



A Broader Perspective

Bulletin

To: Our Clients and Friends

March 8, 2010

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

FDA Calls On Food Industry to Correct Labeling Violations; Issues Warning Letters to 17 Companies

On March 3, 2010, FDA Commissioner Margaret Hamburg issued an [open letter to industry](#) to serve as a reminder of the standards required for making claims on food labels. In conjunction with the [17 warning letters that were posted to the FDA's web site](#) on the same day (see below, *Recent Warning Letters*), Dr. Hamburg hoped to provide further clarification to food manufacturers about what is expected of them as they review their current labeling.

Dr. Hamburg highlighted the following labeling issues in her letter:

- Nutrient content claims that are otherwise authorized by FDA are not authorized to appear on labels for children under two.
- Claims that products are free from trans fats often must be accompanied by a statement directing consumers to the nutrition facts panel for complete nutrition information.
- Food products may not claim to treat or mitigate a disease.
- "Healthy" claims must meet the long- and well-established definition for that term.
- Juice products are not appropriately labeled as juice blends.

FDA also published a [Nutrition Initiative Questions & Answers](#) page on its web site that further explains the methods and reasoning behind the warning letters. The letter to industry and the accompanying warning letters are the latest in a trend of increased FDA enforcement of food labeling regulations, especially those regarding front-of-package (FOP) claims (including symbols), and are an indication that such regulations will become even more strict. In the letter to industry, Dr. Hamburg also mentioned that FDA is continuing its [FOP labeling initiative](#). [The New York Times](#), [The Washington Post](#), and [The Wall Street Journal](#), among other publications, reported on the issue.

FDA Survey Finds More Americans Read Information on Food Labels

According to the latest [survey of dietary habits released by FDA on March 2, 2010](#), a majority of consumers read food labels and are increasingly aware of the link between good nutrition and reducing the risk of disease. For the first time, more than half of those surveyed "often" read a label the first time they buy a product. A [summary of the 2008 findings](#), and [key findings from the 2002 and 2008 surveys](#) are available on FDA's web site.

Produce Safety Project Estimates Cost of Foodborne Illness at \$152 Billion Annually

A [new study commissioned by the Produce Safety Project at Georgetown University](#) estimates that [foodborne illness has an annual price tag of \\$152 billion in the United States](#). The study provides a [state-by-state look at the costs of foodborne illness](#). Hawaii has the highest cost per case amount at just over \$2,000 per case of foodborne illness, while California's total cost of \$18.6 billion is the highest in the country. The study was released the same week as the Make Our Food Safe Coalition held a lobbying action day on Capitol Hill, with advocates hoping that the new and astonishing figures will [help push the Senate to pass the Food Safety Bill \(S. 510\)](#). [The Wall Street Journal Health Blog](#) also reported the story.

Senator Harkin Says Food Safety Legislation Should Be On President's Desk By May

Senator Tom Harkin (D-IA), Chairman of the Senate Health, Education, Labor and Pensions Committee which unanimously approved the FDA Food Safety Modernization Act (S. 510) in November, said that if all goes well, [food safety legislation will be on the President's desk by May](#). The sister bill was passed in the House last July, but the Senate's focus on health care reform legislation has backburnered the Senate's food safety bill.

Senator McCain Withdraws Support for Dietary Supplement Bill

According to [Inside Health Policy](#) (subscription required), Senator John McCain (R-AZ), who earlier this year introduced the Dietary Supplement Safety Act (DSSA, S. 3002), has indicated that he will withdraw his support for DSSA in light of an agreement with a bipartisan group of lawmakers to include certain DSSA provisions in the food safety bill (S. 510). The dietary supplement industry had launched a campaign against DSSA, saying that the proposed legislation would create a significant and unnecessary burdens on manufactures.

GAO Issues Two Reports on FDA Activities and Oversight

GAO recently released two new reports affecting FDA. [Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal and Misconduct Investigations](#) criticizes 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. The report recommends that, to ensure compliance with investigative policies, the Secretary of Health and Human Services should instruct the Commissioner of FDA to have regular assessments of OCI's field offices conducted in accordance with its existing policy. Although dated January 29, 2010, the report was not made public until March 4, 2010. That same day, FDA sent a [letter](#) to Senator Chuck Grassley (R-IA) indicating [that FDA intends to step up prosecutions of pharmaceutical and food industry executives](#), primarily through "the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable," as recommended by an FDA internal committee. [Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe \(GRAS\)](#) recommends that the Commissioner of FDA should develop a strategy to require any company that conducts a GRAS determination to provide FDA with basic information – as defined by the agency to allow for adequate oversight – about this determination, such as the substance's identity and intended uses, and to incorporate such information into relevant agency databases and its public Web site.

California Considering Adding BPA, Acrylamide to Prop 65 Reproductive Harm Toxins

Prop 65 states that "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual" and also requires that the governor of California publish a list of all chemicals known to cause cancer or reproductive toxicity. [California's Office of Environmental Health Hazard Assessment \(OEHHA\) is considering listing BPA as a toxin](#) after Natural Resources Defense Council petitioned the office to add BPA to the list of chemicals known to cause reproductive toxicity. On a related note, acrylamide, which forms naturally when foods high in starch are cooked at high temperatures, has been on the Prop 65 list since 1990 as a known carcinogen. Now [public health officials are seeking to add acrylamide to the list of chemicals known to cause reproductive toxicity](#). OEHHA is currently seeking opinions and comments on whether these substances should be added to reproductive toxicity list.

California Prop 65 Lawsuit Filed Against Fish Oil Supplement Makers and Retailers

A non-profit organization and two individuals are [suing eight fish oil makers and retailers](#) under California's *Safe Drinking Water and Toxic Enforcement Act*, also known as Prop 65. The law suit alleges that several fish oil products fail to include PCB level warnings required by Prop 65. [Nutrition Business Journal](#) summarized the industry's response.

Reducing Salt Intake Could Save Lives, Reduce Health Care Costs

A study published by Stanford University School of Medicine and the Veterans Affairs Palo Alto Health Care System in California found that [cutting salt intake by 10 percent could prevent a significant number of heart attacks and strokes and has the potential to save the United States \\$32 billion in health care costs](#).

Warning Letter Provides Insight into Liquid Supplement Draft Guidance Enforcement

[Innovative Beverage Group](#) was recently warned by FDA that its product, "Drank" is adulterated because it contains melatonin, which is an unapproved food additive. Although Drank is marketed as a dietary supplement, the letter from FDA classified the product as a conventional food, and thus its ingredients are subject to food additive regulations. The draft guidance, put forth in December 2009, [Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods](#) seeks to ensure that manufacturers are properly classifying, labeling, and marketing liquid products. [Health News Daily](#) (subscription required) provides a more in-depth discussion of the issue.

Food Manufacturers Searching for Alternatives to BPA

[The Washington Post](#) reports that even before FDA expressed concern over the safety of BPA, food manufacturers, under pressure from consumers, began looking for alternatives to the plastic substance. However, not only are solutions proving to be elusive, but BPA is being found in foods that are supposedly being packaged in BPA-free containers, leading food manufacturers to believe that the substance may be omnipresent in the food supply and much more difficult to eliminate than originally thought.

White House Requests FY2011 Budget Amendments, Including \$8 Million More for FDA

In a [February letter to Speaker of the House Nancy Pelosi](#), the White house requested several FY 2011 budget amendments including an amendment that would increase the budget authority for FDA by \$8 million (and outlays by \$7 million) to correctly reflect the policy assumed in the FY 2011 Budget. The funds would be used to support food program activities based on section 728 of the FY 2010 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act (Public Law 111-80).

BASF Wins First EU Approval of GMO Crop In More Than 10 Years

BASF's genetically modified potato is the [first GMO crop to win approval from the European Union since 1998](#). The potatoes are designed for the starch industry (to be used in thickening agents for paper, adhesives, and textiles) and not for human consumption. [The Wall Street Journal](#) also reported the story.

Australia Rescinds Ban on Beef Imports

On March 1, 2010, [Australia announced that it would rescind its ban on beef imported from countries where cows had tested positive for bovine spongiform encephalopathy \(BSE\)](#), commonly known as mad cow disease. Countries that wish to export their meat to the region must submit an application to Food Standards Australia New Zealand (FSANZ).

Briefly Noted

[Harris Poll finds that 4 in 10 Americans have had foodborne illness in last two years, analyzes impact on food industry.](#)

[Dallas Grocery chain launches NuVal nutrition rating system in stores.](#)

[Consumers weary of new technologies such as nanotechnology, irradiation, and animal cloning.](#)

[U.S. Consumers would like to see third-party certifications for food safety on labels.](#)

[UAE will launch national surveillance system to track foodborne illnesses.](#)

[Johns Hopkins University signs deal with local Maryland government to improve biotech activity.](#)

[FDA's Most Recent Update on the Salmonella Montevideo outbreak.](#)

[FDA Warns Consumers in Puerto Rico of Harmful Bacteria in Hand Sanitizers.](#)

[CDC Issues Investigation Update on the Multistate Outbreak of Human Salmonella Montevideo Infections.](#)

[Washington State University develops new microwave sterilization process to boost shelf life, improve food safety.](#)

[Senator Gillibrand \(D-NY\) pushes for County of Origin Labeling for Dairy following more melamine-tainted milk recalls.](#)

[UK Food Standards Agency announces strategy for science and evidence to guide methodologies for next five years.](#)

Recent Recalls

[Basic Food Flavors, Inc. hydrolyzed vegetable protein \(HVP\)](#) due to Salmonella contamination. The FDA conducted an investigation at the facility after a customer of Basic Food Flavors reported finding *Salmonella* Tennessee in one production lot of HVP to the new FDA Reportable Food Registry. (March 4, 2010). The contamination was identified before any illnesses occurred and FDA is taking measures to instruct industry on how to properly deal with contaminated product. FDA also published a [consumer alert](#) on the recall. HVP is a common food additive and thus many products containing HVP are also in the process of being recalled. [Food Safety News](#) reports that the recall has expanded to 56 products. Recalls related to the contaminated HVP include:

- [Mincing Overseas Spice Company black pepper](#) (March 5, 2010).
- [McCormick & Company French Onion and Vegetable Dip Mixes, Onion Gravy Mix, and Corn Bread Stuffing](#) (March 5, 2010).
- [National Pretzel Company Honey Mustard Onion flavored pretzels](#) (March 5, 2010).
- [Delicioso, De la Casa, Rojo's and Fresh Food Concepts brand Spinach Dips](#) (March 5, 2010).
- [HERB-OX bullion products](#) (March 4, 2010).
- [Concord Foods Vegetable Dip Seasoning mix](#) (March 5, 2010).
- [Various Earth Island Follow Your Heart products](#) due to potential Salmonella contamination (March 3, 2010).
- [Homemade Gourmet Tortilla Soup Mix](#) (March 3, 2010).
- [Castella Chicken Soup Base](#) (March 2, 2010).
- [Tim's Cascade Snacks Hawaiian Kettle Style Potato Chips Sweet Maui Onion and Hawaiian Sweet Maui Onion Rings](#) (March 2, 2010).

[Estrella Family Creamery Old Apple Tree Tomme cheese](#) due to potential Listeria contamination (March 5, 2010).

[Wegmans Food You Feel Good About Medium Seafood Sauce](#) due to undeclared soy and anchovies (March 5, 2010).

[Randolph Packing Co. beef products](#) due to possible E. Coli contamination (March 2, 2010).

[OM Seafood and Oregon Oyster Farms Inc. oysters](#) due to norovirus contamination (February and March 2010)

Recent Warning Letters

On March 3, 2010, in conjunction with an open letter to industry regarding the importance of accurate claims on food labels (see above, [Top News](#)), [FDA issued warning letters to 17 food manufacturers concerning 22 of their food products.](#)

The violations cited in the warning letters include unauthorized health claims, unauthorized nutrient content claims, and the unauthorized use of terms such as "healthy" and others that have strict, regulatory definitions. FDA also published a [Nutrition Initiative Questions & Answers](#) page on its web site that further explains the methods and reasoning behind the warning letters. The companies who received warning letters have 15 business days to inform the FDA of the steps they will take to correct their labeling. Letters were issued to the following companies:

- [Pom Wonderful](#)
- [Dreyer's Ice Cream Inc.](#)
- [Sunsweet Growers Inc.](#)
- [Spectrum Organic Products, Inc.](#)
- [Pbm Products, LLC](#)
- [Redco Foods, Inc.](#)
- [First Juice](#)
- [Beech-Nut Nutrition Corporation](#)
- [Diamond Food Inc.](#)
- [Ken's Foods, Inc.](#)
- [Fleminger Inc.](#)
- [Gorton's, Inc.](#)
- [Pompeian, Inc.](#)
- [Guangzhou Yong Want Foods Ltd](#)
- [Gerber Products Co](#)
- [Schwan's Consumer Brands](#)
- [Nestle USA](#)

Regulatory Notices

FSIS Updates

FSIS issues notices and directives to protect public health. The following policy update was issued recently:

- Notice 12-10, [Export Library Revisions For February 2010](#).
- Directive 5500.2 - [Revision 4, Significant Incident Response](#).

All notices and directives are available at http://www.fsis.usda.gov/Regulations_&_Policies/index.asp.

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

- [Mexico Plant List](#) (Mar 4, 2010)
- [Costa Rica](#) (Mar 1, 2010)

FSIS Extends Comment Period on Nutrition Labeling

On Dec. 18, 2009, FSIS published a [supplemental proposed rule](#) entitled, "Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products" (<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2005-0018.pdf>). The comment period on the rule was scheduled to end on Feb. 16, 2010. In response to multiple requests, FSIS extended the comment period for 30 days, to March 18, 2010.

Upcoming Meetings

Senate Appropriations Committee To Hold Hearing on FDA's Budget

On 10 a.m. on **March 9, 2010**, the Agriculture, Rural Development, FDA and Related Agencies Subcommittee of the Senate Appropriations Committee will hold a hearing on the FY2011 Food and Drug Administration Budget. FDA Commissioner Margaret Hamburg is scheduled to testify. The hearing will be held at 192 Dirksen Senate Office Building.

FSIS to Hold Public Meeting on Product Tracing

FSIS will hold a second public meeting on product tracing to discuss and receive public input on procedures for suppliers of source material used to produce raw ground beef product that tests positive for E. coli O157:H7. The Product Tracing public meeting will be held on **March 10, 2010** from 9 a.m. to 1 p.m. in Washington, DC. For additional information and to pre-register, visit http://www.fsis.usda.gov/news_&_events/Reg_Traceability_031010/index.asp.

USDA and DOJ Host Joint Workshops to Explore Competition and Regulatory Issues

The Department of Justice and the U.S. Department of Agriculture (USDA) will host a [series of joint workshops to explore competition and regulatory issues in the agriculture industry](#) beginning on **March 12, 2010**, at the Des Moines Area Community College's FFA Enrichment Center in Ankeny, Iowa. The general public and media interested in attending the initial workshop should register at <https://go.dmacc.edu/ffa/agworkshop>.

USDA to Host Web Outreach Seminar on Sanitary Dressing Procedures

FSIS will host a Web outreach seminar on sanitary dressing procedures on **March 23, 2010** from 11:30 a.m. to 1 p.m. ET. Participants will gain insight on FSIS sanitary dressing procedures and how they are critical to reducing *E. coli* O157:H7 to undetectable levels. The discussion will also provide a better understanding of validated HACCP plans and interventions. To learn more, go to http://www.fsis.usda.gov/News_&_Events/Regulatory_Web_Seminars/index.asp.

USDA to Host 2010 Food Safety Education Conference

USDA and [NSF International](#) are hosting the 2010 Food Safety Education Conference, *Advancements in Food Safety: Trends, Tools and Technologies*, **March 23-26, 2010**, at the Hyatt Regency in Atlanta. Food safety educators and other professionals worldwide will have the opportunity to discover the latest advancements in food safety education. To register and get more information, visit <http://www.fsis.usda.gov/Atlanta2010>.

FSIS to Host Public Meeting to Draft U.S. Positions for Codex Committee Meetings

FSIS announced a public meeting to draft U.S. positions and receive comments on agenda items for discussion at the 26th session of the Codex Committee on General Principles (CCGP). The public meeting will be held **March 23, 2010** in Washington, DC. A complete agenda and documents relating to the 26th session of CCGP will be available on the Codex Alimentarius Web site at <http://www.codexalimentarius.net/current.asp>. For more information about the public meeting, contact Barbara McNiff at (202) 690-4719 or Barbara.McNiff@fsis.usda.gov. Individuals are invited to submit their comments electronically to uscodex@fsis.usda.gov. The 26th session of CCGP takes place in Paris, France April 12 - 16, 2010. Additional information is available at http://www.fsis.usda.gov/News_&_Events/NR_030110_01/index.asp.

Additionally, on **March 29, 2010**, the [USDA Office of Food Safety and FDA](#) are 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 4th Session of the Codex Committee on Contaminants in Food (CCCF). Documents related to the 4th Session of the CCCF will be accessible via the World Wide Web at the following address: <http://www.codexalimentarius.net/current.asp>. The 4th Session of the CCCF takes place in Izmir, Turkey on April 26 – 30, 2010.

FDA, FSIS, and CDC to Host Public Workshop Measuring Progress on Food Safety

On **March 30, 2010**, in Washington, DC, FDA, FSIS, and CDC will co-host "Measuring Progress on Food Safety: Current Status and Future Directions," an inter-agency workshop where officials will discuss current and potential measurements for assessing progress in food safety and associated methodological issues as well as potential improvements. For registration information and general questions regarding the workshop, contact Juanita Yates at (301) 436-1731 or juanita.yates@fda.hhs.gov. Due to limited seating, preregistration is encouraged. Attendees may register in advance before March 24 at <http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm201102.htm>.

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
Alan K. Parver	Partner	alan.parver@bryancave.com	1 202 508 6332	Washington
Steven Kent Stranne	Partner	steven.stranne@bryancave.com	1 202 508 6349	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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