

To: Our Clients and Friends

December 8, 2009

## Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



### Top News

#### **FDA Commissioner Hamburg Addresses Codex Committee on Food Hygiene; Highlights Plan for Increased Oversight of Food Imports into United States**

In November, Dr. Margaret Hamburg became the first FDA Commissioner to address the Codex Committee on Food Hygiene. [In her remarks](#), Dr. Hamburg highlighted current efforts in the United States – including pending food safety legislation – to “transform a system built on trying to react to an outbreak of food-borne illness once it occurs, to one that endeavors to prevent contaminated food from entering consumer markets in the first place.” Noting that the U.S. food industry, consumer groups, and leaders in Congress all support these efforts, Dr. Hamburg then focused the rest of her speech on how FDA needs to completely overhaul its oversight of food imports to accomplish the ultimate goal of assuring U.S. consumers that the food supply is safe. Such overhaul could include the following components:

- Holding importers accountable for demonstrating that products meet U.S. safety and compliance standards prior to arrival (this authority would be granted by pending food safety legislation).
  - Strengthening third-party certification programs, in which foreign governments or qualified third-party agents certify that imported products meet U.S. safety standards.
- Encouraging participation of foreign producers in voluntary certification programs to enable government regulators throughout the world to more effectively allocate resources for greater public health protection.
  - Increasing FDA inspection of foreign food facilities and FDA investment in countries and regions that are major trading partners with the United States.

Dr. Hamburg then acknowledged the critical role played by Codex (which establishes international standards for food, among other things) in global food safety. She also discussed the effect of food safety measures on fair trade, noting that the two are not at odds. However, critics in other countries have pointed out that the new FDA authority to regulate imports that is being contemplated in the pending food legislation may potentially violate World Trade Organization rules. These rules require that import controls to ensure food safety focus on the safety of the food itself and not production processes.

## **BPA Remains Controversial as FDA Misses Safety Evaluation Deadline**

Under pressure from consumer advocates groups and Congress, in June, [FDA said it would review the safety of Bisphenol-A \(BPA\)](#) and issue a report sometime in November. However, the November 30 deadline passed without any news from FDA, who told [NPR](#) that “an announcement will be forthcoming.” The debate over the safety of BPA – a controversial chemical found in drinking bottles and food containers, among other things – has heated up this year in the wake of recent studies that have linked the chemical to [aggressive behavior in female toddlers](#) and [male impotency](#), in addition to a [report that BPA is present in measurable amounts in many of the soups, juices, and other products](#) that are packaged in BPA-lined containers. While [other recent research](#) indicates that BPA is safe and the American Chemistry Council consistently refutes findings that BPA might be dangerous, consumers do not appear to be convinced and are looking to the federal government for answers. Although FDA has not issued the BPA safety report it promised in November, the National Institutes of Health (NIH) just announced that it will [spend more than \\$30 million to research the safety of BPA](#) and the Environmental Protection Agency (EPA) will [review BPA](#) as a part of a program to evaluate 6 of the most high-profile chemicals of concern. Not to be left out, members of congress have also taken action on BPA. Most recently, in November, [Senator Charles Schumer \(D-NY\) unveiled the BPA-Free Kids Act](#) which would ban the use of BPA in the packaging of foods that are marketed for children ages three and younger. [The controversy also extends beyond U.S. borders](#), with Canada set to finalize a ban on BPA in baby bottles by the end of 2009 and U.K. groups calling for a similar ban in the United Kingdom citing “compelling scientific evidence” that links BPA to chronic conditions, including cancer. However, [Germany, after a finding by the German Federal Institute for Risk Assessment, maintains that BPA is safe](#) for normal use in baby bottles.

## **Senator Feinstein Introduces Legislation To Ensure Pathogen Free Foods**

[Senator Dianne Feinstein \(D-CA\) introduced legislation](#) that would amend several federal laws to prohibit the sale of food unless it has undergone a pathogen reduction treatment or has been certified to contain no verifiable traces of pathogens.

## **Institute of Food Technologists Issues Report on Food Product Tracing**

The Institute of Food Technologists (IFT) reported the results of a food traceability study (commissioned by FDA) that surveyed 58 companies in the areas of produce, packaged consumer goods, processed ingredients, distribution, food service, retail, and animal feed. Recommendations from the expert panel include standardizing data collection, identifying where data needs to be captured, and making traceability a part of audits, training, and education. The full report is available at visit <http://www.ift.org/traceability/>.

## **E. Coli Vaccine Finally In Testing Stage**

A new vaccine that would immunize cattle against the most dangerous form of E. coli is finally being tested after bureaucratic delays in Washington stalled the process for several years, reports [The New York Times](#). Researchers estimate that the vaccine could reduce the number of cattle carrying E. coli by 65 to 75 percent. Beef producers agree that a vaccine would generally be good for the industry, but would also lead to increased costs.

## **FDA and CDC Investigating Whether Norovirus Illnesses Linked to Texas Oysters**

The FDA, along with the Centers for Disease Control and Prevention (CDC) and the states of North Carolina, South Carolina, and Texas, are [investigating about a dozen reports of norovirus-related illnesses](#) in South Carolina and North Carolina consumers who ate oysters recently harvested from the San Antonio Bay. In the meantime, FDA is advising consumers to avoid eating oysters harvested from the San Antonio Bay on or after Nov. 16.

## **Consumer Reports: Two-Thirds of Store-Bought Chicken Contaminated**

A recent study by Consumer Reports found that [two-thirds of store-bought chicken are contaminated](#) with harmful bacteria, primarily salmonella and campylobacter.

## **FDA Cracks Down on Caffeine in Booze and Antibiotics in Cattle**

At the prompting of 18 state attorneys general, who expressed grave concern over the potential hazards caused by the behavior of “wide awake drunks,” [FDA sent warning letters to 30 manufacturers of alcoholic beverages](#) in November. The letter warned that “there are no food additive regulations that permit the addition of caffeine at any level in alcoholic beverages” and allowed companies one month to respond by presenting scientific evidence that caffeine can safely be added to alcoholic beverages.

In an unrelated matter, [FDA also sent warning letters to two Minnesota dairy farms](#), stating that they “hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply.” FDA inspectors had found dangerously high levels in antibiotics in two cattle that were subsequently pulled from the food production line.

## **FTC to “Size Up” the Effects of Food Marketing on Kids**

On December 15, 2009, the Federal Trade Commission (FTC) will hold a public forum titled “Sizing Up Food Marketing and Childhood Obesity” to present research on the impact of food advertising on children and discuss the statutory and constitutional issues surrounding governmental regulation of food marketing. Additional information, including speakers, agenda, and registration information, is available at <http://www.ftc.gov/opa/2009/11/sizingup.shtm>.

## **Child Food Allergies Increasing in United States**

The December issue of *Pediatrics* reports that [food allergies in U.S. children have increased 18 percent between 1997 and 2007](#), with peanut allergies being most common, followed by egg and milk allergies.

## **USDA Releases First Draft of Proposed Crop Insurance Agreement**

USDA's Risk Management Agency (RMA), which administers the Federal crop insurance program [released the first draft of a proposed new Standard Reinsurance Agreement](#) between the Federal Crop Insurance Corporation and the crop insurance companies which deliver the program nationally. The 2008 Farm Bill authorized RMA to renegotiate the agreement which was last negotiated in 2005.

## **New Law Could Be A Spoiler for Food Producers**

A 2007 [law that requires all freight to be screened before being loaded as cargo into passenger planes](#) could cause fresh fruit and vegetables, fish, and other perishable food items to sit in warehouses in potentially unsanitary conditions that could also lead to spoilage while waiting for clearance. The Transportation Security Administration (TSA), responsible for implementing the new law, is encouraging manufacturers to join a program that will allow them to expedite the screening process by implementing certain security measures, such as conducting background checks on employees.

## **Tyson Foods Refutes Conclusions in Recent FDA Warning Letter**

[FDA issued a warning letter to Tyson Foods](#) on November 13, 2009, citing significant violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation based on an inspection that took place in August 2009. However, [Tyson Foods claims the warning letter drew erroneous conclusions](#) and that the problem “is really a documentation issue involving the plant's written food safety plan.”

## **FDA Seeks Permanent Injunction Against Sharkco Seafood International Inc.**

[FDA is seeking a permanent injunction against Sharkco Seafood International Inc.](#) of Louisiana to stop the seafood processing company from distributing scombrototoxin-forming fish. Consumption of scombrototoxin-forming fish that are not properly preserved or refrigerated can result in scombroid food poisoning, a foodborne illness that results from eating spoiled or decayed fish. According to the government's complaint, FDA inspections showed that the defendants failed to have an adequate written Hazard Analysis and Critical Control Point (HACCP) plan for their scombrototoxin-forming fish operation, despite numerous warnings by FDA.

## **New Food Defense Tool from FDA and APHIS Helps Farmers, Producers**

[The FDA and the Animal and Plant Health Inspection Service \(APHIS\) of the USDA have created an online tool to help farmers and producers assess and mitigate vulnerabilities in their production processes.](#) The risk assessment tool, called Agriculture CARVER + Shock, is designed to help the food industry at the farm level implement food production security methods. The free software is available at <http://www.fda.gov/Food/FoodDefense/CARVER>.

## **USDA Launches Toll-Free Help Desk for Small Meat and Poultry Processors**

[USDA launched its new small plant help-desk,](#) which will provide for operators of small and very small meat, poultry, and processed egg products establishments seeking help with agency requirements with direct access to knowledgeable staff specialists. The help-desk also will provide assistance to state and local food regulatory agencies as a continued part of the partnership to keep meat, poultry and egg products safe for consumers.

## **Summary of 2009 Food Code Now Available on Bryan Cave Web site**

In November 2009, FDA published the new FDA Food Code, a model code and reference document that provides a scientifically sound technical and legal basis for regulating the retail and food service segment of the food industry. Bryan Cave has published a [summary of the changes in the 2009 edition of the FDA Food Code](#) from the last edition, which was published in 2005 with a supplement published in 2007.

## **Recent Recalls**

[Slim-Fast Ready-to-Drink products in cans](#) due to possible bacillus cereus contamination (December 4, 2009).

[Beef Packers](#) ground beef products that may be linked to salmonella outbreak (December 4, 2009).

[College Inn No MSG Chicken Broth](#) due to undeclared wheat and mislabeling of MSG (December 4, 2009).

[Several Snax In Pax products](#) due to undeclared milk (December 2, 2009).

[Sunny Lake Trading Radix Polygonati Officinalis](#) due to undeclared sulfites (December 2, 2009).

[Fiesta 12 Flour Burrito Tortillas](#) due to undeclared whey (milk allergen) (November 30, 2009).

[Advanced Food Company frozen beef steak fritters](#) that may contain foreign materials (November 27, 2009).

[Diamond Pet Foods Premium Edge Finicky Adult Cat and Premium Edge Hairball Cat Foods](#) due to the potential that these foods may produce Thiamine Deficiency, which can seriously affect health of cat (November 27, 2009).

[Elf Branded Herring in Sour Cream product](#) due to undeclared wheat (November 24, 2009).

[Rikki USA Toi Sauce Thai Red Curry \(Panang\)](#) due to undeclared shrimp in red curry paste (November 24, 2009).

[Limited number of Timco seedless watermelons](#) due to possible salmonella contamination (November 22, 2009).

[Certain Shedd's Country Crock chilled side-dish products](#) due to possible undeclared sulfites (November 20, 2009).

[Majesty Cantaloupes](#) due to possible salmonella contamination (November 20, 2009).

[Superior Foods Lemon Pepper Catfish and Marinated Cajun Style Marinated Catfish](#) due to undeclared soy and FD&C Yellow #5, and undeclared milk, respectively (November 17, 2009).

## **Regulatory Notices**

### **FDA Seeks Comment on Draft Guidance for Industry on Liquid Dietary Supplements**

On December 4, 2009, FDA issued a [Federal Register notice](#) announcing draft [Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods](#). The draft guidance describes factors that can be used to identify liquid products that are excluded from being dietary supplements because they are represented as conventional foods. Further, the draft guidance reminds manufacturers and distributors of beverages and other conventional foods, particularly those that contain novel ingredients, about the requirements of the Federal Food, Drug, and Cosmetic Act (the act) regarding ingredients and labeling. Although comments on guidance documents may be submitted at any time, in order to be considered before FDA begins work on the final guidance document, comments must be received by *February 2, 2010*.

### **FDA Seeks Comment on Draft Compliance Policy Guide for Dairy Products**

On December 1, 2009, FDA issued a [Federal Register notice announcing a draft Compliance Policy Guide Sec. 527.300 Dairy Products—Microbial Contaminants and Alkaline Phosphatase Activity \(CPG 7106.08\)](#) (draft CPG). The draft CPG, when finalized, will provide guidance for FDA staff on its enforcement policies for pathogens and other indicators of inadequate pasteurization or postpasteurization contamination of dairy products. Although comments on any CPG may be submitted at any time, in order to be considered before FDA begins working on the final version of the CPG, comments must be received by *February 1, 2010*.

### **FDA Notice Experimental Studies of Nutrition Symbols on Food Packages**

On December 1, 2009, FDA issued a [Federal Register notice proposing to conduct two experimental studies to assess quantitatively consumer reactions to various Front of Package \(FOP\) nutrition labeling schemes](#). The studies will provide critical input to ensure the usefulness of FOP nutrition information provided to U.S. consumers. The notice details the information to be collected in each of the two proposed studies and provides background information regarding need for the studies.

### **FDA Issues Proposed Rule to Amend Regulations Regarding Declaration of Certified Food Additives on Animal Food Labels**

On November 23, 2009, FDA issued a [Federal Register notice proposing to amend its regulations regarding the declaration of certified color additives on the labels of animal food](#) including animal feeds and pet foods. The amendment is in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which amended the Federal Food, Drug, and Cosmetic Act (the act) by requiring, among other things, the listing on food labels of the common or usual names of all color additives required to be certified by FDA. An additional purpose of this amendment is to make these regulations consistent with the regulations regarding the declaration of certified color additives on the labels of human food. The proposed rule also suggests appropriate terminology for the declaration of certification-exempt color additives on the labels of animal food. *Comments are due by February 22, 2010*.

## USDA Issues Final Rule on Poultry Records

USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA) issued a [Federal Register notice announcing that they are amending the regulations issued under the Packers and Stockyards P&S Act, 1921, as amended](#), (7 U.S.C. 181 et seq.) (P&S Act) regarding the records that live poultry dealers must furnish poultry growers, including requirements for the timing and contents of poultry growing arrangements. The amendments to the regulations will require that live poultry dealers timely deliver a copy of an offered poultry growing arrangement to growers; include information about any Performance Improvement Plans (PIP) in poultry growing arrangements; include provisions for written termination notices in poultry growing arrangements; and notwithstanding a confidentiality provision, allow growers to discuss the terms of poultry growing arrangements with designated individuals. The rule is effective on January 4, 2010 (December 3, 2009). Additional information is available on the [GIPSA web site](#).

## FSIS Extends Proposed Interstate Meat and Poultry Shipment Rule Comment Period

The USDA Food Safety Inspection Service extended until Dec. 16 the comment period for its [proposed rule to allow interstate shipment of meat and poultry products produced in selected state-inspected establishments](#).

## FSIS Library of Export Requirements Updates and Policy Updates

USDA FSIS recently [updated the Brazil, Indonesia and Taiwan export requirements](#) in its Library of Export Requirements. FSIS additionally issued policy updates on the *Importation of Canadian Cattle, Bison, Sheep and Goats into the United States* ([Notice 80-09](#)) and *Enhanced Inspection of Poultry Related to a Notification of a Highly Pathogenic Avian Influenza (HPAI) Outbreak* ([Directive 6020.1](#)). All notices and directives are available at [http://www.fsis.usda.gov/Regulations\\_&Policies/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/index.asp).

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## Upcoming Meetings

### USDA Announces Second Business Conference for Boosting Food Commodity Contracting Opportunities For Small Businesses And Rural Cooperatives

USDA announced the [second in a series of small business conferences aimed at increasing USDA's Food Commodity Contracting Opportunities for Rural America initiative](#). The second conference will take place on December 9, 2009 at the University of Arkansas Pine Bluff in Pine Bluff, Arkansas. Space is limited. Email or fax your name, company name, full address, telephone number and email address to: [smallbizconf@da.usda.gov](mailto:smallbizconf@da.usda.gov) or fax: 202-720-3001, or phone: 202-720-7380 or 202-205-5949.

## 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 farmers and the poultry, dairy, livestock industries. The final workshop will focus on price margins.

## FDA and FSIS Public Meeting on Product Tracing Systems

The [FDA and USDA Food Safety and Inspection Service \(FSIS\)](#) have announced a [public meeting](#) on December 9 and 10, 2009 from 9 a.m. to 5 p.m. regarding product tracing systems for food intended for humans and animals, specifically, mechanisms to enhance product tracing systems for food. The notice, including more information about the meeting, how to register, and how to make a request for oral presentation during time allotted for public comment, is available at <http://edocket.access.gpo.gov/2009/pdf/E9-26479.pdf>.

## USDA to Host 2010 Food Safety Education Conference

USDA and NSF International will host the 2010 Food Safety Education Conference *Advancements in Food Safety: Trends, Tools and Technologies*, March 23-26, at the Hyatt Regency in Atlanta. The conference will provide food safety educators and other professionals with information on the latest advancements in food safety education, including trends, tools and technologies. Registration and to additional information is available at [www.fsis.usda.gov/Atlanta2010](http://www.fsis.usda.gov/Atlanta2010).

## More Information

Archived issues of the Bryan Cave Food, Dietary Supplement, and Cosmetic Regulatory and Policy Bulletin are available at [www.bryancave.com](http://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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