

To: Our Clients and Friends

April 2, 2010

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

400 Experts Meet in DC to Discuss Food Safety

On March 31, 2010, FDA, CDC, and USDA's FSIS hosted a joint public workshop, *Measuring Progress on Food Safety: Current Status and Future Directions*, in Washington, D.C. that drew 400 experts, including leaders in public health, science, the food industry, and public advocacy. [Food Safety News](#) reported extensively on the conference. In addition to the workshop materials, which will be posted to a [docket](#) at www.regulations.gov, FDA has posted [slide presentations](#) and USDA has posted [remarks given by Jerold Mande, USDA's Deputy Undersecretary for Food Safety at the workshop](#).

Wide Support for Meat Safety and Accountability Act

Last week, [Senator Jon Tester \(D-MT\)](#) introduced the [Meat Safety and Accountability Act](#), which would improve the ability to trace contaminated meat by requiring FSIS to "design and implement – using its existing budget – an initiative to trace tainted meat back to the original source of contamination," and hold "the right people accountable when something goes wrong" according to Senator Tester. Since the bill's introduction, food safety advocates and the former USDA undersecretary of food safety, Dr. Richard Raymond, have expressed strong support for the bill.

FDA Reviewing Investigation into Seafood Pricing

Weights and measures inspectors in 17 states recently found that manufacturers were erroneously calculating the weight of their frozen seafood products by wrongly including the coating of ice that protects the quality of seafood during storage and distribution ice. [FDA is "reviewing the results and determining whether FDA should take any action and, if so, what actions \[it\] should take."](#)

EFSA Publishes New Daily Intake Recommendations for Sugar, Carbs, Fats, and Water

The European Food Safety Authority ([EFSA](#)) has published the new dietary reference values (DRVs) for several [nutrients](#), including sugar, carbohydrates, fiber, fats, and water. The new amounts are in line with proposals made last year, but have also drawn criticism from scientists even though public consultations were held before confirming the new values. Updates on the DRV amounts for protein and energy, which is already in progress, and vitamins and minerals, which EFSA will start evaluating later in 2010.

EFSA International BPA Summit Yields Helpful Scientific Discussion

At the end of March, the European Food Safety Authority ([EFSA](#)) [hosted an international conference to discuss the safety of BPA](#). Twenty-five experts from 19 countries met to discuss EFSA's draft opinion on BPA safety and to attempt to reach an agreement about how . The head of EFSA's food contact panel said the discussion was "very useful."

FDA Seeks Permanent Injunction Against Texas Egg Roll Manufacturer

FDA [is seeking a permanent injunction against Chung's Products LP and two of the firms top officials](#). The complaint, filed in the U.S. District Court for the Southern District of Texas, charges the defendants with violating the Federal Food, Drug, and Cosmetic Act (the "Act") by preparing, packing and holding shrimp egg rolls under insanitary conditions, whereby they may have become contaminated with filth and rendered injurious to health. The complaint concerns Chung's fish and fishery products. It does not include Chung's other food products. The shrimp egg rolls produced by Chung's are sold in grocery stores and large retail stores nationwide.

Science Board to FDA Posts Materials from February 22 Meeting

FDA recently posted to [its Advisory Committee Materials](#) web page, documents from the Science Board to FDA meeting that took place on February 22, 2010. The materials included the [final agenda](#), [final meeting roster](#), [meeting minutes](#), and a [transcript](#).

GAO Says Opportunities Exist to Better Address Management Challenges

GAO was asked to review FDA's strategic planning and management. In a report titled [Food and Drug Administration: Opportunities Exist to Better Address Management Challenges](#) and recently posted to GAO's web site, GAO found that "overall, while FDA is aware of its challenges and has taken steps to address them, the agency does not fully use practices for effective strategic planning and management." The report identifies five major management challenges that could effect FDA's ability to carry out its mission.

New Mexico Governor Vetoes Proposed Tax on Food

The New Mexico state legislature recently passed a tax on food that would provide \$68 million in revenues to help balance the state's budget in the coming year, however [Governor Bill Richardson vetoed the bill](#), citing that the tax was regressive and would hurt poor families.

Briefly Noted

[USDA Releases 2010 Benchmark State Yields and Actual 2009 State Yields.](#)

[GMA CEO editorializes on food manufacturers response to the call for healthier foods in USA Today.](#)

[American Veterinary Medical Association lobbies against antibiotics ban.](#)

[Court rules against meat industry and in favor of California law banning sale of "downer" cows and pigs.](#)

[Daniele International sues pepper suppliers for providing pepper that contaminated firm's RTE salami products.](#)

[Scientists develop two-in-one E. coli detection tests.](#)

[British Food Associations Publish Guidance on the Shelf Life of Ready-to-Eat Products.](#)

[Health Canada allows caffeine as an additive in all carbonated beverages.](#)

[France warns that manufacturers should be cautious in using nanotechnology.](#)

Recent Recalls

Recalls related to the recall of black pepper due to potential salmonella contamination include:

- [Binell Bros. Black Ground Pepper](#) (March 30, 2010).
- [Bass Pro Shops' Uncle Buck's Beer Batter Mix Lightly-Seasoned](#) (March 18, 2010).

Recalls related to the recall of Hydrolyzed Vegetable Protein (HVP) include:

- [Watkins Crab Snack Dip & Seasoning](#) (March 31, 2010).
- [Tom's Barbeque Potato Chips](#) (March 29, 2010).

Additional recalls include:

- [Zatarain's Original Dirty Rice Mix](#) due to undeclared wheat and barley ingredients (April 1, 2010).
- [Masxtreme Capsules \(Dietary Supplement\)](#) due to undeclared ingredient and drug (March 30, 2010).
- [Glutino Raisin Bread](#) due to undeclared egg product (April 1, 2010).

eFoodAlert.com has compiled a complete list of the many products recalled due to [contaminated HVP](#) and [contaminated pepper](#) (which led to the Salmonella Montevideo outbreak).

Regulatory Notices

FDA Issues Final Rule Revising Organization and Conforming Changes to Regulations

In the [April 1, 2010 Federal Register](#), FDA issued a final rule that is effective April 1, 2010 to amend the regulations to reflect organization change in the agency and to make other conforming changes. The rule is editorial in nature and is intended to improve the accuracy of the agency's regulations.

FSIS Updates

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

- [Taiwan](#) (Apr 1, 2010)
- [European Union](#) (Mar 31, 2010)
- [Mexico Plant List](#) (Mar 30, 2010)
- [China, People's Republic of](#) (Mar 29, 2010)

FDA Amends Color Additive Regulations

On [March 26, 2010, FDA amended the color additive regulations](#) to increase the permitted use level of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp. This action is in response to a petition filed by Combe, Inc. and effective April 27, 2010. Electronic or written objections and requests for a hearing may must be submitted by **April 26, 2010**.

FDA Transparency Task Force Requests Comments

FDA is soliciting comments from interested persons on ways in which FDA can increase transparency between FDA and regulated industry. In addition to the [Federal Register Notice](#), FDA also issued a [press release on the subject](#). Interested parties must submit electronic or written comments **by April 12, 2010**.

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 control plans, that is, its 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**.

Upcoming Meetings

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

FSIS announced a [public meeting to provide information and receive public comments on agenda items and draft United States positions that will be discussed at the 38th Session of the Codex Committee on Food Labeling \(CCFL\)](#). The public meeting will be held **April 7, 2010** in Washington, DC. A complete agenda and documents relating to the 38th session of CCFL will be available on the Codex Alimentarius Web site at <http://www.codexalimentarius.net/current.asp>. Individuals are invited to submit their comments electronically to Ritu.Nalubola@fda.hhs.gov. The 38th session of CCFL takes place in Quebec City, Canada May 3 - 7, 2010. Additional information is available in the [Federal Register Notice](#) announcing the meeting.

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. All interested persons, regardless of whether they can attend, may submit written comments to the docket, which will remain open for 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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