



## FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

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### Top News

#### Campbell Soup Becomes First Major Company to Support GMO Labeling Law

Last week, [Campbell Soup Co.](#) became the first major company to announce that it will label all U.S. products derived from genetically modified ("GM") ingredients. Campbell, which makes Goldfish crackers and Pepperidge Farm cookies in addition to its well-known soup line, has announced its support of federal legislation for mandatory labeling standards for both foods derived from genetically modified organisms ("GMOs") and foods claiming they are GMO-free.

In a [letter posted on its website](#), Campbell stresses that although it "in no way disput[es] the science behind GMOs or their safety," the announcement is part of a "Consumer First" approach that places transparency at the forefront.

The company further announced its withdrawal from efforts by groups that oppose mandatory labeling rules, separating Campbell from its major food-industry rivals. In the absence of a federal mandate, Campbell will start labeling its foods before [the Vermont mandatory GMO labeling law](#) goes into effect in July 2016.

#### New Federal Rule Permits Seafood Farming in Gulf of Mexico

Last week, the [National Oceanic and Atmospheric Administration \("NOAA"\)](#) filed a final rule implementing the United States's first comprehensive regulatory program for aquaculture

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in federal waters. Aquaculture is the practice of raising marine species in controlled environments.

Currently, there are no commercial aquaculture operations permitted in federal waters. The rule creates a coordinated permitting system for the Gulf of Mexico that, according to NOAA, allows expanded seafood production and the creation of new jobs in an environmentally sustainable manner. Under the rule, NOAA can issue permits to grow species like red drum, cobia, and albacore jack in federal waters in the Gulf for an initial 10-year period. NOAA claims that "[t]he permit process includes comprehensive safeguards to ensure healthy oceans and coasts and considers other uses of ocean space, such as fishing."

### **EPA Finds Common Pesticide Threatens Beehives**

The U.S. Environmental Protection Agency ("EPA") announced that neonicotinoid, a commonly used insecticide, harms beehives when it comes into contact with certain crops that attract pollinators. The announcement is the first of several expected actions to be taken as part of [President Obama's pollinator health initiative](#), announced in May 2015.

### **Other News**

[USDA Loosens Livestock Export Requirements](#)

[GM Potatoes Make Their Way to Produce Section](#)

[Sixty Democrats ask USDA to Delay New Hog Slaughter Rule](#)

[South Africa Ends Trade Dispute with U.S. Over Chicken Imports](#)

## **Regulatory Updates**

### **AMS Issues Final Guidance on Substances Used in Post-Harvest Handling of Organic Products**

In the [January 14, 2016, Federal Register](#), USDA's Agricultural Marketing Service ("AMS") issued a final guidance titled "Substances Used in Post-Harvest Handling of Organic Products (NOP 5023)" clarifying USDA's organic regulations regarding substances used in post-harvest handling activities such as washing, packing, and storage of organic products. The guidance document is intended for use by accredited certifying agents and by certified and exempt organic operations. ***The final guidance was effective January 19, 2016.***

### **FNS Proposes Supplemental Nutrition Assistance Program Photo Electronic Benefit Transfer Card Implementation Requirements**

In the [January 5, 2016, Federal Register](#), USDA's Food and Nutrition Service ("FNS") proposed that a Supplemental Nutrition Assistance Program ("SNAP") Electronic Benefit Transfer ("EBT") card contains a photo of one or more household members. The proposed rule would clarify parameters for existing federal requirements regarding photos on EBT cards. In addition, this rule proposes to amend program regulations to codify guidance issued on December 29, 2014, requiring states that intend to implement the photo EBT card option to submit a comprehensive Implementation Plan to ensure state implementation is consistent with all federal requirements and that program access is protected for participating households. ***Comments are due March 7, 2016.***

### **AMS Withdraws U.S. Standards for Livestock and Meat Marketing Claims**

In the [January 12, 2016, Federal Register](#), USDA's AMS announced withdrawal of the U.S. Standards for Livestock and Meat Marketing Claims. Specifically, AMS is withdrawing: (i) the Grass (Forage) Fed Claim for Ruminant Livestock and the Meat Products Derived from Such Livestock (Grass (Forage) Fed Marketing Claim Standard), and (ii) the Naturally Raised Claim for Livestock and the Meat and Meat Products Derived From Such Livestock

(Naturally Raised Marketing Claim Standard). ***Withdrawal is effective January 12, 2016.***

### **FNS Adjusts Reimbursement Rates for Meals Served in the Summer Food Service Program for Children**

In the [January 17, 2016, Federal Register](#), USDA's FNS informed the public of the annual adjustments to the reimbursement rates for meals served in the Summer Food Service Program for Children. These adjustments address changes in the Consumer Price Index, as required under the National School Lunch Act. ***The adjustment was effective January 1, 2016.***

### **FNS Requests Technology Solutions for the National School Lunch and School Breakfast Programs**

In the [January 13, 2016, Federal Register](#), USDA's FNS requested information from Management Information Systems software and hardware vendors and developers to learn about the functionality of State and School Food Authority National School Lunch and School Breakfast Program ("NSLP/SBP") data management information systems. USDA is seeking information that will inform future data reporting requirements for the Department's oversight and management of NSLP/SBP. The objectives of this request for information are to: (i) obtain background data to inform later research on State and School Food Authority ("SFA") NSLP/SBP data management information systems, (ii) describe the functionality and capabilities of systems currently in use by state agencies and SFAs, or available to states and SFA for purchase, (iii) describe the typical costs of system development, installation, maintenance, and upgrades, and (iv) identify which states and SFAs are using particular systems. ***Comments are due March 14, 2016.***

### **APHIS Proposes Amendments to Select Agent and Toxin Regulations**

In the [January 19, 2016, Federal Register](#), USDA's Animal and Plant Health Inspection Service ("APHIS") proposed to amend and republish the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Agricultural Bioterrorism Protection Act of 2002 requires the biennial review and republication of the list of select agents and toxins and the revision of the list as necessary. This action would implement the findings of the fourth biennial review of the list. In addition, APHIS is proposing several amendments to the regulations, including the addition of provisions to address the inactivation of select agents, provisions addressing biocontainment and biosafety, and clarification of regulatory language concerning security, training, incident response, and records. These changes would increase the usability of the select agent regulations as well as provide for enhanced program oversight. ***Comments are due March 21, 2016.***

### **GIPSA Requests Public Comments on Services Currently Offered or Needed to Facilitate the Marketing of Grain and Related Products**

In the [January 19, 2016, Federal Register](#), USDA's Grain Inspection, Packers and Stockyards Administration ("GIPSA") solicited comments to facilitate the marketing of grain and related commodities. Specifically, GIPSA is inviting comments from producers, handlers, processors, food manufacturers, exporters, importers, consumers, scientists, academicians, industry stakeholders, and other interested persons on how GIPSA can best facilitate the marketing of grains, oilseeds, rice, pulses, and related products or products made from them, including co-products of ethanol production, commonly referred to as distillers' grains, based on market-identified quality attributes. To ensure that standards and official grading practices remain relevant in the market, GIPSA invites interested parties to comment on the relevance of current standards, methods, and grading practices, and on potential market needs for new standards or services. ***Comments are due April 18, 2016.***

### **AMS Issues Final Guidance on Natural Resources and Biodiversity Conservation**

In the [January 19, 2016, Federal Register](#), USDA's AMS issued a final guidance titled "Natural Resources and Biodiversity Conservation (NOP 5020)," responding to approximately 964 individual comments on the draft guidance document. This guidance

clarifies, among other things: (i) the certified organic operator's responsibility to select, carry out, and record production practices that "maintain or improve the natural resources of the operation," (ii) the accredited certifying agent's responsibility to verify operator compliance with this requirement, and (iii) how domestic organic operations that participate in a USDA Natural Resources Conservation Service program and the NOP can reduce their paperwork burdens. The guidance document is intended for use by accredited certifying agents and by certified operations. ***The final guidance was effective January 20, 2016.***

### **FNS Finalizes Rule Establishing Criteria for "Major Changes" in SNAP Operations**

In the [January 19, 2016, Federal Register](#), USDA's FNS issued a final rule amending the SNAP regulations to establish criteria for changes that would be considered "major changes" in program operations. The rule also identifies the data state agencies must report in order to identify problems relating to integrity and access. The rule was required by the Food, Conservation and Energy Act of 2008, Review of Major Changes in Program Design, which requires USDA to identify standards for major changes in operations of state agencies' administration of SNAP. The provision also requires state agencies to notify the USDA if they implement a major change in operations and to collect and report data that can be used to identify and correct problems relating to integrity and access, particularly for certain vulnerable households. It also sets forth when and how state agencies must report on the implementation of a major change. ***Final rule was effective January 19, 2016.***

### **Other USDA Announcements:**

- APHIS Announces Receipt of Petition from Scotts Company and Monsanto Company to Seek Determination of Nonregulated Status of Genetically Engineered Creeping Bentgrass
- The Federal Crop Insurance Corporation Proposes to Amend the Common Crop Insurance Regulations, Texas Citrus Fruit Crop Insurance Provisions
- AMS Proposes to Revise the U.S. Standards for Grades of Shelled Pecans and for Grades of Pecans in the Shell
- AMS Revises Regulations Governing Inspection of Eggs to Allow Electronic Filing with CBP of Import requests for Table, Hatching Eggs, and Inedible Liquid Eggs
- AMS Proposes to Revise Minimum Quality and Handling Standards for Domestic and Imported Peanuts Marketed in the U.S.
- GIPSA Seeks Comment Regarding U.S. Standards for Oats under the United States Grain Standards Act
- GIPSA Seeks Comment Regarding U.S. Standards for Sunflower Seed under the United States Grain Standards Act

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

- [7 CFR part 245](#)—Determining Eligibility for Free and Reduced Price Meals and Free Milk in Schools
- Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (Fast Track)

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

- Risk Management Education Partnerships; Request for Applications
- General Administrative Regulations; Interpretations of Statutory and Regulatory Provisions
- Application for Authorization to Use the 4-H Name and/or Emblem
- Local Food Marketing Practices Survey

## **European Regulatory Updates**

### **EFSA Updates Health Claims Guidance**

The European Food Safety Authority ("EFSA") has updated its [advice for applicants](#)

[seeking approval of health claims made on food products](#). In addition to revising the general scientific guidance, which applies to health claims across the board, EFSA has updated its [specific guidance for claims related to the immune system and the gastrointestinal tract](#). Under the regulation, health claims can be authorized for use in the EU only after a scientific assessment has been carried out by EFSA. According to EFSA's Nutrition Unit, the updated guidance is aimed at providing applicants with "a better understanding of the step-by-step approach followed by [EFSA] nutrition experts," including: (i) a detailed explanation of each step of the evaluation process—characterization of the food/constituent, characterization of the claimed effect, identification of pertinent human studies—illustrated with concrete examples from previous evaluations; (ii) an explicit differentiation between the principles applied to the evaluation of health claims based on the essentiality of nutrients and those applied to other claims (these differences relate to the definition of the claimed effect, the substantiation of the claim, and the conditions of use); (iii) examples of applications that have been evaluated with a positive outcome to indicate the number, type, and quality of studies that may be needed for substantiation of a claim; (iv) examples of applications evaluated with an unfavorable outcome to illustrate the kind of shortcomings that can prevent the substantiation of certain claims; and (v) guidance on the main steps and scientific aspects that applicants should consider when preparing an application.

### **Commission to Provide Legal Analysis on Applicability of GMO Legislation to New Plant Breeding Techniques**

A European Commission ("EC") spokesperson has [confirmed](#) that a legal analysis discussing whether [new plant breeding techniques](#) should or should not fall under EU GMO legislation will be completed by the first quarter of 2016. The technologies under consideration include gene-editing techniques, cisgenesis, intragenesis (technologies using transformation with genetic material restricted to the species' own gene pool), emerging techniques to induce controlled mutagenesis or insertion (ODM, Zinc Finger Nuclease technologies 1-3), and other applications such as grafting on GM rootstocks or reverse breeding. Plants derived from such new breeding techniques contain no foreign DNA and arguably may have developed naturally by chance mutations or through an application of classic mutagenesis. The International Federation of Organic Agriculture Movements EU has published a [position paper](#) urging the EC to classify such techniques as falling within the scope of the GMO legislation. However, supporters of the technology [argue that such techniques](#) show great technical potential and are necessary to meet the challenges of global changes such as population growth and climate change. Whatever the outcome of the EC's analysis is, the spokesperson from the Commission reminded that "it is the sole prerogative of the European Court of Justice to provide a final and binding opinion on the interpretation of EU law."

### **Glyphosate: The Debate Continues**

EFSA has [responded to criticism](#) of its [assessment of the toxicological profile of glyphosate](#), which concluded that glyphosate is "unlikely to be carcinogenic." A scientist who contributed to [a report on glyphosate by the International Agency for Research on Cancer](#), which concludes that glyphosate is "probably carcinogenic to humans," sent [a letter](#) to the EU Commissioner for Health and Food Safety objecting to the process and the conclusions of EFSA's assessment. Nonetheless, EFSA's Executive Director's [reply](#) to the scientist concludes, "EFSA considers that the arguments brought forward in the open letter do not have an impact on the EFSA conclusion on glyphosate."

## **Upcoming Meetings, Workshops, and Conferences**

[Public Meeting to Provide Information and Receive Public Comments Regarding 48th Session of the Codex Alimentarius Commission Committee on Food Additives, February 16, 2016](#), in College Park, MD.

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