

To: Our Clients and Friends

February 5, 2010

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

FDA Launches Program to Improve Safety of Imports

This week, [FDA Commissioner Margaret A. Hamburg announced a new FDA program to help assure the safety and quality of imported goods](#). The PREDICT (Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting) Program, an automated system that will allow FDA to monitor products at the port of entry, to more reliably identify the most likely sources of contaminated food and drugs in foreign shipments, and to target for inspection those shipments posing the greatest risk.

[Speaking at the Center for Strategic and International Studies](#), Dr. Hamburg said that FDA expects nearly 20 million shipments of food, devices, drugs, and cosmetics to arrive at U.S. ports of entry in 2010 (compared to 6 million ten years ago). About 15 to 20 percent of all food now consumed in the U.S. originates outside our borders, including an estimated 70 percent of seafood and 35 percent of fresh produce. In addition to significant growth in the volume of imports and foreign facilities, there has also been an increase in the variety and complexity of imported products, and a large expansion in the number of countries involved in producing these products. Simultaneously, the supply chain has become more complex. All of these factors have made oversight significantly more difficult.

Acknowledging that it was impossible for FDA to inspect all foreign facilities, Dr. Hamburg outlined FDA's strategy for improving the safety of imported food and other FDA-regulated products, which includes: seeking better point-of-production controls, holding importing companies responsible for their supply chain, and deploying the agency's resources as strategically as possible. The PREDICT Program in particular will further the third element of the strategy and is expected to be implemented nationwide during 2010.

2011 Budget Request Includes \$7 million Funds for FDA Nanotechnology Initiative

[FDA Week](#) (subscription required) reports that President Obama's FY2011 budget calls for \$7 million in FDA funds for a nanotechnology initiative. The proposal would task FDA with categorizing nanotechnology products, design a system to assess safety and efficacy of these products, and study nanoscale materials in biological systems and their effects on human health. The initiative would also focus on laboratory capacity, training, and collaborative research, all three of which were identified as priority areas by the FDA Nanotechnology task force in 2007. Nanotechnology legislation was introduced in the Senate earlier this year. Some of the programs between the budget proposal and legislation overlap.

Dietary Supplement Industry Criticizes FDA's Latest Guidance

In December, FDA issued Draft Guidance for Liquid Dietary Supplements titled [Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods](#). To be considered before FDA begins work on the final guidance, comments are due this month. Several industry stakeholders have used the opportunity to express concern that the guidance is confusing and conflicts with FDA's 1997 final rule that says supplements "may be similar to conventional foods in composition and form."

President's Budget Calls for \$400 Million for Food Stores

President Obama's budget proposal called for [more than \\$400 million to invest in food stores](#), including new and expanded supermarkets and farmers' markets. The investment would be split among USDA, HHS, and the Treasury Department and would include tax credits and a public/private grant program.

FSIS Announces Poultry Study

In a [Notice issued on January 27, 2010](#), USDA's Food Safety Inspection Service (FSIS) announced that it would be [conducting a nationwide raw chicken parts microbiological baseline data collection program](#). The program will collect rinses of raw chicken parts at certain establishments and study the levels of specific foodborne pathogens and microorganisms.

USDA Announces Food Safety Initiatives

Agriculture Secretary Tom Vilsack [announced several new initiatives to assure the safety and quality of food purchased by USDA for the National School Lunch Program and other food and nutrition assistance programs](#). The initiatives are a combined effort of the Agricultural Marketing Service (AMS), the Agricultural Research Service (ARS), the Food Safety and Inspection Service (FSIS), the Farm Service Agency (FSA) and the Food and Nutrition Service (FNS). The initiatives include food safety purchasing requirements, increased sharing to better monitor vendor performance and identify food safety issues, and establish a Center of Excellence devoted to research on school food safety issues in FNS child nutrition programs, among other initiatives. [USA Today](#) also reported the story.

USDA Announces New Framework for Animal Disease Traceability

USDA [announced that USDA will develop a new, flexible framework for animal disease traceability in the United States](#), and undertake several other actions to further strengthen its disease prevention and response capabilities. The framework, announced on February 5, 2010 at the National Association of State Departments of Agriculture (NASDA) Mid-Year meeting, provides the basic tenets of an improved animal disease traceability capability in the United States. USDA's efforts will: (1) Only apply to animals moved in interstate commerce; (2) Be administered by the States and Tribal Nations to provide more flexibility; (3) Encourage the use of lower-cost technology; and (4) Be implemented transparently through federal regulations and the full rulemaking process.

U.S. Marshalls Seize more than 1,500 Cases of Food from Wisconsin Facility

At the request of the U.S. Food and Drug Administration, [U.S. Marshalls on Tuesday seized a wide range of human and animal food products stored under insanitary conditions](#) (and thus adulterated under the Federal Food, Drug, and Cosmetic Act) at Mid-States Closeouts, a distribution warehouse in Ellsworth, Wisconsin. During an FDA inspection, the agency found widespread and active rodent infestation, among other evidence of insanitary conditions.

Briefly Noted

[FDA grants GRAS status to zero-calorie fruit-based sweetener.](#)

[Salt-reduction initiatives taking place in all EU member states.](#)

[Kellogg announces salt-reductions in cereals, calls for industry to follow.](#)

[German Federal Institute for Risk Assessment issues 14-page statement calling for ban on energy shots.](#)

[Seventy-four percent of Cadbury shareholders vote to accept Kraft's purchase offer.](#)

[HHS Awards \\$119 million in grants to states and territories for public health efforts, including those to improve nutrition.](#)

[USDA FSIS issues news release on how to prevent foodborne illness at a Super Bowl party.](#)

[USDA will release new 10-year agricultural projections on February 11, 2010.](#)

USDA names members to the [National Mango Board](#) and [Hass Avocado Board](#).

[USDA releases study on the economic impacts of the nationwide salmonella outbreak.](#)

Recent Recalls

[Murphy House Pork Barbeque Products](#) due to undeclared allergen (February 5, 2010).

[Daniele International again expands its recall of meat products](#) due to Salmonella poisoning (February 4, 2010). The recall release was updated on February 4, 2010 to include two additional products. The additional products are separate from those listed on the [January 31 expansion](#). FDA [issued an updated statement](#) about its investigation in collaboration with USDA and the Centers for Disease Control and Prevention. [Foodsafety.gov](#) also posted information on how to avoid serving recalled food products at Super Bowl parties. [Food Safety News](#) has also been following the story in more detail.

[Cousins Spinach Vinaigrette \(16 oz. Jars\)](#) due to undeclared allergens (February 4, 2010).

[Haifa Smoked Fish Whole Schmaltz Herring](#) due to evisceration (February 3, 2010).

[Pierino Frozen Foods Jumbo Shells With Cheese](#) due to undeclared eggs (February 3, 2010).

Regulatory Notices

FSIS Updates

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

- Directive 9500.3, *Label Verification Procedure of Imported Products*
- Directive 7120.1 Revision 1, *Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products*

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

FDA Confirms Effective Dates for Color Additive Rules

In the [February 5, 2010 Federal Register](#), FDA confirmed two effective dates:

- December 8, 2009 as the effective date for a final rule published on November 5, 2009 that amended the color additive regulations to provide for the safe use of astaxanthin dimethyldisuccinate as a color additive in the feed of salmonid fish to enhance the color of their flesh. Interested parties had until December 7, 2009 to file objections; FDA received none.
- December 17, 2009 as the effective date for a final rule published on November 16, 2009 that amended the color additive regulations to provide for the safe use of paracoccus pigment as a color additive in the feed of salmonid fish to enhance the color of their flesh. Interested parties had until December 16, 2009 to file objections; FDA received none.

FDA Soliciting Comments on Guidance for Industry on How to Submit A Notice of Intent to Slaughter for Human Food Purposes in Electronic Format to CVM

In the February 5, 2010 Federal Register, FDA issued a [notice to solicit comments on the reporting requirements](#) for the information collection on how to submit a notice of intent to slaughter for human food purposes in electronic format to the Center for Veterinary Medicine (CVM). Written or electronic comments are due on April 6, 2010.

Upcoming Meetings

Public Meeting To Address Agenda Items for the a 42nd Session of the Codex Committee on Food Additives

FDA and USDA will hold a public meeting on **February 8, 2010** to discuss information and receive public comments on agenda items and draft U.S. positions that will be discussed at the 42nd Session of the Codex Committee on Food Additives (in China, March 15 – 19, 2010). Registration encouraged by February 4, 2010. Additional information is available in the [news release announcing the meeting](#). Additional Public meetings concerning the Codex are posted on [USDA's web site](#).

USDA Opens Registration for USDA Agricultural Outlook Forum 2010

The 2010 USDA Agriculture Outlook Forum will be held **February 18-19, 2010** in Arlington, Virginia. Since 1923, USDA has hosted the Agricultural Outlook Forum to promote an "intelligent balance of production, marketing and consumption of farm products for the greatest good of the entire Nation." Each year, members from farm organizations, food and fiber firms, academia, foreign governments and news media gather for discussions of the coming year in agriculture. This year's theme, "Sustainable Agriculture: The Key to Health and Prosperity," will focus on topics including organics, conservation, climate change and food safety and defense.

FSIS will host a breakout session at the Forum, called "Strengthening America's Food Safety System." Panelists will include FSIS Administrator Al Almanza, as well as industry and consumer group leaders. The FSIS session will take place on Friday, **February 19**, from 10:00 a.m. to 11:30 a.m.

For more information or to register for the Forum, visit www.usda.gov/oce/forum. The last day to register is February 16.

USDA to Host Web Outreach Seminar on Sanitary Dressing Procedures

FSIS will host a Web outreach seminar on sanitary dressing procedures on **February 18, 2010**. 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.

Meeting of the Science Board to FDA

On **February 22, 2010**, the Science Board will hear about and discuss an interim report from its subcommittee reviewing research at the Center for Food Safety and Applied Nutrition (CFSAN). The Science Board will also hear about and discuss plans to establish another subcommittee to review research programs at the Center for Drug Evaluation and Research (CDER). The Science Board will then hear and discuss updates on science programs at the Office of Regulatory Affairs (ORA) and the National Center for Toxicological Research (NCTR). The meeting will be held in Bethesda, MD. The notice was published in the [January 27 Federal Register](#) and additional information is available in the [Meeting Announcement is posted on the FDA web site](#).

U.K. Food Standards Agency to hold 10th Anniversary Conference

The U.K. Food Standards Agency (FSA) recently published its [strategy for 2010 - 2015](#). **On February 24, 2010**, FSA presents *FSA10: Ensuring safe food and healthy eating for all* in London. FSA invites consumers and stakeholders from the U.K. to participate and help shape the agency's work in the context of its strategic plan for the next five years. The conference will also be broadcast live from the FSA web site. Additional information is available at <http://www.glasgows.co.uk/fsa10/>.

FDA Risk Communication Advisory Meeting

On February 25 and 26, 2010, the FDA Risk Communication Advisory Committee will meet discuss strategies and lessons from a selection of the FDA's previously issued communications, emphasizing communications challenges. For more specific agenda information, please visit the following Web site and scroll down to the appropriate advisory committee link <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>, or call the FDA Advisory Committee Information Line at 1-800-741-8138 (or301-443-0572 in the Washington, DC area), code 8732112560. Additional information is available in the [Federal Register Notice](#) of the meeting.

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>.

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](#).

If you have any questions regarding any of these issues, please contact:

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