



FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

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Top Stories

FDA Report: Sales of Livestock Antibiotics Rising Substantially

FDA recently released a [report](#) showing the amount of antibiotics sold for use in livestock increased by 16 percent from 2009 to 2012. The report [measures sales and distribution](#) of such antibiotics, not actual use, and the data does not differentiate the drug sales by species. The report comes as FDA and [other federal leaders take actions](#) to reduce the growing threat of antimicrobial resistance, and its findings could be used to help retool those efforts. In 2013, FDA began a voluntary plan to reduce the use of antibiotics in animals, calling for an end to using antibiotics to promote growth and directing producers to obtain prescriptions in cases of animal illness. The latest data shows there is a long way to go before reaching that second goal: in 2012, 97 percent of livestock drug sales were over the counter. FDA may use this recent report to determine whether such voluntary measures are working or need to be revised.

Consumer Group Study Confirms Many Foods Labeled "Natural" Contain GMOs

Late last year, the Grocery Manufacturers Association asked FDA to [consider a labeling definition](#) for the term "natural" that would be broad enough to encompass foods derived from biotechnology. A new study released this month confirms that, in fact, many foods marketed as "natural" contain ingredients with genetically modified organisms ("GMOs"). *Consumer Reports* [recently surveyed](#) more than 80 different corn- and soy-based foods and found that nearly all samples labeled "natural" had significant amounts of GMO ingredients, whereas products labeled "non-GMO" or "organic" generally did not. There have been several actions by plaintiffs against GMO food producers, alleging their "natural" claims are misleading. Despite these activities, FDA has yet to adopt a definition

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for the term "natural."

Federal Court Dismisses States' Suit Against California Egg Law

On October 2, 2014, a federal court [dismissed a suit challenging a California ban on the sale of eggs](#) produced under conditions that do not meet certain animal care standards, including space considerations. The dispute involved a ballot measure approved four years ago requiring egg-laying hens to be raised in free-range spaces—rules that state lawmakers subsequently extended to out-of-state farmers who sell their products in California. Missouri filed a complaint, joined by Alabama, Iowa, Kentucky, Nebraska, and Oklahoma, in claiming the law violates the Commerce Clause of the federal Constitution. Together, farmers in the six states produce 20 billion eggs annually and sell two billion in California. This month, the court dismissed the states' case for lack of standing. The California law is set to take effect in 2015.

USDA Establishes Federal Program to Coordinate State Phytosanitary Efforts

Earlier this month, USDA announced a new [federal program](#) to promote coordinated efforts to reduce plant-pest risks at U.S. ports of entry. The process allows states to petition the Animal and Plant Health Inspection Service ("APHIS") for federal recognition of their phytosanitary programs, which target limited-distribution pests that APHIS either is not already regulating or is considering no longer regulating. Under the program, if a state-managed pest is detected at a port of entry, then APHIS or U.S. Customs and Border Protection will require the importer to comply with the state's phytosanitary mitigation requirements. The program will also allow USDA to [relax entry requirements](#) for plant pests no longer considered risks by the federal or state governments.

Other News

[FDA Launches Data Dashboard to Share Inspection, Compliance, and Recall Information](#)

[Newly Minted Fruit and Vegetable Committee Sets Goals for Advising USDA](#)

[FDA Food Facility Registration Renewal Due December 31, 2014](#)

[USDA Invests \\$118 Million in Grants to Support Specialty Crop Producers](#)

[Supreme Court Leaves California Foie Gras Ban Intact](#)

Regulatory Updates

USDA Announces Process for Recognizing State-Managed Phytosanitary Programs

In the [October 1, 2014, Federal Register](#), USDA announced it is implementing a process for states to petition the USDA's APHIS for federal recognition of their phytosanitary programs developed to eradicate, exclude, or contain plant pests of limited distribution within the United States. Through the petition process, APHIS will evaluate and consider recognizing state regulatory programs for certain plant pests that APHIS is not currently regulating or is considering no longer regulating. Federal recognition will help USDA know whether to take control actions against such pests at U.S. ports of entry prior to interstate movement of potentially affected plants into states with regulatory programs.

USDA Adopts Final Rule Relaxing Grade Requirements for Valencia Oranges

In the [September 30, 2014, Federal Register](#), USDA adopted, as a final rule without change, an interim rule altering the minimum grade requirements prescribed under the marketing order for oranges, grapefruit, tangerines, and tangelos grown in Florida. The rule reduces the minimum grade requirement for Valencia and other late-type oranges shipped to interstate markets for certain periods in each season. **The rule is effective October 1, 2014.**

USDA Announces Concurrence with World Organization on BSE Designations

In the [October 1, 2014, Federal Register](#), USDA announced its decision to concur with the World Organization for Animal Health's bovine spongiform encephalopathy ("BSE") risk

designations for 15 regions. By regulation, USDA's APHIS must classify every country of the world as having negligible risk, controlled risk, or undetermined risk for BSE, and this recent decision reclassifies 15 regions as negligible risk or controlled risk. The list of regions can be accessed on the APHIS website.

FDA Announces Filing of Food Additive Petition for Mesquite Bean Flour

In the [October 3, 2014, Federal Register](#), FDA announced its filing of a citizen petition, proposing that the food additive regulations be amended to provide for the safe use of ionizing radiation to treat mesquite bean flour. Food producers use ionizing radiation to reduce the levels of food-borne pathogens.

USDA Allows Import of Bananas from Philippines into Hawaii, Certain Territories

In the [October 10, 2014, Federal Register](#), USDA issued a final rule amending the fruits and vegetables regulations to allow the importation of fresh bananas from the Philippines into Hawaii, Guam, and the Northern Mariana Islands. As a condition of entry, the bananas will have to be produced in accordance with a systems approach, which includes monitoring for fruit flies, harvesting of only hard green bananas, and inspecting shipments for quarantine pests. ***The rule is effective November 10, 2014.***

FDA Information Collection Activities

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

[Veterinary Feed Directive](#) (*comments due November 24, 2014*)

FDA Announced the Following Information Collections Have Been Submitted to OMB

[Electronic Records; Electronic Signatures](#) (*comments due to OMB November 3, 2014*)

[Exports: Notification and Recordkeeping Requirements](#) (*comments due to OMB November 13, 2014*)

FDA Announced the Following Information Collections Have Been Approved by OMB

[General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions](#)

USDA Information Collection Activities

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

[Supplemental Nutrition Assistance Program Waivers Under Section 6\(o\) of the Food and Nutrition Act](#) (*comments due December 1, 2014*)

[Special Supplemental Nutrition Program for Women, Infants, and Children Infant and Toddler Feeding Practices Study](#) (*comments due December 5, 2014*)

USDA Announced the Opportunity to Comment on the Following Request for Revisions to and/or Extensions of Approval of Information Collections

[Dairy Products Mandatory Sales Reporting](#) (*comments due December 8, 2014*)

USDA Announced the Following Information Collections Have Been Submitted to OMB

[Importation of Plants for Planting; Establishing a Category for Plants for Planting Not Authorized for Importation Pending Pest Risk Analysis](#) (*comments due to OMB November 3, 2014*)

[National Animal Health Monitoring System; Equine 2015 Study](#) (*comments due to OMB November 5, 2014*)

Other USDA Announcements

Expansion of Areas in the Philippines Considered Free of Mango Seed Weevil and Mango Pulp Weevil and Establishment of a Lower Irradiation Dose as a Treatment for Mango Pulp Weevil

Decision to Allow Interstate Movement of Fresh Achachairú Fruit from Puerto Rico

Relaxation of Handling Regulations for Irish Potatoes Grown in Colorado and Imported Irish Potatoes

Upcoming Meetings, Workshops, and Conferences

Meeting of the National Agricultural Research, Extension, Education, and Economics Advisory Board, **October 21–23, 2014**, in Washington, D.C.

Meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses, **October 28, 2014**, College Park, MD.

Meeting of the Organic Standards Board, **October 28–30, 2014**, Louisville, KY.

FDA Risk Communications Advisory Committee Meeting, **November 3–4, 2014**, in Washington, DC.

Meeting of the Grain Inspection Advisory Committee, **November 5, 2014**, in Kansas City, MO.

Science Board to FDA, **November 19–20, 2014**, in Silver Spring, MD.

FDA Food Advisory Committee Meeting, **December 16–17, 2014**, in Washington, D.C.

Enforcement Updates

Recent Product Recalls

Several food products were recently recalled for undeclared allergens, microbial contaminations, and inspection deficiencies.

According to FDA's website, companies recalled five products because their packages did not list certain allergenic ingredients: chocolate cherries for undeclared peanuts, organic pasta for undeclared soy, rice cakes for undeclared milk, and waffles and a cheese dip for undeclared egg. FDA also posted recalls of prepackaged sandwiches, anchovies, and a cheese product due to concerns of potential *Listeria* contamination. A brand of jarred pesto sauce was called back because improper processing made it susceptible to botulism toxin.

USDA posted information about recalled beef jerky and a pork blood product that were produced without inspection. A company recalled ground beef for foreign material contamination, including pieces of metal, and another producer called back its beef filling because the products did not meet critical cooking limits. There were also recalls of breakfast meat and poultry products for possible *Listeria* contamination.

View a complete list of [product recalls for FDA-regulated products](#) and [for USDA-regulated products](#).

Recent Warning Letters

FDA recently warned a dietary supplement company for illegally producing drugs because its products contained undeclared active pharmaceutical ingredients. In an unusual case, the company was also cited for refusing to grant the FDA inspector access to an inventory of sampled products, as required by the inspection notice. FDA issued this warning pursuant to new authorities under the Food and Drug Administration Safety and Innovation Act, or FDASIA, which, as described in [guidance](#), allows the agency to deem a

product adulterated if it was manufactured or packaged in a facility that delays an inspection, limits access to certain areas or records, or refuses entry altogether.

In addition, FDA cited two dairy farms for illegal drug residue found in cows sold for slaughter. It also sent warning letters to two seafood processing facilities for hazard analysis and critical control points ("HACCP") violations, including failing to list maximum and minimum critical points, keep adequate compliance records, and provide corrective actions in the HACCP plan.

View the [FDA's Warning Letters Home page](#) (scroll down for listing of recently posted Warning Letters).

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