

To: Our Clients and Friends

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Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

FDA Posts Update After Missing Self-Imposed November 30 Deadline to Issue BPA Safety Report

In June 2009, FDA promised to issue a report on the safety of Bisphenol A (BPA) by November 30, 2009. FDA missed the deadline, citing that more research was needed and an update would be forthcoming. On January 15, 2010, FDA posted the much anticipated update to its web site. In [Update to Bisphenol A for Use in Food Contact Applications: January 2010](#), FDA opens by saying they generally believe that BPA is safe, however they are taking reasonable steps to minimize exposure to BPA in the food supply and facilitating alternatives to replace BPA. However, FDA notes that it shares the perspective of the National Toxicity Program that recent studies provide reason for concern about the potential effects of BPA. Thus, FDA is pursuing additional studies in an attempt to better understand the effects of BPA exposure. These studies are enumerated in the update.

In addition to scientific research, FDA will also open a public docket for 60 days to allow the public an opportunity to comment and provide additional information. The docket will include the Center for Food Safety and Applied Nutrition's review of the low dose toxicity studies and recently published studies, expert reviews, and other relevant material. FDA will accept comments on these documents, other available evidence, and the agency's regulatory options. Based on the new studies and outside input, FDA will update its assessment on BPA and be prepared to take additional actions if needed. The update also includes information on FDA's interim public health recommendations, the existing regulatory framework of BPA, and FDA's collaboration with international partners.

President Obama Names Michael Taylor Deputy Commissioner of Foods

On January 13, 2010, President Obama named Michael Taylor to the new post of Deputy Commissioner of Foods. Taylor had been serving as an adviser to Margaret Hamburg on food safety issues since July, but in his new position he will be responsible for overseeing the FDA's food and nutrition programs, with a focus on implementing food safety measures, including those anticipated in the food safety legislation that Congress expects to pass this year. Taylor began his career as a staff attorney at FDA in 1976. He also ran the food safety program at the USDA, was the Vice President of Public Policy for Monsanto, and most recently had been teaching at George Washington University. [The New York Times](#) and [The Washington Post](#) both reported the story in detail.

Court Orders Firm to Pay \$2 million to FTC for Making Deceptive Weight Loss Claims on Dietary Supplements

A federal district court has ordered the marketers of an herbal tea and a diet patch to pay nearly \$2 million to the Federal Trade Commission for making deceptive claims that both products would allow users to lose weight quickly without diet or exercise. For nearly two years before the FTC complaint was filed, Bronson Partners, LLC and its officer, Martin Howard, marketed Chinese Diet Tea, telling consumers they could lose as much as six pounds a week by drinking one cup of the green tea after each meal to “neutralize the absorption of fattening foods.”

FDA Rings In New Year with Continued Food Safety Crack Downs

In the first eight days of 2010, FDA went after three firms whose facilities or food products did not meet FDA food safety standards. On January 4, 2010, FDA announced it's intentions to ask a Federal Court to shut down a New Jersey cheese manufacturer with an alleged history of operating under insanitary conditions and producing cheese contaminated with *Listeria monocytogenes*. Two days later, at the request of FDA, U.S. Marshals seized bulk restaurant food product at a food processor and warehouse in Nashville, Tennessee, because the FDA determined that the products were adulterated under the Federal Food Drug and Cosmetic Act because they may have been held under unsanitary conditions whereby they may have become contaminated with filth. The Wall Street Journal also reported on the seizure. Then on January 8, 2010, FDA filed a consent decree of permanent injunction in U.S. District Court in Maryland against Congressional Seafood. The decree allows FDA to shut down Congressional Seafood, recall its products, or take other corrective action in the event of future violations. The decree requires the defendants to pay the costs of inspections performed pursuant to the decree. Failure to abide by the agreement can lead to civil or criminal penalties.

FDA Issues Baby Food and Pet Foods Safety Alerts

FDA has issued two alerts so far in January 2010. In a rare move, on January 13, 2010, FDA issued a consumer warning for HappyTot products with defective packaging before the manufacturer issued its recall, which it did the next day. A day later, FDA issued a health warning for Merick Beef Filet Squares dog treats, which were found to contain salmonella.

FDA Launches FDA Basics, First Phase of Transparency Initiative

On January 12, 2010, FDA launched FDA Basics, unveiling the first phase of its Transparency Initiative which is designed to explain agency operations, how it makes decisions, and the drug approval process. FDA Basics includes questions and answers about the agency and the products it regulates and short video conversations with agency personnel about their work at FDA.

FSIS Has Developed New Pathogen Reduction Performance Standards for Poultry and Will Soon Issue Draft Guidance for Cattle and Poultry Slaughter Establishments

In response to certain key recommendations of the President's Food Safety Working Group to reduce the prevalence of disease-causing bacteria in poultry, USDA's Food Safety and Inspection Service (FSIS) has developed new pathogen reduction performance standards for control of Salmonella and Campylobacter bacteria in chilled carcasses at young chicken (broiler) and turkey slaughter establishments that are eligible for agency verification sampling. FSIS already had standards for *Salmonella* but not for *Campylobacter*.

USDA also announced that it will soon publish to its web site draft guidance on known practices for pre-harvest management to reduce *E. coli* O157:H7 contamination in cattle. These guidelines will focus on the prevention of *E. coli* O157:H7 through reduced fecal shedding on the farm and during live animal holding before slaughter. FSIS will also post on its web site the draft third edition of compliance guidelines for poultry slaughter. It will include additional pre-harvest recommendations for controlling *Salmonella* and *Campylobacter* in poultry. Both documents are priorities for the President's Food Safety Working Group.

New York City Health Dept. Announces Proposed Targets for Voluntary Salt Reduction

The New York City Health Department is coordinating [The National Salt Reduction Initiative](#), a nationwide effort to prevent heart attacks and strokes by reducing the amount of salt in packaged and restaurant foods. On January 11, 2010, the Health Department [unveiled its proposed targets to guide a voluntary reduction of salt levels in packaged and restaurant foods](#). In technical consultation with food industry leaders over the last year, the Initiative developed specific targets to help companies reduce the salt levels in 61 categories of packaged food and 25 classes of restaurant food (some products already meet these targets). The Health Department will solicit additional comments on the targets until February 1, 2010, and the Initiative will adopt final targets this spring.

Dairy Association Criticizes FDA for Making FOP Study Too Narrow

The [International Dairy Foods Association \(IFDA\)](#) is criticizing FDA for making its [Front-of-Packaging \(FOP\) labeling study](#) too narrow. IFDA argues that the scope of the study should also evaluate shelf tags and consumer understanding, in addition to FOP labeling and consumer purchasing decisions.

EU Sets Food Sector Priorities for Next Six Months

The Confederation of Food and Drink Industries of the EU (CIAA), a trade association of the European food and beverage industry, laid out its priorities for the next six months during which Spain has the EU Presidency. [The top priorities include competitiveness, food information, research, novel foods, and environmental sustainability](#).

Russian Bans U.S. Poultry Treated with Chlorine

On January 1, 2010, [Russia imposed a ban on all U.S. poultry that has been treated with chlorine](#). The EU has had a similar ban in effect since 1997. Virtually all U.S. poultry are cleaned with chlorine, using a process that the USA Poultry and Export Council (USAPEEC) claims leaves no detectible chlorine residue on the finished product. In spite of the bans on these products, USAPEEC says it will continue to use chlorine, citing lack of effective alternatives, although industry officials are hopeful they can resolve the issue. [Food Safety News](#) also reported on the story.

U.K. House of Lords Committee Criticizes Food Industry for Nanotechnology Secrecy

The U.K. House of Lords Science and Technology Committee issued a report, *Nanotechnologies and Food*, on January 8, 2010 that [criticized the food industry for not being more transparent about its research and development of nanotechnologies and nanomaterials](#) and warned that secrecy would encourage public backlash. The food packaging industry responded by denying allegations of secrecy and saying that the technology was not progressing as quickly slower uptake of the technology in the packaging sector

U.K. Updates Nutrition and Health Claims Guidance; Issues Herbal Viagra Warning

The [U.K. Food Standards Agency \(FSA\)](#) updated its [nutrition and health claims guidance since it was last issued in 2008](#) and is accepting comments through March 23, 2010. The updated guidance includes recommendations from health professionals, among other items.

The [U.K. Medicines and healthcare Products Regulatory Agency \(MHRA\)](#) issued a [public warning against using herbal products intended to treat erectile dysfunction](#). Many of these products have been found to be adulterated because they contain unauthorized pharmaceutical products.

Secretary Vilsack Takes a NuVal Tour through Grocery Store

[USDA Secretary Tom Vilsack](#) toured a grocery store to learn more about NuVal, a system which provides [nutritional ratings on grocery products](#). The NuVal system rates grocery products using a system of 0 – 100; products with higher scores have a higher nutritional value. This year, USDA plans to launch the Health Initiatives Program, which will provide \$20 million in grants to test projects to incentivize consumers to buy more fruits and vegetables.

Experts Call for Caffeine Labeling Standards

Because of the significant effects that caffeine can have on the body, [experts are calling upon the FDA to develop labeling standards to inform consumers about the amount of caffeine in products.](#)

Center for Science in the Public Interest Calls for Health Claims Crackdown; FTC Regional Director Warns that Increased Health Claims Enforcement Is Likely

The [Center for Science in the Public Interest \(CSPI\)](#) sent a 158-page report to the FDA that, according to CSPI's press release, "documents some of the most egregious examples of false claims, ingredient obfuscations, and other labeling shenanigans." [CSPI is urging FDA to crack down on false and misleading claims on food products.](#)

On a related note, although not in response to CSPI's report, Leonard Gordon, director of the Federal Trade Commission's northeast regional office said that [FTC is keeping a closer eye on health and nutritional claims](#) made by major food marketers. He predicted increased enforcement for claims that are unsubstantiated or otherwise not compliant with U.S. law.

New Developments in BPA Safety Debate

Choice, an [Australian consumer action group](#) asked the government to phase out BPA, even while acknowledging that the hazards of BPA are uncertain, because using the risky plastics is not necessary.

After analyzing data from the United States, [researchers from two U.K. Universities found a link between BPA and reported heart disease](#) in adults in the United States.

Briefly Noted

[The New York Times](#) reported on fitness supplements in a recent article that explored the use of such supplements to boost effectiveness of workouts, especially by younger people.

[Food Safety News](#) reports on iPhone applications that assist consumers with food safety.

[Nestle again found E. Coli in cookie dough manufactured in its Virginia facility](#), however safety measures prevented the product from entering the food supply chain. Nestle continues to take steps to resolve the issues.

[USTR, USDA Issue Joint Statement](#) on Taiwan's proposed food sanitation act amendment that would bar import of some U.S. beef products.

[USDA implemented its new crop disaster assistance program](#); producers may begin applying for SURE Program at FSA County Office.

[Tyson settled a class action law suit](#) surrounding antibiotic-free claims on its chicken for \$5 million.

[The New York Times](#) reported on the safety of beef processing methods.

[CNN](#) Reported on a study that found fecal material in soda fountains.

Recent Recalls

[Nurture HappyTot Stage 4 and HappyBaby Stage 1 and Stage 2 pouch meals](#) due to defective packaging that could potentially lead to bacteria in the product (January 13, 2010).

[Heluva Good Cold Pack Cheese Food](#) due to possible Listeria contamination (January 11, 2010).

[Adams Farm Slaughterhouse beef products](#) due to possible E. coli contamination (January 11, 2010).

[Rudolph Foods pork skin products](#) due to mislabeling and undeclared milk (January 9, 2010).

[Various Parkers Farm products](#) due to possible Listeria contamination (January 8, 2010).

[Bao Ding Seafood Boiled Horse Mackerel](#) due to possible clostridium botulinum contamination (January 7, 2010).

[Harry Langond Chocolate Pecan Caramel Stars](#) due to undeclared wheat and certified colors (January 4, 2010).

[Limeno Rico Queso duro blanco](#) due to possible salmonella contamination (January 4, 2010).

[Nutty Guys Butter Toffee Peanuts and Yogurt Covered Peanuts](#) due to insects being discovered in some of these products (December 31, 2009).

[Publix Pumpkin Pecan Streusel Pie](#) due to mislabeling and undeclared pecans (December 31, 2009).

[Janzen Farms Hazelnut Kernels](#) due to possible salmonella contamination (December 29, 2009).

[Mountain Man Nut & Fruit Co. Hazelnuts](#) due to possible salmonella contamination (December 24, 2009).

[Associated Grocers of Maine ham products](#) due to possible Listeria contamination (December 24, 2009).

[National Steak and Poultry beef products](#) due to possible E. coli contamination (December 24, 2009).

Regulatory Notices

FDA Publishes Tentative 2010 Advisory Meeting Schedule

FDA published its tentative 2010 schedule of advisory committee meetings. According to the [Federal Register notice](#), the Food Advisory Committee is slated to meet May 20 - 21.

FDA Extends Temporary Permit for Marketing Skinless and Boneless Sockeye Salmon

FDA granted Yardarm Knot Fisheries' request to extend its temporary permit to market test products designated as "skinless and boneless sockeye salmon" that deviate from the U.S. standard of identity for canned Pacific salmon. The permit is valid while FDA is considering the firm's petition to amend the standard of identity for canned Pacific salmon. The [Federal Register notice](#) provides additional details.

Upcoming Meetings

Meeting of the Codex Committee on Milk and Milk Products

The Office for Food Safety, and the Agricultural Marketing Service (AMS) of USDA are sponsoring a public meeting on January 13, 2010 to provide information and receive public comments on agenda items and draft United States positions that will be discussed at the 9th Session of the Codex Committee on Milk and Milk Products (CCMMP) of the Codex Alimentarius Commission (Codex), which will be held in Auckland, New Zealand, February 1-5, 2010. The public meeting will be held in Room 3074, South Agriculture Building, USDA in Washington, DC. Documents related to the 9th Session of the CCMMP will be accessible via the World Wide Web at the following address: <http://www.codexalimentarius.net/current.asp>. The U.S. Delegate to the 9th Session of the CCMMP, Duane R. Spomer, AMS, invites interested U.S. parties to submit their comments electronically to the following e-mail address:

Susan.Sausville@ams.usda.gov. Additional information is available in the [Federal Register Notice announcing the meeting](#).

Meeting to Discuss Agenda Items Coming Before 18th Session of Codex Committee

The USDA Office of Food Safety will hold public meeting to discuss agenda items coming before the 18th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) in Australia from March 1-5, 2010. The public meeting will be held on Tuesday, January 19, 2010, from 2 to 4 p.m. in Washington, D.C., however participants may also call in. Additional information is available on the [USDA web site](#).

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 famers 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](#).

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