



ML Strategies Update

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SEPTEMBER 18, 2015

## Food Safety, Labeling, and Nutrition Update

The Obama Administration has been making robust use of executive authority on issues related to food safety, labeling, and nutrition, continuing to position these issues as a priority for the remainder of the President's term in office. The Food and Drug Administration (FDA) and Department of Agriculture (USDA) have also taken significant actions this year on the Food Safety Modernization Act (FSMA) and Genetically Modified Organisms (GMOs), among other issues.

In the coming weeks, the House and Senate are scheduled to act on food safety, labeling, and nutrition-related issues, whether it is through new legislation on the labeling of bioengineered foods or debate on the funding and organization of federal food safety and nutrition programs.

### Food Safety Modernization Act

Progress on Final Rules implementing the Food Safety Modernization Act (FSMA) took a significant step forward last week when FDA released its first two, comprising the final rules on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for [Human Food](#) and [Food for Animals](#).

The final rule on Preventive Controls for Human Food creates and revises requirements for covered food facilities in three ways. The final rule:

1. Modernizes FDA's current good manufacturing practice (cGMP) regulations, which govern the manufacturing, processing, packing, or holding of human food;
2. Requires covered facilities to establish and implement hazard analysis and risk-based preventive controls for human food; and
3. Clarifies the scope of the exemption for farms in FDA's current food facility registration regulations and makes corresponding revisions to FDA's current regulations for the establishment, maintenance, and availability of records.

The final rule on Preventive Controls for Animal Food establishes new requirements for the production of animal food by registered food facilities. Specifically, the final rule:

1. Creates new cGMP regulations that, for the first time, specifically address the manufacturing, processing, packing, and holding of food for animals; and
2. Requires covered facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals.

These rules come in the midst of a long fight on Capitol Hill over funding for FDA and FSMA implementation and enforcement. To date, Congress has been unable to reach an agreement that would provide President Obama's requested FDA budget increase of \$109 million for FSMA implementation in FY2016. This budget uncertainty hampers FSMA implementation. In the Senate Agriculture's September 16 hearing on FDA food safety efforts, Michael Taylor, FDA's deputy commissioner for foods and veterinary medicine, stated: "There is no good outcome if we get the partial funding because something significant will have to give, whether it's in whole program areas, simply delaying or disrupting, or just doing everything inadequately...There will be hard choices." FDA is also stuck in FSMA-related disputes with growers, who have concerns about duplicative requirements with Department of Agriculture oversight, as well as with food safety groups that want the agency to require testing of more processed foods and produce under the law.

To continue its outreach and engagement with the regulated community on FSMA, FDA hosted a series of [three webinars](#) on the two Preventive Controls final rules. These webinars focused on who is covered by the rules, the final definition of "farm," and the significant provisions of the Preventive Controls for Human Food and the Preventive Controls for Animal Food final rules. A [public meeting](#) about both Preventive Controls final rules will be held in Chicago on October 20, 2015.

These final rules and notices of the availability of the qualitative risk assessments were [published in the Federal Register](#) on September 17, 2015 - an important date to keep in mind in order to accurately calculate compliance dates for your business as you work towards the new post-FSMA world.

### **Child Nutrition Reauthorization**

This week, the Senate Agriculture Committee delayed a scheduled mark-up of the child nutrition bill reauthorizing \$30 billion in annual spending, with Senator Roberts (R-KS) saying he needs more time to finish writing the reauthorization. Senator Roberts and Senate Agriculture Ranking Member Stabenow (D-MI) are purportedly "nearly at the finish line" in their negotiations to move forward on reauthorization of the Healthy Hunger-Free Kids Act, which is set to expire on September 30. The act authorizes funding and sets policy for USDA's core child nutrition programs, including the School Breakfast, National School Lunch, Child and Adult Care Food, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and the Fresh Fruit and Vegetable Programs.

A key provision of the 2010 Healthy Hunger-Free Kids Act is the Community Eligibility Provision, which allows high-poverty schools to serve universal free breakfasts and lunches. To date, however, focus on the Hill has centered on the School Lunch program, with Republicans hoping to roll back the Obama administration's regulations limiting sodium, fat and sugar as well as the mandates that all grain products are whole grain-rich and that kids take a serving of fruits or vegetables.

Senator Hoeven (R-ND), chairman of the Agriculture Subcommittee on Nutrition, is another

key player in this fight, having earlier this year introduced the Healthy School Meals Flexibility Act, which included provisions to roll back the whole grain-rich requirement to apply to half of all grain products (instead of all of them) and to stave off future sodium restrictions. Agriculture Secretary Tom Vilsack has emerged as a champion of the opposite position, calling the Healthy Hunger-Free Kids Act as 'a key component' of the Obama administration's strategy to improve nutrition for millions of children and stating "reauthorizing the nutritional programs has a direct and significant impact not just on children, but on the country in general."

Significant bipartisan interest has also been shown toward improvements to the summer meals program. The program, which replaces the meals low-income children receive at school during the summer months, is today only reaching 18% of eligible children. Several bipartisan pieces of legislation on this issue, including the Hunger-Free Summer for Kids Act, the Summer Meals Act, and the Stop Child Summer Hunger Act, have been referred to the Agriculture Committee for consideration in the reauthorization process. These bills seek to make improvements to the summer meals program to reach more eligible children.

Senator Roberts has stated his commitment to a "reauthorization package that is bipartisan, increases efficiency and effectiveness, has flexibility so all schools may achieve success in their meal programs, and addresses program integrity, high error rates, and improper payments within the programs." It remains to be seen, however, if the Senate will be able to draft and pass a reauthorization bill before the act expires on September 30.

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