ML Strategies Update

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ML Strategies, LLC
701 Pennsylvania Avenue, N.W.
Washington, DC 20004 USA
202 296 3622
www.mlstrategies.com

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FOOD LABELING, FOOD SAFETY & NUTRITION

The Obama Administration's robust use of executive authority on issues related to food labeling, food safety, and nutrition continue to position these issues as a priority for the remainder of the President's term in office. This is evidenced by the national action plan on combating antibiotic-resistant bacteria in food-producing animals and effort to update and simplify Federal oversight of biotechnology products, as well as by the release of guidelines for the Voluntary Qualified Importer Program and ban on trans fats by the Food and Drug Administration (FDA).

On Capitol Hill, the House and Senate appear poised to take action on food and nutrition-related issues, whether it is through newly re-introduced legislation on the labeling of bioengineered foods, or debate on the funding and organization of federal food safety and nutrition programs.

Following these developments in the Executive and Legislative branch and the changed legal and regulatory environment, new food product litigations are springing up. ML Strategies and Mintz Levin are pleased to share this Update on Food Labeling, Food Safety, & Nutrition, highlighting some of the key regulatory, legislative, and litigation developments.

REGULATORY OUTLOOK

FDA and the U.S. Department of Agriculture (USDA) have primary regulatory authority and an active regulatory agenda for issues related to food labeling, food safety, and nutrition. The regulatory agendas for both agencies, along with more than 60 other federal departments and agencies, can be found here. Highlights of regulatory and other administrative actions are below.

White House Action Plan for Combating Antibiotic-Resistant Bacteria

On June 2, the White House convened a Forum on Antibiotic Stewardship to bring together key constituencies involved in the development, promotion, and implementation of activities to ensure the responsible use of antibiotics. More than 150 food companies, retailers, and human and animal health stakeholders took part to discuss changes to slow the emergence of resistant bacteria and prevent the spread of resistant infections. Following the Forum, President Obama signed a Presidential Memorandum directing Federal departments and agencies to create a preference for meat and poultry produced with responsible antibiotic use.

Genetically Modified Organisms

On July 2, the White House's Office of Science and Technology Policy issued a statement ordering EPA, FDA, and USDA to update and simplify the Federal government's Coordinated Framework for the Regulation of Biotechnology, which aims to ensure the safety of biotechnology products (GMOs). The current system is cobbled together using traditional roles of three different agencies: USDA has authority to approve all releases of GMOs to ensure they do not create an environmental hazard; EPA must approve all crops that contain insect-killing genes; and FDA is responsible for evaluating whether GMOs are safe to eat. The statement announced three public listening sessions, starting with one in Washington, D.C., in the fall, to seek input clarifying the current roles and responsibilities of EPA, USDA and FDA in the regulatory process. The Coordinated Framework update will also undergo public notice and comment before it is finalized. More on the announcement and GMOs can be read here.

FDA VQIP Release

On June 4, FDA released a draft VQIP guidance document for industry that lays out the scope of the Voluntary Qualified Importer Program (VQIP), the criteria for participation and the application process, and the actions FDA will take if a participating importer is found to be out of compliance with the conditions of participation. Interested parties have 75 days to submit comments for FDA to consider.

FDA Trans Fat Decision

On June 16, FDA finalized its determination that partially hydrogenated oils (PHOs), the primary dietary source of artificial trans fat in processed foods, are not "generally recognized as safe" (GRAS) for use in food. This action is expected to reduce coronary heart disease and to prevent thousands of fatal heart attacks each year. FDA has set a compliance period of three years. This will allow food manufacturers to either reformulate products without PHOs and/or petition the FDA to permit specific uses of PHOs.

LEGISLATIVE OUTLOOK

While the regulatory agenda is certain to outpace legislative outcomes on issues related to food labeling, food safety, and nutrition, there are various measures in the House and Senate that will see debate and potentially become law.

GMO Labeling

The House Agriculture Committee this week approved Rep. Mike Pompeo's (R-KS) "Safe and Accurate Food Labeling Act" (H.R. 1599) to give more authority on the issue to the Department of Agriculture. Introduced by Reps. Pompeo and G.K. Butterfield (D-NC), the legislation has evolved through bipartisan discussions between the Agriculture Committee and the House Energy and Commerce Committee. The Agriculture Committee-approved legislation expands on provisions in an earlier version of the bill that set up a certification program at the USDA and aims to pre-empt state labeling efforts under a provision of the Agricultural Marketing Act, instead of the Federal Food Drug and Cosmetic Act. The House Energy and Commerce Committee has yet to schedule a markup of the legislation. Senator John Hoeven (R-ND) is expected to release in the near future a Senate companion to the Pompeo bill, titled the "Nonbioengineered Food Certification Act of 2015".

Country-of-Origin Labeling Requirements

On June 10, the House voted 300-131 to remove country- of-origin labels on beef, pork and chicken

sold in the U.S., hoping to prevent a combined $3.6 billion in retaliatory tariffs from Canada and Mexico. The bill was intended to ease tensions between the U.S. and its two neighbors, who won a WTO appeal ruling in May. The Senate has yet to vote on the measure.

Fiscal Year 2016 Appropriations

There have already been a number of hearings by both the House and Senate Appropriations Committees on the various spending bills, including hearings by the House and Senate Appropriations Subcommittees on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies on FDA's fiscal year 2016 budget request. With FDA's increased funding request for implementation of the Food Safety Modernization Act as a key topic of discussion. In addition to hearings on FY16 spending, with the Republican-controlled Congress making oversight of the Democratic-led Administration a priority, there will surely also be various oversight hearings on food safety and nutrition issues.

LITIGATION OUTLOOK

Food product manufacturers, distributors, and retailers face a unique set of legal issues and a constantly changing regulatory landscape. Litigation challenges involve not only the food industry, but also over-the-counter and homeopathic drugs, cosmetics, and supplements, who are also regulated by FDA.

"Natural" Litigation Continues

Lawsuits against food, cosmetics, over-the-counter, and supplement companies continue to be filed across the nation, alleging that labels claiming the products are "natural" is deceptive. These lawsuits are based on state consumer protection statutes for false advertising and unfair competition, but are often in federal court. A typical claim in such a lawsuit will contend that the use of the word "natural" is misleading if the product contains or was processed with something perceived by plaintiffs to be artificial or synthetic. The problem in these lawsuits is that the term "natural" is generally undefined, and even FDA says that it is difficult to define a food product that is natural because it has likely been processed and is no longer a "product of the earth."

Lawsuits Involving Genetically Modified Organisms

Federal Courts are becoming involved in legislative attempts to regulate GMO crops at the state (Vermont) and county (Humbolt County, CA; Benton and Jackson Counties, OR; and Maui, Hawaii, and Kauai, HI) level. In Vermont, the Grocery Manufacturer's Assn. is suing the state challenging the constitutionality of legislation requiring labeling of food containing GMO (Act 120). The lawsuit, however, has not stopped Vermont's plans to become the first state to require labeling beginning July 1, 2016. Legislation in all three Hawaiian counties prohibiting the cultivation of GMO crops has been overturned as preempted by federal law, while a federal judge has thus far allowed Jackson County's GMO crop ban to continue. There are also class action lawsuits brought by private parties claiming violation of the same consumer protection lawsuits as used in the "natural" litigation for falsely marketing products as "non-GMO" when using a non-profit's certification that verifies products complying with its private guidelines.

Trans Fat Lawsuits Beginning

Since FDA's move against trans-fats, many major food companies are already the target of litigation. A number of large food companies have been sued in Federal Court for allegedly falsely advertising their products as containing no trans-fats when they are claimed to contain partially hydrogenated oils.

California's Proposition 65

The Food industry has also been impacted by California's Proposition 65, which requires businesses to notify Californians about significant amounts of chemicals in the products they purchase that are

on the State's published list of chemicals known to cause cancer, birth defects, or other reproductive harm. Safe harbor levels have been established for many of the chemicals listed, and exposure below these levels are exempt from Prop 65's reporting requirements. A Prop 65 plaintiffs' group filed a lawsuit alleging that baby food manufacturers needed Prop 65 warnings on food containing small amounts of naturally occurring lead. An appellate court recently ruled in the food manufacturer's favor, accepting the opinion of the manufacturers' toxicology expert that the regulatory safe harbor levels for lead were met by the food products. This ruling is important because it places scientific evidence as the first line of defense in Prop 65 cases. Note that another lawsuit has been filed seeking to force the State of California to adjust the safe harbor level for lead

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For more information on ML Strategies' Food Labeling, Food Safety and Nutrition Practice Group please contact Neal Martin at RNMartin@mlstrategies.com or 202.434.7458.

For more information on Mintz Levin's Food Litigation Practice Group please contact Michelle Gillette at MGillette@mintz.com or 415.432.6106.

View ML Strategies professionals.

Boston · Washington www.mlstrategies.com