

To: Our Clients and Friends

May 10, 2010

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

Food Safety Discussion Gaining Momentum

Last week, the safety of imported food was the subject of a Congressional hearing and GAO report. Additionally, FDA announced that the implementation of PREDICT (the computer program that helps customs officials conduct targeted inspections) has been postponed and the agency continues to weigh an equivalency system. In the meantime, the finance reform continues to postpone the Senate's consideration of the food safety bill, S. 510.

House Oversight and Investigations Subcommittee Holds Hearing on the Role and Performance of FDA in Ensuring Food Safety

On May 6, 2010, the House Energy and Commerce Subcommittee on Oversight and Investigations held a hearing entitled "[The Role and Performance of FDA in Ensuring Food Safety](#)." The hearing examined two reports relating to the FDA's management of international food imports (issued by [GAO](#) on the day of the hearing (see below)), and inspections of domestic food facilities (issued by the [HHS Office of Inspector General](#) in April, finding that FDA's inspection of domestic food facilities was lacking). FDA, CDC, and HHS OIG officials testified on the report findings and recommendations. Members of the subcommittee were most interested in the statutory authority FDA needs to implement the report recommendations.

GAO: FDA Could Strengthen Oversight of Imported Food

On May 6, 2010, the Government Accountability Office (GAO) published a report, "[Food Safety: FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities](#)." In the report, GAO quantified FDA's inspection efforts and identified gaps in its enforcement policies. GAO identified certain statutory authorities that could help FDA in its oversight of food safety and recommended that FDA seek these authorities from Congress in order to make food more safe. The report specifically identifies mandatory recall authority and explicit authority from Congress to issue regulations requiring preventive controls by firms producing foods that have been associated with repeated instances of serious health problems or death, such as produce.

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FDA Postpones PREDICT System

FDA was forced to suspend implementation of PREDICT, the agency's highly touted import evaluation computer program that had been successful in the pilot stage in helping customs officials target shipments for inspection. According to FDA officials, the agency's aging technology infrastructure could not support a nationwide deployment of the program, however FDA is working to resolve the issue and expects full nationwide implementation of PREDICT by 2011.

FDA Considering Equivalence System to Ensure Safety of Imported Foods

In addition to current safety measures in place to ensure the safety of imported food, FDA also continues to consider implementing an equivalence system. Such a system would allow FDA to consider inspections by foreign officials as equivalent to those conducted by FDA's inspectors. Implementing an equivalence system is challenging because it requires extensive negotiations with many different countries, however, once implemented, it would provide added assurance that imported foods meet FDA standards.

USDA Secretary Vilsack Reappoints Almaza as FSIS Administrator

Agriculture Secretary Tom Vilsack has appointed Alfred V. Almanza as the administrator of USDA's Food Safety and Inspection Service (FSIS). In his role as Administrator, Almanza will oversee the regulation of meat, poultry and processed egg products. Almanza has been in a limited term appointment as the administrator of FSIS since July 2007.

USDA Announces New Performance Standards for Salmonella And Campylobacter

USDA announced new performance standards to reduce Salmonella and Campylobacter in young chickens (broilers) and turkeys, fulfilling another key recommendation of the President's Food Safety Working Group. The new standards will help prevent tens of thousands of illnesses per year, according to USDA. USDA's Food Safety and Inspection Service (FSIS) also released a compliance guide to help the poultry industry address Salmonella and Campylobacter and a compliance guide on known practices for pre-harvest management to reduce E. coli O157:H7 contamination in cattle.

Procter and Gamble Argues to Keep Cosmetics Classification for Teeth Whiteners

In response to a citizen petition filed by the American Dental Association (ADA) asking FDA to reclassify consumer tooth whiteners as drugs, Procter & Gamble sent a letter to FDA defending the products' classification as cosmetics. ADA claims that consumer tooth whiteners could have adverse effects on professional dental work and oral health. Procter & Gamble, the maker of Crest Whitestrips, says that the ADA's concerns have already been addressed, that ADA's petition is financially motivated, that Procter & Gamble's products are extensively tested, and that teeth whiteners are appropriately classified as cosmetics.

FDA Likely to Issue New Dietary Ingredient Notification Guidance

FDA is likely to publish a New Dietary Ingredient Notification Guidance in the next several months. This kind of notification is required by the Dietary Supplement Health and Education Act (DSHEA) when a dietary supplement manufacturer wishes to market a supplement that contains a new dietary ingredient in order to give FDA information that supports the conclusion that a supplement containing the ingredient will reasonably be expected to be safe. Although FDA approval is not required, even the notification process has been confusing for dietary supplement manufacturers, who have been pressing FDA for guidance.

Rep. Kind Introduces Health Choices Act

Rep. Ron Kind (D-WI), along with several cosponsors, last week introduced The Healthy CHOICES Act (The Healthy Communities through Helping to Offer Incentives and Choices to Everyone in Society Act). It is the first legislation of its kind to bring together the grocery industry, the health care industry, and government to comprehensively fight the obesity epidemic. The bill seeks to decrease obesity by providing doctors with increased ability to diagnose and treat obesity, ensuring access to healthy foods, and bringing federal food programs in line with government nutritional guidelines.

FDA Issues Guidance for Food Manufacturers in Areas Subject to Boil-Water Advisory

In light of the recent boil-water advisory in Massachusetts the first week of May, FDA has issued [a Guidance for Industry: Use of Water by Food Manufacturers in Areas Subject to a Boil-Water Advisory](#). This guidance advises food manufacturers that once a boil-water advisory has been issued they should stop using the water subject to the advisory until the water again meets the applicable federal and state drinking water quality standards. The guidance additionally is intended to assist food manufacturers in evaluating food that already was produced with water subject to the advisory.

Briefly Noted

[USDA launches Food Safety Discovery Zone, a 40-foot interactive, traveling food safety teaching tool.](#)

[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.](#)

[FoodSafety.gov celebrates Food Allergy Awareness Week.](#)

[Oil Spill will not likely cause shortages in food supply.](#)

Recent Recalls

[Romaine Lettuce with use by date of May 12](#) due to potential E. coli contamination (May 6, 2010). ([FDA press release](#))

Vienna Beef fully cooked mini pretzel dog products due to [misbranding](#) (no USDA mark of inspection) and [lack of inspection](#) (May 6 and 7, 2010).

[Mt. Vikos Brand Manouri – Sheep & Goat’s Milk Cheese](#) due to possible Listeria contamination (May 6, 2010).

[Freshway Foods romaine lettuce](#) due to E. coli contamination (May 6, 2010).

[Boston Salads and Provisions buffalo style chicken salad products](#) that may contain foreign materials (May 5, 2010).

[Orlando Greco & Son](#) and [International Gourmet](#) Prosciutto Products due to Listeria contamination (May 4 and 5, 2010).

[Nestlé CARNATION Famous Fudge Kits](#) due to undeclared allergens (May 4, 2010).

New Regulatory Notices

FSIS Updates

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

- [European Union](#) (May 6, 2010)
- [Japan](#) (May 6, 2010)

All April 2010 Export Library revisions are consolidated in [FSIS Notice 24-10](#).

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 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**.

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 an 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 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 (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**.

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 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

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.

USDA Announces Meeting to Discuss U.S. Positions for Codex Meeting

On Tuesday, **June 8, 2010**, USDA's Office of Food Safety is sponsoring a [public meeting to provide information and receive public comments on agenda items and draft U.S. positions](#) that will be discussed at the 33rd Session of the Codex Alimentarius Commission (CAC), to be held in Geneva, Switzerland, July 5-9, 2010.

FDA Announces Food Protection Workshop

FDA's Office of Regulatory Affairs (ORA), Southwest Regional Office (SWRO), in cosponsorship with the University of Arkansas (UA) Institute of Food Science and Engineering, is announcing "Food Protection Workshop," a public workshop to provide information about food safety, food defense, the regulations authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and other related subjects to the Food Protection Plan as it relates to food establishments such as farms, manufacturers, processors, distributors, retailers, and restaurants. This public workshop will be held on **June 9 and 10, 2010**. Additional information is available in the [Federal Register Notice](#) announcing the workshop.

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.

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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