

To: Our Clients and Friends

December 18, 2009

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

Nanoparticles Have Great Potential but Safety Uncertain

In what could prove to be a significant development in food packaging, a [Purdue University scientist has discovered how to use a modified corn nanoparticle to extend the shelf life of food products and preserve the health benefits](#). Nanotechnology, or the manipulation of matter at the nanoscale (molecular to micron levels, where scientists believe conventional laws of physics cease to apply), could offer great benefits to the food industry, however some are still concerned about the potential risks of nanotechnology to food safety.

[Nanotechnology](#) is currently used to kill microbes in cooking and cleaning items, to strengthen plastic food and beverage containers, and to prolong shelf life of packaged foods. Because nanotechnology is new, there are safety concerns such as whether nanoparticles in food packaging may migrate into food and whether nanoparticles may interact differently with the body or have different toxicity than their full-size analogues. [The United States and European Union recently announced their separate efforts to explore the possible health effects and other implications of nanotechnology](#).

FDA Names Ralph Tyler Chief Counsel; Deputy Commissioner For Foods Unfilled

[Maryland Insurance Commissioner Ralph Tyler will be the FDA's new Chief Counsel](#). Mr. Tyler and FDA Deputy Commissioner Dr. Joshua M. Sharfstein worked for the City of Baltimore together. While critics are skeptical of Mr. Tyler's lack of food and drug law experience, Mr. Tyler acknowledged that the new job would be a challenge, according to the [Maryland Daily Record](#). In related news [FDA Week](#) (subscription required) reports that "roughly six months since FDA stakeholders learned the agency was creating the new position of deputy commissioner for foods to oversee and coordinate its food-related efforts, ... the top slot remains vacant with practically no indication from FDA on when it might be filled."

USADA Launches Supplement Safety Now to Combat Illegal Dietary Supplements; Senators Hatch and Harkin Focus on Full Funding for DSHEA

The United States Anti-Doping Agency (USADA), in partnership with several major sports organizations, including the NFL, NBA, NHL, and MLB, launched an “effort to end the dangerous and unscrupulous practices of “rogue” manufacturers within the national supplement industry.” The [Supplement Safety Now](#) initiative will “work to eliminate the practice of selling dangerous products containing steroids and other drugs as safe and legal dietary supplements.” The Counsel for Responsible Nutrition (CRN) and Natural Products Association, [two of the largest organizations within the dietary supplements industry are supportive](#), but believe that existing laws provide an adequate framework to address the problem. This month, Senators Orren Hatch (R- UT) and Tom Harkin (D-IA) also indicated that they will re-introduce legislation that would fully implement and fund the Dietary Supplement Health and Education Act of 1994 (DSHEA).

FTC Leads Working Group for Proposed Nutritional Standards for Advertising to Kids

On December 15, 2009, the FTC hosted the “Sizing Up Food Marketing and Childhood Obesity” forum to gather industry representatives, federal regulators, consumer groups, scientific researchers, and legal scholars [to discuss issues related to food marketing to children](#), specifically current research on the impact of food advertising on children and the statutory and constitutional issues surrounding governmental regulation of food marketing. A Federal working group to address this issue was commissioned by Congress in 2008 develop proposals for how foods should be marketed to children ages 2 to 17 and includes representatives from FTC, FDA, CDC, and USDA. Proposals will be published for public comment in early 2010 and the working group’s final report to Congress is due next July. [CNN](#) and [Food Navigator](#) also reported on the issue.

UN Jumps On BPA-Review Bandwagon and Other BPA Developments

The International Food Safety Authorities Network (INFOSAN) – a collaboration of the World Health Organization (WHO) and the Food and Agricultural Organization of the United Nations (FAO), the two United Nations bodies primarily concerned with food safety – recently published an information note titled [BISPHENOL A \(BPA\) - Current state of knowledge and future actions by WHO and FAO](#). The note summarizes the controversy over BPA and announces that WHO and FAO will convene an ad hoc expert consultation to assess the safety of BPA in October 2010 (tentatively), with large support from Canada’s health agency, Health Canada. Canada recently passed a law banning BPA in baby bottles. Several countries, including the United States, France, Germany, and the United Kingdom, have also recently considered the safety of BPA.

Two other recent news stories highlight increased BPA fears. The [Milwaukee Journal Sentinel](#) reports that Linda Birnbaum, Director of the National Institute of Environmental Health Sciences (part of the U.S. National Institutes of Health) warned people, and especially pregnant women, against ingesting BPA saying that she had seen a sufficient number of BPA studies to be concerned about the chemical’s effect on health. In Europe, [The French National Institute of Agronomic Research \(INRA\) published a study](#) that found a negative reaction in rat intestines that were exposed to BPA, even at low levels.

Customs and Border Protection Opens Import Food Safety Center

The Department of Homeland Security ([DHS](#)) [announced the creation Import Safety Commercial Targeting and Analysis Center \(CTAC\)](#), a new U.S. Customs and Border Protection (CBP) facility designed to streamline and enhance federal efforts to address import safety issues. The import safety CTAC, located in Washington, D.C., is one of CBP’s six commercial targeting centers in the United States. It will specifically target shipments of imported cargo, including food, for possible safety violations. The USDA’s Food Safety and Inspection Service (FSIS) and other partnering government agencies, including FDA, the Environmental Protection Agency, and the Consumer Product Safety Commission, will provide on-site expertise at the Center.

FDA Expands International Presence with New Post in Mexico City

On December 15, 2009, [FDA announced the opening of its Mexico City Post](#), the Agency's third post in Latin America and its tenth international post in the past 13 months. Staff assigned to the FDA's Mexico City post will work with their counterparts in the Mexican government to harmonize regulations and guidance standards and to work on other collaborative initiatives. These collaborations will include, for example, information-sharing on the respective regulatory systems and joint workshops on the safety of food and medical products. Agencies in both governments also will make efforts to find opportunities for joint training on food-borne illnesses and the oversight of food traded internationally.

FDA to Update GMPs

[FDA Week](#) (subscription required) reports that FDA is "finally signaling its intent to update its more than 20-year-old food good manufacturing practices regulations after several failed attempts to move in that direction." According to the FDA's most recent regulatory agenda, the agency expects to issue a proposed rule next October.

FDA Debars Convicted Virginia Seafood Dealer from Importing Food for 20 Years

In its first-ever debarment of a food importer the [FDA has barred the president of Virginia Star Seafood Corporation of Virginia from importing food into the United States for 20 years](#). Peter Xuong Lam was also sentenced to five years in prison for his role in a conspiracy to import catfish from Vietnam for fraudulent sale to avoid paying federal import tariffs. The debarment may signal stricter enforcement efforts as it is the first time FDA has exercised its debarment authority.

Study Finds Mixing Caffeine and Alcohol Is Dangerous

Recently, FDA and state attorneys general have expressed concern about the safety of alcoholic beverages that contain caffeine. Last month, [FDA issued warning letters](#) giving manufacturers of such beverages one month to provide evidence that the products are safe. In the meantime, [a study published in Behavioral Neuroscience](#) indicates that the safety concerns surrounding mixing caffeine and alcohol may be warranted.

HHS OIG: Food Manufacturers Not Compliant with Bioterrorism Act

This month, the U.S. Dept. of Health and Human Service Office of Inspector General (OIG) published its findings on [FDA's Food Facility Registry](#). The [OIG's audit found that almost half of companies required by the Bioterrorism Act to provide food facility registration information to the FDA did not provide accurate information](#) and recommended that FDA seek more legal authority to fine violators.

Pending EU Vitamin Law Could Result in Recalls if Strictly Enforced

[An amendment to EU's supplement laws would ban the sale of all vitamins and minerals that are not explicitly listed on a new approval list](#). Strict enforcement would require products that are currently legal to be pulled from the shelves.

EFSA Reaffirms Safety of GMO Rapeseed Oil, Approves Two Food Contact Substances

At the request of the European Commission, the European Food Safety Authority ([EFSA](#)) [reevaluated the safety of GMO oilseed rape](#) and confirmed its earlier finding that the product is safe for humans, animals, and the environment. [EFSA also approved two new food contact substances.](#)

Greenpeace Palm Oil Claims Give Rise to Corporate Action

Several corporations are taking action in response to Greenpeace's report [Illegal Forst Clearance and RSPO \(Round table on Sustainable Palm Oil\): Case Study of Sinar Mas](#). The report alleges that Sinar Mas is breaking Indonesian law and undermine sustainable environmental practices by engaging in widespread deforestation and peatland clearance in Indonesia (both practices release vast amounts of carbon dioxide into the atmosphere). [Nestlé and Kraft, the world's two largest food companies, have initiated internal investigations](#) to review the allegations contained in the report and evaluate the source of their palm oil supplies. [Unilever has ceased all purchases of palm oil from Sinar Mas companies](#).

SPC Publishes Green Packaging Guidelines; Experts Consider Worldwide Standards

The Sustainable Packaging Coalition (SPC) publicly released its [version 1.0](#) of the Indicators and Metrics Framework, a list of about 60 measures for progress towards sustainable packaging. The document [seeks to offer a consistent framework against which companies can judge sustainable packaging](#). On a related note, experts from the United States, Asia, and Europe are convening in Stockholm this week for the first meeting of an International Standards Organization (ISO) special committee [to establish international criteria for reducing the carbon footprint of packaging](#).

FAO Warns that Global Food Prices are Increasing

The United Nation's Food and Agriculture Organization ([FAO](#)) reported that the "Food Basket" index reached its [highest number since September 2008](#). Higher ingredient costs generally cause prices throughout the food production process to rise and a spike in food prices can have significant consequences, but a food spike similar to the one that occurred in June 2008 is unlikely without the same confluence of market factors present at that time.

FDA Expected to Issue Sunscreen Monograph to Replace AAD Seal of Recognition

The American Association of Dermatologists ([AAD](#)) plans to phase out its [AAD Seal of Recognition program in light of the expectation that FDA will soon issue a sunscreen monograph](#). The FDA-issued monograph is expected to be similar to the stringent standards of the AAD program, and will allow the AAD to focus its efforts on other public education campaigns related to the dangers of excessive sun exposure.

Other News

[Wall Street Journal reports cereal makers to reduce the amount of sugar in children's cereals.](#)

[USA Today reports 26,500 school cafeterias lack required inspections.](#)

[USDA Announces Dairy Economic Loss Assistance Payment Program.](#)

[USDA and Dairy Producers Sign Historic Agreement to Cut Greenhouse Gas Emissions By 25% By 2020.](#)

[Missouri governor backs proposal for biotechnology incentive fund.](#)

[Food safety biggest food story of 2009.](#)

[Erema gets FDA approval to use rPET packaging for RTE frozen foods.](#)

[Chilean Scientists find that superchilling and modified atmosphere packaging can extend salmon shelf life an additional 11 days.](#)

[European Food Safety Authority and Japanese FSC Sign Food Safety Cooperation Agreement.](#)

Recent Recalls

[Kunze Farms Hazelnut Kernels](#) due to potential Salmonella contamination (December 17, 2009).

[Willamette Filbert Growers Shelled Hazelnuts](#) due to potential Salmonella contamination (December 17, 2009).

[Willamette Shelling Shelled Hazelnuts](#) due to potential Salmonella contamination (December 17, 2009).

[Health Valley Organic No Salt Added Split Pea Soup](#) due to undeclared dairy allergen (December 16, 2009).

[Simple Foods selected products containing Carob](#) due to undeclared traces of milk (December 14, 2009).

[Atlas Operations sexual enhancement dietary supplements](#) due to presence of a drug (December 11, 2009).

[Organicgirl Berries & Balsamic Salad](#) due to condiment packet with undeclared walnuts (December 10, 2009).

[Pet Carousel Beef Hoof and Pig Ear Products](#) due to possible salmonella contamination (December 9, 2009).

[Rock Creek Nut Company "Quick Fix" trail mix](#) due to undeclared milk and soy (December 7, 2009).

Regulatory Notices

FSIS Issues Supplement Proposed Rule on Nutrition Labeling

On December 18, 2009 USDA's Food Safety and Inspection Service (FSIS) issued a supplemental proposed rule that, if finalized, will amend the Federal meat and poultry products inspection regulations to require nutrition labeling of the major cuts of single-ingredient, raw meat and poultry products, unless an exemption applies. Comments are due on or before February 16, 2010. The complete Federal Register notice is available at <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2005-0018.pdf>.

Food Additive Petition Filed for vitamin D bakers yeast

FDA is announcing that Lallemand, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of vitamin D2 bakers yeast as a dual purpose nutrient supplement and leavening agent or dough relaxer in yeast-containing baked products. The Federal Register notice is available at <http://edocket.access.gpo.gov/2009/pdf/E9-29961.pdf>.

USDA Updates Export Requirements Library

The Library of Export Requirements has been updated to reflect changes in export requirements for Canada, Colombia, Hong Kong, and Kazakhstan. Complete information is available at http://www.fsis.usda.gov/Regulations_&Policies/Export_Information/index.asp.

Upcoming Meetings

USDA to Host Web Seminars For Industry H1N1 Pandemic Preparedness

FSIS will host two Web outreach seminars on Jan. 6 and 7 on industry preparation for a human influenza pandemic to assist small and very small plants. These seminars will provide plant owners and operators information about how to prepare for an influenza pandemic, how it spreads and the scope of the 2009 H1N1 pandemic. Suggestions and informational resources for personal emergency and pandemic preparation will also be provided. To register and download the presentation before the meeting, go to www.fsis.usda.gov/News_&_Events/Regulatory_Web_Seminars/index.asp.

USDA Workshops to Explore Competition and Regulatory Issues

In 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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