



## FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

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### Top News

#### White House Orders Review of GMO Regulatory Scheme

In response to [widespread discontent](#) with the current genetically modified organism ("GMO") regulatory scheme, the [Obama administration has ordered a review of the rules that govern GMOs](#). The administration claims that the nearly 30-year-old system, known as the "coordinated framework," has become outdated and confusing and does not foster public confidence. Some consumers and food groups claim the system is actually a "failure" and that tighter regulations should be in place, while some in the biotech industry, as well as some academic scientists, argue the regulations are unnecessarily tough, making it too expensive and difficult to bring genetically modified ("GM") crops to market.

The coordinated framework, announced in 1986 and updated in 1992, was established when GMOs were not yet being marketed, and it divided responsibility for regulating GM crops among FDA, USDA, and EPA. In some respects, this has led to an unusual regulatory scheme. For instance, FDA regulates GM animals (such as GM mosquitoes designed to help combat dengue fever) as animal drugs, and USDA regulates GM crops under rules governing plant pests like insects and pathogens. However, companies are currently developing crops that do not fall under USDA's narrow jurisdiction.

### CONTACTS

[Edgar J. Asebey](#)  
Miami

[Cristiana Spontoni](#)  
Brussels

[Colleen M. Heisey](#)  
Washington

[Jonathan Berman](#)  
Washington

[Emily K. Strunk](#)  
Washington

[Katherine M. Llewellyn](#)  
Brussels

[Aleš Bartl](#)  
Brussels

[Stephanie L. Resnik](#)  
Washington

[Brigid C. DeCoursey](#)  
Washington

[Matthew R. Bowles](#)  
Washington

*Marina E. Moreno, FDA Coordinator in the Miami Office, assisted in the preparation of this Update.*

[Detailed Contact Information](#)

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Under the new framework, the White House aims to "[prevent unnecessary barriers to future innovation and competitiveness](#)" and has ordered EPA, FDA, and USDA to review, update, and improve the current regulations. Significant changes will not happen in the immediate future. The administration's focus during the first year will be to clarify jurisdictional responsibility for products and each agency, rather than changing regulations. As part of this process, the White House announced it will hold three public meetings starting in the fall. The updated framework will be open for comments.

### **FDA Issues Supplement to 2013 Food Code**

Last week, FDA [issued a Supplement](#) to the [2013 Food Code](#) to address recommendations made by regulatory officials, industry, academia, and consumers at the [2014 Biennial Meeting of the Conference for Food Protection](#). The Food Code and its Supplement provide government and industry with recommended practical, science-based controls for reducing the risk of foodborne illness in retail and foodservice establishments. The Food Code and the Supplement are joint projects of FDA, Centers for Disease Control and Prevention ("CDC"), and USDA's Food Safety and Inspection Service ("FSIS"). The Food Code is a model for retail food regulations in all 50 states, the District of Columbia, and Puerto Rico and a model for safeguarding public health and ensuring food is unadulterated. It represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service.

The Supplement modifies the 2013 Food Code to expand responsibilities of people in charge of retail establishments, expand and clarify what information should be provided in a Hazard Analysis and Critical Control Points Plan, and emphasize what cleaning agents should be provided and made available at all hours of operation, among other things.

### **Senator Proposes Voluntary COOL Meat Labeling Rules**

Last week, Senator Stabenow (D., Mich.) proposed [a voluntary country-of-origin label](#) for pork and beef, which would require labels indicating where animals are born, raised, and slaughtered before the meat could be considered domestic. With this action, Stabenow is setting "the basis for a bipartisan solution," which would allow the United States to comply with international trade regulations, back the House's decision on repealing [U.S. COOL meat regulations](#) to avoid retaliatory tariffs from Canada and Mexico, and still protect Americans' interest in knowing where their meat comes from.

As discussed in previous Jones Day [Updates](#), the World Trade Organization ("WTO") has ruled in favor of Canada and Mexico, finding U.S. COOL meat label rules a violation of WTO commitments. Canada and Mexico have threatened the United States with annual retaliatory tariffs of a combined \$3 billion as a result of the negative economic effect U.S. rules would have on their sales. Pat Roberts, Senate Agriculture Committee Chairman, praised Stabenow's proposal as a "positive step" but added that "[retaliation is imminent and ... repeal of mandatory COOL is the surest way to protect the U.S. economy.](#)"

### **Other News**

[Maui County's Ban on GMO Crops Preempted by Federal and State Law, Federal Judge Rules](#)

[Floridians Offer Perspective on Cuba's Potential Agricultural Market](#)

[American Trade Officials in Talks to Lift South African Meat Embargo](#)

[U.S. Takes First Step to Open Market for Fresh Beef from Brazil and Argentina](#)

[Senate Gives Final Approval to Enhance President Obama Trade Negotiating Powers](#)

## **Regulatory Updates**

### **FDA Issues Final Order on Infant Formula Requirements**

In the [June 23, 2015, Federal Register](#), FDA announced a final rule amending regulations on nutrient specifications and labeling for infant formula to add mineral selenium to the list of required nutrients and to establish minimum and maximum levels of selenium in infant formula. FDA has determined that the minimum level will be 2.0 mg/100 kcal, with a maximum level of 9.0 mg/100 kcal. These levels are required to avoid deficiency or toxicity of the mineral. Additionally, the final rule requires that selenium be included in the nutrient list on the label of all infant formulas. ***The rule is effective June 22, 2016.***

### **USDA Affirms Import Reporting Requirements to Add Electronic Form Filing for Commodities**

In the [June 25, 2015, Federal Register](#), USDA affirmed as final an interim rule amending the reporting requirements for fruit, vegetable, and specialty crop commodities exempt from import regulations by adding an option to electronically file an "Importer's Exempt Commodity Form" (FV-6 form). These changes would bring the import regulations into conformance with the Marketing Order Online System ("MOLS"), an internet-based application, and the International Trade Data System ("ITDS"), an economic initiative to automate the filing of import and export information by the trade. Additional changes have been made regarding definitions, AMS contact information, date and raisin import regulations, and administrative data. ***The rule is effective June 29, 2015.***

### **APHIS Notifies Petition to Amend Reporting Requirements for Research Facilities Under Animal Welfare Act Regulations**

In the [June 24, 2015, Federal Register](#), USDA's Animal and Plant Health Inspection Service ("APHIS") notified the public of a petition to amend regulations requiring research facilities to include information about the use of or intention to use live animals in research, tests, experiments, or for teaching in an annual report submitted to APHIS. The petition is available to the public, and APHIS is soliciting comments. ***Comments are due August 24, 2015.***

### **USDA and NRCS Request Nominations for the Agricultural Air Quality Task Force**

In the [June 29, 2015, Federal Register](#), USDA and the Natural Resources Conservation Service ("NRCS") solicited nominations for candidates for a two-year term on the Agricultural Air Quality Task Force, which was established by the Federal Agriculture Improvement and Reform Act of 1996 to provide recommendations to the Secretary of Agriculture on agricultural air quality issues. The task force expects to meet two to three times each year, with meetings held at various locations across the United States.

***Nominations are due by August 13, 2015.***

### **AMS Issues Final Rule Amending Procedures for Conduct of Sign-up Period of Cotton Research and Promotion Program**

In the [June 24, 2015, Federal Register](#), USDA's Agricultural Marketing Service ("AMS") published a final rule amending rules and regulations regarding the sign-up period for eligible cotton producers and importers to request a continuance referendum on the 1991 amendments to the Cotton Research and Promotion Order provided in the 1990 amendments to the Cotton Research and Promotion Act. The amendments update various dates, name changes, and addresses and make other administrative changes. ***The rule is effective July 24, 2015.***

### **USDA Announces Product Coverage and Trigger Levels for Safeguard Measures Provided in WTO Agreement on Agriculture**

In the [June 29, 2015, Federal Register](#), USDA announced the updated quantity-based trigger levels for products that may be subject to additional import duties under the safeguard provisions of the WTO Agreement on Agriculture. This Agreement, negotiated in the 1986-94 Uruguay Round, involved agreement by member governments to improve market access and reduce trade-distorting subsidies in agriculture. The notice also includes the relevant period applicable for the trigger levels on each of the listed products. ***The rule is effective June 29, 2015.***

## **USDA Solicits Members for National Agricultural Research, Extension, and Economics Advisory Board**

In the [June 22, 2015, Federal Register](#), the USDA announced a solicitation for nominations to fill nine vacancies on the National Agricultural Research, Extension, Education, and Economics Advisory Board. The Board was established in 1996 to provide advice to the Secretary of Agriculture and land-grant colleges and universities on top priorities and policies for food and agricultural research, education, extension, and economics. **Nominations are due July 31, 2015.**

### **Other USDA Announcements**

- NRCS Provides Determination of Secretary of Agriculture on SW Florida Water Management District Cost-Share Payments
- AMS Implements Final Rule Revising Determination of Sales History for Cranberries Grown in MA, RI, CT, NJ, WY, MI, MN, OR, WA, and NY
- AMS Implements Final Rule for Increased Assessment Rate of Olives Grown in California
- USDA Announces Public Availability of FY 2014 Service Contract Inventories
- Grain Inspection, Packers, and Stockyards Administration ("GIPSA") Designates Grain Inspection Services in KS, IA, ND, and OH
- GIPSA Designation Opportunity and Comments Request on Official Agencies Servicing CA, ID, IN, SC, and VA
- APHIS Adopts Final Rule Regarding Importation of Beef from a Region in Brazil
- APHIS Adopts Final Rule Regarding Importation of Beef from a Region in Argentina
- AMS Announces Hearings on Proposed Marketing Order Concerning Pecans Grown in the States of AL, AR, AZ, CA, FL, GA, KS, LA, MO, MS, NC, NM, OK, SC, and TX
- National Agricultural Library Seeks Approval to Collect Information for Electronic Mailing List Subscription Form for People Interested in Water Resources and Agriculture

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

- Food Program and Reporting System

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

- PPQ Form 816, Contract Pilot and Aircraft Acceptance

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

- Application for Authorization to Use 4-H Club Name and/or Emblem
- Expanded Food and Nutrition Education Program

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

- Importation of Peppers from Certain Central American Countries
- Pesticide Use Proposal
- Professional Services to Support Requirements-Gathering Sessions for Safe Food Handling
- Emergency Management Response System
- NIFA Grant Application
- Census of Agriculture Content Test

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

- Electronic User Fee Payment Request Fees

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

- Emergency Shortages Data Collection System

- [Animal Food Labeling: Declaration of Certifiable Color Additives](#)

### **FDA Announced that the Following Collections Have Been Approved by OMB**

- [Export Certificates for Food and Drug Administration Regulated Products](#)

## **European Regulatory Updates**

### **EP Endorses New Procedure for Novel Foods Authorization**

On June 25, 2015, following the approved final compromise text on EU rules on Novel Foods (see our last Jones Day [Update](#)), the Environment Committee of the European Parliament ("EP") approved a [draft document](#) aimed at simplifying the authorization procedure for novel foods. Novel foods are foods that were not used for human consumption to a significant degree within the EU before May 15, 1997. The document provides a new single and centralized procedure for the authorization of novel foods and a new definition for "nanomaterials." Before entering into force, the draft rules must be approved by the Parliament and the Council.

### **EFSA Issues Opinion on Chlorates in Foods**

On June 24, 2015, the European Food Safety Authority ("EFSA") issued an [opinion on the presence of chlorates in foods](#). Chlorates can appear in foods from the use of chlorinated water during their processing and from disinfection of food-processing equipment. Currently most of the national enforcement authorities apply a default maximum residue limit ("MRL") of 0.01 mg of chlorates/kg of food, which is generally applicable to traces of unapproved pesticides. In practice, however, this limit is often exceeded. In the aforementioned Opinion, EFSA concluded that consuming foods with an MRL of 0.7 mg/kg would not exceed an acute reference dose for chlorates in foods and thus would not cause health concerns. This Opinion provides support to the European Commission ("EC") in a potential future adoption of a MRL of 0.7 mg/kg of chlorates in foods.

### **EU Issues New Regulations on Maximum Levels of Lead and Inorganic Arsenic**

On June 25, 2015, EC published two regulations, [Regulation 2015/1005](#) and [Regulation 2015/1006](#), which amend Regulation Annex No. 1881/2006 by setting maximum levels of lead and inorganic arsenic in certain foodstuffs, respectively. The new regulations will apply starting January 1, 2016. However, foodstuffs not complying with the mentioned regulations already on the market prior to that date may continue to be marketed until they expire.

### **Other European Regulatory Updates**

[EFSA Publishes Scientific Opinion on Reevaluation of Sorbic Acid \(E 200\), Potassium Sorbate \(E 202\), and Calcium Sorbate \(E 203\) as Food Additives](#)

[EFSA Reevaluates Oxidized Polyethylene Wax \(E 914\) as Food Additive](#)

[U.K. Department of Health Publishes Bulletin on EC's Working Group Meeting on Health Claims](#)

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

[Public Meeting of the Agricultural Research Service Animal Handling and Welfare Review Panel, July 14, 2015](#), via teleconference.

[Public Meeting of the National Advisory Council on Maternal, Infant, and Fetal Nutrition, July 21–23, 2015](#), in Arlington, VA.

[General Conference Committee of the National Poultry Improvement Plan, July 23, 2015](#), in Salt Lake City, UT.

[Public Meeting of the Codex Alimentarius Commission Committee on Fresh Fruits and](#)

Vegetables, **August 6, 2015**, in Washington, D.C.

Public Meeting of the Codex Alimentarius Commission Committee on Spices and Culinary Herbs, **August 19, 2015**, in Washington, D.C.

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

## Jones Day FDA Regulatory & Compliance Counseling Contacts

**Edgar J. Asebey**

Miami  
+1.303.714.9707  
easebey@jonesday.com

**Cristiana Spontoni**

Brussels  
+32.2.645.14.48  
cspontoni@jonesday.com

**Colleen M. Heisey**

Washington  
+1.202.879.3449  
cmheisey@jonesday.com

**Jonathan Berman**

Washington  
+1.202.879.3669  
jberman@jonesday.com

**Emily K. Strunk**

Washington  
+1.202.879.3778  
estrunk@jonesday.com

**Katherine M. Llewellyn**

Brussels  
+32.2.645.14.47  
kllewellyn@jonesday.com

**Aleš Bartl**

Brussels  
+32.2.645.14.52  
abartl@jonesday.com

**Stephanie L. Resnik**

Washington  
+1.202.879.5458  
sresnik@jonesday.com

**Brigid C. DeCoursey**

Washington  
+1.202.879.3651  
bdecoursey@jonesday.com

**Matthew R. Bowles**

Washington  
+1.202.879.3604  
mbowles@jonesday.com

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