

To: Our Clients and Friends

April 29, 2010

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

FDA Seeks Comments, Information, and Data on Front-of-Pack Labeling and Shelf Tag Symbols

FDA is continuing its efforts to maximize the number of consumers who use point-of-purchase information to make nutritious choices for themselves and their families. Toward that end, [FDA announced that it is seeking public participation as it deliberates about how to enhance the usefulness to consumers](#). In addition to front-of-pack (FOP) labeling, FDA is also interested in shelf tags in retail stores. Specifically, FDA wants to know more about the extent consumers notice, use, and understand FOP labeling and shelf tags, research about the effectiveness of different FOP approaches, design and marketing strategies that can better provide point-of-purchase information to consumers, and how point-of-purchase information affects decisions by food manufacturers to reformulate products. FDA is accepting comments until July 28, 2010. Additional information is available in the [Federal Register Notice](#). FDA Commissioner Dr. Margaret Hamburg also [spoke on the issue at the 2010 Nutrition Summit](#).

FDA To Develop Regulations for Safe Transport of Food

The [Sanitary Food Transportation Act of 2005 \(SFTA\)](#) reallocated responsibility for developing regulations for the safe transport of food from being entirely within the Department of Transportation's (DOT's) jurisdiction to be shared among FDA, USDA, and DOT and directs the Secretary of HHS to develop regulations for sanitary food transportation. The law also requires FDA to develop a list of nonfood products that may be safely transported alongside food. Due to other pressing priorities and limited resources, FDA has not yet developed any regulations, however, FDA says the agency now has the time and resources and has begun the rulemaking process. Once OMB finishes its preliminary review, FDA plans to issue an Advanced Notice of Proposed Rulemaking.

FDA Issues Letter to Industry, Urges Additional Steps to Prevent Cargo Theft

On April 28, 2010, [FDA issued a letter](#) to manufacturers, wholesalers, pharmacy, device, and infant formula trade associations to: (1) increase their awareness about cargo theft and each firm's responsibility to review and strengthen security practices; (2) inform firms of the actions FDA will take when it becomes aware of a large-scale theft and of the steps firms should take; and (3) emphasize importance of notifying its supply chain and the public when thefts occur.

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.

FTC Enforcement Priorities Shift from Dietary Supplements to Conventional Foods

FTC has indicated that it will allocate more of its resources to enforcing advertising standards for conventional foods, closely scrutinizing whether these products’ claims for disease treatment or prevention are substantiated. Although FTC will continue to evaluate dietary supplement claims, the conventional foods has taken a priority for enforcement measures.

FDA Puts Teeth to Its Promise to Target Executives with Misdemeanor Charges

FDA is making good on the promise it expressed in a March 4 letter to Senator Chuck Grassley (R-IA) that FDA intends to step up prosecutions of pharmaceutical and food industry executives, primarily through “the appropriate use of misdemeanor prosecutions ... to hold responsible corporate officials accountable,” as recommended by an FDA internal committee. Dr. Hamburg’s March 4 letter corresponded with the publication of a [GAO Report](#) that criticized FDA’s Office of Criminal Investigations (OCI), saying that the division has operated with little or no oversight or accountability to FDA’s top officials. Less than two months later, FDA’s OCI is assisting in the prosecution of an Orange County man (already in prison for health care fraud) for illegally marketing dietary supplements for sexual enhancement that contained an active drug ingredient for erectile dysfunction.

Companies Promise to Cut Salt Content

Sixteen food companies, including Kraft and Starbucks, have [committed to reducing the amount of sodium in their food](#) products as a part of New York City Mayor Michael Bloomberg’s National Salt Reduction Initiative, which seeks to reduce sodium consumption by 20 percent. The news comes in the wake of an Institute of Medicine study concluding that Americans consume unhealthy amounts of sodium and calling for new government standards for sodium levels.

USADA to Produce List of Products that Contain Banned Substances

The U.S. Anti-Doping Agency (USADA) is planning to publish a list of dietary supplements that contain substances banned by the organization, which has been recognized by Congress as “the official anti-doping agency for Olympic, Pan American and Paralympic sport in the United States.” The list of products will be developed from direct testing of dietary supplements that USADA has been purchasing from various vendors and web sites.

France Recommends Systemic Labeling of BPA in Packaging

AFSSA, the French Food Safety Agency, which continues to evaluate the safety of BPA, issued a recommendation that systemic labeling should be implemented in order to let consumers know about levels of BPA present in food packaging. AFSSA explained that chemicals from food contact substances, such as packaging, can leach into the foods themselves, especially when the product is heated, and consumers should be informed. In related news, the European Food Safety Authority is expected to issue its opinion on the risks of BPA at the end of May.

New York City Board of Health to Grade Restaurants

After a public hearing and subsequent comment period, in March, the New York City Board of Health approved a measure that will give city restaurant goers more information about the cleanliness of the restaurants where they eat. The [Health Department will institute a grading system](#) that is based on the number of violations documented at the restaurant in the previous year. This summer, the health department will publish for public comment proposed rules on how the program will be implemented

USDA Taking Longer to Approve Genetically Modified Seeds

Biotech companies seeking approval for genetically modified seeds are experiencing longer than normal approval times from USDA, who must review and clear the GM seeds before they can be marketed. USDA says that the longer approval times are due to an increased number of petitions and increased comments from the public.

Briefly Noted

[Wegmans Food Markets conducts independent inquiry into BPA safety and makes certain product categories BPA-free.](#)
[Proposed Hong Kong food safety law would require U.S. government to issue health certificate for seafood exports.](#)
[Deloitte survey finds that consumers, while more aware of food safety issues, are less anxious about getting sick.](#)

Recent Recalls

[MiDAS Foods International Instant Beef Soup and Instant Beef Stroganoff sauce mixes](#) due to possible Salmonella contamination (April 27, 2010).

New Regulatory Notices

FDA Notice of Food Additive Petition for Hydrogen Peroxide in Manufacture of Whey

In the [April 28, 2010 Federal Register](#), FDA announced that Fonterra (USA) Inc. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of hydrogen peroxide in the manufacture of modified whey by the ultrafiltration method.

FSIS Updates

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

- [Azerbaijan](#) (Apr 27, 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 (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**.

Upcoming Meetings

FDA is Seeking Consumer Representatives on Advisory Committees

FDA is holding a public meeting on **April 30, 2010** for individuals and groups interested in nominating or serving as consumer representatives to FDA's advisory committees and panels. Additional information about the meeting and the criteria for selecting consumer representatives is available in the [meeting announcement](#) on FDA's web site.

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. For additional information, contact Denise Gallman at (301) 504-3346 or 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.

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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