

To: Our Clients and Friends

March 30, 2010

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

President Signs Major Health Care Reform Bill Into Law

On March 23, 2010, [President Obama signed the Patient Protection and Affordable Care Act into law](#). Although it may prove to be one of the most significant pieces of social legislation in history, there are relatively few provisions that concern food, dietary supplements, or cosmetics. However, many believe that the Senate will turn their attention to the food safety bill (S. 510) once they have completed the health care overhaul legislation. Members of the House of Representatives, which passed its version of the food safety bill last year, have increasingly been putting pressure on the Senate to enact food safety legislation. A week later, on March 30, 2010, President Obama finalized the health care overhaul effort by signing the Health Care and Education Reconciliation Act, which modifies the Patient Protection and Affordable Care Act by removing some of the more controversial provisions.

Health Care Reform Includes Calorie Count Provision

The [Associated Press](#) reports that "a requirement tucked into the nation's massive health care bill will make calorie counts impossible for thousands of restaurants to hide and difficult for consumers to ignore." The provision, which applies to restaurants with more than 20 locations, directs FDA to establish national standards for labeling menus. These standards would require calorie counts on the menus of restaurants, including menu boards and drive-thru menus at fast-food restaurants. The restaurant industry generally supported the provision, as it will supersede local laws which can be inconsistent from place to place.

FDA Issues Guidance on Submitting Reports for Multiple Facilities to the RFR

FDA recently posted a new food safety guidance to its web site. [Submitting a Report for Multiple Facilities to the Reportable Food Electronic Portal as Established by the Food and Drug Administration Amendments Act of 2007](#) provides guidance intended to assist those parties responsible for complying with the Reportable Food Registry requirements. Specifically, the document addresses the question of how a company should submit a combined report when reportable food is located at more than one of a company's facilities. In September 2009, FDA issued a related guidance document entitled "[Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007](#)."

EPA to Scrutinize Environmental Impact of Bisphenol A

On March 29, 2010, U.S. Environmental Protection Agency ([EPA](#)) announced a number of actions to address the [potential effects of bisphenol A \(BPA\)](#), a chemical used in the manufacture of a wide range of consumer and industrial products. EPA's BPA action plan focuses on the environmental impacts of BPA and will look to add BPA to EPA's list of chemicals of concern and require testing related to environmental effects. These actions are part of Administrator Lisa P. Jackson's comprehensive effort to strengthen the agency's chemical management program and assure the safety of chemicals.

Public Health Agencies Collaborating on NoroVirus Outbreak, Warning of Raw Milk

FDA is working with state health officials from Mississippi and Louisiana to [notify consumers, food service operators and retailers nationwide about an outbreak of norovirus associated with oysters](#) recently harvested from an area near Port Sulphur, La. known as Area 7. The oysters were sold or distributed nationwide. FDA, along with several state agencies, is also [alerting consumers to an outbreak of campylobacteriosis associated with drinking raw milk](#). At least 12 confirmed illnesses have been recently reported in Michigan, and FDA is collaborating with the state agencies to investigate the outbreak.

FDA Takes Action Against New York Dairy Farmer

FDA sought and [won a permanent injunction against New York State dairy farmer who was cited by FDA for selling cows that had illegal residues of antibiotics](#). The consent decree of permanent injunction was ordered by the U.S. District Court for the Western District of New York this week to stop offering the animals for slaughter until he complies with federal law.

U.S. Attorneys Office Arrests Two For Illegally Importing Weight Loss Medication

In a joint international undercover investigation by FDA Office of Criminal Investigations, U.S. Immigration and Customs Enforcement, and U.S. Postal Inspection Service, the [U.S. Attorneys office in Colorado arrested two individuals for importing weight loss products containing Sibutramine from China and illegally marketing them as dietary supplements](#).

Owner of Dietary Supplement Company Pleads Guilty to Selling Supplements Over the Internet with False Claims to Prevent, Cure Diseases

Charles Thao, owner of Nutrapha Research LLC, [pleaded guilty in federal court to his role in a conspiracy to fraudulently market dietary supplements over the Internet with illegal claims that these supplements could prevent, treat or cure a number of diseases](#). Several Web sites were used to sell more than \$17.4 million worth of products in 2005 and 2006.

HACCP Systems Validation Documents Now Available on the Web; FSIS Seeks Comments on Draft Compliance Guide on the Subject

FSIS is making available three documents on the validation of HACCP systems on its Web site at http://www.fsis.usda.gov/PDF/HACCP_Validation_Ltrs.pdf (PDF Only). The documents include: (1) A March 17, 2010 letter from FSIS Administrator Al Almanza to nine trade associations that sets out the agency's current thinking on changes it intends to make in its approach to verifying that establishments have appropriately validated their HACCP systems; (2) A draft compliance guide on HACCP systems validation; and (3) A September 22, 2009, letter to which Almanza is responding. FSIS is interested in receiving comments on the guidance document from all interested persons, and has provided the additional documents to inform interested persons. Interested parties should submit their comments to DraftValidationGuideComments@fsis.usda.gov, or mail comments to the Docket Clerk, USDA, FSIS, Room 2-2127, 5601 Sunnyside Avenue, Beltsville, MD 20705. After April 19, FSIS will begin its review on the comments it receives and its process of deciding how it will proceed with respect to the validation of HACCP systems.

FSIS Selects Humane Handling Enforcement Coordinator

FSIS has selected Dr. Sallee Dixon as the agency's humane handling enforcement coordinator. In this position, Dr. Dixon will serve as the primary contact for issues of humane handling of livestock and good commercial practices for poultry. Dr. Dixon will oversee the national coordination of humane handling policy implementation and the correlation of the humane handling activities of FSIS' 15 district veterinary medical specialists.

Briefly Noted

[Scientists convert sugar beets into liquid fuels.](#)

[USDA Schedules First Meeting of Dairy Industry Advisory Committee for April 13-15.](#)

[Mars and Nestle support school nutrition standards.](#)

[EU and Argentina Settle WTO GMO dispute.](#)

[Peanut Corporation of America owner hires criminal defense attorney.](#)

[Thailand launches food traceability initiative.](#)

[Food Safety News reports that a new salmonella vaccine is in the works.](#)

Recent Recalls

Recalls related to the recall of black pepper due to potential salmonella contamination include:

- [Little Caesars Spice Paks](#) (March 23, 2010).
- [McCain All American Roasters frozen potato product](#) (March 19, 2010).
- [Various Archer Farms and Fisher brand snack mixes](#) (March 19, 2010).
- Various products from C.H. Guenther & Son, Inc. ([March 23, 2010](#); [March 22, 2010](#); [March 18, 2010](#)).
- [Perfect Candy & Packaging Co whole black peppercorns](#) (March 25, 2010).
- [FDA posted its most recent update](#) on this recall on March 29, 2010.

Recalls related to the recall of Hydrolyzed Vegetable Protein (HVP) include:

- [Modern Products, Inc. various seasonings](#) (March 25, 2010).

Additional recalls include:

- [Flying Horse White Sesame Chewy Candy](#) due to undeclared peanuts (March 22, 2010).
- [Perdue Farms sweet Italian turkey sausage](#) due to undeclared milk (March 19, 2010).

eFoodAlert.com has compiled a complete list of the many products recalled due to [contaminated HVP](#) and [contaminated pepper](#) (which led to the Salmonella Montevideo outbreak).

Dr. Linda M. Katz, Interim Chief Medical Officer for the FDA's Center for Food Safety and Applied Nutrition (CFSAN) posted an entry to the blog at FoodSafety.gov, [What to do if you have a recalled product?](#), to provide consumers with useful information.

Recently Posted Warning Letters

A warning letter to [Cucina Fresca, Inc.](#) stated that FDA inspectors found significant violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulations causing the firm's seafood ravioli products to be adulterated.

A warning letter to [NY Fish Co.](#) stated that FDA inspectors found *Listeria monocytogenes* at the firm's facility in addition to serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) and Current Good Manufacturing Practice (CGMP) requirements for manufacturing, packing, or holding human food regulations causing the firm's ready-to-eat cured and smoked fish products to be adulterated.

Warning letters to [Pacific American Fish Co., Inc.](#) and [C & S Wholesale Grocers, Inc.](#) stated that FDA inspectors found serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) and Current Good Manufacturing Practice (CGMP) requirements for manufacturing, packing, or holding human food regulations at the company's seafood processing facility and importer establishment causing the firms' fish and fishery products to be adulterated.

A warning letter to [Seoul Trading, Inc.](#) stated that inspectors documented serious deviations from applicable regulations regarding Current Good Manufacturing Practice (CGMP) requirements for manufacturing, packing, or holding human food that caused the products being held and repackaged in the firm's facility to be adulterated.

A warning letter to [Simplydelicious LLC dba Bobo's Oat Cakes](#) warned that significant deviations from applicable regulations regarding Current Good Manufacturing Practice (CGMP) requirements for manufacturing, packing, or holding human food caused the firm's ingredients and finished food products to be adulterated.

Warning letters to [1008 Grinstead Mill Road Dairy](#) and [Double B Dairy, LLC](#) stated that FDA inspectors found that the dairy offered for sale an animal for slaughter as food that was adulterated due to the presence of a drug in edible tissue in excess of the allowed amounts, and because the firms hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply.

A warning letter to [Healthy Body Forero Inc.](#) stated that FDA inspectors found that certain "Fat Burner" products were marketed and distributed in violation of the Federal Food, Drug, and Cosmetic Act because they contained an active pharmaceutical ingredient from an FDA-approved prescription drug for obesity. Dietary supplements may not include ingredients that are approved as new drugs, unless the article was marketed as a dietary supplement before the ingredient's approval as a new drug.

A warning letter to [Registry Steaks & Seafood Ltd.](#) stated that FDA inspectors found serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation at the company's seafood processing facility and that the company's products were additionally adulterated and misbranded because ingredients were added to the product to increase the product's bulk or weight, the net quantity of contents on that product was misleading, and another product was marketed as one type of fish, but was in fact another type of fish.

Regulatory Notices

FSIS Updates

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

- [Russia \(Beef\) Plant List](#) (Mar 19, 2010)
- [China, People's Republic of](#) (Mar 29, 2010)
- [Russia \(Pork\) Plant List](#) (Mar 29, 2010)
- [Canada](#) (Mar 29, 2010)
- [South Africa](#) (Mar 29, 2010)

FSIS recently posted [FSIS Notice 16-10](#) on Reporting Field Screen Residue Results in the eSAMPLE Application.

FDA Withdraws Compliance Policy Guide Section 540.375 on Canned Salmon

On March 22, 2010, [FDA announced the withdrawal of Compliance Policy Guide Sec. 540.375 Canned Salmon — Adulteration Involving Decomposition](#) (CPG 7108.10) (CPG Sec. 540.375). CPG Sec. 540.375 is included in FDA's Compliance Policy Guides Manual, which was listed in the Annual Comprehensive List of Guidance Documents that published on March 28, 2006.

FDA Amends Color Additive Regulations

On [March 26, 2010](#), FDA amended the [color additive regulations](#) to increase the permitted use level of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp. This action is in response to a petition filed by Combe, Inc. and effective April 27, 2010. Electronic or written objections and requests for a hearing may must be submitted by **April 26, 2010**.

FDA Transparency Task Force Requests Comments

FDA is soliciting comments from interested persons on ways in which FDA can increase transparency between FDA and regulated industry. In addition to the [Federal Register Notice](#), FDA also issued a [press release on the subject](#). Interested parties must submit electronic or written comments **by April 12, 2010**.

FDA Requests Comments on Prior Notice of Imported Food Information Collection

FDA published a [Federal Register Notice](#) to solicit comments on the information collection provisions of FDA's regulations requiring that the agency receive prior notice before food is imported or offered for import into the United States. Interested parties must submit electronic or written comments by **May 17, 2010**.

FDA Requests Comments on Reportable Food Registry Information Collection

FDA published a [Federal Register Notice](#) to solicit comments on the information collection provisions of the agency's regulations that require registration for domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. Interested parties must submit electronic or written comments by **May 17, 2010**.

FDA Requests Comments on Cosmetics Labeling Information Collection

FDA published a [Federal Register Notice](#) to solicit comments on information collection provisions in FDA's cosmetic labeling regulations. Interested parties must submit electronic or written comments by **May 17, 2010**.

FSIS Seeks Comments on New Rules to Enhance Food Safety

USDA Food Safety and Inspection Service (FSIS) is [proposing to implement provisions of the Food, Conservation, and Energy Act of 2008 \(2008 Farm Bill\)](#) by adopting regulations that require official establishments to promptly notify the appropriate District Office that an adulterated or misbranded meat or poultry product has entered commerce; require official establishments to prepare and maintain current procedures for the recall of meat and poultry products produced and shipped by the establishment; and require official establishments to document each reassessment of the establishment's process control plans, that is, its Hazard Analysis and Critical Control Point plans. The notice was published in the [March 25, 2010 Federal Register](#). Interested parties must submit electronic or written comments by **May 24, 2010**.

Upcoming Meetings

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

FSIS announced a [public meeting to provide information and receive public comments on agenda items and draft United States positions that will be discussed at the 38th Session of the Codex Committee on Food Labeling \(CCFL\)](#). The public meeting will be held **April 7, 2010** in Washington, DC. A complete agenda and documents relating to the 38th session of CCFL will be available on the Codex Alimentarius Web site at <http://www.codexalimentarius.net/current.asp>. Individuals are invited to submit their comments electronically to Ritu.Nalubola@fda.hhs.gov. The 38th session of CCFL takes place in Quebec City, Canada May 3 - 7, 2010. Additional information is available in the [Federal Register Notice](#) announcing the meeting.

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 famers 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:

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