

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

Democrats Introduce Safe Cosmetics Act of 2010

On July 21, 2010, three Democratic Members of the House of Representatives introduced the Safe Cosmetics Act of 2010 (H.R. 5786) and Senator Dianne Feinstein (D-CA) is working to introduce similar legislation in the Senate. Under current law, FDA cannot mandate recalls of harmful cosmetics and personal care products, nor can the agency require cosmetics manufacturers to conduct safety assessments.

The [Campaign for Safe Cosmetics](#) says that “the cosmetics industry as a whole has not kept pace with safety innovations due to a weak regulatory system that encourages ignorance about chemical hazards and allows companies to hide the true toxicity of products,” and remarks that the legislation will “the playing field for businesses that are making the safest products.”

The [Personal Care Products Council](#) (which represents the cosmetic and personal care products industry) is also interested in strengthening FDA oversight of cosmetics and personal care products, but believes that H.R. 5786 is not based on scientific principles, is unduly burdensome on FDA, and would create an unmanageable regulatory structure that would not significantly contribute to improved product safety. They propose an alternative regulatory scheme.

[The Chicago Tribune](#) says that the increased congressional focus on the regulation of the cosmetics industry was sparked by an investigation by the newspaper in May. The [investigation](#) consisted of an independent lab testing 50 skin-lightening creams, six of which were found to contain mercury, which FDA banned in such products beginning in 1990. [ABC News](#) and [Pittsburgh Post-Gazette](#) also reported on the topic.

Food Safety Legislation Still on Hold in Senate

Although passed a year ago by the House of Representatives, Food Safety legislation has still not received full-floor consideration in the Senate. First stalled by health care reform and then by financial reform, now more issues, including appropriations and Elena Kagan’s Supreme Court nomination, threaten to postpone the Senate’s consideration of the food safety bill. Furthermore a controversial amendment that would ban BPA entirely has threatened industry’s support of the bill. Food safety advocates fear that without a significant push from the President and Senate Majority Leader Harry Reid (D-NV), food safety legislation has a slim chance of passing before the session is over.

FDA Details Voluntary Compliance with New Federal Menu Labeling Requirements

On July 21, 2010, FDA released details on how retail food establishments and vending machine operators with fewer than 20 locations can choose to become subject to the new federal menu labeling requirements. The new requirements generally cover companies with 20 or more stores or machines. Restaurants and vending machines that are subject to the new law are exempt from state and local menu labeling laws. If smaller establishments choose to be subject to federal requirements by voluntarily registering, they will no longer be subject to state or local nutrition labeling requirements unless those requirements are identical to federal requirements. [CFSAN's Constituent Update](#) and the [Federal Register notice](#) provide additional details.

FDA Publishes Outcome of ICCR-4 Meeting on Cosmetics Regulations

From July 13 to 15, 2010, the International Cooperation on Cosmetic Regulation (ICCR) held its fourth annual meeting (ICCR-4) in Toronto, Canada to discuss issues related to cosmetics and cosmetic-like drug/quasi-drug products. ICCR is an international group of cosmetic regulatory authorities from Canada, the European Union, Japan, and the United States. FDA recently published a [summary of the meeting](#), describing the main topics of discussion and outcomes.

FDA Deputy Commissioner Testifies before House Subcommittee on Antibiotics Use

On July 14, 2010 FDA Principal Deputy Commissioner Joshua M. Sharfstein, M.D. testified before the House Committee on Energy and Commerce subcommittee on Health on the topic of Antibiotic Resistance and the Use of Antibiotics in Animal Agriculture. His [testimony](#) provided background information on antimicrobial resistance, described FDA's actions to combat resistance and promote product development, and discussed the newly released draft guidance, [The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals](#).

USDA Secretary Vilsack Reestablishes NACMPI Charter, Appoints 2010-2012 Members

Agriculture Secretary Tom Vilsack has reestablished the charter of the National Advisory Committee on Meat and Poultry Inspection (NACMPI) and appointed members of the Committee for 2010-2012. Established in 1971, NACMPI meets on food safety concerns and advises the Secretary of Agriculture on matters affecting federal and state inspection program activities. It also contributes to USDA's regulatory policy development. Recommendations are sent to USDA's Under Secretary for Food Safety for consideration and review by the Secretary of Agriculture. The [USDA press release](#) lists the members of the committee.

FSIS Announces New Online Food Defense Risk Mitigation Tool

FSIS' Office of Data Integration and Food Protection has developed a [Food Defense Risk Mitigation Tool](#), an online resource for plant owners and operators. This tool allows companies to identify possible countermeasures that could be incorporated into the facility's food defense plan and help reduce the risk of the intentional contamination of food products. The user can also retrieve lists of general inside, outside and personnel security measures, as well as management actions that can enhance food defense. The tool compliments [existing written guidance materials on food defense plans and mitigation strategies](#). Individuals can also receive assistance from the Small Plant Help Desk at 1-877-FSISHELP.

Briefly Noted

[Food Safety at the Farmer's Market \(from FoodSafety.gov\).](#)

[Latest Issue of EdNet, a multi-agency \(CDC, FSIS, FDA\) electronic newsletter providing information about food safety and nutrition programs and activities for educators, consumer advocates, government officials, and industry representatives.](#)

[USDA Provides Emergency Assistance to Producers of Honeybees, Livestock and Farm-Raised Fish for 2009 Losses.](#)

[USDA Offers Food Safety Tips as Tropical Storm Bonnie Crosses Southeastern U.S.](#)

[USDA Offers Food Safety Tips for Iowa, Illinois Flooding.](#)

[USDA Offers Food Safety Tips as Tropical Storm Bonnie Crosses Southeastern U.S.](#)

[Giant Salmon is first genetically modified animal available as a food.](#)

[Biotech fish farming research will look into cultivating seafood indoors.](#)

[CDC says that salsa and guacamole are increasingly a source of foodborne illness.](#)

[Baltimore hires food policy coordinator, one of first cities in country to have a paid "Food Czar."](#)

[Industry lobbying efforts to combat soda taxes proving effective.](#)

[Europe seeks to ban food from cloned animals.](#)

[Washington Post analyzes effectiveness of FDA food safety system.](#)

[European Food Safety Authority publishes final guidance for food flavorings assessment data.](#)

[European Commission Proposes Plan to Break Impasse on GMO foods.](#)

[Nestle Settles Boost Kids Essential Drinks Products Claims with FTC](#)

Recent Recalls

[J & H Besta Corp. Joyful Slim Herb Supplement](#) due to undeclared drug ingredient (July 22, 2010).

[DeBoles Kids Only! Gluten Free Tubettini Corn Pasta](#) due to undeclared wheat (July 21, 2010).

[Perdue Farms frozen chicken nugget products](#) due to foreign materials (July 19, 2010).

[J & H Besta Corp. Slim-30 Herb Supplement](#) due to undeclared drug ingredient (July 16, 2010).

[Good Health, Inc. Vialipro supplement for sexual enhancement](#) due to undeclared drug ingredient (July 16, 2010).

[Feline's Pride expanding its July 1, 2010 cat food recall \(Feline's Pride Raw food with ground bone for cats and kittens, Natural Chicken Formula\)](#) due to Salmonella contamination (July 15, 2010).

[D & M Smoked Fish Haifa brand vacuum packaged Schmaltz Herring](#) due to product being unviscerated (July 15, 2010).

[Diamond USA Dry Apricot Rolled](#) due to undeclared sulfites (July 13, 2010).

[Fresh Express Romaine lettuce salad products](#) due to potential E. coli O157:H7 contamination (July 13, 2010).

[Quality Food Center \(QFC\) stores Broccoli Raisin Salad](#) due to undeclared walnuts (July 10, 2010).

Recently Posted Warning Letters

FDA warned [Triple G Dairy](#) and [Dick-mar Farms](#), and that FDA investigators found that their dairy operations offered an animal for sale for slaughter as food that was adulterated because it contained an unsafe or unsafe amount of an animal drug and the animal was held under insanitary conditions. FDA also warned [Regancrest Holsteins, Inc.](#) that FDA found that its dairy operation had adulterated drugs and used them inappropriately on lactating dairy cows.

FDA warned [Knott's Wholesale Foods, Inc.](#) that their products were misbranded due to violations of FDA labeling regulations and adulterated due to its failure to file a scheduled process with FDA for this product for each container size as required for acidified food products.

FDA warned [Industrias Alimentarias De Navarra, S.A.U.](#) and [Cruz Perez Hermanos S.A.](#) that FDA investigators found serious deviations from the low-acid canned food regulations at their low-acid canned food facility.

FDA warned [Crowley Foods Arkport, Division of HP Hood, LLC](#) that FDA inspectors found serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation.

FDA Warned [Lamberts Inc](#) that FDA inspectors also found serious violations of the Current Good Manufacturing Practice (CGMP) regulation for foods, Processing and Bottling of Bottled Drinking Water, causing their water and coffee products to be adulterated.

New Regulatory Notices

FDA Announces Final Rule Permitting Ammonium Formate in Swine Feed

In the [July 19, 2010 Federal Register](#) FDA announced a final rule amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of ammonium formate as an acidifying agent in swine feed. This action is in response to a food additive petition filed by Kemira Oyj of Finland. The rule is effective July 19, 2010. Submit either electronic or written objections and requests for a hearing by August 18, 2010. See section V of this document for information on the filing of objections.

FDA Announces the Sterigenics International Inc. Withdraws Food Additive Petition

In the [July 12, 2010 Federal Register](#), FDA announced the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 3M4744) proposing that the food additive regulations be amended to provide for the safe use of ionizing radiation in the production of shelf stable foods, including multiple ingredient shelf stable foods.

FDA Seeks Comments on Information Collection for Food Labeling

In the [July 15, 2010 Federal Register](#), FDA announced that a proposed collection of information an opportunity for public comment on an information collection concerning food labeling regulations. Interested parties must fax written comments by **August 16, 2010**.

FDA Seeks Comments on Information Collection for CGMPs for Dietary Supplements

In the [July 14, 2010 Federal Register](#), FDA announced an opportunity for public comment on an information collection for Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements. Interested parties must electronic or written comments by **September 13, 2010**.

FDA Seeks Comments on Information Collection for Juice HACCP

In the [July 14, 2010 Federal Register](#), FDA announced an opportunity for public comment on an information collection concerning Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice. Interested parties must electronic or written comments by **September 13, 2010**.

FDA Seeks Comments on Information Collection for Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients

In the [July 20, 2010 Federal Register](#), FDA announced an opportunity for public comment on an information collection concerning a petition to request an exemption from 100 percent identity testing of dietary ingredients: current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements. Interested parties must electronic or written comments by **September 20, 2010**.

FDA Details Voluntary Compliance with New Federal Menu Labeling Requirements

FDA Announces In the [July 23, 2010 Federal Register](#), FDA issued a notice giving details on how retail food establishments and vending machine operators with fewer than 20 locations can choose to become subject to the new federal menu labeling requirements. [CFSAN's Constituent Update](#) and provides additional details. Interested parties must submit electronic or written comments by **October 21, 2010**.

FSIS Policy Updates

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

- [Russia](#) (Jul 23, 2010)
- [Russia \(Poultry\) Plant List](#) (Jul 23, 2010).
- [Mexico Plant List](#) (Jul 22, 2010)
- [Russia \(Pork\) Plant List](#) (Jul 21, 2010)
- [Australia Plant List](#) (Jul 21, 2010)
- [Colombia](#) (Jul 20, 2010)
- [Colombia \(Egg Products\)](#) (Jul 20, 2010)
- [Japan \(Cold Storage Facilities\)](#) (Jul 16, 2010)
- [Russia \(Prepared Products\) Plant List](#) (Jul 16, 2010)

FSIS recently published the following new notice(s):

- [FSIS Notice 36-10](#), *Communicating with the Office of Inspector General (OIG)*
- [FSIS Notice 37-10](#), *Communicating with the Office of Inspector General (OIG)* **Note:** cancels FSIS Notice 36-10.
- [FSIS Notice 38-10](#), *Fifth Food Defense Plan Survey*

Regulatory Notices with Open Comment Periods

FSIS Announces Nominations for Membership on the National Advisory Committee on Microbiological Criteria for Foods

In the [July 8, 2010 Federal Register](#), USDA's Food Safety and Inspection Service announced it is accepting nominations for membership on the National Advisory Committee on Microbiological Criteria for Foods. Nominations, including the nominee's typed resume or curriculum vitae and a USDA Advisory Committee Membership Background Information form AD-755 must be received by **August 9, 2010**. USDA Advisory Committee Membership Background Information form AD-755 is available on-line at: <http://www.ocio.usda.gov/forms/doc/AD-755.pdf>.

FDA Seeks Comment on Proposed Information Collection on Additive Petitions

In a [June 14, 2010 Federal Register Notice](#), FDA solicited comments on the information collection provisions of FDA's regulations for submission of petitions, including food and color additive petitions (including labeling) and generally recognized as safe (GRAS) affirmations, submission of information to a Master File in support of petitions, and electronic submission using FDA Form 3503. This notice also notifies the public of and solicits comments on FDA's proposed changes to Form FDA 3503 and elimination of Form FDA 3504. Interested parties must submit electronic or written comments on the collection of information by **August 13, 2010**.

FDA Issues Advance Notice of Proposed Rulemaking to Implement 2005 SFTA

In the [April 30, 2010 Federal Register](#), FDA announced an advance notice of proposed rulemaking to implement the Sanitary Food Transportation Act of 2005. FDA is specifically requesting data and information on the food transportation industry and its practices, as well as data and information on the contamination of transported foods and associated outbreaks. The regulations would address the risks to human or animal health associated with the transportation of food. Interested parties must submit electronic or written comments by **August 30, 2010**.

USDA Announces Notice of Request for Revision of a Currently Approved Information Collection (Pathogen Reduction/HACCP)

In the [June 29, 2010 Federal Register](#), USDA announced that it is revising the Pathogen Reduction/HACCP systems information collection based on its most recent establishment data. In addition, FSIS is adding information concerning the use of video recordkeeping for HACCP records and Sanitation Standard Operating Systems (SOPs) records. Interested parties must submit comments by **August 30, 2010**.

FDA Seeks Public Input on Restaurant Menu Labeling

In the [July 7, 2010 Federal Register](#), FDA invited the public to submit comments and information to help the agency implement a new federal law that requires the posting of calorie content and other nutrition information on menu items at certain chain restaurants and similar retail food operations and vending machines. FDA has opened a docket to gather comments and information. The new law, part of health care reform, requires restaurants and chain retail food establishments with 20 or more locations to list calorie content information on menus and menu boards, including drive-through menu boards. More information is available on the web site for [Docket No. FDA-2010-N-0298](#) and on [FDA's web site](#). Written or electronic comments must be received by **September 7, 2010**.

Upcoming Meetings

FSIS, CDC, FDA to Hold Public Meetings on Measuring Food Safety Progress

Food Safety and Inspection Service (FSIS), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC), are jointly hosting two public meetings to obtain stakeholder input. The first was on July 21, 2010, in Chicago, IL. The second will be held on **October 20, 2010, in Portland, OR**. The Agencies are requesting information from all stakeholders, including the regulated food industry, State regulators, and consumer groups, on appropriate

metrics to be used to assess performance in food safety. The Agencies are also interested in input on stakeholders' understanding and perceptions of metrics currently being used by the Federal Agencies. Although the Agencies are primarily interested in obtaining stakeholder input, the Agencies will present a limited amount of background on the Food Safety Working Group's charge to create meaningful metrics to measure the effectiveness of the Nation's food safety system and the Agency's current thinking on these issues. More information is available in the [Federal Register Notice](#).

FDA to Hold Food Labeling Workshop

FDA Office of Regulatory Affairs, Southwest Regional Small Business Representative (SWR SBR) Program, in collaboration with the University of Arkansas (UA), is announcing a public Food Labeling Workshop intended to provide information about FDA food labeling regulations and other related subjects to the regulated industry, particularly small businesses and startups. The public workshop will be held on **August 4 and 5, 2010**, from 8 a.m. to 5 p.m. in Fayetteville, AR (located downtown). For additional information, see the [Federal Register Notice](#) or contact David Arvelo at david.arvelo@fda.hhs.gov.

USDA Designs Inspection Seminars for International Government Officials

USDA will host the second of three meat and poultry inspection seminars for international officials in Washington, D.C., from **August 9 – 20, 2010**. The 2-week, in-depth seminar will be in English and will focus on verification and enforcement of HACCP and pathogen reduction regulations in order to familiarize participants with U.S. inspection regulations and procedures used by USDA to ensure that the nation's meat, poultry and egg products are safe, wholesome and properly labeled. For more information and to register, visit http://www.fsis.usda.gov/news_&_events/2010_Meat_&_Poultry_Inspection_Seminars/index.asp.

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:

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