

To: Our Clients and Friends

June 14, 2010

## Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



### Top News

#### **Dietary Guidelines Advisory Committee Report Says New Guidelines Should Focus on Fighting Obesity; USDA and HHS Solicit Public Comments**

On June 15, 2010, [USDA and HHS announced](#) that the [Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010 \(Advisory Report\)](#) is now available. More than ever before, the guidelines address issues specific to obesity. The goal of the 2010 Dietary Guidelines is to help people get the right nutrients while cutting calories. Drafted by a panel of 13 nutrition and health experts, the Advisory Report calls for a plant-based diet focused on whole grains, fruits, and vegetables with moderate amounts of meat, poultry, and eggs. The Advisory Report also calls for reduced amounts of salt, sugar, and saturated fats. [The Los Angeles Times](#) and [The New York Times](#) both published stories further discussing the proposed requirements.

Congress requires that the Dietary Guidelines be revised every five years to review and change as needed the federal definition of a healthy diet. This definition is subsequently incorporated into food labels, school nutrition programs, and anywhere else the federal government regulates or serves food. The 2010 Dietary Guidelines will not be official until the final version is published in the fall. Until then, the [2005 Dietary Guidelines](#) remain in effect.

USDA and HHS encourage individuals and organizations to view the *Advisory Report* now posted along with public comments. Written comments will be accepted from June 15, 2010 to July 15, 2010. Oral testimony may be provided at a public meeting to be held in Washington, DC, on July 8, 2010. More information is available in the [June 15, 2010 Federal Register Notice](#).

#### **FDA Issues Guidance Letters to Industry on Liquid Vitamin D, Gulf Seafood**

FDA recently issued two new industry guidances in the form of letters. A [Letter to Industry Concerning Liquid Vitamin D Dietary Supplements](#) was issued in response to FDA's concern that more vitamin D dietary supplements on the market could lead to infants receiving unsafe amounts of vitamin D and recommends safeguards to prevent this. Additionally, a [Letter to Fish and Fishery Products Industry Regarding the Gulf of Mexico Oil Spill](#) reminds fish and fishery product processors of FDA's regulations and policy concerning the food safety hazard of environmental chemical contaminants.

## FDA Deputy Commissioner for Foods Testifies on Health Effects of the BP Oil Spill

FDA Deputy Commissioner for Foods Michael Taylor testified this week before the [House Committee on Energy and Commerce, Subcommittee on Health](#) and [Senate Committee on Health, Education, Labor and Pensions](#). Substantially similar before both committees, his testimony focused on FDA's efforts to ensure the safety of food coming from the gulf area and discussed fishing area closures, surveillance and testing of seafood, the role of FDA's seafood Hazard Analysis and Critical Control Point (HACCP) programs, and the protocol for reopening fishing waters.

## NOAA, FDA Continue Ramping Up Efforts to Ensure Safety of Gulf of Mexico Seafood

FDA, and the National Oceanic and Atmospheric Administration (NOAA) [are taking additional steps to enhance inspection measures](#) designed to ensure that seafood from the Gulf of Mexico reaching America's tables is safe to eat. The federal government, led by FDA and NOAA, in conjunction with Gulf States' regulatory agencies, is taking a multi-pronged approach to ensure that seafood from Gulf waters is not contaminated by oil. The strategy includes precautionary closures, increased seafood testing inspections and a re-opening protocol. FDA also released its latest [Gulf of Mexico Oil Spill Update](#) on June 14, 2010.

## USDA Announces Proposed Rule for Fairness in the Marketing of Livestock, Poultry

On June 18, 2010, USDA announced that on June 22, 2010 USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA) will publish a proposed rule, as required by the 2008 farm bill and through existing authority under the Packers and Stockyards Act. The proposed rule would provide significant new protections for producers against unfair, fraudulent, or retaliatory practices. [USDA's press release](#) goes into greater detail.

## Briefly Noted

[FDA Publishes \*Barbecue Basics: Tips to Prevent Foodborne Illness\*.](#)

[U.S. Department of Transportation considers peanut ban on flights.](#)

[Coca-Cola CFO calls for industry collaboration in fighting soda taxes.](#)

[Soda sales increase in a down economy.](#)

[FSIS Food Defense Plan: Security Measures for Food Defense now available in four languages.](#)

## Recent Recalls

[Campbell Soup SpaghettiOs with Meatballs](#) due to possible under-processing (June 17, 2010).

[Marie Callendar's Cheesy Chicken and Rice frozen meals](#) due to salmonella contamination (June 17, 2010).

[Kent Feeds swine products](#) due to insufficient Vitamin D levels (June 17, 2010).

[Portland Shellfish Company lobster meat products](#) due to potential Listeria contamination (June 14, 2010).

[Sirob Imports Strawberry Farm Sun Dried Tomatoes](#) due to undeclared sulfites (June 11, 2010).

## Recently Posted Warning Letters

FDA warned [Saurabh Overseas](#) and [Homeopathy for 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 [Songkla Canning Public Company Limited](#) that FDA inspectors found serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation.

FDA Warned [Troyer Farms](#) and [Clearview Farms](#) that FDA investigators found that the firms 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.

## ***New Regulatory Notices***

### **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](http://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 Confirms Effective Date for Hair Coloring Color Additive Regulation Amendment**

In the [June 17, 2010 Federal Register](#), FDA confirmed the effective date of April 27, 2010, for the final rule that appeared in the Federal Register of March 26, 2010. The final rule amended the color additive regulations by increasing the permitted use level of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp.

### **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**.

## ***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](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](mailto: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**.

## **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 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](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**.

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## 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](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](mailto: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.

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## More Information

Archived issues of the Bryan Cave Food, Dietary Supplement, and Cosmetic Regulatory and Policy Bulletin are available at [www.bryancave.com](http://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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