Food, Dietary Supplement & Cosmetics Regulatory Update
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Top News

Obama Administration Releases New Dietary Guidelines Focusing on Limiting Sugar
The Obama administration has released the updated Dietary Guidelines for Americans with a new focus on limiting sugar. The Guidelines are revised every five years by USDA and the U.S. Department of Health and Human Services ("HHS"), based largely on advice from the Dietary Guidelines Advisory Committee. Although the new Guidelines contain familiar advice—eat more vegetables, fruits, and whole grains—the focus on limiting sugar represents a significant change from previous Guidelines. For the first time, the U.S. government is advising Americans, who consume up to 22 teaspoons daily, to limit sugar to no more than 10 percent of daily calories. High levels of sugar consumption have been linked to an increased risk of Type 2 diabetes and heart disease.

The Guidelines also conclude that teenage boys and men consume too much protein, recommending that men and boys reduce their intake of meat, poultry, and eggs. Another notable change is that the new Guidelines remove longstanding limits on dietary cholesterol, a victory for U.S. egg producers.

USDA and HHS did not include all recommendations made by the Advisory Committee, such as the recommendations to cut back on red and processed meats and to include sustainability as a factor in making food choices. But the Guidelines are clear that Americans will need to change their eating patterns to meet these new goals.

CONTACTS

Edgar J. Asebey
Miami

Cristiana Spontoni
Brussels

Colleen M. Heisey
Washington

Jonathan Berman
Washington

Katherine M. Llewellyn
Brussels

Aleš Bartl
Brussels

Stephanie L. Resnik
Washington

Matthew R. Bowles
Washington

Marina E. Moreno, FDA Coordinator in the Miami Office, assisted in the preparation of this Update.

Detailed Contact Information

RELATED PRACTICES

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FDA Creates New Office for Dietary Supplements
FDA has announced the creation of the new Office of Dietary Supplement Programs ("ODSP"), a program that has existed for 20 years as a division of FDA's Office of Nutrition Labeling and Dietary Supplements. Creation of the ODSP underscores the growth of the dietary supplement industry, from about $6 billion to more than $35 billion in annual sales, over those same 20 years. According to the Agency, "[e]levating the program's position will raise the profile of dietary supplements within the agency, and will enhance the effectiveness of dietary supplement regulation by allowing ODSP to better compete for government resources and capabilities to regulate this rapidly expanding industry."

The creation of the new office is a reflection of FDA's efforts to step up regulation of the supplement industry in response to public health concerns. ODSP will use existing resources to monitor dietary supplements on the marketplace. ODSP's former parent office will continue its other activities under the shortened name, the Office of Nutrition and Food Labeling, and the leadership of Doug Balentine, who recently joined FDA. Balentine will oversee the development of policy and regulation for nutrition labeling and food standards, infant formula, and medical foods.

Congress Repeals Controversial COOL Rule
On December 18, 2015, Congress repealed the controversial U.S. Country-of-Origin-labeling ("COOL") rule, thereby avoiding the $1 billion in retaliatory tariffs from Canada and Mexico recently authorized by the World Trade Organization ("WTO"). The repeal, which drew bipartisan support, took the form of a provision of the recently passed federal spending bill. As discussed in previous Jones Day *Updates*, the WTO found that the COOL rule violated international trade commitments. In response to concerns about mad-cow disease and other food safety issues, the 2009 COOL rule has required meat products to indicate where animals were born, raised, and slaughtered before the meat could be considered domestic. Now, beef and pork no longer have to comply with COOL rules, although chicken and lamb must still be labeled. Following the repeal, USDA Secretary Tom Vilsack announced that USDA would no longer enforce the COOL requirements for beef and pork, although he assured consumers that "all imported and domestic meat will continue to be subject to rigorous inspections by USDA to ensure food safety."

President Obama Signs Law Prohibiting Use of Microbeads in Cosmetic Products
On December 28, 2015, President Obama signed into law the "Microbead-Free Waters Act of 2015" (H.R. 1321), prohibiting the manufacture of rinse-off cosmetic products and nonprescription drugs containing intentionally added plastic microbeads as of July 1, 2017, and July 1, 2018, respectively. Additionally, introduction into interstate commerce is prohibited as of July 1, 2018, for all cosmetics containing microbeads (even if not intentionally added) and as of July 1, 2019, for all nonprescription drugs containing microbeads. Plastic microbeads are solid plastic particles that are less than five millimeters in size and used in toothpastes, soaps, and body wash products intended to exfoliate or cleanse the body. The tiny size of microbeads prevents them from being filtered by water plants, potentially resulting in the contamination of lakes and rivers, and the ingestion of plastic microbeads by fish and wildlife. Some states, including California, Colorado, Illinois, Indiana, Maine, Maryland, New Jersey, and Wisconsin, had already approved similar bills to protect their waters and wildlife. Michigan, Minnesota, Oregon, the District of Columbia, and New York also introduced bills to prohibit the use of microbeads in cosmetics and in over-the-counter products. The Microbead-Free Waters Act preempts any state law that prohibits the manufacture and sale of cosmetic products containing microbeads.

Other News
FDA Revokes Food Additive Approval for the Use of Long-Chain Perfluorinated Compounds as Oil and Water Repellents for Paper Used in Food Packaging

WTO Reaches Deals on Agricultural Export Subsidies and Credits

U.S. Concerned that Russia Moves Away from WTO Commitments

Regulatory Updates

FDA Extends Comment Period on Use of Term "Natural" on Food Labeling
In the December 28, 2015, *Federal Register*, FDA announced the extension of the comment period for a docket to receive comments on use of the term "natural" on labeling of human food products, including genetically engineered foods or foods containing genetically engineered ingredients. The deadline has been extended from February 10, 2016, as announced in the November 12, 2015, *Federal Register*, to May 10, 2016, in response to requests for extensions. ***Comments are now due May 10, 2016*.**

FDA Announces Withdrawal of Draft Guidance on Acidified Foods
In the December 30, 2015, *Federal Register*, FDA announced the withdrawal of a draft guidance for industry on Acidified Foods. The guidance, titled "Draft Guidance for Industry: Acidified Foods," was published in 2010 and was intended to complement FDA's regulations for specific current good manufacturing practices by assisting food processers in determining whether they were subject to the regulations, and how to comply. FDA is withdrawing the draft guidance because the topics are now addressed in other documents, namely FDA's recently issued guidance on the topic, and because FDA issued a final rule in the September 17, 2015, *Federal Register*, to help food processors in ensuring safe manufacturing processes and quality control procedures. ***The withdrawal was effective December 30, 2015***.

FDA Amends Food Additive Regulations to No Longer Permit Use of Three Food-Contact Substances
In the January 4, 2016, *Federal Register*, FDA amended the food additive regulations to no longer provide for the use of three specific food-contact substances ("FCSs") that contain perfluoroalkyl ethyl. The substances are used as oil and water repellants for paper and paperboard for use in contact with aqueous and fatty foods. The amendment is in response to a petition filed by the Natural Resources Defense Council, the Center for Food Safety, the Breast Cancer Fund, and other organizations demonstrating that there is no longer a reasonable certainty of no harm from the food-contact use of these FCSs. ***The rule was effective January 4, 2016; objections and requests for a hearing are due February 3, 2016***.

Organizations Petition to Remove Authorization of Seven Synthetic Flavoring Food Additives
In the January 4, 2016, *Federal Register*, FDA announced notice of a petition by the Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, and other organizations, proposing FDA amend the food additive regulations to no longer authorize the use of seven synthetic flavoring food additives and to establish zero tolerances for the additives. The seven food additives are: (i) benzophenone, (ii) ethyl acrylate, (iii) eugenyl methyl ether, (iv) myrcene, (v) pulegone, (vi) pyridine, and (vii) styrene. The petition provides new data establishing these substances are carcinogenic and therefore not safe for use in food. ***Comments are due March 4, 2016***.

FDA Announces Renewal of Food Advisory Committee
In the January 5, 2016, *Federal Register*, FDA announced the renewal of the Food Advisory Committee by the FDA Commissioner. The Food Advisory Committee reviews and evaluates emerging food safety, nutrition, and other food- or cosmetic-related health issues. ***The new charter will be effective until December 18, 2017***.

USDA Issues Semiannual Regulatory Agenda
In the December 15, 2015, *Federal Register*, USDA issued an agenda summarizing significant and not significant regulations being developed in conformance with Executive

Orders 12866 "Regulatory Planning and Review," and 13563 "Improving Regulation and Regulatory Review." The agenda also describes regulations affecting small entities, and regulatory actions that are being reviewed, for which USDA requests public comments. For this edition of the USDA regulatory agenda, the most important significant regulatory actions and a Statement of Regulatory Priorities are included in the Regulatory Plan, which appears in both the online regulatory agenda and in part II of the *Federal Register* notice.

AMS Proposes Rule to Address Recommendations Submitted by the NOSB in April 2015

In the December 16, 2015, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") issued a proposed rule that would address recommendations submitted to the Secretary of Agriculture by the National Organic Standards Board ("NOSB") following their April 2015 meeting. These recommendations pertain to the 2016 Sunset Review of substances on the USDA's National List of Allowed and Prohibited Substances ("National List"). Consistent with the recommendations from the NOSB, this proposed rule would remove five nonorganic nonagricultural substances from the National List for use in organic handling: (i) egg white lysozyme, (ii) cyclohexylamine, (iii) diethylaminoethanol, (iv) octadecylamine, and (v) tetrasodium pyrophosphate. ***Comments are due February 16, 2016***.

CCC Issues Final Rule Regarding Payment Limitation and Eligibility for Persons Engaged in Farming

In the December 16, 2015, *Federal Register*, USDA's Commodity Credit Corporation ("CCC") issued a final rule changing the requirements for a person to be considered actively engaged in farming for the purpose of payment eligibility for certain Farm Service Agency and CCC programs. Specifically, this rule amends and clarifies the requirements for a significant contribution of active personal management to a farming operation. This rule will apply to eligibility for payments earned for the 2016 crop or program year for farming operations with only 2016 spring planted crops, and to eligibility for payments for the 2017 and subsequent crop or program years for all farming operations (those with either spring or fall planted crops). The provisions of this rule do not apply to persons or entities composed entirely of family members, and does not change the existing regulations as they relate to contributions of land, capital, equipment, or labor, or the existing regulations related to landowners with a risk in the crop or to spouses. ***Final rule is effective December 16, 2015***.

APHIS Proposes Consolidating Regulations Governing Bovine Tuberculosis and Brucellosis

In the December 16, 2015, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") proposed to consolidate the regulations with regard to bovine tuberculosis and brucellosis, transitioning the tuberculosis and brucellosis programs away from a state classification system based in disease prevalence. Instead, states and Native American tribes would implement animal health plans that identify sources of the diseases within the state or tribal lands and specify mitigations to address the risk posed by those sources. The consolidated regulations would also: (i) set forth standards for surveillance, epidemiological investigations, and affected herd management that must be incorporated into each animal health plan, with certain limited exceptions; (ii) provide revised conditions for the interstate movement of cattle, bison, and captive cervids; and (iii) provide revised conditions for APHIS approval of tests, testing laboratories, and testers for bovine tuberculosis or brucellosis. In addition, APHIS proposes to revise the bovine tuberculosis- and brucellosis-related import requirements for cattle and bison to make these requirements clearer and ensure that they more effectively mitigate the risk of introduction of these diseases into the United States. ***Comments are due March 15, 2016***.

FSIS Issues Revised Guidelines for Controlling *Salmonella* and *Campylobacter* in Raw Poultry

In the December 16, 2015, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") announced the availability of a revised guideline to assist poultry establishments

in controlling *Salmonella* and *Campylobacter* in raw poultry. The Agency has revised its guideline to provide updated information for establishments to use to control pathogens in raw poultry products with the goal of reducing human illnesses. The guideline represents the best practice recommendations of FSIS based on scientific and practical considerations. ***Comments are due February 16, 2016***.

FSIS Issues Final Rule Amending Its Recordkeeping Regulations
In the December 21, 2016, *Federal Register*, USDA's FSIS issued a final rule amending its recordkeeping regulations to require all official establishments and retail stores that grind raw beef products for sale in commerce to maintain the following records: (i) the establishment numbers of establishments supplying material used to prepare each lot of raw ground beef product; (ii) all supplier lot numbers and production dates; (iii) the names of the supplied materials, including beef components and any materials carried over from one production lot to the next; (iv) the date and time each lot of raw ground beef product is produced; and (v) the date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized. These requirements also apply to raw beef products that are ground at an individual customer's request when new source materials are used. ***Final rule is effective June 20, 2016***.

GIPSA Requests Comments on U.S. Standards for Rough Rice, Brown Rice for Processing, and Milled Rice
In the December 22, 2015, *Federal Register*, USDA's Grain Inspection, Packers, and Stockyards Administration ("GIPSA") sought comments from the public regarding the U.S. Standards for Rough Rice, Brown Rice for Processing, and Milled Rice under the Agriculture Marketing Act of 1946. To ensure that standards and official grading practices remain relevant, GIPSA invites interested parties to comment on whether the current rice standards and grading practices need to be changed. ***Comments are due March 21, 2016***.

AMS Issues Final Rule Regarding Late Payment and Interest Charges on Past Due Assessments
In the December 24, 2015, *Federal Register*, USDA's AMS issued a final rule prescribing late payment and interest charges on past due assessments under the Paper and Paper-Based Packaging Promotion, Research and Information Order ("Order"). Under the Order, assessments are collected from manufacturers and importers and used for projects to promote paper and paper-based packaging. This rule implements the authority contained in the Order that allows the Paper and Packaging Board to collect late payment and interest charges on past due assessments. ***Final rule is effective January 25, 2016***.

FCIC Amends Crop Insurance Regulations
In the December 29, 2015, *Federal Register*, USDA's Federal Crop Insurance Corporation ("FCIC") amended the Common Crop Insurance Regulations, Cotton Crop Insurance Provisions, and Extra Long Staple Cotton Crop Insurance Provisions providing policy changes and clarifying existing policy provisions to better meet the needs of policyholders. FCIC received requests to simplify program administration consistent with evolving farming practices in cotton crop production. The changes will be effective for the 2017 and succeeding crop years. ***Comments are due February 29, 2016***.

FSIS Clarifies Its Approach within the National Residue Program
In the December 29, 2015, *Federal Register*, USDA's FSIS clarified its approach within the National Residue Program's Tier 2 exploratory program when it tests tissue samples collected from livestock and poultry carcasses and detects chemicals that do not have established tolerances or other regulatory levels. This approach applies to potentially hazardous chemicals that are not animal drugs or pesticide chemicals with established tolerances. The Agency also intends to apply this approach to egg products should these products become subject to chemical testing and to products from fish of the order Siluriformes when the final rule to make these species amenable to the Federal Meat Inspection Act is fully implemented. ***Comments are due February 29, 2016***.

AMS Issues Final Rule Exempting Organic Products from Assessment Under a Commodity Promotion Law
In the December 31, 2015, *Federal Register*, USDA's AMS amended the current organic assessment exemption regulations to allow persons that produce, handle, market, process, manufacture, feed, or import "organic" and "100 percent organic" products to be exempt from paying assessments associated with commodity promotion activities, including paid advertising, conducted under a commodity promotion program administered by the AMS, regardless of whether the person requesting the exemption also produces, handles, markets, processes, manufactures, feeds, or imports conventional or nonorganic products. Currently, only persons who exclusively produce and market products certified as 100 percent organic are eligible for an exemption from assessments under commodity promotion programs. ***Final rule is effective February 29, 2016***.

FSIS Announces 2016 Rate Changes for the Basetime, Overtime, Holiday, and Laboratory Services Rates
In the December 31, 2015, *Federal Register*, USDA's FSIS announced the 2016 rates that it will charge meat and poultry establishments, egg products plants, and importers and exporters for providing voluntary, overtime, and holiday inspection and identification, certification, and laboratory services. The 2016 basetime, overtime, holiday, and laboratory services rates will be applied beginning the first FSIS pay period approximately 30 days after the publication of this notice. ***This pay period begins on February 7, 2016***.

Other USDA Announcements:
- AMS Establishes Free and Restricted Percentages for the 2015–16 Crop Year for Tart Cherries Grown in Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin
- Agricultural Research Service Announces Intent to Grant Oregon State University of Corvallis an Exclusive License to a Blackberry Plant Named "Columbia Giant"
- Agriculture Department Corrects Two Provisions of the Egg Products Inspection Act
- Agriculture Department Corrects One Provision Regarding Law Enforcement Authorities
- Food and Nutrition Services ("FNS") Revises a Provision under Title 7 C.F.R., Parts 210 to 299, Determining Eligibility for Free and Reduced-Price Meals and Free Milk in Schools
- FNS Corrects a Provision under Title 7 C.F.R., Parts 210 to 299, Regarding the Child and Adult Care Food Program
- FNS Corrects a Provision under Title 7 C.F.R., Parts 210 to 299, Regarding the Performance Reporting System
- FNS Corrects a Provision under Title 7 C.F.R., Parts 210 to 299, Regarding Participation of Retail Food Stores, Wholesale Food Concerns, and Insured Financial Institutions
- FSIS Corrects a Provision under Title 9 C.F.R., Part 200 to End, Regarding Labeling, Marking Devices, and Containers
- GIPSA Corrects a Provision under Title 9 C.F.R. under the Packers and Stockyards Act
- Federal Crop Insurance Corporation Corrects a Provision under Title 7 C.F.R., Parts 400 to 699, Regarding General Administrative Regulations
- APHIS Corrects Three Provisions under Title 7 C.F.R., Parts 300 to 399, Regarding Foreign Quarantine Notices
- APHIS Corrects a Provision under Title 7 C.F.R., Parts 300 to 399, Regarding Domestic Quarantine Notices
- CCC Publishes Sugar Overall Allotment Quantity ("OAQ"), Beet and Cane Sugar Marketing Allotments, and Processor Allocations for FY2016, and a Summary of the OAQ's, Sugar Marketing Allotments, and Allocations for FY2015 and FY2014

USDA Announced the Following Requests for Information:
- Information Collection for the Summer Food Service Program

- Operating Reports for Telecommunications and Broadband Borrowers
- 7 C.F.R. Part 1728, Electric Standards and Specifications for Materials and Construction

USDA Announced the Following Proposed Information Collections:

- Veterinary Medical Loan Repayment Program

USDA Announced the Following Information Collections Have Been Revised, Renewed, and/or Extended:

- 7 C.F.R. Part 210 National School Lunch Program, Part 220 School Breakfast Program, and Part 215 Special Milk Program

USDA Announced the Following Information Collections Have Been Submitted to OMB:

- Survey of Customers of the Official Grain Inspection and Weighing System
- Laboratories
- Forms Pertaining to the Peer Preview of ARS Research Projects
- Multiple Peril Crop Insurance
- Volunteer Program—Earth Team
- Risk Management Education Partnerships; Request for Applications

European Regulatory Updates

EFSA and CFIA Promote Scientific Cooperation in Risk Assessment
On December 14, 2015, the European Food Safety Authority ("EFSA") and the Canadian Food Inspection Agency ("CFIA") signed a Memorandum of Cooperation to enhance their scientific cooperation and dialogue related to risk assessment. The future cooperation focuses on two main areas: (i) the collection, analysis, and sharing of technical data in risk assessment, and (ii) the sharing of views and expertise in the area of methodologies for data collection, risk assessment, and risk communication. The Memorandum was signed for an initial period of five years.

European Parliament Objects to Authorization of Glyphosate-Tolerant GM Maize
On December 16, 2015, the European Parliament ("EP") objected to the EU Commission's authorization for use of glyphosate-tolerant genetically modified ("GM") maize NK603xT25 in food and feed. The EP noted that glyphosate, an herbicide, is classified as "probably carcinogenic" by the World Health Organization, and thus glyphosate-tolerant maize should not be marketed in the EU. The EP also expressed its concerns that the procedure used by the Commission for authorizing the GM maize in question is the subject of longstanding concerns and is currently under review (see our previous Jones Day *Update*). The EP has therefore urged the Commission to suspend any authorizations for GM food until the review of the GM authorization procedure has been completed. The Commission is now required to review the authorization, taking the EP's position into account.

Upcoming Meetings, Workshops, and Conferences

Public Meeting to Provide Information and Receive Public Comments Regarding 22nd Session Meeting of the Codex Alimentarius Commission Committee on Food Import and Export Inspection and Certification Systems, **January 14, 2016**, in Washington, D.C.

Public Meeting to Provide Information and Receive Public Comments Regarding 37th Session of the Codex Alimentarius Commission Committee on Methods of Analysis and Sampling, **January 19, 2016**, in Washington, D.C.

Public Advisory Committee Meeting of the Allergenic Products Advisory Committee, **January 21, 2016**, in Silver Spring, MD.

Jones Day FDA Regulatory & Compliance Counseling Contacts

Edgar J. Asebey
Miami
+1.303.714.9707
easebey@jonesday.com

Cristiana Spontoni
Brussels
+32.2.645.14.48
cspontoni@jonesday.com

Colleen M. Heisey
Washington
+1.202.879.3449
cmheisey@jonesday.com

Jonathan Berman
Washington
+1.202.879.3669
jberman@jonesday.com

Katherine M. Llewellyn
Brussels
+32.2.645.14.47
kllewellyn@jonesday.com

Aleš Bartl
Brussels
+32.2.645.14.52
abartl@jonesday.com

Stephanie L. Resnik
Washington
+202.879.5458
sresnik@jonesday.com

Matthew R. Bowles
Washington
+1.202.879.3604
mbowles@jonesday.com

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