

To: Our Clients and Friends

April 27, 2010

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

IOM Calls On FDA to Change GRAS Policy on Salt

In response to a Congressional request in 2008, The Institute of Medicine (IOM) released a report on Tuesday, April 20, 2010, [*Strategies to Reduce Sodium Intake in the United States*](#), concluding that “Americans consume unhealthy amounts of sodium in their food.” New government standards for the acceptable level of sodium are required to reduce the sodium content of foods in order to make significant progress toward reducing the risk of hypertension and major cardiovascular events for Americans. Because voluntary efforts have not succeeded thus far, the new standards should be mandatory. Specifically, the report recommended that FDA modify the amount of sodium that, when added to processed foods, is generally recognized as safe (GRAS).

[FDA issued a news release in response](#) to the report stating that “over the coming weeks, the FDA will more thoroughly review the recommendations of the IOM report and build plans for how the FDA can continue to work with other federal agencies, public health and consumer groups, and the food industry to support the reduction of sodium levels in the food supply. The Department of Health and Human Services will be establishing an interagency working group on sodium at the Department that will review options and next steps.” FDA acknowledged that some food manufacturers had already announced a commitment to reducing sodium levels in food, but that a coordinated national action would be necessary to achieve the goals of reduced sodium intake. The [Washington Post](#) also reported on the subject.

Industry Threatens to Withdraw Support for S. 510 if BPA Ban Becomes Part of Bill

Although the food safety bill currently being considered in the Senate (S.510, the House passed similar legislation last July) has garnered widespread and bipartisan backing, an amendment that would ban BPA in all food and beverage containers threatens that support. In a letter to Congress, the Grocery Manufacturers Association (GMA) and other industry groups, including the U.S. Chamber of Commerce, said they would [withdraw support for the food safety bill being considered in the Senate](#) if an amendment to ban BPA was included in the bill. Senator Dianne Feinstein (D-CA) introduced the amendment and said that she believed strongly that the “government should protect people from dangerous chemicals.” Opponents of the amendment note that BPA has been used to improve food quality and safety for more than 30 years and that Congress should not undermine FDA’s current ongoing effort to evaluate BPA’s safety.

Small Businesses Air Serious Concerns Over Pending Food Safety Legislation

More than 100 organizations representing farmers, consumers, ranchers, and local food producers [signed a letter expressing "serious concerns over the pending food safety legislation."](#) The letter asks congress to provide additional exceptions for small businesses, claiming that most of the major foodborne illness outbreaks were attributed to "industrialized food supply chains," and says that food safety should be addressed without harming "local food systems that provide an alternative for consumers."

Congressman Dingell Calls Upon Senate to Consider Food Safety Legislation Now

In an editorial published on April 20, 2010 in [Politico](#), Congressman John Dingell (D-MI) emphasized the importance of passing food safety legislation. The House passed its version of food safety legislation last summer with bipartisan report. Rep. Dingell criticized the U.S. Senate for delaying its consideration of the measure, which appears to enjoy bipartisan support in the Senate as well.

Wall Street Reform Could Make Dietary Supplement Claims More Difficult

As the Senate considers the Wall Street Reform and Consumer Protection Act, the dietary supplement industry, among others, is concerned that a provision expanding the Federal Trade Commission's (FTC's) authority by allowing the Commission to undertake formal rulemaking without congressional approval. Some have expressed fears that this could lead to FTC creating unreasonable standards that supplement firms would have to meet in order to make claims on their products. On April 22, 2010, more than 40 major trade associations sent a [letter to Senate leadership](#) calling for certain provisions to be removed.

FDA Announces Draft Revised Guidance on Transparency and Advisory Committees

On April 21, 2010, [FDA announced draft guidance that would expand transparency and disclosure when the agency grants a conflict of interest waiver](#) to permit an individual's participation at an FDA advisory committee meeting. The draft guidance, [Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers](#), would expand the information disclosed about waivers prior to committee meetings. Specifically, the FDA proposes to post online the name of the company or institution associated with the financial interest along with the type of conflict of interest. The Guidance was published in the [April 22, 2010 Federal Register](#) and FDA is requesting comments by May 5, 2010 to be considered in the soonest revision.

Concerned Groups Band Together to Call for International Standard for GM Labeling

On April 20, 2010, more than 80 consumer, farmer, environmental, ethical investing, organic food organizations and food producers and processors signed a [letter to FDA and USDA](#) officials asking that the United States change its position to support a Codex document that "simply states that countries can adopt different approaches to labeling of [Genetically Modified/Genetically Engineered] GM/GE foods, in line with existing Codex guidance." Currently the United States opposed the document, which the signatories say could pose significant problems for food producers who wish to label their products as GM/GE-free.

Supreme Court will Hear Arguments In Roundup Ready Alfalfa Ban Case

After a lower court issued a nationwide injunction on planting herbicide-resistant alfalfa pending an environmental assessment, Monsanto and its co-petitioners appealed the decision to the U.S. Supreme Court claiming that the U.S. Court of Appeals for the Ninth Circuit failed collect enough evidence to support a finding of irreparable environmental harm. Oral arguments are scheduled for next Tuesday, April 27, 2010.

House Energy and Commerce Committee To Hold Hearing On Antibiotic Resistance

In the wake of controversy over the use of antibiotics in raising animals for food, the [House Energy and Commerce Committee will hold a hearing on "Antibiotic Resistance And The Threat To Public Health"](#) on Wednesday, April 28, 2010 at 2 p.m. in room 2123 of the Rayburn House Office Building. Witnesses include Thomas Frieden, M.D., M.P.H., the director of the CDC, and Anthony Fauci, M.D., the director of the National Institute of Allergy and Infectious Diseases.

FDA Crack Down on Raw Milk Continues with Warning Letter

Last year, [FDA warned](#) that raw milk was not safe and advised consumers to avoid it. Last month, the agency issued a [press release](#) warning the public about outbreaks of campylobacteriosis associated with raw milk. On April 20, 2010, FDA issued a [warning letter to Rainbow Acres Farm](#) in Kinzers, PA stating that the firm had violated the Public Health Service Act by introducing unpasteurized milk into interstate commerce.

USDA Seeks to Eliminate Two Synthetic Additives in Organic Milk and Baby Formula

In a continuing trend of cracking down on organic foods, the Obama Administration and USDA are planning to initiate administrative procedures to remove fatty acids DHA and ARA from the list of items permitted in milk products that carry the organic seal. Although USDA says the two synthetic additives are not a risk to safety, they are not appropriate for products labeled as organic. USDA plans to issue a draft guidance that includes a grace period for reformulation, collect public comments, and then make a final decision.

Mexico Publishes New Standard for Food Labeling to Begin in 2011

On April 5, 2010, the Mexican Ministry of the Economy and the Ministry of Health, published the Mexican Official Standard (NOM) NOM-051-SCFI/SSA1-2010. The NOM lays out the new commercial and sanitary information that must be included in the labeling of all food and non-alcoholic beverages traded in the country. In order to give industry sufficient time to comply with the new regulation, the Mexican government has agreed to a January 1, 2011 implementation date. USDA [published a report](#) that summarizes the major changes.

FSIS Announces Signing Of Procedural Agreement With Mexico

USDA's Food Safety and Inspection Service (FSIS) [announced the signing of a procedural agreement with Mexico's National Service of Health, Food Safety, and Agro-Alimentary Quality \(SENASICA\)](#). The "Terms of Reference" is a documented procedure for the way in which FSIS engages with its Mexico counterpart, SENASICA. The document has been a collaborative effort between the governments of Mexico and the U.S., and represents a new level of interaction and cooperation between FSIS and SENASICA. [The full written procedural agreement is available at the FSIS web site.](#)

Canada Seeks to Modify "Made in Canada" Rules to Account for Certain Ingredients

Canada's Minister for State announced that the government would continue to consult with industry to find a compromise on the Product of Canada/Made in Canada requirements. Currently, foods that claim they are a Product of or Made in Canada must be at least 98 percent ingredients from Canada. Industry proposes an 85 percent threshold, but the government favors making an exemption for ingredients that are difficult to source in Canada.

Two Arrested for Importing Contaminated Food into the United States

FDA and Immigration and Customs Enforcement (ICE) agents [arrested two individuals](#) from Honduras in Florida for importing cheese that was contaminated with Staphylococcus aureus and cheese that had not been pasteurized.

USDA Seeks to Establish Center of Excellence for School Food Safety Research

The U.S. Department of Agriculture, Food and Nutrition Service (FNS) is seeking to establish a Center of Excellence for School Food Safety Research, subsequently to be referred to as the Center, to provide science-based support to improve the safety of foods provided through the FNS nutrition assistance programs, particularly those served in schools and child care settings. Interested parties must submit their intent to submit an application by May 7, 2010 and applications are due June 11, 2010. [Additional details are available in the formal Request for Applications.](#)

Maryland Enacts Measures to Study, Promote Nanobiotechnology

New laws recently enacted in Maryland establish a nanobiotechnology research task force to evaluate the benefits of and make recommendations to grow nanobiotechnology in Maryland.

Briefly Noted

[USDA helps consumers find farmers markets in their area.](#)

[New York State Assemblywoman Barbara Clark \(D-Queens\) introduces legislation to ban high-fructose corn syrup.](#)

[FoodSafety.gov: Getting the Big Picture on Foodborne Disease.](#)

[Soda companies change their advertising strategies to keep up with the times.](#)

[Closed airports lead to grocery shortages in Europe.](#)

[USDA Seeking public input on proposals for biofuel project loans.](#)

[USDA Highlight Efforts To Improve School Meals And Health Of Nation's Children.](#)

[Meat prices expected to increase due to demand increasing as supply declines in light of increased feed prices.](#)

[Wisconsin Governor likely to sign bill that would allow limited raw milk sales in Wisconsin.](#)

[USDA releases major report on agricultural transportation in United State – first ever of this magnitude.](#)

[Majority of California voters would support a soda tax to fight obesity.](#)

Recent Recalls

[Beltex Corporation beef trip products](#) due to possible E. coli contamination (April 21, 2010).

Recently Posted Warning Letters

FDA issued a warning letter [Rainbow Acres Farm](#) in Kinzers, PA stating that the firm had violated the Public Health Service Act by introducing unpasteurized milk into interstate commerce.

FDA warned several firms marketing dietary supplement, herbal, and personal care products, including [Super Body Care](#), [E-Holistic Health](#), [Silver Soft for Skin](#), and [Shreeji Homeo Clinic](#) that their products were being illegally marketed because their web sites offered a product for sale that is intended to diagnose, mitigate, prevent, treat (including to treat the symptoms of) or cure the H1N1 Flu Virus in people, although the products have not been approved or otherwise authorized by FDA for such use.

FDA warned [Mid South Produce Distributors, LLC](#) that an FDA inspection documented serious violations of Current Good Manufacturing Practice (CGMP) regulations and revealed that food in storage areas was adulterated.

FDA warned [7Seas LLC](#) that its dietary supplement products were misbranded and being illegally marketed for conditions that caused the products to be drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease.

FDA warned [John Yurkanin](#) that his dairy operation offered for sale an animal for slaughter that was adulterated due to being held under insanitary conditions and containing residue of drugs in excess of allowed amounts.

FDA warned [Sushi on a Roll](#) that an FDA inspection documented serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation that renders the fish or fishery products adulterated.

New Regulatory Notices

Sixth and Final Dietary Guidelines Advisory Committee Meeting

USDA and HHS announced in the [Federal Register](#) on Tuesday, April 20, 2010 that the Dietary Guidelines Advisory Committee will meet via Webinar format on May 12, 2010, from 8 a.m. to 5:30 p.m. Eastern Time. Written comments pertinent to the Dietary Guidelines for Americans must be received by 5 p.m. Eastern Time on **April 29, 2010**, to ensure transmission to the Committee prior to this meeting. Written comments on the Committee deliberation process will not be accepted after this deadline.

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 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 Updates

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

- [Kuwait](#) (Apr 21, 2010)
- [United Arab Emirates](#) (Apr 21, 2010)
- [European Union](#) (Apr 21, 2010)
- [Russia \(Pork\) Plant List](#) (Apr 21, 2010)
- [Japan](#) (Apr 21, 2010)
- [Dominican Republic](#) (Apr 20, 2010)
- [Russia](#) (Apr 20, 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 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.

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:

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