



FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

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Top News

Senators Ask FDA to Delay Menu Labeling Rule

Last week, a group of 32 senators urged FDA to delay implementation of the final rule "[Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments](#)" for one year, arguing the rule lacks clarity on "[many of the key components of the final rule](#)." The rule, which is to take effect on December 1, 2015, requires restaurants and other food retailers that are part of a chain of 20 or more locations (including retailers such as movie theaters and amusement parks) to conspicuously display calorie information on their menus and menu boards. Although FDA published a [guidance](#) in March 2015, the senators express concerns that "the lack of clear and consistent guidance from the agency will make it difficult, confusing, and burdensome ... to implement the new requirements by the [] deadline"

USDA Offers New Certification, Labeling for GMO-Free Foods

USDA has announced a [new, voluntary certification and labeling program for foods free of genetically modified organisms](#) ("GMOs"). Companies must pay for the certification but once approved, their products may carry a "[USDA Process Certified](#)" label along with a claim the products are GMO-free. Currently, companies may put their own GMO-free labels on foods, most through the private label developed by the nonprofit [Non-GMO Project](#), but there are no government labels identifying a food as GMO-free.

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The USDA label is similar to what was proposed in a [GOP House bill](#) introduced earlier this year that attempts to block mandatory state-level GMO labeling efforts nationwide, such as [Vermont's](#) state law. If the GOP bill survives, it would override any state laws requiring such labels. Last week, one company became the [first to receive USDA Process Verified Program verification for non-GMO foods](#). Agriculture Secretary Tom Vilsack says that "other companies are already lining up to take advantage of this service."

U.S. Loses WTO Appeal in Meat-Label Row

Last week, the [World Trade Organization \("WTO"\)](#) rejected a U.S. appeal over USDA's controversial [country-of-origin meat labeling \("COOL"\) requirements](#) that Canadian and Mexican producers have been fighting since 2008. The COOL rule was an effort to help consumers make informed choices by [requiring producers to label beef, pork, chicken, and other meat products to reveal where animals were born](#). WTO found the requirements in the [final rule](#), issued in May 2013, violate global trade rules, specifically discriminating against Canadian and Mexican producers. Although the Obama administration has defended the COOL rules, House Agriculture Chairperson K. Michael Conaway (R-TX) introduced a bill to repeal the COOL rules in an effort to [avoid retaliatory tariffs against the United States](#), such as those recently announced by the Canadian Agricultural Minister. Last Wednesday, the [House panel voted 38-6](#) to repeal the COOL requirements.

Health Association Petitions FDA to Amend Dietary Supplements cGMP Regulations

The Organic and Natural Health Association ("ONHA") recently [petitioned](#) FDA to amend the regulations governing dietary supplements so that all dietary ingredient suppliers have to comply with current Good Manufacturing Practices ("cGMPs"). In its petition, ONHA argues that quality manufacturing requires responsibility at the ingredient level, and current mechanisms are not sufficient to ensure quality. ONHA also asks FDA to clarify the regulatory responsibilities of private label distributors, arguing it is not clear whether the manufacturer or the private labeler is obligated to test finished products. The petition is just one example of increased attention on the dietary supplement industry by consumers, state attorneys general, and FDA. As covered in previous [Jones Day Updates](#), recently a group of 14 state attorneys general asked Congress to investigate the herbal supplements industry.

Other News

[FDA Investigates *Listeria* in Ice Cream Products from Blue Bell Creameries](#)

[White House Announces Plan to Promote Honey Bee Health](#)

[CDC Links *Salmonella* Outbreak in Nine States to Raw Tuna in Sushi](#)

[Scientists Discover How to "Grow" Meat](#)

Regulatory Updates

FSIS Announces Final Revision of Compliance Guideline for HACCP

In the [May 14, 2015, Federal Register](#), USDA's Food Safety and Inspection Service ("FSIS") announced the availability of the final revision of the Compliance Guideline for Hazard Analysis Critical Control Point ("HACCP") systems validation, which contains requirements for the initial validation of an establishment's HACCP plan and the need for establishments to conduct activities designed to determine that the HACCP plan is functioning as intended. In addition, FSIS responded to comments received on the [draft guide FSIS published in May 2013](#) and announced its plans to verify that establishments meet all validations requirements. ***The guideline is effective now; verification of validation requirements begins January 4, 2016.***

FSIS Issues Final Rule Amending Federal Meat Inspection Regulations

In the [May 18, 2015, Federal Register](#), USDA's FSIS amended the federal meat inspection

regulations to require cooking instructions and the use of the descriptive designation "mechanically tenderized," "blade tenderized," or "needle tenderized" on the labels of raw or partially cooked needle- or blade-tenderized beef products. FSIS also announced the availability of an updated guidance for the use of federally inspected establishments in developing validated cooking instructions for mechanically tenderized products. ***The rule is effective May 17, 2016.***

FSIS Proposes to Amend Regulations on Ante-Mortem Inspection of Disabled Veal Calves

In the [May 13, 2015, Federal Register](#), USDA's FSIS proposed to amend its regulations on ante-mortem inspection to remove a provision permitting establishments to set apart and hold for treatment veal calves that are unable to rise from a recumbent position and walk. Under the proposed rule, nonambulatory disabled veal calves offered for slaughter will be condemned and promptly euthanized. FSIS also proposed that all nonambulatory disabled cattle must be promptly disposed of after they have been condemned. ***Comments are due July 13, 2015.***

APHIS Proposes Alteration to Inventory Record System

In the [May 12, 2015, Federal Register](#), USDA's Animal and Plant Health Inspection Service ("APHIS") proposed an alternative to the existing system of records, titled Veterinary Services—Records of Accredited Veterinarians. The records system maintains information pertaining to veterinarians who are or have been accredited, or who have applied for accreditation, under the authority of section 10410 of the Animal Health Protection Act. ***Comments are due June 11, 2015; system will be adopted June 22, 2015.***

AMS Extends Nomination Period for NOSB

In the [May 18, 2015, Federal Register](#), USDA's Agricultural Marketing Service ("AMS") extended the nomination period for the National Organic Standards Board ("NOSB") by 30 days in order to ensure adequate opportunity for all interested members of the public to submit nominations. USDA requested nominations to fill five upcoming vacancies to serve a five-year term of office commencing on January 24, 2016, and ending January 23, 2021. ***Nominations are now due June 17, 2015.***

CCC and FSA Extend Comment Period for Final Rule Amending the Biomass Crop Assistance Program

In the [May 20, 2015, Federal Register](#), USDA's Commodity Credit Corporation ("CCC") and USDA's Farm Service Agency ("FSA") extended the comment period for the final rule amending the Biomass Crop Assistance Program ("BCAP"), published on February 27, 2015, to allow the public more time to provide input and recommendations. The final rule amended the BCAP regulations to implement changes required by the 2014 Farm Bill. ***Comments are due May 27, 2015.***

GIPSA Seeks Nominations to Serve on the Advisory Committee

In the [May 26, 2015, Federal Register](#), USDA's Grain Inspection, Packers, and Stockyards Administration ("GIPSA") announced it is seeking nominations for individuals to serve on the Advisory Committee, which represents the interests of grain producers, processors, handlers, merchandisers, consumers, exporters, and scientists. The Advisory Committee meets twice annually to advise GIPSA on the programs and services it delivers under the U.S. Grain Standards Act. ***Nominations are due June 25, 2015.***

Rural Business-Cooperative Service Invites Applications for Value-Added Producer Grants

In the [May 15, 2015, Federal Register](#), the Rural Business-Cooperative Service published a correction of a previous [notice of May 8, 2015](#), that contained an incorrect date and contact telephone number for submitting applications for the Value Added Producer Grant Program. ***Applications are due by July 7, 2015.***

Other USDA Announcements

- AMS Issues Final Rule to Implement Increased Assessment Rate for Grapes Grown in Southeastern California
- AMS Issues Final Rule Establishing Salable Quantities and Allotment Percentages of

Spearmint Oil Produced in the Far West for Marketing Year 2015–2016

USDA Announced the Following Request for Information

- Certificates of Medical Examination

USDA Announced the Opportunity to Comment on the Following Proposed Information Collections

- Supplemental Nutrition Assistance Program Forms: Applications, Periodic Reporting, and Notices
- Evaluation of Supplemental Nutrition Assistance Program Employment and Training Pilots
- State Telecommunications Modernization Plan

USDA Announced Its Intent to Revise and/or Extend the Following Previously Approved Information Collections

- Requirements for Official Establishments to Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain HACCP Plan Reassessments
- Mink Survey
- Importation of Christmas Cactus and Easter Cactus in Growing Media from Netherlands and Denmark
- Voluntary Recalls of Meat and Poultry Products
- 7 CFR 1944-I, Self-Help Technical Assistance Grants
- Egg, Chicken, and Turkey Surveys

USDA Announced the Following Information Collections Have Been Submitted to OMB

- Advisory Committee and Research and Promotion Board Membership Background Information
- Agricultural Resource Management, Chemical Use, and Post-Harvest Chemical Use Surveys
- Airplane Pilot Qualifications and Approval Record, Helicopter Pilot Qualifications and Approval Record, Airplane Data Record, and Helicopter Data Record

FDA Announced the Opportunity to Comment on the Following Proposed Information Collection

- Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim

FDA Announced the Following Information Collections Have Been Submitted to OMB

- Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements
- State Enforcement Notifications

FDA Announced that the Following Collections Have Been Approved by OMB

- Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program
- Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body
- Substances Prohibited from Use in Animal Food or Feed
- Infant Formula Requirements
- FDA Recall Regulations

FDA Issued the Following Draft and Final Guidance Documents

Revised Guidance for Industry: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing, May 13, 2015, *Federal Register*.

European Regulatory Updates

UK Publishes Guidance on Food Labeling

On April 27, 2015, the United Kingdom's Department for Environment, Food and Rural Affairs and the Food Standards Agency published [guidance](#) on the information that should be provided to consumers to comply with the European Food Information to Consumer Regulation No. 1169/2011.

Ireland Publishes New Guidance for Use of Food Marketing Terms

On May 14, 2015, the Food Safety Authority of Ireland published [new guidance](#) aimed at ensuring consumers are not misled by the use of marketing terms on foods. The guidance will assist in the responsible use of marketing terms by food manufacturers, retailers, and food service businesses when placing their products on the market to ensure they convey clear, nonmisleading meanings. The guidance outlines the general legal requirements that food businesses must follow when using marketing terms on food and also provides guidance for the food industry concerning the use of specific marketing terms, such as "artisan/artisanal," "farmhouse," "traditional," and "natural."

EFSA Publishes Scientific Opinions on Six Health Claims

On May 13, 2015, the European Food Safety Authority ("EFSA") published its scientific opinion on six new health claims. These include, among others, [Coffee C21 for the reduction of DNA damage and Vitamin D for the normal function of the immune system](#).

EFSA Opens Magnesium Consultation

EFSA's [Scientific Opinion on dietary reference values for magnesium](#) is now open for public consultation. The draft opinion proposes adequate intakes based on observed intakes in healthy populations in the EU. The deadline for comments is June 7, 2015.

Upcoming Meetings, Workshops, and Conferences

Public Meeting, "USDA's Receipt for Service Initiative," Held by Office of Advocacy and Outreach, **June 3, 2015**, in Washington, D.C.

Public Meeting of National Advisory Committee on Microbiological Criteria for Foods, **June 10, 2015**, via audio conference call.

Public Meeting to Discuss 38th Session of Codex Alimentarius Commission, **June 17, 2015**, in Washington, D.C.

FDA and AFDO Conference titled *In Motion: Science Transforming Policy in Food, Drug, and Medical Device Regulation*, **June 20–24, 2015**, in Indianapolis, IN.

General Conference Committee of the National Poultry Improvement Plan, **July 23, 2015**, in Salt Lake City, UT.

EFSA's 2nd Scientific Conference, **October 14, 2015**, in Milan, Italy.

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