



FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

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Top News

Canada Warns U.S. Regarding Proposed Bill that Would Establish Standards for Voluntary Country of Origin Designations

Sen. Debbie Stabenow [proposed a bill](#) that would allow producers of beef or pork to voluntarily designate their products as exclusively having United States country of origin, if certain conditions are met. This proposed country-of-origin labeling ("COOL") law met with a hostile reaction from Canada's Minister of Agriculture Gerry Ritz, who warned, "[should the U.S. move forward with their short-sighted proposal, Canada will have no choice but to impose billions of dollars of retaliatory tariffs on U.S. exports.](#)" The World Trade Organization ("WTO"), which recently ruled against the U.S. mandatory COOL laws as being discriminatory toward Canada and Mexico, is now hearing the dispute relating to the US\$3 billion in retaliatory tariffs sought from the U.S. by Canada and Mexico.

At the end of July 2015, the United States Trade Representative ("USTR") filed a legal brief with the WTO [stating](#) the retaliatory tariffs were calculated using a "flawed" methodology and "severely overestimate the level of nullification or impairment attributable" to COOL, requesting to lower the tariff amount to a total of US\$91 million. The WTO will review this matter in Geneva, on September 15–16, 2015.

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GMA Files Food Additive Petition with FDA for Low-Level Trans Fat Uses

On August 5, 2015, the Grocery Manufacturers Association ("GMA") [petitioned](#) FDA to approve low-level partially hydrogenated oils ("PHOs" or "trans fat") for uses that are important for the production of safe foods, including for use as color and flavor carriers, and to deliver certain consumer-desired textural characteristics that other oils cannot provide (e.g., flakiness in doughs). For this purpose, GMA filed a food additive petition with FDA following the agency's recent decision on reclassifying PHOs from "GRAS" ("generally recognized as safe") to "food additives." For details on FDA's decision, see our *Jones Day Alert*, "[FDA Finds that Artificial Trans Fats Are Unsafe](#)." The association uses a highly detailed analysis of scientific evidence to claim there is a "reasonable certainty of no harm" from consumption of the uses and use levels of PHOs specified in the petition. In sharp contrast, the Physicians Committee for Responsible Medicine filed a [citizen petition](#) requesting the Commissioner to ban all trans fat acids, including the elimination of any exemptions, standing on the fact that "there is no consensus among qualified experts that trans fatty acids of any type are generally recognized as safe for any use in human food."

Released Documents Assert Flawed Rulemaking Process Related to Waters Rule

On July 30, 2015, the House Committee on Oversight and Government Reform released [documents](#) revealing the Army Corps of Engineers' ("Corps") disapproval of the U.S. Environmental Protection Agency ("EPA") officials' rulemaking process in producing the "[Waters of the United States](#)" final rule. The Corps asserts that EPA based its expansion of the categories of bodies of waters subject to federal pollution controls on a flawed economic analysis. The Corps' documents maintain, for example, that [it would be "difficult to determine whether a \[pond\] after a rainstorm ..." would be regulated "water" or an excluded "puddle."](#) These documents also echo some of the American Farm Bureau Federation's ("AFBF") concerns about the controversial rule. AFBF President Bob Stallman referred to the "flawed economic study" as only one of the issues surrounding the rule. The AFBF is calling for an immediate withdrawal of the rule and a redraft that better addresses the concerns of affected parties, such as farmers, ranchers, and business owners across the country.

EC Renews Financial Support to EU Farmers Hit by Russia's Newly Extended Embargo

On August 7, 2015, the [European Commission](#) ("EC") [announced the extension of safety net measures available to Europe's agriculture sector](#), renewing benefits previously provided to farmers hit by Russia's ban on import of EU fruits and vegetables. The new aid package, which will last until June 30, 2016, aims to ease market pressures for the main groups of fruits and vegetables that were previously exported to Russia. The move follows the [announcement](#) by the Russian government that it would continue its embargo on meat, fish, dairy products, and fruits and vegetables from the EU, the U.S., Australia, Canada, and Norway for a further 12 months. In addition, any food introduced into the country despite the import bans would be destroyed. Russia, which banned the import of certain foods and drinks as a response to Western sanctions over Ukraine's crisis, announced that this list of countries would also include Albania, Montenegro, Liechtenstein, and Iceland.

Other News

[Senators Urge FDA to Ban Powdered Caffeine Sales](#)

[U.S. Pork, Beef, and Lamb Exports Drop for First Half in 2015](#)

[Poultry and Egg Producers Hit by Bird Flu Helped with Federal Funds](#)

[9th Circ. Upholds California's Shark Fin Ban Law](#)

[EU and Vietnam Achieve Free Trade Agreement](#)

Regulatory Updates

FDA Issues Draft Guidance on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels

In the [July 30, 2015, Federal Register](#), FDA announced the availability of a draft guidance for industry titled "FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels: Guidance for Industry." The guidance, when finalized, will describe FDA's policy on how to determine the amount to declare on the nutrition label for certain nutrients and dietary ingredients that are present in a small amount. **Comments are due September 28, 2015.**

FDA Confirms Effective Date of Final Rule on Mica-Based Pearlescent Pigments

In the [August 4, 2015, Federal Register](#), FDA confirmed the effective date of July 9, 2015, for the [final rule](#) published on June 8, 2015. The final rule amends the color additive regulations to expand the permitted uses of mica-based pearlescent pigments prepared from titanium dioxide and mica as color additives in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, nonalcoholic cocktail mixers, and mixes, and in egg decorating kits for coloring shell eggs.

FDA Issues Final Guidance for Use of Nanomaterials in Animal Food

In the [August 5, 2015, Federal Register](#), FDA announced the availability of a final guidance titled "Use of Nanomaterials in Food for Animals," which describes FDA's perspective regarding the use of nanomaterials or the application of nanotechnology in animal food. The purpose of the guidance is to help interested parties and the industry in determining what issues may arise relating to the safety or regulatory status of animal food containing nanomaterials or using nanotechnology. For this guidance, FDA considered the comments requested on the draft guidance of June 2014. **Comments are due at any point.**

FDA and Health Canada Publish Assessment on Risk of Listeriosis from Soft-Ripened Cheese

In the [August 3, 2015, Federal Register](#), FDA and Health Canada announced the availability of the ["Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada."](#) The assessment will help FDA and Health Canada to evaluate the effects of factors such as the microbiological status of milk, cheese-manufacturing steps, and conditions during distribution and storage on the overall risk of invasive listeriosis to the consumer of soft-ripened cheese in the United States or Canada.

FDA Requests Comments to Evaluate Risk of Foodborne Illness from Consumption of Cheese

In the [August 3, 2015, Federal Register](#), FDA published a request for comments and scientific data and information that would assist in identifying and evaluating intervention measures that might have an effect on the presence of bacterial pathogens in cheese manufactured from unpasteurized milk. **Comments are due November 2, 2015.**

FDA Announces Adisseo France S.A.S. Filed Food Additive Petition for Animal Use

In the [August 13, Federal Register](#), FDA announced Adisseo France S.A.S. filed a petition proposing that the food additive regulations be amended to provide for the safe use of selenomethionine hydroxy analogue as a source of selenium in feed for chickens, turkeys, swine, dairy cattle, and beef cattle. The petitioner has requested a categorical exclusion from preparing an environmental assessment or environmental impact statement, for which FDA requests **comments be submitted by September 14, 2015.**

AMS Issues Final Rule Amending U.S. Antitrust Laws, Immunity, and Liability Under Marketing Order Programs

In the [July 30, 2015, Federal Register](#), USDA's Agricultural Marketing Service ("AMS") issued a final rule amending the general regulations for federal fruit, vegetable, and specialty crop marketing agreements and marketing orders that would accentuate the

applicability of U.S. antitrust laws to marketing order programs' domestic and foreign activities. This action advises marketing order board and committee members and personnel of the restrictions, limitations, and liabilities imposed by those laws. ***Final rule is effective July 31, 2015.***

AMS Announces Public Hearing on Proposed Rulemaking to Establish Federal Milk Marketing Order

In the [August 6, 2015, Federal Register](#), USDA's AMS announced a public hearing to consider and take evidence on a proposal to establish a federal milk marketing order to regulate the handling of milk in the entire state of California. USDA received four proposals from interested parties, some of which include certain milk pricing and pooling provisions not found in current federal milk orders. Additional features would recognize California quota premium and fluid milk fortification values. None of these proposals would modify any existing federal milk marketing orders. The hearing will be held on September 22, 2015, in Clovis, California.

AMS Issues Proposed Rule Addressing NOSB's Recommendations to Secretary on USDA National List

In the [July 30, 2015, Federal Register](#), USDA's AMS issued a proposed rule addressing recommendations by the National Organic Standards Board ("NOSB") to the Secretary of Agriculture pertaining to the 2015 Sunset Review of substances on USDA's National List of Allowed and Prohibited Substances ("National List"). Consistent with the recommendations from the NOSB, this proposed rule would remove: (i) two nonorganic agricultural substances from the National List for use in organic handling—marsala and sherry fortified cooking wines, and (ii) two listings for synthetic substances allowed for use in organic crop production on the National List—streptomycin and tetracycline, as their use exemptions expired on October 21, 2014. ***Comments are due August 31, 2015.***

NRCS Issues Notice of Availability for VPA-HIP

In the [August 4, 2015, Federal Register](#), USDA's Natural Resources Conservation Service ("NRCS") determined that implementing the Voluntary Public Access and Habitat Incentive Program ("VPA-HIP") is not a major federal action significantly affecting the quality of the human environment and therefore an Environmental Impact Statement will not be prepared. The primary objective of VPA-HIP is to support state and tribal government programs that encourage owners and operators of privately held farm, ranch, and forest land to voluntarily make that land available for access by the public for hunting, fishing, and other wildlife-dependent recreation.

AMS Announces ITDS Pilot Test for Electronic Submission of Data Related to Importation of Fruits, Vegetables, and Specialty Crops

In the [August 6, 2015, Federal Register](#), AMS announced a pilot test of the International Trade Data System ("ITDS") involving the electronic submission of data related to importations of fruits, vegetables, and specialty crops regulated by AMS, using the Partner Government Agency ("PGA") Message Set component of the Automated Commercial Environment ("ACE") system. The pilot program will test the electronic transmission of AMS data through the U.S. Customs and Border Protection's ("CBP") ACE program, known as PGA Message Set, which enables importers and brokers to electronically transmit data required by AMS directly to ACE. This electronic process will replace the paper-based process currently used. The notice also invites importers and brokers who are importing commodities subject to section 8e regulations to request participation in the AMS pilot, and invites public comment on any aspects of the pilot.

APHIS Announces Pilot Plan to Test and Assess ITDS for Electronic Submission of Lacey Act Import Declaration Data for Plants and Paper Products

In the [August 6, 2015, Federal Register](#), USDA's Animal and Plant Health Inspection Service ("APHIS") announced that it and CBP have developed a pilot plan to test and assess the ITDS for the electronic submission of Lacey Act import declaration data in certain ports. The pilot test will use APHIS PGA Message Set and the Automated Broker

Interface to transmit, and the ACE to process, trade data required by the Lacey Act for the importation of plant and paper products. **Comments are accepted during the duration of the test commencing on August 6, 2015.**

FSN Seeks Comments for Procurement and Implementation of Electronic Benefit Transfer Services

In the [August 12, 2015, Federal Register](#), USDA's Food and Nutrition Service ("FNS") announced its interest in identifying ways to stimulate increased competition in the electronic benefit transfer ("EBT") marketplace and identify procurement or systems features that are barriers to new entrants. EBT systems are used by the Supplemental Nutrition Assistance Program ("SNAP") and Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC") state agencies, using magnetic stripe cards similar to debit or credit cards. FNS is seeking comments from EBT stakeholders and other financial payment industry members and interested parties, to improve procurement of the delivery of EBT transaction processing services through modifications to, or replacement of, the existing business model. **Comments are due October 24, 2015.**

GIPSA Extends Comment Period on Request for Information Regarding Regulation Issued Under the Packers and Stockyard Act

In the [August 10, 2015, Federal Register](#), Grain Inspection, Packers and Stockyards Administration ("GIPSA") announced an extension to the request for information period, to provide an opportunity for interested parties to submit written comments in response to the GIPSA regulations that address circumstances under which a market agency selling livestock on a commission basis may permit its owners, officers, and employees to purchase livestock from consignments to the market. **Comments are due October 13, 2015.**

APHIS Adds Two Treatment Options for Use in Controlling Imported Fire Ant

In the [August 11, 2015, Federal Register](#), USDA's APHIS advised the public that they have determined that it is necessary to add to the Plant Protection and Quarantine Treatment Manual two treatment options for use in controlling Imported Fire Ant ("IFA"). The treatments comprise: (i) the addition of two insecticidal baits, Abamectin and Metaflumizone, to the list of chemicals already allowed in the IFA program, and (ii) the modification of the technique used to apply the Chlorpyrifos (Insecticide) drench treatment for use in control of IFA. Additionally, APHIS prepared treatment evaluation documents and a supplemental environmental assessment. **Comments are due October 13, 2015.**

APHIS Publishes FEIS Regarding Feral Swine Damage Management

In the [August 11, 2015, Federal Register](#), USDA's APHIS advised the public of their Final Environmental Impact Statement ("FEIS"), titled "Feral Swine Damage Management: A National Approach," which evaluates ways to reduce the damage and risks stemming from feral swine in the U.S., Guam, Puerto Rico, U.S. Virgin Islands, the Northern Mariana Islands, and American Samoa. In addition, APHIS announces the availability of the [record of decision](#) to implement the preferred alternative of the FEIS. **The record of decision is effective August 11, 2015.**

USDA Announces Solicitation for Nominations for the National Genetic Resources Advisory Council

In the [August 10, 2015, Federal Register](#), USDA announced the solicitation of nominations to fill five vacancies on the National Genetic Resources Advisory Council ("NGRC"), which is a subcommittee of the National Agricultural Research, Extension, Education, and Economics ("NAREEE") Advisory Board. The NAREEE formulates recommendations on actions and policies for the collection, maintenance, and utilization of genetic resources; makes recommendations for coordination of genetic resources plans of several domestic and international organizations; and advises the NGRC Director of new and innovative approaches to genetic resources conservation. **Nominations are due August 28, 2015.**

Other USDA Announcements

- Foreign Agricultural Service Announces an Importation of Certain Dairy Articles License Fee of \$250 for 2016 TRQ
- USDA Issues Final Rule on 2015 Dairy Tariff-Rate Import Quota Licensing Regulation
- APHIS Affirms Determination to Amend Hot Water Treatment Schedule T102-a in Plant Protection and Quarantine Treatment Manual to Extend it to Mango Commodities
- NRCS Gives Notice that an Environmental Impact Statement for Rehabilitation of Upper North River Watershed Dam No. 77, Augusta County, Virginia Will Not Be Prepared
- AMS Issues Final Rule Prescribing Late Payment and Interest Charges on Past Due Assessments Under Processed Raspberry Promotion, Research, and Information Order
- AMS Withdraws Proposed Rule to Establish Regulation for Farmers' Market Promotion Program
- USDA Proposes Rule to Implement California Walnut Board's Recommendation to Increase Walnut Assessment Rate
- USDA's OIG Proposes to Revise its Systems of Records
- APHIS Issues Technical Amendment to Final Rule Concerning Importation of Fresh Unshu Oranges from Japan into the United States
- APHIS Issues Amendment to Asian Longhorned Beetle Regulation Removing Manhattan, Staten Island, and the Counties of Suffolk and Norfolk in Massachusetts from List of Quarantined Areas
- Federal Crop Insurance Corporation Issues Correction of Final Regulation for Macadamia Tree Crop Insurance Provisions
- APHIS Received Petition from Monsanto Company Seeking Determination of Nonregulated Status for Maize Designate as MON 87419

USDA Announced the Following Proposed Information Collections:

- Specialty Crops Inspection Division Order Forms
- Cost of Pollination Survey
- Field Crops Production
- Voluntary Recalls of Meat and Poultry Products
- 7 CFR part 1980-E, Business and Industry Loan Program
- Information Collection for Document Delivery Services
- Request for Aerial Photography
- Food Programs Reporting System

USDA Announced the Following Information Collection Has Been Revised and/or Extended:

- USDA/1890 National Scholars Program Application

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

- 7 CFR 1944-I, "Self-Help Technical Assistance Grants"
- Domestic Quarantines
- Requirements to Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain HACCP Reassessments

USDA Announced the Following Information Collections are Requesting an Extension of or Revision to the Following Previously Approved Information Collections:

- Export Certificate Request Forms

FDA Announced the Opportunity to Comment on the Following Proposed Information Collections:

- Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities

- Labeling of Certain Beers Subject to Labeling Jurisdiction of the Food and Drug Administration

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

- Veterinary Feed Directive
- State Enforcement Notifications
- Regulations Under the Federal Import Milk Act
- Irradiation in the Production, Processing, and Handling of Food

FDA Issued the Following Draft and Final Guidance Documents

Draft Guidance for Industry: FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels, July 30, 2015, *Federal Register*. **Comments are due September 28, 2015.**

Guidance for Industry: Use of Nanomaterials in Food for Animals, August 5, 2015, *Federal Register*.

European Regulatory Updates

Risk Assessment of Soybeans 305423, MON 87705, and MON 87769 Remain Valid

On July 30, 2015, the European Food Safety Authority ("EFSA") published its [response](#) to issues raised by two non-governmental organizations ("NGOs") (GeneWatch UK and TestBiotech) against three Commission Decisions to authorize the genetically modified ("GM") soybeans 305423, MON 87705, and MON 87769, which have altered fatty acid content. The NGOs argued that there is a lack of a specific guidance for assessing GM crops with significantly altered nutrient composition. In response, EFSA considers that the nutritional issues raised by such type of GM crops do not differ in principle from those arising from non-GM novel foods. Accordingly, EFSA concluded that conclusions of the previous risk assessment on soybeans 305423, MON 87705, and MON 87769 remain valid.

Upcoming Meetings, Workshops, and Conferences

[Public Meeting of the National Advisory Committee on Microbiological Criteria for Foods](#), **September 9–11, 2015**, in Washington, D.C.

[Public Meeting in Preparation for International Cooperation on Cosmetics Regulation](#), **September 10, 2015**, in College Park, MD.

[Public Meeting of the Fruit and Vegetable Industry Advisory Committee](#), **September 15–16, 2015**, in Washington, D.C.

[Public Meeting of the Council for Native American Farming and Ranching Committee on USDA Programs and Activities, and Committee's Priorities](#), **September 21–22, 2015**, in Washington, D.C.

[Public Hearing on Proposed Rulemaking to Establish Federal Milk Marketing Order](#), **September 22, 2015**, in Clovis, CA.

[Public Meeting of the Codex Alimentarius Commission Committee on Fish and Fishery Products](#), **September 24, 2015**, in College Park, MD.

[EFSA's 2nd Scientific Conference](#), **October 14–16, 2015**, in Milan, Italy.

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