



## FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

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### Top News

#### FDA Warns Consumers about Use of Pure Powdered Caffeine

The U.S. Food and Drug Administration ("FDA" or "Agency") has [issued](#) warning letters to five distributors of pure powdered caffeine, asserting pure powdered caffeine products are adulterated "present[ing] a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling." The Agency argues that while one teaspoon of pure powdered caffeine is equivalent to 28 cups of regular coffee, safe quantities can be nearly impossible to measure because the line between safe and overdose is very small. Also, individual preexisting conditions can intensify the effects of caffeine and make the product more dangerous. FDA, which previously issued [Consumer Advice](#) for this product after the death of two young healthy men in 2012, said it "will continue to aggressively monitor the marketplace for pure powdered caffeine products and take action as appropriate." Six senators had previously [requested](#) that FDA ban the sale and marketing of pure and highly concentrated bulk powdered caffeine products outside of pharmaceutical and food production purposes.

#### Democrats Request FDA Clarification of New FSMA Rules for Small Farmers

Sen. Chris Murphy (D-Conn) and Rep. Rosa DeLauro (D-Conn), along with an additional 10 senators and two representatives, sent a [letter](#) to FDA's Acting Commissioner Stephen Ostroff, requesting the Agency to expedite implementation of [Section 209](#), which includes FDA's obligation to provide technical

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assistance and training to owners and operators of farms, small food processors, and fruit and vegetable merchant wholesalers.

The letter alleges this is necessary to reduce confusion stemming from the new [Food Safety Modernization Act](#) ("FSMA") regulations, and more specifically from the [produce safety rule](#) and the [preventive controls for human food rule](#). Lawmakers assert small farmers and processors face particular and unique challenges while making business decisions for next year, and hence FDA should "begin distributing written materials and start conducting outreach and education now ...." The final preventive controls rule was [submitted](#) to the *Federal Register* for publication on August 31, 2015. As of the date of this *Update*, publication is still pending.

### **North Dakota Judge Enjoins "Waters of the United States" Rule**

The Clean Water Act applies to "Waters of the United States," a term that the Environmental Protection Agency ("EPA") and the Army Corps of Engineers sought to define through a new final rule. On August 27, 2015, the day before the "[Waters of the United States](#)" Rule ("Rule") would have become effective, Judge Ralph Erickson of the District Court of North Dakota [issued an Order](#) ("Order") to stop the Rule on the grounds that it is likely arbitrary and capricious as it lacks a "rational connection between the facts found and the Rule as it will be promulgated." The Rule has been contested by several states and industry bodies. For example, the National Cattlemen's Beef Association blasted the Rule, writing that it "[is nothing more than an attempt to put more land and water under federal jurisdiction, blatantly disregarding private property rights.](#)"

EPA has announced the Rule will be implemented in the states that are unaffected by Judge Erickson's Order. Therefore the Rule will not apply to the following states: Alaska, Arizona, Arkansas, Colorado, Idaho, Missouri, Montana, Nebraska, Nevada, North Dakota, South Dakota, and Wyoming. EPA's view is that "[EPA and the U.S. Army are ensuring that waters protected under the Clean Water Act are more precisely defined, more predictable, easier for businesses and industry to understand, and consistent with the law and the latest science.](#)" For more information regarding this Rule, see our previous [Update](#).

### **Europe's Agriculture Committee Opposes National Ban on Use of GM Food and Feed**

On September 3, 2015, the European Parliament's Agriculture Committee ("Committee") voted against a European Commission [proposal](#) that would allow member states to restrict or prohibit the use of EU-approved genetically modified ("GM") food or feed in their territory. The Committee expressed fears that national bans could distort competition on the EU's single market and jeopardize European food production sectors, which are heavily dependent on GM feed imports. Indeed, Albert Dess, a member of the Committee, stated that: "[today's vote in the agriculture committee sends a clear message: the Commission's proposal \[...\] must be rejected. We have not been building the EU's single market to let arbitrary political decisions distort it completely.](#)" However, the Agriculture Committee is not the lead on this issue. Rather, it is the Environment Committee, whose vote is expected on a draft report on October 12–13, 2015. Once the Environment Committee adopts a position, the proposal will be scrutinized in plenary session on October 26–29, 2015.

### **Other News**

[Senator Boozman \(R-AR\) Says "It's Time to End COOL"](#)

[Bird Flu Quarantine Areas Lifted in Iowa](#)

[Japan Partially Lifts Ban on U.S. and Canada Poultry](#)

[U.S. Studies Unfold Mince Contamination and Mislabeling](#)

[Lithuanian Meat Becomes Eligible for Export to the U.S.](#)

[U.S. Poultry and Pork Exporters Request a Break under the AGOA](#)

## Regulatory Updates

### **FDA Issues Final Rule to Amend Color Additive Regulations**

In the [August 21, 2015, Federal Register](#), FDA announced it is amending the color additives regulations to provide for the safe use of spirulina extract as a color additive in coating formulations applied to dietary supplements, drug tablets, and capsules. ***Final rule is effective September 21, 2015.***

### **APHIS Issues Environmental Assessment for Highly Pathogenic Avian Influenza**

In the [September 4, 2015, Federal Register](#), the U.S. Department of Agriculture's ("USDA") Animal and Plant Health Inspection Service ("APHIS") announced availability of an Environmental Assessment ("EA") relative to a national approach for the control of highly pathogenic avian influenza outbreaks within the United States. Based on the EA, APHIS concluded that such approach will not have a significant impact on the quality of the human environment. ***Comments are due October 5, 2015.***

### **APHIS Proposes Amending Virus-Serum-Toxin Act Regulations**

In the [September 4, 2015, Federal Register](#), USDA's APHIS proposed to amend the Virus-Serum-Toxin Act regulations, requiring veterinary biologics licensees and permittees to record and submit reports concerning adverse events associated with the use of biological products they produce or distribute. Separate guidance documents would provide information to be included in the adverse event reports. ***Comments are due November 3, 2015.***

### **APHIS Finds that Field Testing Swine Influenza Vaccine, H1N1 & H3N2, Modified Live Virus Has No Significant Environmental Impact**

In the [September 4, 2015, Federal Register](#), USDA's APHIS prepared an environmental assessment concerning authorization to ship for the purpose of field testing, and then to field test, an unlicensed Swine Influenza vaccine, H1N1 & H3N2, Modified Live Virus. APHIS determined that field testing this veterinary vaccine will not have a significant impact on the quality of the human environment, and that an environmental impact statement need not be prepared. In addition, APHIS intends to issue a U.S. Veterinary Biological Product license for this vaccine, provided that (i) the field test data supports the conclusions of the environmental assessment, (ii) a finding of no significant impact is issued, and (iii) the product meets all other requirements for licensing. ***Comments are due October 5, 2015.***

### **AMS Withdraws Proposed Rule Establishing Regulation for the FMPP**

In the [August 18, 2015, Federal Register](#), USDA's Agricultural Marketing Service ("AMS") withdrew a proposed rule published on [January 19, 2011](#), to (i) establish eligibility and application requirements, (ii) establish the review and approval process, and (iii) grant administrative procedures for the AMS's Farmers' Market Promotion Program ("FMPP"). The FMPP is a competitive grant program that makes funds available to eligible entities for projects to establish, expand, and promote farmers markets, roadside stands, community-supported agriculture programs, agritourism activities, and other direct producer-to-consumer marketing opportunities. ***Withdrawal is effective August 19, 2015.***

### **AMS Proposes Revision to U.S. Standards for Canned Baked Bean Grades**

In the [August 19, 2015, Federal Register](#), USDA's AMS proposed to revise the United States grade standards for canned baked beans by replacing process-specific language with language reflective of current canned baked bean manufacturing practices. Additionally, AMS proposed separating the canned dried beans, canned pork and beans, and canned baked beans grade standards from one shared standard document into three

separate standard documents. These changes would bring the grade standards for canned baked beans in line with the present quality levels and would provide guidance in the effective use of these products. **Comments are due October 19, 2015.**

### **AMS Proposes Rule to Prescribe Late Payment and Interest Charges on Past Due Assessments**

In the [August 19, 2015, Federal Register](#), USDA's AMS proposed to prescribe 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. Two additional changes are proposed to reflect current practices and update the Order and regulations. **Comments are due October 19, 2015.**

### **FSIS Proposes to Amend Definition for "Roaster" Chicken**

In the [August 19, 2015, Federal Register](#), USDA's Food Safety and Inspection Service ("FSIS") proposed to amend the definition and standard of identity for the "roaster" or "roasting chicken" poultry class to better reflect the characteristics of "roaster" chickens in the market today. "Roasters" or "roasting chickens" are described in terms of the age and ready-to-cook ("RTC") carcass weight of the bird. Genetic changes and management techniques have continued to reduce the grow-out period and increased the RTC weight for this poultry class. Therefore, FSIS is proposing to amend the "roaster" definition to remove the eight-week minimum age criterion and increase the RTC carcass weight from five pounds to 5.5 pounds. **Comments are due October 19, 2015.**

### **FSIS Announces Availability of Updated Food Standards and Labeling Policy Book**

In the [August 19, 2015, Federal Register](#), USDA's FSIS announced its intent to revise the Food Standards and Labeling Policy Book, which will provide updated information for establishments when creating new labels and modifying existing labels for meat and poultry products. FSIS has stopped adding policy guidance to it; however, FSIS will continue to amend or remove items in the book, as necessary, to remain consistent with Agency policies and regulations. **Comments are due October 19, 2015.**

### **AMS Proposes Rule to Revise U.S. Standards for Processed Raisin Grades**

In the [August 21, 2015, Federal Register](#), USDA's AMS proposed to revise the United States grade standards for Processed Raisins by removing five references to the term "midget." These changes would modernize and clarify the standards by removing dual terminology for the same requirement. **Comments are due October 20, 2015.**

### **AMS Proposes Revising U.S. Grade Standards for Fresh Fruits and Vegetables, Fruits and Vegetables for Processing, Nuts, and Specialty Crops**

In the [September 2, 2015, Federal Register](#), USDA's AMS proposed revising U.S. grade standards for fresh fruits and vegetables, fruits and vegetables for processing, nuts, and specialty crops by removing the "Unclassified" category. This would provide the industry with greater flexibility and would bring grade standards in line with other recently amended standards and current terminology. **Comments are due November 2, 2015.**

### **NASS Announces Intent To Request Revision and Extension of Two Currently Approved Information Collections**

In the August 21 and 24, 2015, [Federal Register \(here and here\)](#), USDA's National Agricultural Statistics Service ("NASS") announced its intention to request revision and extension of the currently approved information collections: (i) the List Sampling Frame Surveys, and (ii) the Bee and Honey Survey. Revision to burden hours will be needed due to changes in the size of the target population, sampling design, and/or questionnaire length. **Comments are due October 20 and October 23, 2015, respectively.**

### **ARS Patent Culture Collection Proposes Rule to Change Fees and Payment Methods**

In the [September 2, 2015, Federal Register](#), USDA's Agricultural Research Service ("ARS")

proposed to increase the fees the ARS Patent Culture Collection charges, and a revision of the method of payment. ARS's Patent Culture Collection receives about 120 patent deposits, and distributes about 450 cultures per year, at a price of \$500 and \$20, respectively. The current fees, which were established in 1985, do not reflect the actual costs, and thus ARS proposes to increase them to \$670 and \$40, respectively. In addition, ARS requests to add [www.pay.gov](http://www.pay.gov) as a method of paying deposit and distributions fees.

### **AMS Issues Final Rule Expanding Membership of the U.S. Highbush Blueberry Council**

In the [September 3, 2015, Federal Register](#), USDA's AMS expanded membership of the U.S. Highbush Blueberry Council ("Council") under the Blueberry Promotion, Research and Information Order ("Order"), increasing the number of Council members from 16 to 20, adding two producers, one importer, and one exporter. This rule also adds eligibility requirements for the public member, clarifies the Council's nomination procedures and its ability to serve the diversity of the industry, and increases the number of members needed for a quorum. This rule also prescribes late payment and interest charges for past-due assessments. **Final rule is effective January 1, 2016.**

### **FNS Issues Final Rule Amending Supplemental Nutrition Assistance Program**

In the [September 3, 2015, Federal Register](#), USDA's Food and Nutrition Service ("FNS") announced a final rule amending Supplemental Nutrition Assistance Program ("SNAP") regulations to codify certain nondiscretionary provisions of the Agricultural Act of 2014 ("2014 Farm Bill"). The final rule (i) excludes medical marijuana from allowable medical expense deductions for SNAP purposes, (ii) updates Quality Control ("QC") error tolerance threshold for FY 2014 and indexes this amount for FY 2015 based on an adjustment in the Thrifty Food Plan, (iii) eliminates the Department's ability to waive any portion of a state's QC Liability amount except as provided in SNAP regulations, (iv) ensures state agencies may use high-performance bonus payments only for SNAP administrative expenses, and (v) prohibits SNAP benefits from being used to pay for container deposit fees in excess of the state fee reimbursement. **Final rule is effective November 2, 2015.**

### **Other USDA Announcements**

- AMS Proposes Rule to Increase Assessment Rate of California Walnuts and Raisins
- AMS Issues Interim Rule for a Decrease in the Assessment Rate of Idaho-Eastern Oregon Onions
- AMS Affirms Interim Rule as Final Rule for Irish Potatoes Grown in Southeastern States
- AMS Implements Interim Rule Decreasing Assessment Rate of Washington Apricots
- APHIS Announces Availability of Final Environmental Assessment and Finding of No Significant Impact for Biological Control of Emerald Ash Borer Infestations
- AMS Affirms Marketing Order Regulating Handling of Spearmint Oil Produced in the Far West, and Revision of the Salable Quantity and Allotment Percentage for Class 3 (Native) Spearmint Oil for the 2014–2015 Marketing Year
- FSIS Amends Federal Meat Inspection Regulations to Add Lithuania to the List of Eligible Countries to Export Meat and Meat Product to the U.S.
- APHIS Adds EU and EU Defined Regions to African Swine Fever List
- APHIS Announces Determination of Nonregulated Status of GMO Innate™ Potato
- AMS Issues Final Rule Adjusting Cotton Board Rules and Regulations
- APHIS Affirms Interim Rule as Final Rule to Amend Gypsy Moth Regulations by Adding Minnesota, Virginia, West Virginia, and Wisconsin to the List of Generally Infested Areas

### **USDA Announced the Following Requests for Information:**

- Generic Clearance for the Development of Nutrition Education Messages and Products for the General Public

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

- Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

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

- Agriculture Wood Apparel Manufacturers Trust Fund
- NIFA Proposal Review Process
- Importation of Small Lots of Seeds Without Phytosanitary Certificates
- Understanding Value Trade-Offs Regarding Fire Hazard Reduction Programs in the Wildland-Urban Interface
- 7 CFR part 220, School Breakfast Program
- Survey of Customers of the Official Inspection, Grading, and Weighing Programs (Grain and Related Commodities)
- Organic Certifier Survey
- SuperTracker Information Collection for Registration, Login, and Food Intake and Physical Activity Assessment Information

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

- Guidance for Industry on Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act
- Dietary Supplement Labeling Requirements and Recommendations Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act
- Interstate Shellfish Dealers Certificate

## 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.

Science Board to the Food and Drug Administration, **September 15, 2015**, in Silver Spring, MD or via webcast.

Public Meeting of the Science Board to the Food and Drug Administration 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.

Public Meeting of FDA/USDA/CDC on Collecting On-Farm Antimicrobial Use and Resistance Data, **September 30, 2015**, in Washington, D.C.

EFSA's 2nd Scientific Conference, **October 14–16, 2015**, in Milan, Italy.

Public Meeting of the Codex Alimentarius Commission Committee on Food Hygiene, **October 19, 2015**, in Washington, D.C.

Public Meeting of the Codex Alimentarius Commission Committee of Nutrition and Foods for Special Dietary Uses, **October 27, 2015**, in College Park, MD.

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