

AGRICULTURE, FOOD, AND HEALTH ISSUES TO WATCH FOR 2016

As the agriculture and food industries head into the new year, a number of important cases and regulatory issues that have the potential to dramatically affect the industry are front and center. Below, Armstrong Teasdale's Agriculture, Food and Health industry group has provided an overview of the status of several of the key cases and issues that related industries should keep an eye on during 2016.

Waters of the United States

On October 9, 2015, following an earlier ruling by the U.S. District Court for the District of North Dakota, the United States Circuit Court for the Sixth Circuit issued a nationwide stay of the so-called "Waters of the United States" or "WOTUS" rule. The stay halted implementation of the WOTUS rule, pending resolution of jurisdictional issues that were the subject of oral argument on December 8, 2015. Those jurisdictional issues are focused on whether the Sixth Circuit is the proper venue to hear challenges to the rule. A ruling is expected in 2016.

A number of district court cases across the country also remain pending, and the District of North Dakota's earlier injunction against implementation of the WOTUS rule in 13 states, including Missouri, remains in place.

Vermont Act 120

On October 8, 2015, the U.S. Circuit Court of Appeals for the Second Circuit heard oral argument of an appeal filed by the Grocery Manufacturers Association and other plaintiffs seeking review of the U.S. District Court for the District of Vermont's denial of their Motion for Preliminary Injunction on April 27, 2015. The motion sought a preliminary injunction enjoining implementation of Vermont Act 120, passed on May 8, 2014, with an effective date of July 1, 2016. Act 120 would, among numerous provisions, mandate new labeling requirements on the part of manufacturers and other food processors for any food that is "produced with genetic engineering," "partially produced with genetic engineering," or "may be produced with genetic engineering." Violators of Act 120 are subject to civil penalties of up to \$1,000 per day, per product.

A decision is expected in the first two quarters of 2016 in advance of the July 1, 2016, effective date of the law.

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Federal Activity Regarding GMOs and the Safe and Accurate Food Labeling Act

The U.S. House of Representatives passed the Safe & Accurate Food Labeling Act (SAFL) on July 23, 2015. The SAFL Act would, among other things, serve to pre-empt any state laws governing labeling of GMO-containing food products, including Vermont's Act 120 due to become effective on July 1, 2016. Despite pressure on the U.S. Senate to address the SAFL Act and pass a companion or similar bill before the end of 2015, efforts to include any such bill or related provisions in the year-end omnibus spending bill were unsuccessful. Senate Agricultural Committee Group leaders, including Sen. Debbie Stabenow, D-Mich., have pledged to make the issue a top priority in January 2016, and many expect Sen. John Hoeven, R-N.D., to play a role in trying to secure passage of a bipartisan bill.

Food Safety Modernization Act Roll-Out

The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011, and represents the most comprehensive overhaul of the U.S. food safety regulatory scheme since the passage of the Food, Drug and Cosmetic Act in 1938. For nearly five years, the U.S. Food and Drug Administration (FDA) has been developing the seven final rules that implement FSMA. Each final rule impacts a different fundamental area of the U.S. food system.

In September and November 2015, the FDA issued the first five of the seven final rules: (1) Preventive Controls for Human Food; (2) Preventive Controls for Animal Food; (3) Foreign Supplier Verification Program; (4) Standards for Produce Safety; and (5) Accredited Third-Party Certification. The issuance of these rules initiates the countdown for the relevant compliance deadlines for covered entities.

It is anticipated that the final two FSMA rules regarding **Sanitary Transportation** and **Intentional Adulteration** will be issued on March 31, 2016. The Sanitary Transportation final rule will establish criteria for the sanitary transportation of food, including criteria targeted at shipping conditions and practices, employee training, and record keeping. The Intentional Adulteration final rule will require domestic and foreign food processing facilities to address vulnerabilities in their operations to prevent acts on the food supply intended to cause large-scale public harm. In 2016, the FDA will also be working with certain alliance groups to further develop FSMA compliance and enforcement guidance.

FDA Menu Labeling Requirements

Section 4205 of the Affordable Care Act charges the FDA with establishing labeling requirements for certain retail food establishments and vending machines. On December 1, 2014, the FDA issued two rules requiring calorie information to be listed on menus and menu boards at retail food establishments if they are a part of a chain of twenty or more locations operating under the same name and offering for sale substantially the same



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restaurant-type food items.

In July 2015, the FDA announced that the compliance deadline for the menu labeling rule was being extended by one year. All covered establishments (e.g., restaurants, grocery stores, and gas station convenience stores) now have until December 1, 2016, to identify calorie count and other information on their menus and menu boards as required by the FDA menu labeling rules.