

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



### Top News

#### USDA to Hold Meeting Addressing Codex Committee on Processed Fruits and Vegetables

On August 18, 2010, USDA announced a public meeting to provide information and receive comments on agenda items and draft U.S. positions that will be discussed at the 25th Session of the [Codex Committee on Processed Fruits and Vegetables \(CCPFV\)](#), to be held in Denpasar, Indonesia, Oct. 25 - 29, 2010. The public meeting is scheduled for **Monday, Aug. 30, 2010**, from 10:00 a.m. to 12:00 p.m., in Room 2068, USDA, South Building, 1400 Independence Avenue, SW, Washington, DC. To participate through teleconference, dial (888) 996-4918, and enter the passcode 63757. A complete agenda and documents relating to the 25th Session of CCPFV will be available on the Codex Alimentarius Web site at [www.codexalimentarius.net/current.asp](http://www.codexalimentarius.net/current.asp).

#### FDA Issues Guidance on New Egg Safety Rule

On August 12, 2010, FDA published additional guidance for egg producers to help them further comply with the new federal egg safety rule. The guidance, entitled "[Guidance for Industry: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation](#)", provides recommendations on certain provisions contained in the rule, including how to implement *Salmonella* Enteritidis (SE) prevention measures, how to sample for SE, and how to maintain records documenting compliance with the final rule.

#### USDA Selects Massachusetts for the SNAP Healthy Incentives Pilot

On August 19, 2010, USDA announced that Hampden County, MA will conduct the first-ever [Healthy Incentives Pilot \(HIP\)](#) – an incentives-based program to empower low-income Americans to eat more fruits and vegetables. The 2008 Farm Bill authorized \$20 million to research whether incentives for participants in the [Supplemental Nutrition Assistance Program](#) (formerly the Food Stamp Program) will increase their purchase of healthful foods.

## Feds Say Seafood from Open Gulf Water is Safe

As gulf fisheries continue to reopen, [FoodSafety.gov reported on the comprehensive, coordinated, and multi-agency program](#) to ensure the safety of the Gulf Coast seafood. The web site reports that “Americans can confidently and safely enjoy Gulf seafood again,” and provided the following facts:

1. Every seafood sample from reopened waters has passed testing.
2. When waters were impacted by oil or at risk of being impacted by oil, they were closed to fisherman.
3. Areas considered for reopening must be free of oil before testing even starts.
4. Dispersants were not applied in areas that are opened for fishing, and tests of reopened waters do not show the presence of any dispersants.
5. FDA and NOAA test samples for oil and dispersants, and every sample from reopened waters has passed those tests.

FoodSafety.gov also referred consumers to web pages on [FDA's Role In Seafood Safety](#) and FDA's information page on the [reopening of closed waters information by state](#), as well as [NOAA's Role in Seafood Safety](#) and NOAA's site on [assessing Gulf Coast seafood](#).

## Briefly Noted

[Federal District Judge revokes government's approval of Monsanto's GM sugar beets.](#)

[FTC Approves Corn Products Int. acquisition of National Starch.](#)

[Ongoing salmonella outbreak prompts egg recall.](#)

[FDA says China is improving food and drug safety.](#)

[National Food Policy Conference will be held Sept. 22 and 23 in Washington, DC.](#)

[Nanotechnology Needed To Feed World in 2050.](#)

[Baltimore Sun Editorial on how poor ingredient labeling affects those with food allergies.](#)

[FTC gets restraining order against firm marketing acai supplements for weight loss and colon-cleansing.](#)

## Recent Recalls

[Glow Industries Mr. Magic Male Enhancer](#) (supplement) due to presence of active drug ingredient (August 18, 2010).

[J & H Besta Corp expands recall of Slim-30 Herb Supplement](#) due to presence active drug ingredient (August 18, 2010).

[Moonstruck Chocolate selected truffle products](#) due to undeclared peanuts (August 18, 2010).

[NuCal Foods Shell Eggs](#) due to potential Salmonella contamination (August 18, 2010).

[Sunny Lake Trading Inc Golden Bridge Dried Dates](#) due to undeclared sulfites (August 17, 2010).

[Food City brand Low Carb Tortilla products](#) due to undeclared soy (August 16, 2010).

[Leiner Health Products various AirHealth, Air Protector, and other products marketed as dietary supplement](#) due to undeclared soy (August 17, 2010).

[Certain Merrick Pet Care pet treats](#) due to potential Salmonella contamination (August 16, 2010).

[Kroger brand Meals Made Simple Shrimp Linguini](#) due to undeclared milk (August 14, 2010).

[Wright County Egg Shell Eggs](#) due to potential Salmonella contamination (August 13, 2010) ([Expanded on August 18](#)).

## Recently Posted Warning Letters

FDA warned [Juice Pac Inc](#), that FDA inspectors found serious violations of the juice Hazard Analysis and Critical Control Point (HACCP) regulation.

FDA warned [Factoria Del Lago C.A.](#), [Corporacion Del Mar](#), [Pescamarca](#), and [Gropoint Seafood Industries Sdn Bhd](#), that FDA inspectors found serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation.

## ***New Regulatory Notices***

### **FDA Announces Information Collection From U.S. Processors That Export to the EC**

In the [August 18, 2010 Federal Register](#), FDA announced that it is requesting information from processors that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to the EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to the EC quarterly. Inclusion on the list is voluntary. Interested parties may submit either electronic or written comments on the collection of information by **October 18, 2010**.

### **FSIS Policy Updates**

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

- [Australia Plant List](#) (Aug 19, 2010)
- [Russia Plant List, Pork](#) (Aug 17, 2010)

## ***Regulatory Notices with Open Comment Periods***

### **FDA Issues Advance Notice of Proposed Rulemaking to Implement 2005 SFTA**

In the [April 30, 2010 Federal Register](#), FDA announced an advance notice of proposed rulemaking to implement the Sanitary Food Transportation Act of 2005. FDA is specifically requesting data and information on the food transportation industry and its practices, as well as data and information on the contamination of transported foods and associated outbreaks. The regulations would address the risks to human or animal health associated with the transportation of food. Interested parties must submit electronic or written comments by **August 30, 2010**.

### **USDA Announces Notice of Request for Revision of a Currently Approved Information Collection (Pathogen Reduction/HACCP)**

In the [June 29, 2010 Federal Register](#), USDA announced that it is revising the Pathogen Reduction/HACCP systems information collection based on its most recent establishment data. In addition, FSIS is adding information concerning the use of video recordkeeping for HACCP records and Sanitation Standard Operating Systems (SOPs) records. Interested parties must submit comments by **August 30, 2010**.

### **FDA Seeks Public Input on Restaurant Menu Labeling**

In the [July 7, 2010 Federal Register](#), FDA invited the public to submit comments and information to help the agency implement a new federal law that requires the posting of calorie content and other nutrition information on menu items at certain chain restaurants and similar retail food operations and vending machines. FDA has opened a docket to gather comments and information. The new law, part of health care reform, requires restaurants and chain retail food establishments with 20 or more locations to list calorie content information on menus and menu boards, including drive-through menu boards. More information is available on the web site for [Docket No. FDA-2010-N-0298](#) and on [FDA's web site](#). Written or electronic comments must be received by **September 7, 2010**.

### **FSIS Seeks Comments on Proposed Amendments to Meat/Poultry/Egg Regulations**

In the [August 9, 2010 Federal Register](#), USDA's Food Safety and Inspection Service (FSIS) proposed to amend the meat, poultry products, and egg products regulations pertaining to the schedule of operations. FSIS is proposing to amend these regulations to define the 8-hour work day as including time that inspection program personnel need to spend at the workplace donning and doffing required gear, time spent walking to their workstations after donning required gear, and time spent walking from their work stations prior to doffing required gear. FSIS is amending these regulations to

ensure effective and prudent expenditure of Agency budgetary and other resources while administering its inspection program in accord with the Supreme Court's holding in *IBP, Inc. v. Alvarez*, 546 U.S. 21 (2005) and policy guidance from the Office of Personnel Management. Interested parties must submit comments on or before **September 8, 2010**.

### **FDA Seeks Comments on Information Collection for CGMPs for Dietary Supplements**

In the [July 14, 2010 Federal Register](#), FDA announced an opportunity for public comment on an information collection for Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements. Interested parties must electronic or written comments by **September 13, 2010**.

### **FDA Seeks Comments on Information Collection for Juice HACCP**

In the [July 14, 2010 Federal Register](#), FDA announced an opportunity for public comment on an information collection concerning Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice. Interested parties must electronic or written comments by **September 13, 2010**.

### **FDA Seeks Comments on Information Collection for Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients**

In the [July 20, 2010 Federal Register](#), FDA announced an opportunity for public comment on an information collection concerning a petition to request an exemption from 100 percent identity testing of dietary ingredients: current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements. Interested parties must electronic or written comments by **September 20, 2010**.

### **FSIS Requests Revision of Approved Information Collection on SRMs in Cattle**

In the [July 23, 2010 Federal Register](#), USDA announced the Food Safety and Inspection Service's (FSIS) intention to request revision of an approved information collection regarding specified risk materials (SRMs) in cattle because the OMB approval will expire on January 31, 2011, and to incorporate another approved information collection, Specified Risk Materials--Transport. Comments on this notice must be received on or before **September 21, 2010**.

### **FDA Announces Information Collection Regarding Pet Event Tracking Network—State, Federal Cooperation to Prevent Spread of Pet Food Related Diseases**

In the [July 27, 2010 Federal Register](#), FDA announced that it is conducting an information collection concerning its plans to implement an initiative called "The Pet Event Tracking Network" (PETNet) that will allow FDA and its State partners to quickly and effectively exchange information about outbreaks of illness in companion animals associated with pet food. The PETNet proposal was developed in response to the 2007 outbreak that occurred in companion animals that was associated with the deliberate adulteration of pet food components, such as wheat gluten, with melamine. As envisioned by the subgroup at that time, PETNet would include a system for reporting outbreaks and would be supported by adequate diagnostic laboratory facilities and an established mechanism for conducting national epidemiological investigations. Submit either electronic or written comments on the collection of information by **September 27, 2010**.

### **FDA Announces Draft Guidance on Prevention of Salmonella in Shell Eggs**

In the [August 12, 2010 Federal Register](#), FDA announced the availability of a Draft Guidance titled, *Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation*. Interested parties should submit comments by **October 12, 2010**.

### **FDA Announces Proposed Information Collection on Microbial Food Safety Hazards**

In the [August 11, 2010 Federal Register](#), FDA issued a notice soliciting comments on the information collection provisions in the guidance document titled *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables*. Interested parties must submit comments by **October 12, 2010**.

## FDA Details Voluntary Compliance with New Federal Menu Labeling Requirements

FDA Announces In the [July 23, 2010 Federal Register](#), FDA issued a notice giving details on how retail food establishments and vending machine operators with fewer than 20 locations can choose to become subject to the new federal menu labeling requirements. [CFSAN's Constituent Update](#) and provides additional details. Interested parties must submit electronic or written comments by **October 21, 2010**.

## FDA Announces New CPG for Salmonella in Animal Feed

In the [August 3, 2010 Federal Register](#), FDA announced the availability of a draft guidance for FDA staff entitled Compliance Policy Guide Sec. 690.800 Salmonella in Animal Feed (the draft CPG). The draft CPG, when finalized, is intended to provide guidance for FDA staff on regulatory policy relating to animal feed or feed ingredients that come in direct contact with humans, such as pet food and pet treats, contaminated with Salmonella and also on regulatory policy relating to animal feed or feed ingredients contaminated with a Salmonella serotype that is pathogenic to the target animal for the animal feed. Interested parties may comment on CPG documents at any time, however, to ensure that the agency considers your comment on the draft CPG before it begins work on the final version of the CPG, submit either electronic or written comments on the draft CPG by **November 1, 2010**.

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## Upcoming Meetings

### USDA to Hold Meeting Addressing Codex Committee on Processed Fruits, Veggies

On August 18, 2010, USDA announced a public meeting to provide information and receive comments on agenda items and draft U.S. positions that will be discussed at the 25th Session of the [Codex Committee on Processed Fruits and Vegetables \(CCPFV\)](#), to be held in Denpasar, Indonesia, Oct. 25 - 29, 2010. The public meeting is scheduled for **Monday, Aug. 30, 2010**, from 10:00 a.m. to 12:00 p.m., in Room 2068, USDA, South Building, 1400 Independence Avenue, SW, Washington, DC. To participate through teleconference, dial (888) 996-4918, and enter the passcode 63757. A complete agenda and documents relating to the 25th Session of CCPFV will be available on the Codex Alimentarius Web site at [www.codexalimentarius.net/current.asp](http://www.codexalimentarius.net/current.asp).

### USDA Designs Inspection Seminars for International Government Officials

USDA will host the third of three meat and poultry inspection seminars for international officials in Washington, D.C., from **September 13 – October 1, 2010**. The 2-week, in-depth seminar will be in English and will focus on verification and enforcement of HACCP and pathogen reduction regulations in order to familiarize participants with U.S. inspection regulations and procedures used by USDA to ensure that the nation's meat, poultry and egg products are safe, wholesome and properly labeled. For more information and to register, visit [http://www.fsis.usda.gov/news\\_&\\_events/2010\\_Meat\\_&\\_Poultry\\_Inspection\\_Seminars/index.asp](http://www.fsis.usda.gov/news_&_events/2010_Meat_&_Poultry_Inspection_Seminars/index.asp).

### FSIS, CDC, FDA to Hold Public Meetings on Measuring Food Safety Progress

Food Safety and Inspection Service (FSIS), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC), are jointly hosting two public meetings to obtain stakeholder input. The first was on July 21, 2010, in Chicago, IL. The second will be held on **October 20, 2010, in Portland, OR**. The Agencies are requesting information from all stakeholders, including the regulated food industry, State regulators, and consumer groups, on appropriate metrics to be used to assess performance in food safety. The Agencies are also interested in input on stakeholders' understanding and perceptions of metrics currently being used by the Federal Agencies. Although the Agencies are primarily interested in obtaining stakeholder input, the Agencies will present a limited amount of background on the Food Safety Working Group's charge to create meaningful metrics to measure the effectiveness of the Nation's food safety system and the Agency's current thinking on these issues. More information 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.

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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:

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