Top Stories

USDA Enhances Traceback Procedures for Ground Beef
On August 13, 2014, USDA's Food Safety and Inspection Service ("FSIS") announced new procedures to improve the process for tracing *E. coli*-contaminated ground beef back to its source, recalling contaminated product, and determining the root cause of the contamination. USDA expects that the new procedures will help prevent foodborne illness.

FSIS typically tests samples of ground beef for *E. coli* O157:H7 during the production phase. Under the new procedures, FSIS can inspect a facility or take immediate regulatory action after a sample tests positive for *E. coli*, eliminating a two-day waiting period for lab confirmation, which FSIS says nearly always matched the initial positive result. Another significant change allows FSIS personnel to scrutinize the supplying slaughterhouse's safety system immediately upon a positive *E. coli* result, rather than waiting 30 days to conduct a Food Safety Assessment. The new procedure is intended to more quickly trace the contamination to the root cause and identify whether other grinding facilities may be affected. Food Safety Deputy Under Secretary Brian Ronholm elaborates on the new policies in an August 14, 2014, blog post.

These procedures build on other recent USDA initiatives aimed at improving food safety of ground beef, such as new laboratory methods for testing multiple pathogens simultaneously and a proposed rule for recordkeeping by ground beef establishments and retailers. The traceback procedures will be fully implemented later this fall, but interested parties may submit comments on the recordkeeping proposal through September 22, 2014.

New FDA Gluten-Free Food Labeling Rule Now in Effect
Pursuant to a rule effective August 5, 2014, all food labeled "gluten-free" must comply with FDA requirements for gluten-free labeling. The labeling rule—officially published in August 2013—established a uniform definition requiring foods marked with voluntary claims of "gluten-free" to contain less than 20 parts per million ("ppm") gluten. Food manufacturers were given one year to bring their package labels into compliance with the rule, which is intended to help inform consumers with celiac disease and gluten intolerance about

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Resources

- *Food, Dietary Supplement & Cosmetics Regulatory Update* Printable Version

gluten-free claims. Although the rule does not specifically require manufacturers to test for the presence of gluten, FDA has suggested that inspectors review a company's quality procedures to determine whether they are meeting the less-than-20 ppm requirement.

- Jones Day's FDA Regulatory & Compliance Counseling Practice
- Jones Day's Health Care Practice
- Jones Day's Life Sciences Practice

FDA Allows Vitamin D_3 Additives in Certain Meal Replacement Beverages
Earlier this month, FDA issued a final rule permitting the use of vitamin D_3 supplements in certain meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and for use in foods that are sole sources of nutrition for enteral feedings. Issued in response to a citizen petition, the rule expands the current list of foods to which vitamin D_3 may be added, which already included milk, infant formula, and breakfast cereals, and coincides with new research confirming the importance of vitamin D to personal health. For example, a recent study by a British medical school found that vitamin D deficiency in adults over age 65 significantly increases their risk for developing Alzheimer's disease and other forms of dementia. Vitamin D is also commonly known for its role in promoting strong bones.

FDA Warns Consumers About Infection Risks of Some Tattoo Inks, Kits
Earlier this month, FDA's Center for Food Safety and Applied Nutrition, which oversees the regulation of cosmetics in addition to foods, issued a constituent update warning consumers about the risks of bacterial contamination in certain unopened bottles of tattoo ink and kits used for in-home tattooing. These products are considered cosmetics under the Federal Food, Drug, and Cosmetic Act. Though FDA does not often take regulatory action with regard to cosmetics, the Agency is responding to reports of infection associated with inks and kits marketed by a certain manufacturer, which recalled several products last month. FDA's public warning advises tattoo artists and consumers to be aware of the origin of their materials and to avoid kits that do not list a brand name or the manufacturer's place of business. Users should also contact manufacturers with any concerns about product contamination or adverse events.

Other News
California Assembly Passes Bill to Ban Use of Antibiotics for Livestock Growth Promotion

FDA Issues Consumer Alert on Lupin Allergies

Washington Post Highlights Industry's Increasing Use of Food Additives

NEJM Study Links Low Sodium Consumption with Increased Heart Complications

Regulatory Updates

USDA Implements New Traceback and Recall Procedures for Raw Beef Found Positive for *E. Coli* O157:H7
In the August 13, 2014, *Federal Register*, USDA's FSIS announced it will implement new traceback procedures when FSIS or another federal or state agency finds raw ground beef or bench trim presumptive positive for *Escherichia coli* O157:H7 (*E. coli*). The new procedures eliminate certain waiting periods, which used to require lab confirmation or a Food Safety Assessment before USDA could investigate an initial positive contamination result. USDA also will begin requesting an establishment to recall products if it was the sole supplier of source materials for such contaminated ground beef product and if evidence suggests the contamination most likely occurred at the supplier establishment. In connection with these new policies, FSIS also announced the availability of two updated final guidance documents: *Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing* Escherichia coli *(STEC) Organisms or Virulence Markers* and *Compliance Guidelines for Shiga Toxin* Escherichia coli *(STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings ("Beef Trim")*.

USDA Issues Updated Guidance on Controls for Reducing STEC Shedding in Cattle
In the August 13, 2014, *Federal Register*, USDA's FSIS announced the availability of updated guidance for *Pre-Harvest Management Controls and Intervention Options for Reducing Shiga Toxin-Producing*

Escherichia coli *Shedding in Cattle*. In 2010, FSIS provided initial guidance to beef slaughter establishments about controls for reducing the shedding of STEC in feces during cattle production. The updated guidance clarifies the policy in response to comments. ***Comments are due September 12, 2014***.

FDA Issues Final Rule Allowing Direct Addition of Vitamin D_3 to Certain Beverages
In the August 12, 2014, *Federal Register*, FDA issued a final rule amending its food additive regulations to permit the use of vitamin D_3 as a nutrient supplement in meal replacement beverages other than those intended for special dietary use in reducing or maintaining body weight and for use in foods that are sole sources of nutrition for enteral feedings. The action responds to a petition filed by a manufacturer, which submitted studies in support of the new use. Such additives must meet specifications in the Food Chemicals Codex. This rule is effective immediately.

USDA Issues Final Rule Making Changes to Beef Promotion and Research Board
In the August 12, 2014, *Federal Register*, USDA issued a final rule adjusting representation on the Cattlemen's Beef Promotion and Research Board and making other technical amendments to update information. The final rule decreases the board's membership from 103 to 100, effective with the USDA's appointments for terms beginning in 2015. These updates were made to reflect changes in cattle inventories and cattle and beef imports that have occurred since the last reapportionment rule in July 2011.

FDA INFORMATION COLLECTION ACTIVITIES

FDA Announces the Opportunity to Comment on the Following Proposed Information Collections
Food and Drug Administration Recall Regulations (*comments due October 3, 2014*)

Application for Participation in the Food and Drug Administration Commissioner's Fellowship Program (*comments due October 3, 2014*)

Infant Formula Recall Regulations (*comments due October 6, 2014*)

State Petitions for Exemption From Preemption (*comments due October 6, 2014*)

Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic (*comments due October 10, 2014*)

Food Allergen Labeling and Reporting (*comments due October 14, 2014*)

FDA Announces the Following Information Collections Have Been Submitted to OMB
Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers (*comments due to OMB September 15, 2014*)

FDA Announces the Following Information Collections Have Been Approved by OMB
Voluntary National Retail Food Regulatory Program Standards

USDA INFORMATION COLLECTION ACTIVITIES

USDA Announces the Opportunity to Comment on the Following Proposed Information Collections
Application for Non-Land Grant College of Agriculture Designation (*comments due October 3, 2014*)

Supplemental Nutrition Assistance Program; Retailer Transaction Data (*comments due September 8, 2014*)

USDA Announces the Opportunity to Comment on the Following Request for Revisions to and/or Extensions of Approval of Information Collections
Importation of Eggplant from Israel (*comments due October 6, 2014*)

Virus-Serum-Toxin Act and Regulations (*comments due October 6, 2014*)

Introduction of Organisms and Products Altered or Produced Through Genetic Engineering (*comments due October 10, 2014*)

Importation of Fresh Pitaya Fruit From Central America Into the Continental United States (*comments due October 14, 2014*)

Importation of Baby Squash and Baby Courgettes From Zambia (*comments due October 14, 2014*)

Plan for Estimating Daily Livestock Slaughter Under Federal Inspection (*comments due October 27, 2014*)

USDA Announces the Following Information Collections Have Been Submitted to OMB
Meats, Prepared Meats, and Meat Products (Grading, Certification, and Standards) and Quality Systems Verification Programs (*comments due to OMB September 5, 2014*)

Karnal Bunt; Revision of Regulations for Importing Wheat (comments due to OMB September 8, 2014)

Evaluation of the Pilot Project for Canned, Frozen, or Dried Fruits and Vegetables in the Fresh Fruit and Vegetable Program (*comments due to OMB September 8, 2014*)

2014 Census of Horticultural Specialties (*comments due to OMB September 8, 2014*)

NAHMS Emergency Epidemiologic Investigation (*comments due to OMB September 11, 2014*)

Certified State Mediation Program (*comments due to OMB September 12, 2014*)

Other USDA Announcements
USDA Announces Renewal of National Advisory Committee on Meat and Poultry Inspection

USDA Issues Interim Rule Modifying Container Requirements for Irish Potatoes Grown in Certain Designated Counties in Idaho and in Malheur County, Oregon

USDA Issues Decreased Assessment Rate for Oranges and Grapefruit Grown in Lower Rio Grande Valley in Texas

USDA Intends to Grant Exclusive License to "Royal" Chickpea Variety to Washington State Crop Improvement Association

USDA Announces the Designation for the State of Georgia and State of Montana Areas for Grain Standards Act

USDA Intends to Review U.S. Standards for Grades of Carcass Beef

Upcoming Meetings, Workshops, and Conferences

Meeting of the Codex Committee on Food Import and Export Inspection and Certification Systems, **September 25, 2014**, in Washington, D.C.

Meeting of the Codex Committee on Food Hygiene, **October 23, 2014**, in Washington, D.C.

Enforcement Updates

Recent Product Recalls
Recent food recalls primarily involved microbial or other contaminations. FDA reported individual brands of ground oregano, carob powder, and dietary supplements were recalled due to potential *Salmonella* contamination. USDA reported chicken nuggets and strips were recalled due to foreign matter contamination and quality control deviations.

In addition, a distributor recalled certain chocolate almond candies that failed to list eggs as an ingredient, and another company issued a recall of certain smoked sausage for failing to declare soy ingredients.

An appetite-control supplement was recalled after FDA analysis confirmed the illegal presence of DMAA, which FDA warns can pose dangerous cardiovascular risks.

For a complete list of product recalls, click here for FDA-regulated products, and here for USDA-regulated products.

Recent Warning Letters
Since the last *Update*, FDA posted several warning letters involving manufacturing and processing violations. FDA warned eight seafood processing facilities, including sites in Japan, Peru, and Thailand, for failing to comply with hazard analysis and critical control points ("HACCP") and current good manufacturing practice ("CGMP") regulations. The HACCP violations included having inadequate temperature controls and failing to implement certain affirmative steps. Two juice companies were also cited for HACCP and CGMP violations. In addition, FDA cited two low-acid canned food manufacturers for providing incomplete information to FDA about their processes and for violating temperature- and pH-monitoring requirements.

In the areas of product labeling and marketing, FDA cited three companies for violating nutrition labeling requirements, including a soap manufacturer for failing to declare the trans fat content of coconut oil products. Based on its review of websites and marketing materials, the Agency warned three other firms for promoting dietary supplement and food products for unapproved therapeutic uses.

Other recent warnings included notices to a feed yard operator and cattle dealer for illegal drug residue and a citation to a dairy farm for unapproved uses of an animal drug.

Click here for FDA's Warning Letters Home page (scroll down for listing of recently posted Warning Letters).