



FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

Top Stories

USDA–FSIS Proposes Rule Requiring Records for Raw Ground Beef

USDA's Food Safety and Inspection Service ("FSIS") [proposed a rule](#) requiring all makers of raw ground beef products, [including retailers that grind their own meat](#), to keep more records to facilitate easier traceability of the sources of ground meat. Under the proposed rule, retailers would be required to record the source, supplier, and names of all materials used when making ground beef. The new requirements are [meant to help USDA identify the sources of foodborne illness](#), which is problematic for the Agency under the current rule because ground beef is often produced by combining cuts from multiple sources. The proposal is part of the USDA's [salmonella action plan](#).

FDA Warns of Serious Risks of Using Pure Caffeine Products

On July 20, 2014, [FDA issued a consumer safety alert](#) advising consumers to avoid powdered pure caffeine sold in bulk bags over the internet. These products are essentially 100 percent caffeine, with a single teaspoon the rough equivalent of 25 cups of coffee. "Pure caffeine is a powerful stimulant and very small amounts may cause accidental overdose," [FDA stated](#). "It is nearly impossible to accurately measure powdered pure caffeine with common kitchen measuring tools and you can easily consume a lethal amount." FDA says it is aware of the death of at least one teenager who used these products. These warnings are another example of FDA's and [states' increased enforcement actions](#) of caffeinated products.

Congress Members Call for Ban on Bisphenol A in Food Packaging

Last week, Democrats in both chambers of Congress [introduced legislation banning bisphenol A \("BPA"\) from food packaging](#). Intake of large volumes of the synthetic additive has been linked to cancer, developmental health issues in fetuses, and infertility. Reps. Lois Capps (CA) and Grace Meng (NY), along with Sen. Ed Markey (MA) say BPA is dangerous and want to encourage development of alternatives through the [Ban Poisonous Additives Act](#).

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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](#)

FDA Updates TDS Results Used to Measure Contaminants and Nutrients in Food

On July 11, 2014, FDA released [updated data for its Total Diet Study](#) ("TDS"), an ongoing program that measures levels of

certain chemical contaminants and nutrients in foods. The newly available data provides findings from foods collected from 2006 to 2011 and aids FDA in spotting certain trends over time, such as significant declines in sodium contents of several processed foods.

▪ [Jones Day's Life Sciences Practice](#)

Stakeholders Raise Concerns About USDA's Revised Poultry Slaughter Rule

On July 10, 2014, FSIS [submitted a controversial draft poultry inspection rule](#) to the Office of Management and Budget ("OMB") for review. The draft rule is modeled largely on the HACCP-Based Inspection Models Project ("HIMP"), but the [Government Accountability Office raised serious questions](#) about whether HIMP data being used by FSIS supports USDA's claims of improved food safety benefits in this rule. Organizations representing poultry workers and consumers are calling for USDA to release the rule for public comment, as FDA has done, although the extra step is not required by law. "Although we do not discuss the specifics of a rule under review, the draft rule has been significantly informed by the feedback we received from our stakeholders, as well as from our interagency partners such as the Department of Labor," [said a USDA spokesperson](#). FSIS also argues that the system will improve efficiency, save taxpayer dollars, and prevent at least 5,000 more foodborne illnesses annually. Critics of the draft inspection rule are concerned that the rule privatizes poultry inspections, decreases the number of USDA inspectors, replaces inspectors with untrained company employees, and increases inspection line speeds. [Two Democratic Representatives led a group of 28 members of Congress](#) calling for USDA to publish the rule, raising concerns about worker safety, food safety, and animal welfare.

Other News

[Study Finds Some Organic Foods Have More Nutritional Benefits Than Conventional Foods](#)

[UN Report Ranks Global Health Impact of Foodborne Parasites](#)

[Presidential Council of Advisors on Science and Technology Calls for New Antibiotics](#)

[Codex Alimentarius Commission Limits Lead in Infant Formula and Arsenic in Rice](#)

Regulatory Updates

USDA–FSIS Proposes Rule Requiring Records for Raw Ground Beef

In the [July 22, 2014, Federal Register](#), USDA's Food Safety and Inspection Service ("FSIS") [proposed a rule](#) requiring all makers of raw ground beef products, [including retailers that grind their own meat](#), to keep more records to facilitate easier traceability of the sources of ground meat. "The improved traceback capabilities that would result from this proposal will prevent foodborne illness by allowing FSIS to conduct recalls of potentially contaminated raw ground products in a timelier manner," [said USDA Deputy Under Secretary for Food Safety Brian Ronholm in a news release](#). "By requiring retail outlets to maintain improved records on sources for ground products, the proposal will enable FSIS to quickly identify likely sources of contaminated product linked to an outbreak." The proposal is part of the USDA's [salmonella action plan](#) and, if finalized, will require makers of raw ground beef to keep records identifying the source, supplier, and names of all materials used in preparing the raw ground beef products. **Comments are due September 20, 2014.**

USDA Issues Final Rule on National Poultry Improvement Plan

In the [July 9, 2014, Federal Register](#), USDA's Animal and Plant Health Inspection Service issued a final rule amending the National Poultry Improvement Plan by removing descriptions of specific tests and sanitation procedures. The rule requires tests and sanitation to be conducted pursuant to a program standards document approved by the Administrator. This change is intended to improve USDA's ability to keep safeguards current by streamlining the process for approving new sampling and testing procedures. **The rule is effective on August 8, 2014.**

USDA Withdraws Proposed Rule on Sharing GMO Business Information with States

In the [July 18, 2014, Federal Register](#), USDA withdrew a proposed rule, published in the [February 27, 2013, Federal Register](#), that would have amended its regulations regarding genetically engineered organisms to add provisions for sharing certain business information with state and tribal governments. USDA withdrew the rule to ensure their ability to protect confidential business information.

USDA Issues Final Rule for Nondiscrimination to Protect Political Beliefs and Gender Identity

In the [July 16, 2014, Federal Register](#), USDA amended its regulation on nondiscrimination in programs and activities it conducts. The changes clarify the roles and responsibilities of headquarters staff for data collection and dispute resolution, and they establish political beliefs and gender identity as separate protected bases under its programs. Reporting for program applicants and participants remains voluntary. According to the final rule, gender identity "includes USDA program customers' gender expression, including how USDA program customers act, dress, perceive themselves, or otherwise express their gender."

USDA Issues Final Rule Excluding Women and Children from Commodity Supplemental Food Program

In the [July 9, 2014, Federal Register](#), USDA's Food and Nutrition Service issued a final rule amending its Commodity Supplemental Food Program ("CSFP") regulations to phase out the eligibility of women, infants, and children, in accordance with the 2014 Farm Bill. Under the amendments, women, infants, and children who applied to participate in CSFP after February 7, 2014, will be ineligible, and the program will be available only to low-income elderly persons age 60 or above. ***The rule is effective on August 8, 2014.***

USDA Issues Proposed Rule Exempting Sonora Cattle from Fever Tick Treatment

In the [July 17, 2014, Federal Register](#), USDA proposed to officially recognize the Mexican State of Sonora as free of fever ticks and establish an exemption from acaricide dipping treatment requirements. ***Comments are due September 15, 2014.***

USDA Proposes Rule for Importing Apples from China

In the [July 18, 2014, Federal Register](#), USDA proposed amending its fruits and vegetables regulations to allow importation of fresh apples from China. Apples imported from parts of China where the Oriental fruit fly is known to exist would be subject to additional importation requirements. ***Comments are due September 16, 2014.***

USDA Imposes Interest and Late Fees for Date Handlers

In the [July 16, 2014, Federal Register](#), USDA's Agricultural Marketing Service issued its final rule revising the rules and regulations of the California date marketing order, imposing interest and late fees on overdue assessments. These changes are expected encourage handlers to pay their assessments in a timely manner. ***The rule was effective on July 17, 2014.***

USDA Finalizes Rule Exempting Red Potatoes from Certain Requirements

In the [July 16, 2014, Federal Register](#), USDA's Agricultural Marketing Service affirmed its interim rule that exempts red types of potatoes from minimum quality, maturity, pack, marking, and inspection requirements. The rule is expected to reduce overall industry expenses and increase net returns to producers and handlers while giving the industry the chance to explore alternative marketing strategies. ***The rule was effective on July 21, 2014.***

USDA Finalizes Rule Relaxing Size Requirements for Rio Grande Valley Oranges

In the [July 16, 2014, Federal Register](#), USDA's Agricultural Marketing Service affirmed its interim rule that relaxes the minimum size requirement for domestic and import shipments. The rule is an effort to provide additional oranges to meet market demand. ***The rule was effective on July 17, 2014.***

FDA Corrects Errors in Preamble to Final Rule on Revised Infant Formula Regulations

In the [July 15, 2014, Federal Register](#), FDA corrected a June 10, 2014, [final rule](#), which established CGMP requirements for infant formula. The corrections relate to errors appearing in the preamble to the final rule.

FDA INFORMATION COLLECTION ACTIVITIES

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

[Health and Diet Survey](#), as Used by the Food and Drug Administration (*comments due September 12, 2014*)

USDA INFORMATION COLLECTION ACTIVITIES

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

[National Poultry Improvement Program](#) (*comments due September 5, 2014*)

[Pork and Poultry Products from Mexico](#) (*comments due September 8, 2014*)

[Importing Tomatoes from Spain, Chile, France, Morocco, and Western Sahara](#) (*comments due September 15, 2014*)

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

[SNAP Employment and Training Study](#) (*comments due September 15, 2014*)

[Examination of Cash Nutrition Assistance Program Benefits in Puerto Rico](#) (*comments due September 16, 2014*)

USDA Announces the Following Information Collections Have Been Submitted to OMB

[School Nutrition and Meal Cost Study](#) (*comments due to OMB August 8, 2014*)

[Exemptions from Commodity Import Requirements](#) (*comments due to OMB August 13, 2014*)

[Survey of Meat Slaughter and Processing Establishments](#) (*comments due to OMB August 13, 2014*)

[Conservation Effects Assessment Project](#) (*comments due to OMB August 18, 2014*)

Other USDA Announcements

[National Advisory Committee on Meat and Poultry Inspection](#) (*nominations due July 23, 2014*)

[Request for Stakeholder Input: 2017 Census of Agriculture](#) (*comments due August 4, 2014*)

[Expert Peer Reviewers for Climate Change and Food Security Report](#) (*nominations due August 7, 2014*)

[Pest Risk Analysis for Certain Edible Leaves and Flowers from Guatemala](#) (*comments due September 8, 2014*)

[Child and Adult Care Food Program: National Payment Rates](#) (*rates effective from July 1, 2014, through June 30, 2015*)

[School Lunch Program Reimbursement Rates](#) (*rates effective from July 1, 2014, through June 30, 2015*)

[Value of Donated Foods](#)

Upcoming Meetings, Workshops, and Conferences

[USDA Solicitation of Input from Stakeholders Regarding Centers of Excellence](#), **July 31, 2014**, in a web-based listening session.

[International Association for Food Protection Annual Meeting](#), **August 3–6, 2014**, in Indianapolis, IN.

[Meeting of the Codex Committee on Processed Fruits and Vegetables](#), **August 12, 2014**, in Washington, D.C.

[FDA Food Advisory Committee](#), **September 29–30, 2014**, in Silver Spring, MD.

Enforcement Updates

Recent Product Recalls

FDA recalls for the last two weeks include baked desserts and canned stone fruits for potential *Listeria* contamination. A variety of other processed food items were recalled for undeclared allergens: chocolate chews containing nuts; popsicles containing soy, milk, egg, and wheat; prepared salad containing fish, egg, nuts.

USDA also recalled products for bacterial contamination and undeclared allergens. One chicken producer recalled its products for possible *Salmonella* contamination. Another chicken producer recalled a grilled chicken product that was mistakenly sent out in bags printed for another product.

For a complete list of product recalls, click [here](#) for FDA-regulated products, and [here](#) for USDA-regulated products.

Recent Warning Letters

FDA continues to target dairies for illegal drug residue violations. FDA recently posted warning letters to four dairies and one livestock operation for illegal drug residues in animals intended for human consumption. Dietary supplement makers were also the subject of two recently posted warning letters for CGMP violations, including lack of testing plans and records, and labeling issues amounting to misbranding, according to FDA.

Other warning letters recently posted by FDA included a variety of violations. One egg producer received a warning letter citing violations of *Salmonella* prevention regulations, such as failing to keep records and not following construction rules for poultry facilities. A ready-to-eat salad manufacturing facility was warned for deviations from seafood HACCP and CGMP. A tofu processing facility was also warned for CGMP violations.

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

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