



A Broader Perspective

Bulletin

To: Our Clients and Friends

March 2, 2010

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

Congress To Hold Hearings on Reversing Child Obesity Epidemic and Child Nutrition; MOFS Holds Action Day

Senate Health, Education, Labor and Pensions (HELP) Committee will hold a full committee hearing on *Childhood Obesity: Beginning the Dialogue on Reversing the Epidemic* on Thursday, March 4, 2010 at 10 a.m. in Room 430 of Dirksen Senate Office Building. The witnesses scheduled to appear are Regina M. Benjamin, MD, MBA, Surgeon General, U.S. Department of Health & Human Services; Joe Thompson, MD, MPH, Director, Robert Wood Johnson Foundation Center to Prevent Childhood Obesity; Sandra Hassink, MD, Chair, American Academy of Pediatrics Obesity Leadership Workgroup; and Rashard Mendenhall, Pittsburgh Steelers Running Back, National Football League.

The House Appropriations Committee Subcommittee on New Agriculture, Rural Development, FDA, and Related Agencies will hold a hearing on Child Nutrition on Thursday, March 4, 2010 at 10 a.m. in Room 2362-A at Rayburn House Office Building. The witnesses scheduled to appear are Kevin Concannon, USDA Under Secretary for Food, Nutrition and Consumer Services; Dr. Kelly Brownell, Yale University; Dr. Mariana Chilton, Philadelphia GROW Project; Scott Faber, Grocery Manufacturers Association; and Zoe Neuberger, Center on Budget and Policy Priorities.

On the same day of the hearings, the Make Our Food Safe Coalition (MOFS) will hold a Food Safety Action Day, bringing victims of foodborne illness to the Capitol to encourage lawmakers to act on S. 510, the FDA Food Safety Modernization Act.

FTC Toughening Up Claims Enforcement, Targets Omega-3 Fatty Acids First

[The Federal Trade Commission has sent letters to 11 companies that promote various Omega-3 fatty acid supplements,](#) telling them they should review their product packaging and labeling to make sure they do not violate federal law by making baseless claims about how the supplements benefit children's brain and vision function and development. [FDA Law Blog](#) reports that the letters are consistent with recent remarks given at a conference by an FTC staff attorney, who indicated that FTC plans to look more closely at health claims for omega-3 fatty acids, probiotics, fiber products, antioxidants, and products marketed for use by children.

USDA Launches Your Food Environment Atlas with Statistics on Food Choices

On February 24, 2010, [USDA unveiled its new web-based mapping tool, Your Food Environment Atlas](#), which will enable researchers, policy makers, and the public to find information on a range of factors that affect access to healthy, affordable food, and will allow users to map the data by county. The map will provide highly detailed information on local food environments and health outcomes, including grocery store access and disease and obesity prevalence.

Australia Publishes Strategy for Nanotechnology and Biotechnology

On February 22, 2010, the Australian government published its [National Enabling Technologies Strategy](#), a coordinated national strategy to develop the country's nanotechnology and biotechnology industries with the goal of ensuring the highest standards while maximizing innovation and development.

EFSA Approves Three New Food Contact Substances

The European Food Safety Authority ([EFSA approved](#)) hydrogenated homopolymers and/or copolymers; poly(12-hydroxystearic acid) stearate; and perfluoro acetic acid as food contact substances. All three substances were given a positive safety evaluation after national food safety agencies requested their evaluation under EC regulations.

Boca Raton Man Sentenced for Dietary Supplements Scam

The U.S. Attorney's Office for the Southern District of Florida announced that [a Boca Raton man had been sentenced to 20 years imprisonment for a dietary supplement scam](#). The defendant defrauded more than 130,000 customers out of more than \$7 million by marketing a purported weight loss product, called Lipoban, by misrepresenting that the product was sold in conjunction with a medical facility and clinical test.

FDA Continues to Issue Updates on Salmonella Montevideo Outbreak

[FDA, along with the CDC and the USDA's FSIS, continues to work closely with the Rhode Island Department of Health and other states in the investigation of an outbreak of Salmonella Montevideo infections associated with certain Italian-style sausage products including salami/salame](#). The CDC reports that 238 people have been infected with a matching strain of Salmonella Montevideo in at least 44 states and the District of Columbia. FDA is actively investigating the supply chains of both black and red pepper used in the manufacturing of the recalled meat products. To date, samples from two lots of crushed red pepper collected from Daniele International Inc. have tested positive for the same strain of Salmonella Montevideo associated with the outbreak and have prompted other firms to initiate recalls.

Briefly Noted

[Researchers find more efficient method to turn agricultural waste into biofuels.](#)

[Renewable Fuels Association says making ethanol has become more economical as corn prices fall.](#)

[USDA working to develop more nutritious humanitarian food aid packages.](#)

[USDA joins National Collaborative on Childhood Obesity Research.](#)

[USDA Visits NYC to promote healthy eating and announce \\$5 million for Farmers Market Promotion Program.](#)

Recent Recalls

[T. Marzetti Company Veggie Dips, Oak Lake Chip Dips and Great Value Chip Dips](#) due to potential Salmonella contamination (March 1, 2010).

[Heartland Foods Coarse Ground Black Pepper](#) due to potential Salmonella contamination (March 1, 2010).

[Johnny's Fine Foods French Dip Powdered Au Jus](#) due to potential Salmonella contamination (February 26, 2010).

[American Pecan Co. 1 lb. bags of Pecan Pieces](#) due to potential Salmonella contamination (February 26, 2010).

[Wholesome Spice 25 lb boxes of Crushed Red Pepper](#) due to potential Salmonella contamination (February 25, 2010).

[Thumb Oilseed soybean grits and flour](#) due to potential Salmonella contamination (February 25, 2010).

[Trader Joe's expands Chocolate Chip Chewy Coated Granola Bars recall](#) due to potential Salmonella contamination (February 25, 2010).

Recent Warning Letters

FDA issued a warning letter to [Gourmet Express Marketing, Inc.](#) stating that FDA investigators documented serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation.

FDA issued warning letters to [Juices International, Inc.](#) and [Mystical One LLC](#) stating that FDA has found serious violations of the juice Hazard Analysis and Critical Control Point (HACCP) regulations and Current Good Manufacturing Practice (CGMP) regulations for food.

FDA issued a warning letter to [Innovative Beverage Group, Inc.](#) stating that its product, "Drank" is adulterated because it contains melatonin, which is an unapproved food additive.

FDA issued a warning letter to [Rangen, Inc.](#) stating that an FDA inspection revealed significant deviations from the requirements set forth in the regulations regarding Animal Proteins Prohibited in Ruminant Feed, intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE).

FDA issued a warning letter to [La Mexicana, Inc.](#) stating that, during an inspection of its facility, FDA inspectors found significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for food manufacturers that caused the food to be adulterated because it was prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health.

FDA issued warning letters to [Stardust Dairy, LLC](#) and [Crestview Calves, Inc.](#) stating that the company offered for sale animals for slaughter as food that were adulterated. In an animal offered for sale for slaughter by Stardust Dairy, the animal had residues of animal drugs that were in excess of the amounts permitted by FDA. In an animal sold for slaughter by Crestview Calves, FDA found in the kidney tissues of the animal gentamicin sulfate, for which FDA has not established a tolerance.

Regulatory Notices

FSIS Updates

FSIS issues notices and directives to protect public health. The following policy update was issued recently:

- Notice 11-10, [Sampling Of Low Production Volume Raw Ground Beef Establishments For Salmonella And Escherichia Coli O157:H7.](#)

All notices and directives are available at http://www.fsis.usda.gov/Regulations_&Policies/index.asp.

FSIS also recently published the following revised export requirements and plant lists:

- [Costa Rica](#) (Mar 1, 2010)
- [Colombia](#) (Feb 25, 2010)
- [Canada](#) (Feb 25, 2010)

FDA Requests Comments on Information Collected on Substances Prohibited From Use in Animal Food or Feed and Animal Proteins Prohibited in Ruminant Feed

[FDA is inviting public comments on the proposed recordkeeping requirements](#) of information concerning substances prohibited from use in animal food or feed and animal proteins prohibited in ruminant feed. Written or electronic comments must be submitted by April 27, 2010. (February 26, 2010).

FDA Gives Notice on Collection of Information on Reportable Food Registry

[FDA issued a notice that its information collection on third party disclosure and recordkeeping requirements for reportable food was submitted to the Office of Management and Budget.](#) Although not specific request for comments was included, any written or electronic comments on the notice must be submitted by March 29, 2010. (February 26, 2010).

Upcoming Meetings

FSIS to Hold Public Meeting on Product Tracing

FSIS will hold a second public meeting on product tracing to discuss and receive public input on procedures for suppliers of source material used to produce raw ground beef product that tests positive for *E. coli* O157:H7. The Product Tracing public meeting will be held on **March 10, 2010** from 9 a.m. to 1 p.m. in Washington, DC. For additional information and to pre-register, visit http://www.fsis.usda.gov/news_&_events/Reg_Traceability_031010/index.asp.

USDA and DOJ Host Joint Workshops to Explore Competition and Regulatory Issues

The Department of Justice and the U.S. Department of Agriculture (USDA) will host a [series of joint workshops to explore competition and regulatory issues in the agriculture industry](#) beginning on **March 12, 2010**, at the Des Moines Area Community College's FFA Enrichment Center in Ankeny, Iowa. The general public and media interested in attending the initial workshop should register at <https://go.dmacc.edu/ffa/agworkshop>.

FSIS to Host Public Meeting to Draft U.S. Positions for Codex Committee Meeting

FSIS announced a public meeting to draft U.S. positions and receive comments on agenda items for discussion at the 26th session of the Codex Committee on General Principles (CCGP). The public meeting will be held **March 23, 2010** in Washington, DC. A complete agenda and documents relating to the 26th session of CCGP will be available on the Codex Alimentarius Web site at <http://www.codexalimentarius.net/current.asp>. For more information about the public meeting, contact Barbara McNiff at (202) 690-4719 or Barbara.McNiff@fsis.usda.gov. Individuals are invited to submit their comments electronically to uscodex@fsis.usda.gov. The 26th session of CCGP takes place in Paris, France April 12 - 16, 2010. Additional information is available at http://www.fsis.usda.gov/News_&_Events/NR_030110_01/index.asp.

USDA to Host Web Outreach Seminar on Sanitary Dressing Procedures

FSIS will host a Web outreach seminar on sanitary dressing procedures on **March 23, 2010** from 11:30 a.m. to 1 p.m. ET. Participants will gain insight on FSIS sanitary dressing procedures and how they are critical to reducing *E. coli* O157:H7 to undetectable levels. The discussion will also provide a better understanding of validated HACCP plans and interventions. To learn more, go to http://www.fsis.usda.gov/News_&_Events/Regulatory_Web_Seminars/index.asp.

USDA to Host 2010 Food Safety Education Conference

USDA and [NSF International](#) are hosting the 2010 Food Safety Education Conference, *Advancements in Food Safety: Trends, Tools and Technologies*, **March 23-26, 2010**, at the Hyatt Regency in Atlanta. Food safety educators and other professionals worldwide will have the opportunity to discover the latest advancements in food safety education. To register and get more information, visit <http://www.fsis.usda.gov/Atlanta2010>.

FDA, FSIS, and CDC to Host Public Workshop Measuring Progress on Food Safety

On **March 30, 2010**, in Washington, DC, FDA, FSIS, and CDC will co-host "Measuring Progress on Food Safety: Current Status and Future Directions," an inter-agency workshop where officials will discuss current and potential measurements for assessing progress in food safety and associated methodological issues as well as potential improvements. For registration information and general questions regarding the workshop, contact Juanita Yates at (301) 436-1731 or juanita.yates@fda.hhs.gov. Due to limited seating, preregistration is encouraged. Attendees may register in advance before March 24 at <http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm201102.htm>.

USDA Workshops to Explore Competition and Regulatory Issues

Between March 12 and December 8, 2010, the Department of Justice and USDA will hold [five joint public workshops that will explore competition and regulatory issues in the agriculture industry](#). The workshops target issues of concern to farmers and the poultry, dairy, livestock industries. The final workshop will focus on price margins.

More Information

Archived issues of the Bryan Cave Food, Dietary Supplement, and Cosmetic Regulatory and Policy Bulletin are available at www.bryancave.com on the [FDA Practice Bulletins web page](#).

If you have any questions regarding any of these issues, please contact:

Mark Mansour	Partner	mark.mansour@bryancave.com	1 202 508 6019	Washington
Alan K. Parver	Partner	alan.parver@bryancave.com	1 202 508 6332	Washington
Steven Kent Stranne	Partner	steven.stranne@bryancave.com	1 202 508 6349	Washington
Megan A. Gajewski	Associate	megan.gajewski@bryancave.com	1 202 508 6302	Washington
Patrice M. Hayden	Associate	pmhayden@bryancave.com	1 202 508 6147	Washington
Emily K. Strunk	Associate	emily.strunk@bryancave.com	1 202 508 6360	Washington

This bulletin is published for the clients and friends of Bryan Cave LLP. To stop this bulletin, please reply to this email. To stop this bulletin and all future commercial e-mail from Bryan Cave LLP, please reply to: opt-out@bryancave.com and leave the message blank. Information contained herein is not to be considered as legal advice. Under the ethics rules of certain bar associations, this bulletin may be construed as an advertisement or solicitation.