

To: Our Clients and Friends

June 28, 2010

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

Supreme Court Rules Against Ban on GM Alfalfa

On June 21, 2010, the [Supreme Court issued its first-ever decision on genetically modified crops by overturning a court order](#) that prohibited the planting of Monsanto's pesticide resistant alfalfa seeds until an EPA environmental impact study was complete. The Court's decision was 7 to 1 in [Monsanto v. Geertson Seed Farms](#) that the lower court had abused its discretion in issuing the injunction. Justice Stevens was the sole dissenter and Justice Breyer recused himself because his brother is the District Judge of the San Francisco trial court that issued the order.

The Supreme Court, however, did not overturn the lower court's rejection of the approval, and thus USDA must approve (either partially or fully) the GM alfalfa before it can be planted. In response to the opinion, [56 members of Congress \(50 from the House and six from the Senate\) are urging USDA Secretary Tom Vilsack not to approve the crop](#). The main reason, as was the argument for the injunction in the court case, is that the crop will contaminate other, non-GM alfalfa crops through cross-pollination.

The decision is likely to affect another case pending in U.S. District Court concerning Monsanto's GM sugar beets. Although the Court allowed the planting to continue this year, the judge in that case indicated that he may block future plantings to allow for an environmental review.

Department of Transportation Considers Peanut Ban on Airplanes

Earlier in June, the [Department of Transportation issued a proposal for additional consumer protections for air travelers](#). The proposal asks for comment on several alternatives under consideration to provide greater access to air transportation for people with severe peanut allergies. Among the proposals are a complete ban of peanuts on all flights, a ban of peanuts on flights where a passenger with a peanut allergy is on board and has requested a peanut-free flight in advance, a "peanut-free buffer zone" in the immediate area of the passenger with a medically documented severe peanut allergy. The proposal has created some debate, recently reported no by [Los Angeles Times](#) and [Salon](#).

NGOs, Scientists Call On EFSA to Reduce BPA Exposure

Nineteen scientists and 41 non-governmental organizations from 15 countries sent an open letter to the European Food Safety Authority (EFSA) saying that reducing BPA exposure, especially for pregnant women and young children, is “scientifically sound and in the best interest of public health.” Environmental, health, and women’s organizations were prominent among the NGOs that signed the letter, which was authored by Professor Fredrick vom Saal, Curators Professor of Biological Sciences at the University of Missouri-Columbia. The Independent reported on the issue in an article titled [*Use of BPA must be limited, say scientists.*](#)

UK Institute Says Cut Salt and Saturated Fats in Processed Foods to Save Lives

The [UK’s National Institute for Health and Clinical Excellence \(NICE\)](#) has issued a [new guidance](#) that calls for the food industry to keep cutting the amounts of salt and saturated fats in foods. NICE said that healthier foods would save thousands of lives and spare millions of people from suffering from heart disease and stroke.

Briefly Noted

[Kraft begins marketing foods in India.](#)

[European regulators launch investigation into Monsanto’s sunflower deal with Syngenta.](#)

[Whole Foods store creates garden to help stock its produce section.](#)

[Louisiana passes law requiring strawberries to be labeled with “farm of origin.”](#)

[France bans BPA from baby bottles, but doesn’t muster votes to ban BPA in all plastics.](#)

Recent Recalls

[Pure Base Garlic Spread Concentrate and Ready-to-Spread](#) due to undeclared milk and wheat (June 25, 2010).

[Kellogg’s Corn Pops, Honey Smacks, Fruit Loops, and Apple Jacks](#) due to off-flavor/smell from package (June 25, 2010).

[Great Kitchens BBQ chicken pizza products](#) that may contain foreign materials (June 25, 2010).

[Lancaster Foods, Krisp-Pak, Giant, and America’s Choice](#) brands fresh Spinach due to listeria (June 24, 2010).

[Sampco cooked canned and frozen beef products](#) due to contamination with animal drug Ivermectin (June 24, 2010).

[Pro-Pet Adult Daily Vitamin Supplement Tablets for Dogs](#) due to possible Salmonella contamination (June 22, 2010).

[South Gate Meat ground beef products](#) due to E. coli contamination (June 22, 2010).

[Crown I Enterprises ground beef products](#) due to E. coli contamination (June 22, 2010).

[Natural Balance Sweet Potato & Chicken Dry Dog Food](#) due to potential Salmonella contamination (June 18, 2010).

[Allen Bavarian Crème Filling](#) due to undeclared allergens (June 18, 2010).

FDA Warns Consumers to Avoid [Magic Power Coffee](#), a product marketed as sexual enhancement dietary supplement, due to contamination with an active drug ingredient (June 19, 2010).

Recently Posted Warning Letters

FDA Warned [Atlee Hostetler](#) that FDA investigators found that his dairy operation 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 Warned [Lactasoy Company](#) and [Oxford Falls](#) that FDA investigators found serious deviations from the low-acid canned food regulations at their low-acid canned food facility.

FDA warned [Oxford Falls](#), [Twin Oaks Community Foods](#), [Mickey’s Snacks & Concession Supply Co.](#) that FDA found significant labeling violations that make the firms’ products misbranded. Examples of violations listed in the letters include failing to list all ingredients in the ingredient statement, failing to include required elements of the label (common name, ingredients, allergen declaration), and making claims that do not meet the requirements for doing so.

FDA Warned [CTI Science](#) that it was marketing its products as dietary supplements when they do not meet the definition of a dietary supplement.

New Regulatory Notices

FDA Announces Information Collection about Food Code Adoption

In the [June 24, 2010 Federal Register](#), FDA announced an information collection to facilitate a current, comprehensive, and accurate inventory of food code adoptions by States and U.S. territories, local, and tribal governments. Such an inventory is necessary to determine the status of up-to-date protection of the U.S. population and to identify areas where assistance to these governments may promote the adoption of regulations based on the FDA Food Code. Interested parties may submit comments by **July 26, 2010**.

FDA Announces Proposed Information Collection on Food-Contact Article Substances

In the [June 24, 2010 Federal Register](#), FDA announced a proposed collection of information on the threshold of regulation for substances used in food-contact articles. FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves. Interested parties may submit comments by **July 26, 2010**.

FSIS Policy Updates

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

- [Mexico Plant List](#) (Jun 25, 2010)
- [European Union](#) (Jun 24, 2010)
- [China, People's Republic of](#) (Jun 21, 2010)
- [Mexico Plant List](#) (Jun 21, 2010)

FSIS recently published the following new notice(s):

- [FSIS Notice 30-10](#) *Instructions for Carcass Selection for the National Residue Program Scheduled Samples*

Regulatory Notices with Open Comment Periods

USDA and HHS Solicit Comments on Dietary Guidelines Advisory Committee Report

In the [June 15, 2010 Federal Register](#), USDA and HHS announced the availability of the final Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010, requested written comments on the Report, and provided notice of a public meeting to solicit oral comments on the Report. Interested parties must submit written comments by **July 15, 2010**. The public meeting to solicit oral comments on the Report will be held on July 8, 2010 starting at 9 a.m. E.D.T. Pre-registration for the meeting is required. To register for the meeting or make a request to provide oral testimony, go to www.DietaryGuidelines.gov and click on the link for Meeting Registration or call the meeting planner, Crystal Tyler, at 202-314-4701 by 5 p.m. E.D.T., **June 30, 2010**.

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**.

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**.

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 Announces Information Collection Activities Concerning Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

In the [June 18, 2010 Federal Register](#), FDA announced that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance concerning regulations that place general requirements on persons that manufacture, blend, process, and distribute products that contain or may contain protein derived from mammalian tissue, and feeds made from such products. Interested parties must submit electronic or written comments by **July 19, 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 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 (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 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
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

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