

To: Our Clients and Friends

June 14, 2010

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

Institute of Medicine and National Research Council Report Question FDA's Ability to Keep Food Safe

The [Institute of Medicine \(IOM\)](#) and the [National Research Council \(NRC\)](#) recently issued a report at the request of Congress finding that FDA "should adopt a risk-based approach to food safety and take steps to prevent foodborne illness more effectively." The report blames limited resources for FDA's inability to effectively discover and deal with potential threats to food safety and prevent outbreaks of foodborne illness. IOM and NRC call upon FDA to better use data and expertise to determine where along the food production line food is most likely to become contaminated in order to best utilize its limited resources. The report also calls on the federal government to establish a single, centralized food safety data center that can rapidly collect information and respond to food safety crises and encourages increased reliance on state and local governments.

Selenium Case Ruling May Force FDA to Change Its Health Claims Policies

In May, in a case brought by the Alliance for Natural Health, a U.S. District Court ruled that the Constitution protected dietary supplement manufacturers seeking to make qualified health claims about the benefits of selenium. FDA had previously rejected the claims on the basis that the claims did not meet the requisite scientific standards. Analysts say that the ruling will effectively lower the standards for making health claims, so long as proper disclaimer language is included. FDA has the option to appeal the ruling, but will otherwise have to issue a rule for health claims on dietary supplements that reflects the court's decision that dietary supplement companies may make claims, so long as they accurately reflect the "credible" state of science.

USDA Adopts Standards for Grades of Olive Oil

[USDA has adopted standards for olive oil](#) that will go into effect on October 25, 2010. The standards, [United States Standards for Grades of Olive Oil and Olive-Pomace Oil](#), delineate the requirements that products must meet in order to be labeled "U.S. Extra Virgin" or "U.S. Virgin" olive oil. It replaces the original standards, which have been in effect for more than 60 years. The standards describe quality requirements and serve as a basis for inspection.

Health Canada Moves Forward on Stricter Allergen Labeling Requirements

Last July, Health Canada [issued proposed new labeling requirements for food allergens, gluten, and sulphites](#) and sought public comment. In follow up, the Canadian food agency recently published updates based on the comments it received on the proposed regulations. The updates include Health Canada's [review of and answers to comments received on the enhanced food labeling requirements](#); [proposed modifications to the proposed requirements](#); and [consideration of possible exemptions from the enhanced labeling requirements](#). An [additional document more specific to sulphites](#) was also added.

EU Plans To Propose New Biotech Crops Approval Process by Summer

In the last ten years, the EU has only approved one genetically modified crop application. A proposal by [EU Health and Consumer Affairs Commissioner](#) John Dalli would allow states to opt out of crop cultivation in order to allow member states more individual choice in the GMO debate.

FDA Seizes Bulk Honey Containing a Potent Antibiotic to Protect Public Health

At the request of FDA, [federal marshals seized 64 drums of imported bee's honey from a Philadelphia distribution center](#) on June 4 because it contained a potent antibiotic that could lead to serious illness or death. Chloramphenicol is a potent antibiotic drug that is approved only for use in humans with serious infections when other less toxic drugs won't work. People who are sensitive to chloramphenicol can develop a type of bone marrow depression called aplastic anemia, which can be fatal. The FDA estimates the value of the seized goods to be more than \$32,000. U.S. Marshals executed this seizure pursuant to a warrant issued by the U.S. District Court for the Eastern District of Pennsylvania.

FDA Takes Action Against California Soy-Product Manufacturer Lifesoy

FDA recently cited Lifesoy Inc., a manufacturer of ready-to-eat soy products for preparing, packing, and holding articles of food under insanitary conditions. [The company has since entered into a consent decree of permanent injunction](#) which requires Lifesoy to stop manufacturing and distributing food products until the company registers with the FDA and complies with federal laws regarding sanitary practices. Lifesoy made sweetened and unsweetened soy milk, fried tofu, fresh tofu, soybean pudding, and other soy products.

FDA Updates Information Pages

FDA recently updated several of its information pages, including the following:

- [How is the term "organic" regulated?](#) and [Does FDA have a definition for the term "organic" on food labels?](#)
- [If a food is labeled "organic" according to the USDA, is it still subject to the laws and regulations enforced by FDA?](#)
- How to report a complaint about [restaurant food](#) and [food bought at a supermarket](#).
- [What is the meaning of 'natural' on the label of food?](#)
- [Is Stevia an 'FDA approved' sweetener?](#)

Briefly Noted

FDA posts [origins of the agency](#) and the [Federal Food, Drug, and Cosmetic Act](#) as part of *FDA Basics* series.

FSIS Has updated its [New Technology Table](#).

[FoodSafety.gov: Are Alfalfa Sprouts Safe to Eat?](#)

[HHS Secretary Kathleen Sebelius launches Let's Move cities and towns.](#)

[Temple researchers highlight the need for an interstate system to track, manage foodborne illnesses.](#)

[EFSA Requests data on lead levels in food.](#)

[Germany's Federal Environmental Agency asks companies to limit BPA usage and seek alternate materials.](#)

[USDA bans organic food inspector in China, questions organic certifications of products from China.](#)

[High fructose corn syrup sales decline in wake of criticism.](#)

Recent Recalls

[Bimbo Bakeries USA Soft White Bread](#) due to undeclared milk (June 12, 2010).

[Kroger Deluxe Paradise Ice Cream](#) due to undeclared tree nuts (June 10, 2010).

[Omega NY International Fuma Custard Pie](#) due to undeclared eggs (June 10, 2010).

[Eastern Fish frozen raw extra jumbo shrimp](#) (Made in Mexico) due to undeclared sulfites (June 4, 2010).

[Proctor & Gamble Iams canned cat food](#) due to insufficient levels of thiamine (June 9, 2010).

Recently Posted Warning Letters

FDA warned www.swinefludence.org, www.fludence.net, www.fludence.org, and [Feel Good Natural Health](#) that FDA deemed that the firms' web sites and labeling for certain products marketed those products in a manner intended to diagnose, mitigate, prevent, treat or cure the H1N1 Flu Virus in people. Because these products are not approved drugs, they are being marketed in violation of the Federal Food, Drug, and Cosmetic Act.

FDA warned [Italco Food Products](#), [American Sea Food Company, Inc.](#), and [Sivertson Fisheries, Inc.](#) that FDA inspectors found serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation.

New Regulatory Notices

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 Announces Public Meeting in Preparation for ICCR-4 Meetings

In the [June 9, 2010 Federal Register](#), FDA Announced a public meeting, *International Cooperation on Cosmetic Regulations (ICCR)—Preparation for ICCR-4 Meetings in Toronto, Canada*, to provide information and receive comments on the ICCR as well as the upcoming meetings in Toronto, Canada. The topics to be discussed are the topics for discussion at the forthcoming ICCR Steering Committee meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and expert working group meetings in Toronto, Canada the week of July 12, 2010. The meeting will be held in Rockville, MD on **July 7, 2010**.

FSIS Policy Updates

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

- [Mexico](#) (Jun 14, 2010)
- [Japan](#) (Jun 11, 2010)
- [Australia Plant List](#) (Jun 11, 2010)
- [Russia \(Pork\) Plant List](#) (Jun 11, 2010)
- [Russia](#) (Jun 8, 2010)
- [Russia \(Prepared Products\) Plant List](#) (Jun 8, 2010)

FSIS recently published new notices

- [FSIS Notice 29-10 Export Library Revisions for May 2010](#)

Regulatory Notices with Open Comment Periods

FSIS Issues Notice of Activity of CODEX Commission

In the [June 4, 2010 Federal Register](#), FSIS issued a notice to inform the public of the sanitary and phytosanitary standard-setting activities of the Codex Alimentarius Commission (Codex). This notice, which covers the time periods from June 1, 2009, to May 31, 2010, and June 1, 2010, to May 31, 2011, seeks comments on standards under consideration and recommendations for new standards.

FDA Seeks Volunteers for Pilot Program for Substances GRAS for Food for Animals

In the [June 4, 2010 Federal Register](#), FDA announced that it is seeking participants for a voluntary pilot program whereby persons submit to FDA notices of claims that a particular use of a substance in food for animals is exempt from the statutory premarket approval requirements based on the notifier's determination that such use is generally recognized as safe (GRAS). FDA intends to evaluate these notices and will inform each participant (notifier) in writing either that the notice provides a sufficient basis for the GRAS determination or that FDA has identified questions as to whether the intended use of the substance is GRAS. Interested parties may submit written requests to participate in the pilot program **beginning on June 4, 2010** (no closure date provided).

FSIS Extends Comment Period for HACCP Systems Validation Documents

In March, FSIS made 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 comment period has been extended to **June 19, 2010**. Interested parties should submit their comments to DraftValidationGuideComments@fsis.usda.gov, or mail comments to the Docket Clerk, USDA, FSIS, George Washington Carver Center, Room 2-2127, 5601 Sunnyside Ave., Beltsville, MD 20705. The agency will review comments received and decide how it will proceed with respect to the validation of HACCP systems.

FDA Requests Comments and Data to Inform Risk Profile for Pathogens in Spices

In the [April 20, 2010 Federal Register](#), FDA issued a request for comments and scientific data and information that would assist the agency in its plans to conduct a risk profile for pathogens and filth in spices. The purpose of the risk profile is to ascertain the current state of knowledge about spices contaminated with microbiological pathogens and/or filth, and the effectiveness of current and potential new interventions to reduce or prevent illnesses from contaminated spices. Interested parties must submit electronic or written comments and scientific data and information by **June 21, 2010**.

FSIS Proposing to Permit the Use of Air Inflation of Meat Carcasses and Parts

In the [May 24, 2010 Federal Register](#), USDA's Food Safety and Inspection Service (FSIS) proposed to revise the Federal meat inspection regulations to permit establishments that slaughter livestock or prepare livestock carcasses and parts to inflate carcasses and parts with air if they develop, implement, and maintain written controls to ensure that the procedure does not cause insanitary conditions or adulterate product. FSIS is proposing to require that establishments incorporate these controls into their Hazard Analysis and Critical Control Point (HACCP) plans or Sanitation standard operating procedures (Sanitation SOPs) or other prerequisite programs. In addition, FSIS is proposing to amend its regulations to remove the approved methods for inflating livestock carcasses and parts by air and to remove the requirement that establishments submit requests to FSIS for approval of air inflation procedures not listed in the regulations. Interested parties must submit comments by **June 23, 2010**.

FTC Seeks Comments on Orders to Compel Marketing Data from Food Companies

In a [May 25, 2010 Federal Register notice](#), the Federal Trade Commission (FTC) announced that it is seeking comments on a proposal to compel information from major food and beverage manufacturers, distributors, and marketers, as well as quick-service restaurant companies. The orders seek data about the companies' spending and marketing activities

targeting children and adolescents, as well as nutritional information for food and beverage products that the companies market to these consumers. Comments are due to the Commission on or before **June 24, 2010**.

FDA Announces Submission of Information Collection Activities to OMB for Review and Clearance Concerning Prior Notice of Imported Food and Cosmetics Regulations

In the May 28, 2010 Federal Register FDA announced that proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection concerns the [Registration of Food Facilities](#) and [Prior Notice of Imported Food](#) Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, as well as [Cosmetic Labeling Regulations](#). Interested parties must submit comments by **June 28, 2010** on all three matters.

FDA Seeks Comments on Proposed Information Collection on Infant Formula

In the [May 4, 2010 Federal Register](#), FDA announced that it is soliciting comments on information collection regarding the manufacture of infant formula, including infant formula labeling, quality control procedures, notification requirements, and recordkeeping. Interested parties must submit written or electronic comments by **July 6, 2010**.

USDA Publishes New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments; New Compliance Guides

In the [May 14, 2010 Federal Register](#), USDA's Food Safety and Inspection Service (FSIS) announced new performance standards for the pathogenic micro-organisms Salmonella and Campylobacter for use in young chicken and turkey slaughter establishments. The new performance standards were developed in response to a charge from the Food Safety Working Group. The Agency tentatively plans to implement these new performance standards for chilled carcasses in July 2010. The new standards are based on recent FSIS Nationwide Microbiological Baseline Data Collection Programs: The Young Chicken Survey and the Young Turkey Survey. The Agency invites comments on the new performance standards. FSIS is also announcing that it has posted on its Web site the third edition of the compliance guide for controlling Salmonella and Campylobacter in poultry and a compliance guide on pre-harvest management to reduce E. coli O157:H7 contamination in cattle. Interested parties must submit electronic or written comments by **July 13, 2010**.

FDA Transparency Task Force Publishes Draft Proposals; Seeks Comments

In the [May 21, 2010 Federal Register](#), FDA announced that, as part of the second phase of the Transparency Initiative, the FDA is announcing the availability of a report entitled "FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration." The report includes 21 draft proposals about expanding disclosure of information by the agency while maintaining confidentiality of trade secrets and individually identifiable patient information. FDA is seeking public comment on the draft proposals, as well as on which draft proposals should be given priority. Some of the draft proposals may require extensive resources to implement, and some may require changes to regulations or legislation. Interested parties must submit electronic or written comments by **July 20, 2010**.

FDA Extends Comment Period for Fresh Produce Packing and Production

In the [May 20, 2010 Federal Register](#), FDA announced that the agency is extending to July 23, 2010, the comment period for a notice that appeared in the Federal Register of [February 23, 2010](#). In that notice, FDA established a docket to obtain comments and information about current practices and conditions for the production and packing of fresh produce. The agency is extending this comment period to give interested parties additional time to provide the information requested by FDA in that notice. Interested parties must submit electronic or written comments by **July 23, 2010**.

FDA Issues Second Edition of Draft Guidance for Industry on Reportable Food Registry

In the [May 25, 2010 Federal Register](#), FDA announced the availability of a draft guidance, "Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2)." The draft guidance provides information to the industry in complying with the Reportable Food Registry

requirements prescribed by the Food and Drug Administration Amendments Act of 2007 (FDAAA). Further, the draft guidance addresses inquiries that the agency has received through its Reportable Food Registry help desk and/or by other means since the implementation of the Reportable Food Registry on September 8, 2009, and provides information on the new Safety Reporting Portal. The agency is also seeking comments from industry on the Reportable Food Registry requirements, and specifically on the issue of “transfer” as discussed in the current Edition 1, and draft Edition 2 guidance. Although you can comment on any guidance at any time, to ensure that the agency considers your comments on the draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by **July 26, 2010**.

FSIS Announces Compliance Guide for Mobile Slaughter Units

In the [May 25, 2010 Federal Register](#), USDA’s Food Safety and Inspection Service (FSIS) announced the availability of a compliance guide on mobile slaughter units. FSIS will post this compliance guide on its Significant Guidance Documents Web page http://www.fsis.usda.gov/Significant_Guidance/index.asp. FSIS encourages those who own or manage mobile slaughter units to avail themselves of this guidance document in meeting the pertinent regulatory requirements. FSIS is also soliciting comments on this compliance guide. The Agency will consider carefully all comments submitted and will revise the guide as warranted. Interested parties must submit comments by **July 26, 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 (2005 SFTA, see top news story above). FDA is specifically requesting data and information on the food transportation industry and its practices. FDA also is requesting data and information on the contamination of transported foods and any associated outbreaks. FDA is taking this action as part of its implementation of the 2005 SFTA, which requires the Secretary of HHS to issue regulations setting forth sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, receivers, and others engaged in food transport. This action is also part of a larger agency effort to focus on prevention of food safety problems throughout the food chain. 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**.

Upcoming Meetings

FDA to Host Public Meeting in Preparation for ICCR-4 Meetings

In the [June 9, 2010 Federal Register](#), FDA Announced a public meeting, *International Cooperation on Cosmetic Regulations (ICCR)—Preparation for ICCR-4 Meetings in Toronto, Canada*, to provide information and receive comments on the ICCR as well as the upcoming meetings in Toronto, Canada. The topics to be discussed are the topics for discussion at the forthcoming ICCR Steering Committee meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and expert working group meetings in Toronto, Canada the week of July 12, 2010. The meeting will be held in Rockville, MD on **July 7, 2010**.

FSIS to Host Livestock Slaughter Inspection Training Designed for State Inspectors

USDA’s FSIS is partnering with the [International Food Protection Training Institute \(IFPTI\)](#) in Battle Creek, Mich., and the [Association of Food and Drug Officials](#) to provide FSIS meat and poultry inspection training courses for state inspection personnel. This week-long session, “Livestock Slaughter Inspection Training” will be held **July 12 to 16, 2010** and is at no cost to the states. Applications should be sent directly to IFPTI and must be received by May 28. To download and submit an application, visit http://www.ifpti.org/20100712bc_distributed.pdf.

2010 Scientific Meeting of the National Antimicrobial Resistance Monitoring System

In the [April 2, 2010 Federal Register](#), FDA announced a public meeting entitled “2010 Scientific Meeting of the National Antimicrobial Resistance Monitoring System.” The meeting will discuss results from the National Antimicrobial Resistance Monitoring System (NARMS) and related antimicrobial resistance monitoring and research, including activities

in other national programs. The public meeting will be held on **July 15 and 16, 2010** in Atlanta, Georgia. Interested parties may submit written comments to the docket up to 30 days after the meeting. Additional information, including about registration, requests for oral presentations, and the meeting agenda, is available in the [Federal Register Notice](#).

USDA to Host Red Meat Mobile Slaughter Unit Information Session

USDA will host a [red meat mobile slaughter unit information session](#) on **June 24, 2010** in Boonsboro, MD. The goals of this information session are to educate farmers, ranchers and processors on how to set up mobile slaughter units, receive the federal grant of inspection and meet USDA food safety requirements. The session is being held in response to interest in USDA's efforts to support local/regional slaughter through the "Know Your Farmer, Know Your Food" initiative.

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 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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