food products after the FDA advised them to do so, which led to the FDA forcing a recall.[3]
- 2014 – The FDA required OxyElite to recall their Pro-branded dietary supplements after there were several reports of acute liver failure and hepatitis.[4]
- 2018 – Triangle Pharmanaturals LLC refused to recall their consumable kratom products that testing positive for Salmonella.[5]

The implementation of FSMA and ongoing government guidance continues to be a pressing topic for the food, animal feed and dietary industries. The burden to meet these new regulations has had a lasting financial impact related to improving technology and allocating the appropriate labor to adapt to the new requirements.

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INSURANCE IMPLICATIONS

The average food and beverage recall claim is calculated at approximately $9,200,000.6 Consequently, the demand and awareness for product contamination insurance has increased substantially over the past decade. The latest FDA published guidance regarding the ability to mandate a recall is just one of the evolving tools to further enhance the safety of the food chain. This ultimately creates downward pressure on the food manufacturing industry to adhere to these standards.

As a result, insurance markets have evolved to offer policies that respond to government intervention and mandated recalls. These published guidance documents have led to increased awareness and focus on insuring against the type of scenario which entails the FDA's involvement and/or enforcement. The procurement of a product contamination policy can drastically mitigate a significant financial burden in the event a manufacturer or distributor experiences a recall of one of their products.

The Product Recall specialists at AmWINS are dedicated to helping our retail partners provide insurance and risk management solutions for manufacturers and distributors of nearly any conceivable product. As a leader in the Product Recall wholesale brokerage space, we have helped thousands of insureds, including numerous Fortune 500 companies, understand and manage their product recall and product contamination risks.

SOURCES

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