

To: Our Clients and Friends

January 26, 2010

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



### *Top News*

#### **President Obama and Secretary Vilsack Announce Intent to Nominate Dr. Elisabeth Hagen as USDA Under Secretary for Food Safety**

On Monday, President Obama and USDA Secretary Vilsack announced in a [USDA press release](#) that the President intends to nominate Dr. Elisabeth Hagen to the position of USDA Under Secretary for Food Safety. Dr. Hagen is currently the USDA's Chief Medical Officer, advising on a wide array of public health issues. Prior to her current post, she served as a senior executive at FSIS. Her food safety efforts include urging USDA to include steaks and chops in the categories of meat that are adulterated when they contain surface levels of E. coli, which is currently only considered an adulterant in ground beef. The appointment comes in the wake of criticism against President Obama last week for not having appointed a "Food Czar." [USA Today](#) and [Food Safety News](#) both report that food safety advocates are pleased with the idea that Dr. Hagen will serve in the top USDA food safety post.

#### **Nanotechnology Bill Introduced in Senate**

Senators Mark Pryor (D-AR) and Benjamin Cardin (D-MD) have introduced the [Nanotechnology Safety Act of 2010](#), designed to establish a nanotechnology program at FDA to address potential health and safety risks posed by the technology. [The program would receive \\$25 million a year from 2011 to 2015, and would assess the health and safety implications of the technology and develop best practices for using the technology.](#)

### **USDA Moves Forward with Public Health Information System; Releases Data Sets as Part of Open Government Initiative**

The most recent USDA Food Safety and Inspection Service (FSIS) [Constituent Update](#) provided an update on its progress to develop the Public Health Information System (PHIS), one of the agency's most significant activities to improve food safety and food defense. PHIS is a web-based application that will replace FSIS' legacy systems, like the Performance-Based Inspection System; facilitate data integration and analysis; and automate paper-based business processes, such as export certification and audits of foreign countries' inspection programs. FSIS plans to begin implementing the new system in October 2010. Additionally, FSIS announced that, as part of President Obama's Open.gov initiative, USDA released four data sets to meet the first milestone. Information on the available data sets and where to read the data is also available in the [Constituent Update](#).

## **Monsanto Wins Approvals in Mexico; Will Allow Biotech Seed Patents to Expire**

Monsanto won regulatory approval of three varieties of its genetically modified corn. The varieties, engineered to improve pest control and increase crop yield, are also approved in the U.S. and Canada. Mexico's approval will allow growers in other countries to sell their products in Mexico. Monsanto CEO Hugh Grant also recently announced that the company will not seek to renew the patents on its bioengineered seeds. The first of these patents is for Roundup Ready soybeans, which will expire in 2014.

## **FDA Dietary Supplements Director Joins Herbalife as Senior VP of Compliance**

FDA's Center for Food Safety and Applied Nutrition (CFSAN) will be looking for a new Director of its Division of Dietary Supplement Programs. The current Director, Vasilios "Bill" Frankos, will leave FDA in March to become Senior Vice President of Compliance and Safety at Herbalife, the company announced in a press release on January 19, 2010. Herbalife is a global company that sells weight-management, nutrition, and personal care products. Health News Daily (subscription required) reported that, among others, Mr. Franko's special assistant Brad Williams is a possible candidate to replace Frankos.

## **Global Food Safety Conference to be Held in Washington, D.C. Next Week**

Planned by the Global Food Safety Initiative, the Global Food Safety Conference (GFSC) will be held in Washington, D.C. February 3 – 5, 2010. The conference will gather industry stakeholders, public health officials, and academics to discuss food safety issues. More information on the conference is available at the GFSC web site.

## **EU Regulation Augments Border Control Measures to Improve Food Safety**

On January 25, 2010, Commission Regulation (EC) No 669/2009 went into effect. As described in a statement issued by the European Commission, the new regulation means that "[a]ll EU Member States will step up their border controls on a number of pre-listed products -ranging from peanuts to fruit and vegetables- originating from outside the EU in an effort to limit possible harm to human and animal health."

## **Briefly Noted**

Food Safety News reports on Traceability Summit in Denver, Colorado.

In Switzerland, Nestle Launches SeniorActiv, a nutrient drink designed for the elderly.

Coca Cola introduces soda bottle made from 30 percent sugar cane that is more environmentally friendly.

Peanut Corporation of America victims call on U.S. Senate to pass food safety legislation by Valentine's Day.

Canadian functional protein developer files for GRAS status from FDA for its canola protein extracts.

Whole Foods Market launches "Health Starts Here" healthy eating initiative.

Hong Kong Food and Environmental Hygiene Department's Centre for Food Safety (CFS) includes preservatives for fruits and vegetables in its targeted food surveillance program, citing findings of excessive preservatives in dried food samples.

China reports three more melamine tainted-milk cases from 2009.

## **Recent Recalls**

Daniele International Italian sausage products due to potential Salmonella contamination (January 23, 2010).

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## ***Regulatory Notices***

### **FDA Issues Three Notices Announcing Agency Information Collection Activities, Submission for OMB Review, and Comment Requests**

In the January 26, 2010 Federal Register, FDA announce agency information collection activities, submission to the Office of Management and Budget (OMB) review, and comment request concerning three food, cosmetic, and dietary supplement issues. They are:

- [Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle;](#)
- [Food Labeling; Notification Procedures for Statements on Dietary Supplements;](#) and
- [Interstate Shellfish Dealers Certificate.](#)

### **FSIS Export Requirement Updates**

USDA's Food Safety and Inspection Service (FSIS) updated its library of export requirements to reflect changes in export requirements for Japan, China, and Canada. Complete information is available at [http://www.fsis.usda.gov/Regulations\\_&Policies/Export\\_Information/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/Export_Information/index.asp).

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## ***Upcoming Meetings***

### **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. Additional information is available in the [Meeting Announcement is posted on the FDA web site.](#)

### **U.K. Food Standards Agency to hold 10<sup>th</sup> 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/>.

### **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.

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## ***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:

<b>Mark Mansour</b>	Partner	<a href="mailto:mark.mansour@bryancave.com">mark.mansour@bryancave.com</a>	1 202 508 6019	Washington
<b>Alan K. Parver</b>	Partner	<a href="mailto:alan.parver@bryancave.com">alan.parver@bryancave.com</a>	1 202 508 6332	Washington
<b>Steven Kent Stranne</b>	Partner	<a href="mailto:steven.stranne@bryancave.com">steven.stranne@bryancave.com</a>	1 202 508 6349	Washington
<b>Megan A. Gajewski</b>	Associate	<a href="mailto:megan.gajewski@bryancave.com">megan.gajewski@bryancave.com</a>	1 202 508 6302	Washington
<b>Patrice M. Hayden</b>	Associate	<a href="mailto:pmhayden@bryancave.com">pmhayden@bryancave.com</a>	1 202 508 6147	Washington
<b>Emily K. Strunk</b>	Associate	<a href="mailto:emily.strunk@bryancave.com">emily.strunk@bryancave.com</a>	1 202 508 6360	Washington

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