

Mintz Levin / ML Strategies Update
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Food Safety, Labeling, and Nutrition Update

As 2015 wraps up, there have been several important developments in Food Safety, Labeling, and Nutrition, most notably the [FY 2016 Omnibus Appropriations Bill](#) expected to pass the House and Senate on Friday, December 18. The bill contains several important provisions for the Food and Drug Administration (FDA) and Department of Agriculture (USDA), as well as for supplemental nutrition programs. Legislative activity on these issues will continue into 2016, when Congress may consider several related reauthorizations and legislative measures.

In addition to the 2016 legislative agenda, next year promises important developments in several food product litigations, in addition to three Supreme Court rulings that could clarify the requirements for bringing and obtaining certification in class action lawsuits.

ML Strategies and Mintz Levin are pleased to share this Update on Food Labeling, Food Safety, & Nutrition, highlighting some of the key legislative and litigation developments in 2015 and forecasting what we may expect in 2016.

2015 WRAP-UP

FY 2016 Omnibus Appropriations

The FY 2016 Omnibus Appropriations Bill provides funding for several Food Safety, Labeling, and Nutrition items ML Strategies been tracking throughout 2015.

Food and Drug Administration

The bill allocates total FDA funding in FY2016 at \$4.68 billion, \$238 million above FY2015. This funding includes \$104.5 million for FDA to implement the Food Safety Modernization Act (FSMA), the most sweeping food safety reform in 70 years. The bill also includes a one-year delay on new menu labeling regulations for grocery stores and food retailers.

U.S. Department of Agriculture

The bill contains appropriations for USDA divisions with responsibility for food safety, including \$2.47 billion for the Agricultural Research Service, \$886 million for the Animal and Plant Health Inspection Service, and \$1.015 billion for food safety and inspection programs that work to ensure safe, healthy food for American families, an amount that is \$4 million above the budget request.

Supplemental Nutrition Assistance

The bill provides discretionary and mandatory funding for food and nutrition programs within the USDA, including \$6.35 billion for Special Supplemental Nutrition Program for Women, Infants, and Children; \$80.8 billion for the Supplemental Nutrition Assistance Program; and \$22.149 billion for Child Nutrition Programs to provide free or reduced-price school lunches and snacks for over 30 million children. The bill also contains a provision to ensure that the Dietary Guidelines for Americans are based on significant scientific agreement and are limited in scope to nutritional and dietary information.

Genetically Engineered (GE) Products

The bill includes a provision that forbids FDA from allowing the introduction into interstate commerce of any food that contains the approved [AquAdvantage GE salmon](#) until FDA publishes final labeling guidelines for informing consumers of the GE content of the food. The bill does not, however, include any of the proposed language pre-empting state laws on the labeling of GE foods.

Country-of-Origin Labeling Requirements

The agreement includes language that repeals parts of the Country-of-Origin Labeling (COOL) Law that were recently ruled discriminatory by the World Trade Organization (WTO). The COOL repeal would prevent more than \$1 billion in retaliatory tariffs to the U.S. economy, which are scheduled to be approved by the WTO this Friday.

LEGISLATIVE OUTLOOK

Food Safety, Labeling, and Nutrition

We do not expect any slowdown of activity in the food safety, labeling, and nutrition space in 2016. FDA and USDA are both expected to take additional actions early in 2016 - FDA is required to release its final two [FSMA rules](#) on sanitary transport and intentional adulteration in March and May of 2016, respectively. FDA's "[natural](#)" docket is also open until February - interested parties should be working on their written comment submissions with the Feb. 10 deadline in mind, pending FDA's likely extension of the submission period. Meanwhile, USDA will begin Catfish facility inspections in March 2016 as required by its 2015 Final Rule implementing legislative amendments to the Federal Meat Inspection Act that brought catfish under USDA jurisdiction. USDA, along with the Department of Health and Human Services, is also scheduled to release the 2015 Dietary Guidelines by January 31. On the legislative side, Congress has several important reauthorizations it may address, including the Healthy Hunger-Free Kids Act.

LITIGATION OUTLOOK

Food product manufacturers, distributors, and retailers face a unique set of legal issues and a constantly changing regulatory landscape, including three United States Supreme Court opinions expected in 2016 that could clarify the requirements for bringing and obtaining certification in class action lawsuits.

U.S. Supreme Court Rulings

The Supreme Court's rulings are especially relevant to food manufacturers, as they are increasingly targeted in class action lawsuits, including the slack-fill and supply chain transparency act litigation discussed below.

Spokeo, Inc. v. Robins, No. 13-1339

A holding by the Supreme Court that a plaintiff and/or absent class members would have to show an injury-in-fact to maintain or participate in a class action would potentially result in reducing settlements and exposure to liability based on allegations of technical violations of the law that have caused no actual harm to anyone (what have pejoratively been known as "empty suit" lawsuits).

Tyson Foods, Inc. v. Bouaphakeo, No. 14-1146

This case presents the Court with an opportunity to address the issue of a "no-injury" class action. Although courts approving certification in these cases have indicated that the identification and separation between injured and uninjured plaintiffs can occur at a later time, *Tyson Foods* presents the Court with models of recovery that place all class members together without the necessity of proving that individual class members were injured - therefore, those individuals are potentially obtaining recoveries that far exceed the scope of any actual injury to the class.

Mullins v. Direct Digital

Here, the Supreme Court will have the opportunity to address the ascertainability requirement of

Rule 23; the Supreme Court's decision in this case will hopefully clarify what the ascertainability requirement really means.

Slack Fill Litigation

California's Business & Professions Code §12606.2 prohibits a container or package from having false bottoms, false sidewalls, a false lid or covering, or to "facilitate the perpetration of deception or fraud." There is a continuing trend, however, for slack-fill claims to be brought as civil class actions under the same unfair competition and false advertising laws, with the plaintiffs alleging violations of the Federal Food, Drug & Cosmetic Act because of an allegedly misleading container. The slack fill law becomes problematic for companies doing business in California because of the subjective nature of the enforcement and little case law on the standards used to determine whether the slack-fill is functional or non-functional. In addition, the penalties sought include injunctive relief, i.e., changing the package size or shape (which can be an expensive undertaking), civil penalties, and fees.

Supply Chain Transparency Act

Passed in 2010, the [California Transparency in Supply Chains Act](#) has a worthy aim: requiring retailers and manufacturers doing big business in California to disclose what measures, if any, they are taking to ensure that their suppliers comply with human rights standards. The Act, however, is quickly [becoming a vehicle for private class actions](#) against companies making this information available. With Supply Chain Act disclosures beginning to attract increasing scrutiny, companies with California operations should take care to ensure their accuracy and document their underlying due diligence. Even these efforts, though, may not deter an opportunistic class action suit, as the recent surge in such filings suggests. The companies targeted to date have already raised several defenses, including the argument that the Act requires companies to disclose their efforts to ensure compliance, but not to report every instance of slave labor at the farthest reaches of their supply chains. How courts handle the first wave of these class actions will be instructive for companies dealing with—or hoping to avoid—similar suits.

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