



ML Strategies Update

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Food Safety, Labeling, and Nutrition Update

The past few weeks have seen significant action within the Food and Drug Administration (FDA) on food safety, labeling, and nutrition issues. With the release of three final rules on Food Safety, approval of the first Genetically Engineered (GE) salmon, release of draft and final GE food labeling guidance, and request for information and comments on the use of the term “natural” in food labeling, FDA signaled its commitment to, and set a course of action on, many of these issues.

The Obama Administration and Congress have also been active, with President Obama signing the Illegal, Unreported, Unregulated (IUU) Fishing Enforcement Act ([P.L. 114-81](#)) into law, and the House passing a Menu-labeling bill ([H.R. 2017](#)). Several issues, including GE food labeling and antibiotic resistance efforts, may continue evolving in the coming weeks, as they could be negotiated as part of a fiscal year 2016 omnibus appropriations package.

REGULATORY OUTLOOK

FDA Releases Three Final Rules on Food Safety

On November 13, FDA released three more of the foundational [Final Rules](#) mandated by the Food Safety Modernization Act (FSMA). The rules establish the final requirements for [Foreign Supplier Verification Programs](#), [produce safety](#), and [accredited third-party certification](#). FDA’s rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards; the rule on the Accredited Third-Party Certification establishes a voluntary program for the accreditation of third-party certification bodies, also known as auditors, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce; and the Produce Safety rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

FDA on GE Food Ingredients

Approval of first Genetically Engineered (GE) Salmon

On November 19, FDA [approved](#) the AquAdvantage Salmon as fit for human consumption; making it the first genetically engineered animal intended to be used as food to be approved under the New Animal Drug Application process. The [AquAdvantage Salmon](#) is an Atlantic salmon that has had a single gene from Chinook salmon added to its genome in order to allow

it to reach market size more quickly than non-GE Atlantic salmon. Following the required environmental assessment, FDA determined that the approval of the AquAdvantage Salmon application would not have a significant environmental impact because of the multiple and redundant measures being taken to contain the fish and prevent their escape and establishment in the environment. The salmon may be raised only in land-based, contained hatchery tanks in two specific facilities in Canada and Panama.

Denial of Petitions to Require GE Ingredient Labeling

On November 19, FDA also [denied petitions](#) filed by the [Center for Food Safety](#) and the [Truth in Labeling Coalition](#) that requested FDA mandate GE labeling for biotechnology-derived ingredients in food products because they are “materially different” from other crops. In its [ruling](#), FDA rejected the arguments of those urging mandatory GE labeling that genetically engineered foods are somehow materially different, as a class, than food derived from traditional breeding techniques, citing a 1992 policy statement and its long-standing interpretation of what changes to a food ingredient are “material” for purposes of label statements and representations.

Guidance on Voluntary GE Ingredient Labeling

Also on November 19, FDA published additional guidance on voluntary labeling of food containing genetically engineered ingredients. The guidelines consist of a [draft guidance](#) on voluntary labeling indicating whether food has or has not been derived from GE Atlantic salmon, and [final guidance](#) on voluntary labeling indicating whether food has or has not been derived from GE plants. Under the Federal Food, Drug, and Cosmetic Act, FDA can only require additional labeling of foods derived from GE sources if there is a material difference – such as a different nutritional profile – between the GE product and its non-GE counterpart. Comments on the GE salmon draft guidance should be submitted to the relevant FDA docket before January 25, 2016.

FDA to Address the Term “Natural” used in Food Labeling

In direct response to consumers, legislators, and courts that have requested that the FDA explore the use of the term “natural,” the agency is [asking the public](#) to provide [information and comments](#) on the use of this term in the labeling of human food products. FDA is taking this action partly in response to three Citizen Petitions asking the agency to define the term “natural” for use in food labeling and one Citizen Petition asking the agency to prohibit the term “natural” on food labels, as well as recent requests from judges in the context of private lawsuits involving the term “natural” on consumer products. Since the early 1990s, FDA has considered the term “natural” to mean that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food. However, this policy was not intended to address food production methods, such as the use of pesticides, nor did it explicitly address food processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation. The FDA also did not consider whether the term “natural” should describe any nutritional or other health benefit.

LEGISLATIVE OUTLOOK

Appropriations

Appropriations Fix for GE Labeling

Key senators are working on a deal that would address the issue of federal preemption of state GE labeling laws in the fiscal year 2016 omnibus appropriations package, though it would be contingent on food companies developing an alternative disclosure system for what’s in their products. The push for the proposal is being led by Sen. Debbie Stabenow (D-Mich.), and although it doesn’t go as far as the [House bill](#) from Rep. Mike Pompeo (R-Kan.) that would permanently preempt state labeling efforts, it may be the only way for the food industry to get

the political support needed to prevent a [labeling law in Vermont](#) from going into effect next summer.

Appropriations to Combat Antibiotic Resistance

On November 16, McDonald's, Tyson Foods and Wal-Mart Stores joined the Pew Charitable Trusts and other public health organizations in [asking House and Senate appropriators to increase funding for programs combating antibiotic resistance](#). Prior to the 2015 budget agreement, Senate and House appropriations legislation allocated \$3 million for FDA and \$7.3 million for USDA, respectively, to carry out programs addressing antibiotic resistance. President Obama requested \$77 million for USDA to research the development of antibiotic resistance and how it spreads in animals and humans, as well as to collect on-farm data to further target interventions. Obama also included \$47 million for FDA to improve antibiotic stewardship on farms and in hospitals, monitor drug use, and streamline the development process for new treatments. The FY 2016 budget request supports a five-year [National Action Plan for Combating Antibiotic-Resistant Bacteria](#) outlined by the White House in March 2015.

Menu Labeling Bill Passes House

On November 18, The House Energy and Commerce Committee passed menu-labeling legislation by a bipartisan vote of 36 to 12. The bill, [H.R. 2017](#), would enable menu-labeling compliance for convenience store operators while increasing the availability of both nutrition information and choice for consumers. Although Republicans were supportive of the legislation, a few committee Democrats, including Ranking Member Frank Pallone (D-NJ), expressed concerns with the bill. Citing America's obesity rates, Rep. Pallone stated that access to nutritional information helps consumers make more educated food choices. He argued that any concerns with the current regulations should be addressed through FDA guidance, not through a legislative fix.

Illegal, Unreported, Unregulated (IUU) Fishing Enforcement Act

On November 5, President Obama signed the Illegal, Unreported and Unregulated (IUU) Fishing Enforcement Act ([P.L. 114-81](#)), marking another critical step in the Administration's efforts to combat IUU fishing and seafood fraud. The bipartisan legislation includes a number of provisions preventing illegally harvested fish from entering the United States and supports efforts to achieve sustainable fisheries around the world. The U.S. will now join a global effort to ratify and implement the Port State Measures Agreement (PSMA), which will prevent vessels carrying fish caught illegally from entering U.S. ports and keep illegal products out of U.S. markets. The United States has already implemented most of the measures outlined in the PSMA domestically, and this formal ratification provides the United States additional leverage to encourage ratification and adoption of these measures by other countries so it applies to ports around the world.

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For more information on ML Strategies' Food Labeling, Food Safety and Nutrition Practice Group please contact Katherine Fox at KSFox@mintz.com or 202.434.7493.

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