

## FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

## **Top Stories**

# FDA Issues Guidance on Nanotechnology in Food and Cosmetics

On June 24, FDA issued three final guidance documents on the use of nanotechnology in FDA-regulated products. The guidance documents address whether an FDA product involves the application of nanotechnology, safety of nanomaterials in cosmetic products, and use of emerging technologies in food. FDA based these final guidance documents on corresponding draft guidance documents issued in 2011 and 2012 after considering public comments. FDA also issued a draft guidance document on the use of nanotechnology in animal food on the same day. The guidance documents are part of FDA's efforts to implement the recommendations of the 2007 Nanotechnology Task Force Report.

# Congressional-Executive Commission on China Examines Food Safety

Following a June 17 hearing by the Congressional-Executive Commission on China, Senator Sherrod Brown (D-OH) addressed the safety of pet food, processed chicken, and animal feed from China. Brown announced that he will introduce an amendment to the agriculture appropriations bill specifically asking FDA and USDA to investigate the status of inspectors' visas to China. He has also asked the Obama administration to investigate Chinese food processing standards. Wal-Mart also recently announced it plans to triple its food safety spending in China.

### FDA to Provide New Guidance on Sodium

During recent media interviews, FDA Commissioner Hamburg said FDA will issue new guidance on sodium. The average American currently consumes nearly twice the recommended daily intake of sodium, mainly due to the American diet of processed and restaurant foods. The American Heart Association and the Institute of Medicine recommend Americans reduce their amount of sodium intake by about one-third. High sodium intake contributes to high blood pressure, strokes, and other health problems.

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#### Resources

- Food, Dietary Supplement & Cosmetics Regulatory Update Printable Version
- Jones Day's FDA Regulatory & Compliance Counseling Practice
- Jones Day's Health Care Practice
- Jones Day's Life Sciences Practice

### Food Trade Groups Sue Vermont to Strike Down GMO Labeling Law

National food industry associations have filed suit against Vermont in an effort to overturn a new state law requiring food labels to declare genetically modified ingredients. The lawsuit, filed by Grocery

Manufacturers Association, the Snack Food Association, the International Dairy Foods Association, and the National Association of Manufacturers, alleges the Vermont law impermissibly regulates nationwide interstate commerce and offers no health or safety benefits to consumers. The labeling requirement, which is the first of its kind, will take effect in July 2016.

#### FDA Issues Clarification on Using Wood Shelving in Artisanal Cheesemaking

After a series of *Listeria* contaminations at facilities using wood shelving, FDA reiterated its policy of requiring surfaces that are in contact with food to be "adequately cleanable" and "properly maintained." Historically, FDA has questioned whether wood meets these requirements, often in inspection reports. In response to artisanal cheesemakers' concerns that FDA will ban its longstanding practice of shelving cheese on wood, FDA issued a Constituent Update on June 11, clarifying that it is not prohibiting or banning the practice.

#### California Bill Requiring Warning Labels for Soda Fails in State's Health Committee

A bill to add warning labels to sugar-sweetened drinks passed the California state Senate last month, but the state Assembly's Health Committee rejected it on June 17. The proposed labels warned that "[d]rinking beverages with added sugar(s) contributes to obesity, diabetes, and tooth decay." Assembly members criticized the bill, saying that labeling only soda would give consumers the false impression that avoiding soda was sufficient to stay healthy. Other critics cited the bill's failure to take a holistic approach to diabetes. Proponents of the bill argued that consumers need more information in order to change behavior and that adding warning labels is a step in the right direction.

#### Other News

FDA to Reopen Comment Period on Reportable Food Registry ANPR

FDA Issues Net Effects Study on Fish Consumption

House Debates Agriculture Appropriations Bill

Congressional Hearing Investigates Dr. Oz "Miracle" Weight Loss Claims

Cosmetic Industry Agrees to Ban Microbeads.

## Regulatory Updates

#### FDA Reopens Comment Period on Reportable Food Registry ANPR

In the June 18 Federal Register, FDA announced that it has reopened the comment period on the advance notice of proposed rulemaking for the Reportable Food Registry ("RFR"). The RFR is an electronic portal used by industry to submit reports to FDA regarding reportable foods. A reportable food is an article of food (other than a dietary supplement or infant formula) for which there is a reasonable probability that use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. **Comments due August 17**.

### **USDA Announces Semiannual Regulatory Agenda**

In the June 13 Federal Register, USDA announced its semiannual regulatory agenda, which provides summary descriptions of regulations currently under development in USDA's agencies. The agenda features several rules related to the 2014 Farm Bill, including changes to the National Organic Program, school nutrition and nutrition fact labeling requirements, and the catfish inspection program.

#### USDA Issues Final Rule Adjusting Dairy 2014 Tariff Rate and Notice of 2015 Rates

In the June 16 Federal Register, USDA released the revised appendices to the Dairy Tariff-Rate Import Quota licensing regulation for the 2014 quota year. These appendices reflect all transfers for dairy product import licenses that were either permanently surrendered or revoked. On the same day, the Foreign Agricultural Service announced a \$250 fee for each license issued the 2015 tariff-rate quota year.

#### **USDA Affirms Interim Rule on California Olives**

In the June 11 *Federal Register*, USDA's Agricultural Marketing Service announced it is adopting, as a final rule without change, the interim rule decreasing the 2014 assessment rate for the California Olive Committee from \$21.16 to \$15.21 per ton of olives handled. This rate will remain in effect unless modified, suspended, or terminated. *The final rule was effective June 12*.

#### **USDA to Review Mango Rules**

In the June 20 *Federal Register*, USDA announced it will review its 2004 Mango Promotion, Research, and Information Order. *Comments due August 19*.

#### **USDA Announces Proposed Rule on Avocado Minimum Grade Requirements**

In the June 23 Federal Register, USDA's Agricultural Marketing Service invited comments on its proposed rule to change the minimum grade requirements currently prescribed under the Florida avocado marketing order. **Comments due July 23**.

#### FDA INFORMATION COLLECTION ACTIVITIES

# FDA Announces the Opportunity to Comment on the Following Proposed Information Collections

Testing Communications on Food and Drug Administration-Regulated Products Used in Animals (*comments due August 15*)

#### FDA Announces the Following Collections Have Been Submitted to OMB

Legally Marketed Unapproved New Animal Drugs for Minor Species (comments due to OMB July 21)

CGMP Regulations for Medicated Feeds (comments due to OMB July 21)

CGMP Regulations for Type A Medicated Articles (comments due to OMB July 21)

#### **USDA INFORMATION COLLECTION ACTIVITIES**

# USDA Announces the Opportunity to Comment on the Following Proposed Information Collections

Food Safety Education Campaign Tracking Research (comments due August 11)

Black Stem Rust; Identification Requirements for Addition of Resistant Varieties (*comments due August 11*)

U.S. Origin Health Certificate Template (comments due August 18)

Importation of Poultry Meat and Other Poultry Products From Sinaloa and Sonora, Mexico (*comments due August 18*)

Organic Survey (comments due August 18)

# USDA Announces the Following Collections Have Been Submitted to OMB Summer Food Service Program Study (comments due to OMB July 17)

SNAP Employment and Training (comments due to OMB July 17)

Bees and Related Articles (comments due to OMB July 18)

Food Donation Programs (comments due to OMB July 18)

#### Other FDA Announcements

Temporary Permits for Canned Tuna Deviating from Identity Standard

#### **Other USDA Announcements**

Pest Risk Analysis for Interstate Movement of Fresh Achachairú Fruit from Puerto Rico

Pest Risk Analysis for the Importation of Fresh Figs from Mexico

Evaluation of the African Horse Sickness Status of Saudi Arabia

Sanitary and Phytosanitary Standard-Setting Activities by Codex

National Agricultural Research, Extension, Education, and Economics Advisory Board: Solicitation for Membership (*nominations due July 18*)

### Upcoming Meetings, Workshops, and Conferences

Public Meeting on Proposed Rules on Nutrition and Supplement Facts Labels, June 26, in Washington, DC.

General Conference Committee of the National Poultry Improvement Plan ("NPIP") and the NPIP's 42nd Biennial Conference, July 10–12, in Charlotte, NC.

National Advisory Council on Maternal, Infant, and Fetal Nutrition, July 15-17, in Arlington, VA.

2015 Dietary Guidelines Advisory Committee, July 17-18, via webcast.

International Association for Food Protection Annual Meeting, August 3-6, in Indianapolis, IN.

## **Enforcement Updates**

#### **Recent Product Recalls**

Most recent FDA recalls have been for undeclared allergens in a variety of products, including cheese, baked goods, and candies. Salmon and cheese products were also recalled for *Listeria monocytogenes*. Bagged ice from one facility was recalled for the potential presence of metal fragments. Recent USDA recalls were also primarily for undeclared allergens in meat products that were also misbranded. One meat production facility recalled several thousand pounds of beef because it may have included dorsal root ganglia, part of the cow's nervous system. USDA requires removal of this tissue in cows older than 30 months of age because mad cow disease could be present.

For a complete list of product recalls, click here for FDA-regulated products and here for USDA-regulated products.

#### **Recent Warning Letters**

Dairies and seafood processing facilities remain targets of FDA inspections. FDA posted one warning letter to a dairy facility for drug residues in edible tissues of animals sold for slaughter. FDA also posted a letter to a seafood processing facility alleging HACCP/CGMP violations for insufficient critical control points.

Click here for FDA's Warning Letters Home page (scroll down for listing of recently posted Warning Letters).

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