JONES DAY | **Food, Dietary Supplement & Cosmetics Regulatory Update**
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Top News

U.S. Faces More Than $1B in Retaliatory Tariffs from Canada and Mexico
On December 7, 2015, the World Trade Organization ("WTO") authorized Canada and Mexico to impose retaliatory tariffs of $780M (Canada) and $228M (Mexico) on U.S. products as a consequence of the seven-year dispute over the U.S. country-of-origin meat labeling ("COOL") rule, which required products to indicate where animals were born, raised, and slaughtered before the meat could be considered domestic. The WTO had ruled in favor of Canada and Mexico, finding U.S. COOL meat label rules in violation of WTO commitments. Canada and Mexico had requested a combined retaliation of more than $3B, considerably larger than the tariffs set by the WTO. The United States Trade Representative had requested that WTO lower the tariff amount to a total of $91M.

Although the House voted to repeal the COOL labels in June 2015, a response from the Senate is still pending. Indeed, Sen. Debbie Stabenow (D-Mich.) and John Hoeven (R-N.D.) soon after proposed the implementation of a voluntary country-of-origin label rule. Canadian ministers Freeland and MacAulay have stated that "if the U.S. Senate does not take immediate action to repeal COOL for beef and pork, Canada will quickly take steps to retaliate," and Mexico's economy ministry has said he is already working on removing benefits from some U.S. imports.

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RELATED PRACTICES

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Grocery Manufacturers Association Announces SmartLabel Initiative
On December 2, 2015, the Grocery Manufacturers Association ("GMA") announced an innovative technology, called SmartLabel, that will enable consumers to have easy and instantaneous access to detailed information about food, beverage, personal care, household, and pet care products. This information may cover nutritional information, ingredients, allergens, third-party certifications, and usage instructions, among other pertinent information. It is also projected that by the end of 2017, 20,000 food products will disclose via SmartLabel whether their products have or have not been genetically engineered. The SmartLabel initiative will work by scanning a code on the package, looking for the product online such as in the website of the manufacturer, eventually through an app, and in some cases through customer service desks at point of sale. Pamela G. Bailey, president and CEO of the GMA, asserts that "people's relationship with food has changed dramatically and consumers now want to know more about their food, such as where it came from and what went into making it." According to Bailey, the SmartLabel initiative is intended to put "detailed information right at their fingertips."

Democrats Reintroduce the Food Labeling Modernization Act
On November 18, 2015, Sen. Richard Blumenthal (D-Conn.), and Reps. Rosa DeLauro (D-Conn.) and Frank Pallone Jr. (D-N.J.) introduced the Food Labeling Modernization Act of 2015 (H.R. 4061 and S. 2301), replacing a similar bill introduced in 2013. This bill proposes to amend the Federal Food, Drug, and Cosmetic Act to "to strengthen requirements related to nutrient information on food labels, and for other purposes." Some of the suggested changes to the current regulation include: (i) additional front-of-packaging labeling requirements, (ii) promulgation of a new rule relating to the use of the term "natural" and revision of the current regulation relating to the term "healthy," (iii) modernization of the Nutrition Facts Panel by updating the format and disclosed information, (iv) improving display and format of ingredient labels, (v) the addition of caffeine content in food that contains at least 10 mf caffeine per serving, (vi) the introduction of "sesame" to the definition of "major food allergen," and (vii) the requirement for manufacturers or importers of food to submit and update to the Secretary, as necessary, all the information included in the food label. In addition, the bill proposes new definitions for the terms "artificial" and "synthetic."

California Supreme Court Says Organic Labeling Suit Is Not Preempted
On December 3, 2015, the California Supreme Court overturned an appellate court's ruling unanimously holding that a state law claim that produce is being intentionally mislabeled as "organic" is not preempted by federal law. The court decided that the state claim brought against Herb Thyme Farms, Inc. for selling conventionally grown herbs as organic was not preempted by the Organic Foods Production Act of 1990, because "when Congress entered the field in 1990, it confined the areas of state law expressly preempted to matters related to certifying production as organic, leaving untouched enforcement against abuse of the label 'organic.'" In addition, the court stated the Act's goal was to "permit consumers to rely on organic labels and curtail fraud," and it concluded that "state lawsuits alleging intentional organic mislabeling promote, rather than hinder, Congress's purposes and objectives." In other words, the California court decided that federal law does not foreclose state false advertising suits but does limit states' ability to alter the definition of "organic," or to set up organic certification schemes.

OEHHA Adds Aloe Vera Extract and Goldenseal Root Powder to Prop 65 List
Effective December 4, 2015, the Office of Environmental Health Hazard Assessment ("OEHHA") added (i) aloe vera, non-decolorized whole leaf extract, which consists of the liquid portion of the aloe vera leaf and is a natural constituent of the Aloe Barbadensis Miller plant, and (ii) goldenseal root powder, which is a natural constituent of the goldenseal plant, to the list of chemicals known to the State of California to cause cancer for purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"). OEHHA justifies the addition of these two chemicals to the list as they both were identified by the International Agency for Research on Cancer as "possibly carcinogenic to humans" with sufficient evidence of carcinogenicity in experimental animals. OEHHA provides further information in a document released this month, where it states the listing

is not "route-specific," therefore applying to all routes of exposure.

European Commission to Start Evaluation of Health Claims Regulation
As scheduled in the Evaluation and Fitness Check Roadmap of October 2015, in January 2016, the European Commission ("EC") will begin evaluating Regulation (EC) No 1924/2006 (the "Regulation"), related to nutrition and health claims made on food. The evaluation focuses on "nutrient profiles," which are thresholds for nutrients such as fat, salt, and sugars above which the use of nutrition and health claims are restricted, and on "health claims made on plants and their preparations," which can be used only if authorized by the EC based on a scientific assessment by the European Food Safety Authority ("EFSA") set out in the Regulation. To date, more than 500 claims on plants and their preparations received an unfavorable assessment from the EFSA, and more than 1,500 submissions have not yet undergone the scientific scrutiny. The purpose of the evaluation is to assess whether the respective provisions of the Regulation are "fit for purpose," and whether any amendment or additional guidance is necessary. The evaluation should be finalized by June 2017.

Ales Bartl (Jones Day Brussels Office) will represent the European Food Law Association on the evaluation of the Regulation at the Commission stakeholder meetings.

Other News
The Natural Products Association Asks FDA for a 90-Day Extension to Comment on "Natural" Definition

The Center for Food Safety and Japanese Cooperative Oppose FDA's Approval of GE AquAdvantage Salmon

FDA Issues Warning Letters to Five Companies for Use of Picamilon in Dietary Supplements

Restaurant Industry Sues NYC Over Salt-Warning Labels

Citizen Coalition Appeals Federal District Court Decision Arguing Maui's Anti-GMO Law is Not Federally Preempted

The National Pork Producers Council Asks D.C. Circuit to Force EPA to Exempt Large Farms from Pollution Reporting Requirements

Vietnam Opens Market to French Beef After 15-Year Ban

Regulatory Updates

FDA Confirms Effective Date of Final Rule Amending Color Additive Regulations
In the December 11, 2015, *Federal Register*, FDA issued a final rule confirming the November 2, 2015, effective date for the final rule amending the color additive regulations to provide for the safe use of mica-based pearlescent pigments, prepared from titanium dioxide, and mica as a color additive in certain distilled spirits. The effective date originally appeared in the September 30, 2015, *Federal Register*.

FSIS Issues Final Rule Establishing a Mandatory Inspection Program for Fish of the Order Siluriformes
In the December 2, 2015, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") issued a final rule amending its regulations to establish a mandatory inspection program for Siluriformes fish and products derived from these fish. The final regulations implement provisions of the 2008 and 2014 Farm Bills, which amended the Federal Meat Inspection Act to mandate FSIS inspection of Siluriformes. ***Compliance date for this rule is September 1, 2017. Rule is effective March 1, 2016***.

AMS Issues Final Rule Removing Four Substances from the National List
In the December 14, 2015, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") issued a final rule addressing recommendations submitted to the Secretary of Agriculture by the National Organic Standards Board ("NOSB") following their October 2014 meeting. These recommendations pertain 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, the final rule removes two nonorganic agricultural substances from the National List for use in organic handling, fortified Marsala and Sherry cooking wines. The final rule also removes two listings for synthetic substances allowed for use in organic crop production on the National List, streptomycin and tetracycline; the use exemptions for these synthetic substances expired on October 21, 2014. ***Rule is effective December 14, 2015***.

Specialty Crop Committee Holds a Stakeholder Leasing Session
In the December 1, 2015, *Federal Register*, USDA's Specialty Crop Committee ("Committee"), a subcommittee of the National Agricultural Research, Extension, Education, and Economics Advisory Board, announced it would hold a stakeholder listening session on December 10, 2015, to elicit input from industry and state representatives, national organizations and institutions, local producers, and other groups interested in the issues with which the Committee is charged. The Committee's charge is to study the scope and effectiveness of research, extension, and economics programs affecting the specialty crop industry. The congressional legislation defines "specialty crops" as fruits, vegetables, tree nuts, dried fruits, and nursery crops (including floriculture).

Agricultural Research Service Increases Patent Culture Collection Charges
In the December 1, 2015, *Federal Register*, USDA's Agricultural Research Service ("ARS") announced an increase of its Patent Culture Collection charges and revised the payment method. Currently, ARS charges $500 for each microbial culture deposit and $20 for its distribution. ARS is increasing these fees to reflect their actual costs of $670 and $40, respectively, and to apply the distribution fee to all patent deposits regardless of the date of the deposit. ARS's Patent Culture Collection receives about 120 patent deposits per year and distributes about 450 cultures per year. ***Rule is effective December 1, 2015***.

APHIS Announces Preliminary Concurrence with the World Organization for Animal Health's Bovine Spongiform Encephalopathy Risk Designations for 16 Regions
In the December 4, 2015, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") advised the public of its preliminary concurrence with the World Organization for Animal Health's ("OIE") bovine spongiform encephalopathy ("BSE") risk designations for 16 regions: Bulgaria, Cyprus, Czech Republic, Estonia, France, Hungary, India, Korea, Latvia, Liechtenstein, Luxembourg, Malta, Portugal, Romania, Slovakia, and Switzerland. The OIE recognizes these regions as being of negligible risk for BSE. APHIS is taking this action based on its review of information supporting OIE's risk designations for these regions. ***Comments are due February 2, 2016***.

NIFA Solicits Nominations for Veterinary Medicine Loan Repayment Program
In the December 7, 2015, *Federal Register*, USDA's National Institute of Food and Agriculture ("NIFA") solicited nominations of veterinary service shortage situations for the Veterinary Medicine Loan Repayment Program for FY2016, as authorized under the National Veterinary Medical Services Act, 7 U.S.C. 3151a. This notice initiated the nomination period and prescribed the procedures and criteria to be used by state, insular area, DC, and federal lands to nominate veterinary shortage situations. Each year, all eligible nominating entities may submit nominations, up to the maximum indicated for each entity in this notice. NIFA is conducting this solicitation under a previously approved information collection (OMB Control Number 0524-0046). ***Shortage situation nominations, both new and carryover, must be submitted by February 10, 2016***.

AMS Proposes to Amend Cotton Board Rules and Regulations

In the December 11, 2015, *Federal Register*, AMS proposed to amend the Cotton Board Rules and Regulations to remove the cotton import de minimis provision. Importers are exempt from paying the cotton import assessment ("cotton fee") if a line item on U.S. Customs and Border Protection ("CBP") documentation is $2 or less. The exemption was initially established to lessen the administrative burden of collecting an import assessment, which was originally estimated to be $2 per line item, in instances in which the transaction costs of the collection would exceed the actual value of the assessment. However, technological advances in the CBP documentation process significantly reduced the transaction costs associated with collecting import assessments, and CBP has since stopped charging USDA for the processing and collection of assessments. Given that transaction costs no longer exceed assessment rates of $2 or less, AMS proposes to remove this de minimis provision from the regulations. In addition, the definition of "cotton" with respect to procedures for conducting the sign-up period would also be modified. ***Comments are due January 11, 2016***.

Other USDA Announcements:

- AMS Decreases Assessment Rate of Onions Grown in Certain Designated Counties in Idaho and Malheur County, Oregon
- USDA Determines Not to Conduct a Continuance Referendum Regarding 1991 Amendments to the Cotton Research and Promotion Order
- AMS Increases Assessment Rates of Pistachios Grown in California, Arizona, and New Mexico

USDA Announced the Following Requests for Information:

- Follow-Up to an Assessment of the Roles and Effectiveness of Community-Based Organizations in the Supplemental Nutrition Assistance Program
- APHIS Reaches Preliminary Decision to Extend Determination of Non-Regulated Status of Innate™ Potato to Snowden Potato Variety Event SPS-00V11-6
- APHIS Issues Determination of Non-Regulated Status for Genetically Engineered Maize MON 87403
- Child and Adult Care Food Program Family Day Care Homes Meal Claim Feasibility Study

USDA Announced the Following Proposed Information Collection:

- Urban Agriculture Pilot Surveys

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

- Generic Clearance to Conduct Survey Research Studies
- Agricultural Prices
- Cold Storage Survey
- Intermediary Relending Program
- Residue and Biomass Field Survey

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

- Egg, Chicken, and Turkey Surveys
- Specialty Crops Inspection Division Order Forms
- Annual State Report on Verification of Supplemental Nutrition Assistance Program Participation

European Regulatory Updates

EC to Prepare EU Legislation on Trans Fats

On December 3, 2015, the EC published a report titled "Trans fats in foods and in the overall diet of the European Union population," announcing they will set a legal limit for industrial trans fats in food products based on the rationale that industrially produced fats can be technically reduced, and alternative fats and oils for food production exist. Trans fats are partially hydrogenated unsaturated fats that come from meat and dairy products

and can be industrially produced. In the report, the EC stated trans fats consumption has been shown to increase the risk of coronary heart disease in part by raising the levels of lipoprotein LDL (so-called "bad cholesterol") and lowering the levels of lipoprotein HDL (also known as "good cholesterol"). The EC will soon launch a public consultation and conduct an impact assessment to collect more information from the stakeholders.

Upcoming Meetings, Workshops, and Conferences

Public Meeting of the National Agricultural Research, Extension, Education, and Economics Advisory Board, **December 16–18, 2015**, in Washington, D.C.

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