2016 FDA Year in Review: Food Edition

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As the food industry prepares for a new year, we take a look back at the major developments of the past year. The U.S. Food and Drug Administration ("FDA") released three final rules related to the implementation of the Food Safety Modernization Act of 2011 ("FSMA"), completing the list of the seven foundational rules (other than registration amendments) initially proposed in 2013 and 2014. The FDA also published much-anticipated final rules on changes in serving size and nutrition facts and on supplements labeling, as well as guidance on menu labeling. Here, we provide a brief overview of these final rules and discuss implications for food companies, retail establishments, and their affiliates.

Food Safety Modernization Act

Sanitary Transportation of Human and Animal Food

The FDA released its final rule on the Sanitary Transportation of Human and Animal Food in April 2016. As part of the FDA's effort to "focus on the prevention of food safety problems throughout the food chain," the rule covers transportation operations for food not completely enclosed by a container. Shippers, loaders, carriers, and receivers engaged in food transportation operations must update or establish requirements for record keeping, training, vehicles and transportation equipment, and transportation operations. However, food shipped through the United States to another country or stored in the United States for later export is not subject to the rule. As an important component of FSMA implementation, food companies should make it a priority to establish or implement policies and procedures to comply with the new rule. Small businesses have two years to comply, whereas other businesses (*i.e.*, not small or otherwise exempt) must comply one year from the date of the rule's publication, which means April 2017.

Mitigation strategies to protect food against intentional adulteration

Effective July 2016, the FDA's final rule on Mitigation Strategies to Protect Food Against Intentional Adulteration requires certain domestic and foreign food facilities to prepare a food defense plan to mitigate and respond to internal and external threats that have the potential to cause widespread public health harm.

The rule addresses intentional adulteration in the context of manufacturing facilities, raw agricultural commodities (*i.e.*, fruits and vegetables), and high-risk foods that pose a serious threat to public health. However, farms (other than farms that produce milk) are exempt from the requirement in the context of high-risk foods. While the rule provides several additional exemptions aimed at very small businesses (*i.e.*, companies with less than $10 million in sales over three years) and low-risk production practices, over 3,400 firms (*i.e.*, large companies) that operate 9,800 food facilities are covered under the rule.

Although generally exempt, very small businesses have five years to comply with the rule, while small and other businesses must comply within four years and three years, respectively. For those

companies covered under the rule, the food defense plan must assess vulnerabilities for each step in a facility's process and manage its mitigation strategy through monitoring, corrective actions, and verification. Personnel training and recordkeeping are also required and help to reinforce the establishment and implementation of mitigation strategies.

Amendments to registration of food facilities

Rounding out its implementation of FSMA, the FDA amended its requirements for facility registration in July 2016. Among those requirements, domestic and foreign facilities that manufacture, process, pack, or hold food for consumption in the United States must (1) renew their registration every two years, between October 1 and December 31 of each even numbered year; (2) maintain an email address; and (3) attest in writing that the FDA will have access to inspect their facility according to the applicable sections of the Federal Food, Drug, and Cosmetic Act. Mandatory electronic registration will be delayed until January 4, 2020. Registrations must also contain the type of activity conducted at the facility.

In addition to the above final rules, the FDA is also extending compliance dates for (1) Calorie Labeling of Articles of Food in Vending Machines; (2) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; (3) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; (4) Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; and (5) Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.

Labeling and Nutrition

Menu Labeling

With the final guidance published in April 2016, the Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments continues to create an impact on the restaurant industry. The rule's requirements affect restaurants and similar retail establishments with 20 or more locations, doing business under the same name, that sell substantially the same menu items and sell restaurant-type foods ("covered establishments"). Covered establishments must comply by May 5, 2017.

As compliance and enforcement looms closer, covered establishments have moved towards changing their menus in accordance with the rule. Those changes include: (1) the prominent display of calorie numbers of standard menu items on menus or menu boards; (2) signage displaying calorie numbers of standard menu items adjacent to food on display or self-service food; and (3) additional written nutritional information upon consumer request. The FDA has also made clear that covered establishments must have a "reasonable basis" to determine values for calorie or other nutrition claims provided for standard menu items. Reasonable basis can be determined through a number of means including: (a) calculations; (b) values listed in cookbooks; (c) laboratory analysis of menu items; or (d) other reasonable means.

Updated Nutrition and Supplement Facts Labels

After more than twenty years, the FDA published a final rule in May 2016 updating the nutrition and supplement facts label in an effort to help consumers make more informed decisions about what they eat. The new label, debuting in July 2018 for manufacturers with more than $10 million in annual food sales and a year later for those with less than $10 million in annual sales, features a refreshed design and a revised breakdown of caloric intake. Notably, type size has increased for

"Calories," "servings per container," and "Serving size" declarations. "Sugars" will change to "Total Sugars" and include new information on "Added Sugars" because scientific data shows a correlation between the total daily consumption of 10 percent or more of added sugars and difficulties in meeting dietary goals. There are also changes in required vitamin information: vitamin D and potassium levels are required on the label, whereas vitamins A and C are permitted, but not necessary.

Changes to serving sizes of common foods

Serving sizes also received a significant update. According to the FDA, data suggests what is commonly known: as food consumption increased over the past few decades, so did the typical serving size, and current labels must reflect that change. Specifically, foods that are generally consumed in one sitting (*e.g.*, soda and a pint of ice cream) must be labeled with nutrition facts for one serving, not for two or more servings. Manufacturers must also provide dual columns on larger packages that can be consumed in one or more sittings so consumers can easily understand how much they are actually eating. It will take years of data collection and analysis to provide the FDA, consumers, and food companies with much needed information on whether changes to serving size information can help reduce the risk of chronic diseases while increasing healthy dietary patterns.