

To: Our Clients and Friends

May 4, 2010

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



### Top News

#### **FDA Issues Advance Notice of Proposed Rulemaking Implementing Sanitary Food Transportation Act**

On April 30, 2010, FDA published an [Advance Notice of Proposed Rulemaking \(ANPRM\) on implementing the Sanitary Food Transportation Act of 2005 \(2005 SFTA\)](#). The 2005 SFTA provides broad authority to FDA to regulate the transportation of human and animal food products to protect products from food-safety hazards during transport. The ANPRM is the first step in writing federal regulations that will govern sanitary practices by shippers, motor vehicle and rail carriers, product receivers, and others involved in the transportation of food. The new rule also helps implement the [President's Food Safety Working Group recommendations](#). FDA also issued a [Guidance to Industry on the Sanitary Transportation of Food](#) and has created a page on the FDA web site dedicated to [Food Transportation](#).

#### **FDA Chief Counsel Revamping His Role – Vows to Find Creative Means to Implement Agency Policy Objectives**

FDA Chief Counsel Ralph Tyler has indicated that he is taking a new approach to his role as Chief Counsel at FDA. Noting that FDA “is entitled to a lawyer that is its advocate,” Tyler said that he intends to find creative means of working within the confines of the law to implement FDA’s policy objectives. Tyler’s philosophy, while different from his predecessors, is supported by the current agency leadership but is raising alarm with some industry attorneys who believe that Tyler’s new take on his job could lead to FDA actions that exceed the agency’s authority.

#### **FDA Investigating Dietary Supplement Vita Breath for Unsafe Lead Content**

FDA is working with state officials in New York and California to investigate Vita Breath, a dietary supplement marketed to people with asthma, after the New York City Department of Health and Mental Hygiene notified [FDA about a patient who had suffered lead poisoning after taking Vita Breath](#) and two other dietary supplement products. FDA’s analysis showed that Vita Breath had more than 10,000 times the FDA’s maximum recommended level for lead in candy. In the meantime, [FDA is advising consumers not to purchase nor consume Vita Breath](#) and has also issued a [MedWatch Alert](#) encouraging health care professionals and consumers to report adverse events.

## House Subcommittee To Hold Hearing on Role and Performance of FDA in Food Safety

The House Energy and Commerce Subcommittee on Oversight and Investigations will hold a hearing on “The Role and Performance of FDA in Ensuring Food Safety” on **May 6, 2010**, at 2:00 p.m. in room 2123 Rayburn House Office Building.

## CFSAN Director Steps Down, FDA Names Acting Director, Acting Deputy Directors

[Stephen F. Sundlof is stepping down as Director of the Center for Food Safety and Applied Nutrition \(CFSAN\)](#) to pursue a position at the Virginia-Maryland Regional College of Veterinary Medicine. Michael Landa, who has been at FDA since 1978 and most recently served as CFSAN’s Deputy Director for Regulatory Affairs will be Acting Director. Roberta Wagner and Donald Kraemer, who both have extensive experience at FDA at headquarters and in the field, will serve as Acting Deputy Directors.

## Food Safety Legislation Amendments Pick Up Cosponsor and Draw Criticism

Senator Jon Tester (D-MT) introduced amendments to the food safety legislation pending in the Senate that would exempt small farms from many of the bill’s requirements. Senator Kay Hagan (D-NC) announced last week that she would cosponsor the amendments. However, Make our Food Safe coalition do not support the amendments. In a letter to Senator Tester, the coalition noted that, regardless of size, all farms should be responsible for food safety and that the exceptions contained in the amendments are overly broad and would undercut the ultimate goal of the legislation to keep food safe.

## New Dietary Guidelines in the Works for 2010, Sodium and Sugar in the Spotlight

Every five years, USDA and HHS jointly issue new Dietary Guidelines for Americans. Due out again in 2010, the guidelines provide authoritative advice for people two years and older about how good dietary habits can promote health and reduce risk for major chronic diseases. [American Society of Nutrition \(ASN\) reports](#) that salt and sugar intake are key areas of concern and that each recommendation should consider high prevalence of obesity among Americans, desire to shift the general intake to plant-based diets, and how to change the food environment to help individuals meet the Dietary Guidelines. More information about the Dietary Guidelines is available on [USDA’s web site](#). The 2005 Dietary Guidelines remain in effect until new ones are issued to replace them.

## FDA Commissioner Speaks at 2010 Nutrition Summit

FDA Commissioner Dr. Margaret Hamburg [gave remarks at the 2010 Nutrition Summit on April 28, 2010](#). Dr. Hamburg noted that “Diet-related chronic disease, including obesity, is a defining public health issue of our time” and emphasized that collaboration between industry, government, consumers, and other stakeholders would be necessary to change the paradigm and improve nutrition to make America healthier. She also noted FDA’s commitment to providing consumers with quick information that they can understand and spoke about the front-of-package labeling initiative underway at FDA. She noted that “as of now, we have made no decisions—not even tentative or preliminary ones—about what the labeling will look like,” and asked for the continued feedback from industry and consumers about “what will work for Americans.”

## FDA Tells Public Not to Worry About Tainted Gulf Seafood “At This Time”

FDA’s web site now includes a page that updates consumers on the [food safety issues surrounding the Gulf of Mexico oil spill](#). FDA is currently working with several federal agencies and state authorities to monitor the situation and that impact on the safety of the seafood harvested from the area. As of the last update on April 30, 2010, FDA told the public that “Although crude oil has the potential to taint seafood with flavors and odors caused by exposure to hydrocarbon chemicals, the public should not be concerned about the safety of seafood in the stores at this time.”

## Walmart Will Require Suppliers to Test for Non-O157 Strains of E.Coli

E. coli O157:57 is famous for making people sick, but it is not the only strain of its kind that is dangerous to humans. Non-O157 strains of E. coli have also been responsible for foodborne illnesses. Recently, Senator Kirsten Gillibrand (D-NY) requested that USDA add six strains of non-O157 E. coli to its list of adulterants, but USDA has yet to respond to the issue. While USDA does not require meat producers to test for non-O157 strains of E. coli, Walmart will now require such testing from those who supply products to its retail stores to make the products it offers more safe for consumers.

## US and Mexico Sign Procedural Agreement to Improve Food Safety Cooperation

Last week, USDA's Food Safety and Inspection Service (FSIS) announced that the agency had reached an agreement for increased interaction and cooperation with Mexico's National Service of Health, Food Safety and Agro-Alimentary Quality (SENASICA). The "Terms of Reference" agreement focuses on matters of equivalence, audit procedures, the listing and delisting of eligible establishments for export to the two respective countries and establishing more effective means of communication in areas of public health. The goal of the agreement is to provide an opportunity for improvement of established procedures. FSIS and SENASICA worked together after developing written standard procedures by which the agencies interact on matters of food safety and public health. The full written procedural agreement is available at the [FSIS web site](#).

## EPA Proposes to Remove Saccharin from Hazardous Lists

After receiving a petition from the Calorie Control Council (CCC) to remove saccharin from the hazardous lists, EPA has proposed to do so. The CCC cited the removal of saccharin as a potential human carcinogen by the National Toxicology Program and International Agency for Research on Cancer as justification to remove saccharin and its salts from hazardous listings. More information is available on [EPA's web page discussing the issue](#).

## Director of FDA's Office of Cosmetics and Colors Goes "On The Record"

FDA's [Office of Cosmetics and Colors posted a video](#) where its director, Dr. Linda Katz, explains the role of her office in making sure that cosmetics are safe for consumers.

## Briefly Noted

[Novartis working on potential E. coli vaccine.](#)

[Pennsylvania hosts produce food safety listening session with FDA Deputy Commissioner of Foods on May 13, 2010.](#)

[Organic Trade Association: Sales of organic products outpaced sales of non-organic foods in 2009.](#)

## Recent Recalls

[Custom Corned Beef fully cooked crumbled pork sausage products](#) due to Listeria contamination (May 1, 2010).

[Murphy House Brunswick stew products](#) due to undeclared allergens (April 29, 2010).

[Havista brand "white fungus"](#) due to undeclared sulfites (April 29, 2010).

[Humei Trading Inc dried Pachyrhizus](#) due to undeclared sulfites (April 29, 2010).

## Recently Posted Warning Letters

FDA issued warning letters to [Corner View Dairies](#) and [Jeff Maida](#) (owner of a dairy) stating that FDA investigators found that the dairies offered for sale animals for slaughter as food that was adulterated due to the presence of drug residues in amounts that exceeded the amounts allowed by FDA.

FDA issued a warning letter to [La Estrellita Enterprises, Inc.](#) stating that FDA inspectors had found serious deviations from the Acidified Food regulations that rendered their acidified food adulterated.

FDA issued a warning letter to [Coats International Holdings, Inc.](#) stating that an FDA investigator had found a number of violations of Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements that cause some of the firm's products to be adulterated.

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## ***New Regulatory Notices***

### **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**.

### **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 Proposed Information Collection on Consumers' Knowledge and Behavior During Foodborne Illness Outbreaks or Food Recalls**

In the [May 4, 2010 Federal Register](#), FDA announced a proposed collection of information concerning a real-time survey of consumers knowledge and perceptions, as well as reported behavior, during foodborne illness outbreaks or food recalls, has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. Interested parties must submit written or electronic comments by **June 3, 2010**.

### **FDA Information Collection Concerning Guidance for Industry on Submitting A Notice of Intent to Slaughter for Human Food Purposes in Electronic Format**

In the [April 30, 2010 Federal Register](#), FDA announced that it has submitted a proposed collection of information concerning guidance for industry on submitting a notice of intent to slaughter for human food purposes in electronic format to the Office of Management and Budget (OMB) for review and clearance under the paper work reduction act. Interested parties must submit written or electronic comments by **June 1, 2010**.

## **FSIS Updates**

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

- [Hong Kong](#) (May 4, 2010)
- [Kuwait](#) (May 3, 2010)
- [United Arab Emirates](#) (May 3, 2010)
- [New Zealand \(Egg Products\)](#) (Apr 30, 2010)
- [Russia](#) (Apr 30, 2010)
- [Canada](#) (Apr 30, 2010)
- [Japan](#) (Apr 30, 2010)

## ***Regulatory Notices with Open Comment Periods***

### **FDA Requests Comments on Prior Notice of Imported Food Information Collection**

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

### **FDA Requests Comments on Reportable Food Registry Information Collection**

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

### **FDA Requests Comments on Cosmetics Labeling Information Collection**

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

### **FSIS Seeks Comments on New Rules to Enhance Food Safety**

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

### **FDA Announces Food Additive Petition for Animal Use of Erythromycin Thiocyanate**

In the [April 23, 2010 Federal Register](#), FDA announced that North American Bioproducts Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of erythromycin thiocyanate as an antimicrobial processing aid in fuel-ethanol fermentations with respect to its consequent presence in by-product distiller grains used as an animal feed or feed ingredient. Interested parties must submit written or electronic comments on the petitioner's environmental assessment by **May 24, 2010**.

### **FDA Reopens Comment Period on Quality Standard for Bottled Water**

On April 1, 2010, FDA reopened until June 1, 2010 the comment period for the proposed rule, published in the August 4, 1993 Federal Register, amending the quality standard for bottled water (found at 21 CFR 165.110(b)). Additional information is available in the [Federal Register Notice](#). Electronic or written objections and requests for a hearing may must be submitted by **June 1, 2010**.

### **FDA Seeks Comments on Information Collection for Firms Exporting to Countries that Require an Export Certificate as a Condition of Entry for FDA-Regulated Products**

In the [March 31, 2010 Federal Register](#), FDA issued a notice of information collection seeking comments on information collection requirements imposed on firms that intend to export to countries that require an export certificate as a condition of entry for FDA-regulated products, pharmaceuticals, biologics, and devices as indicated in the Federal Food, Drug, and Cosmetic Act as amended. Electronic or written objections and requests for a hearing may must be submitted by **June 1, 2010**.

## **FDA Issues Notice and Request for Comments on Bisphenol-A Safety Assessment**

In the [April 5, 2010 Federal Register](#), FDA announced the availability of five documents related to FDA's continuing assessment of Bisphenol A (BPA) and soliciting public comments on the four documents prepared by FDA's Center for Food Safety and Applied Nutrition (CFSAN). These documents do not represent an agency opinion or position on BPA, on which an [interim update](#) was recently provided. Rather, these documents provide perspectives and opinions that are being considered by FDA as it continues its safety assessment of BPA. This action will enable FDA to consider comments from the public in its assessment of BPA for food contact applications. Written or electronic information and comments must be submitted by **June 4, 2010**. More information is available in the [Federal Register Notice](#).

## **FDA Seeks Comments on Information Collection Provisions for Fish Processors**

In the [April 9, 2010 Federal Register](#), FDA announced a notice of information collection that also solicits comments on the information collection provisions of FDA's regulations requiring reporting and recordkeeping for processors and importers of fish and fishery products. Written or electronic information and comments must be submitted by **June 8, 2010**.

## **FDA Seeks Comments on Requests for Exemption from Food Additive Listing Regs**

In the [April 9, 2010 Federal Register](#), FDA announced a notice of information collection that also solicits comments on requests for exemption from the food additive listing regulation requirements that are submitted under part 170 (21 CFR part 170). Written or electronic information and comments must be submitted by **June 8, 2010**.

## **FDA Seeks Comments on Collection of Information on Food Code Implementation**

In the [April 14, 2010 Federal Register](#), FDA announced it is soliciting comments on the collection of information from local, State, and tribal governmental agencies concerning their adoption of, or plans to adopt, all or portions of the FDA Food Code or its equivalent by regulation, law, or ordinance. Written or electronic information and comments must be submitted by **June 14, 2010**.

## **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**.

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## **Upcoming Meetings**

### **Let's Talk: Food Safety Assessments (FSAs) and Recalls**

On **May 4**, FSIS will host a Web seminar, *Lessons Learned From FSAs and Recalls During the Fiscal Year 2010 Second Quarter*. This seminar will discuss issues concerning for-cause FSAs and class 1 recalls related to *Listeria*, *E. coli* and *Salmonella*. The meeting will be held on May 4 from 11:30 a.m. to 12:30 p.m. (ET). To participate, call (800) 857-5750, and use the passcode FSA. To join online, go to [www.mymeetings.com/nc/join.php?i=PW7154220&p=FSA&t=c](http://www.mymeetings.com/nc/join.php?i=PW7154220&p=FSA&t=c). For additional information, contact Denise Gallman at (301) 504-3346 or [netmeetingseminars@fsis.usda.gov](mailto:netmeetingseminars@fsis.usda.gov).

## USDA to Hold Meat and Poultry Inspection Seminars for International Officials

**Between May 18 and June 4, USDA will host the first of three meat and poultry inspection seminars for international officials** in Puerto Rico. The purpose of the seminars is to familiarize international government officials with U.S. inspection regulations and procedures used by USDA to assure that the nation's meat, poultry and egg products are safe, wholesome and properly labeled. This seminar will be conducted in Spanish and participation is limited. USDA has a [web page with more information and registration](#). Additional seminars will be held in August and September.

## 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 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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