JONES DAY | **Food, Dietary Supplement & Cosmetics Regulatory Update**
Vol. II | Issue 18 | October 2015 JONES DAY

Top News

FDA Issues FSMA Preventive Controls for Human and Animal Food Final Rules
This month, FDA finalized two rules on current Good Manufacturing Practices ("cGMP") and preventive control requirements, see here and here, under the Food and Safety Modernization Act ("FSMA"). These rules cover human and animal food facilities and aim to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. Requirements for both rules are quite similar, requiring owners, operators, or agents of food facilities to implement written preventive control plans that identify and evaluate known or reasonably foreseeable hazards in the food, including biological, chemical, physical, and radiological hazards. The rules require that such food safety plans must include a hazard analysis, preventive controls, monitoring, corrective action and verification procedures, and recordkeeping. The FDA has stated it has evaluated the comments received from the public, allowing for more flexibility in some of the rules' requirements. For example, the "farms" definition has been extended to narrow the kinds of facilities covered by the rules, and the responsibilities under the supply-chain program have been reduced by, among other things, not requiring facilities where hazards are identified and controlled by a subsequent entity in the distribution chain to implement preventive controls. Additionally, FDA provides industry with staggered implementation based on business size, cGMP requirements, and preventive control requirements. Implementation will occur over a number of years, beginning on September 17, 2016.

CONTACTS

Edgar J. Asebey
Miami

Cristiana Spontoni
Brussels

Colleen M. Heisey
Washington

Jonathan Berman
Washington

Emily K. Strunk
Washington

Katherine M. Llewellyn
Brussels

Aleš Bartl
Brussels

Stephanie L. Resnik
Washington

Matthew R. Bowles
Washington

Marina E. Moreno, FDA Coordinator in the Miami Office, assisted in the preparation of this Update.

Detailed Contact Information

RELATED PRACTICES

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FDA Releases Menu Labeling Draft Guidance
FDA issued a draft guidance titled "A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11)," to help companies comply with the menu labeling final rule. This rule requires that calorie information be listed on menus and menu boards of restaurants and other retail food establishments that are part of a chain of 20 or more locations, do business under the same name, and offer for sale substantially the same menu items. FDA states the guidance covers most frequently asked questions to help restaurants understand the nutrition labeling requirements under the Federal Food, Drug, and Cosmetic Act, and to help them comply with the rule by its already extended compliance date (December 1, 2016). See our previous Jones Day *Update*. FDA asserts that it is "committed to working collaboratively with establishments" and welcomes any additional comments. Part I of the guidance, dated April 2008, is under FDA current revision and hence not available to the public.

Market Opportunities for U.S. Exports in Africa
The U.S. is looking to expand agricultural exports into South Africa. Deputy Secretary of Agriculture Krysta Harden is visiting South Africa for that purpose in November 2015. He claims to be excited to travel to Africa and is counting on "a new group of U.S. agricultural leaders to further explore market opportunities, especially for small, minority and women-owned businesses."

In addition, the U.S. recently negotiated to lift "anti-dumping" duties that had been in effect for 15 years, imposed as a result of a former U.S. outbreak of avian influenza. The U.S. requested the removal of this import barrier, which affected the sale of bone-in chicken in South Africa, at the time of renewing the African Growth and Opportunity Act ("AGOA"), an agreement that allows African countries to export to the U.S. certain products duty-free and that will continue until 2025. Despite the fact that South Africa has not yet enacted rules for a tariff-rate quota system, it has vowed to allow 65,000 metric tons of U.S. poultry imports a year.

European Parliament Bans Cloning of Farm Animals
On August 7, 2015, the European Parliament ("EP") voted on the proposal of two European Commission ("EC") directives aimed to (i) provisionally ban the cloning of farm animals, which include cattle, sheep, goats, pigs, and horses in the EU, (ii) provisionally ban imports of animal clones and the sale within the EU of food derived from them, and (iii) review the applicable legislation in light of the EU countries' implementation experience and on the basis of scientific reviews that may emerge in cloning improvements. The EP supported the proposed ban and added new provisions to also prohibit the marketing of cloned animals' offspring coming from countries outside the EU.

In the EU, food from clones needs premarket approval based on a scientific food safety assessment by the European Food Safety Authority ("EFSA") before it can be put on the market. The proposals come as a result of not only the ethical concerns relating to cloning but also scientific evidence that has emerged indicating that some animals may suffer from poor health due to cloning and may have higher mortality rates. The proposal could enter into force in 2016.

Other News
Montana Farmers Urge Congress to Support COOL

California Pushes for Water Bond to Relieve Drought

Livestock Bluetongue Disease Reported in France, Romania, and Hungary and Canada

Two Senators Introduce "Tribal Nutrition Improvement Act of 2015" Bill to Provide Native Americans with Access to School Meals

Members of EP ("MEPs") Seek Better Aid Packages for Farmers

MEPs Urge European Commission to Issue Animal Welfare Strategy for Period 2016–2020

Regulatory Updates

FDA Issues Final Rules on Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Controls for Human and Animal Food
In the September 17, 2015, *Federal Register,* FDA issued two final rules, here and here, to amend and add regulations on Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Humans and Animals. The rules modernize longstanding current good manufacturing practice requirements and implement new FSMA statutory provisions to build a food safety system for the future that makes modern, science- and risk-based preventive controls the norm across all sectors of the human and animal food system. *See leading story above*. ***The final rules are effective November 16, 2015.***

FDA Publishes New Documents Updating Docket on Proposed Rule to Amend Labeling Requirements for Conventional Foods and Dietary Supplements
In the September 10, 2015, *Federal Register*, FDA announced the availability of documents updating the administrative docket of the proposed rule amending FDA's labeling regulations for conventional foods and dietary supplements. Documents provide updated nutrition information on the Nutrition Facts and Supplement Facts labels to assist consumers in maintaining healthy dietary practices. ***Comment period has been extended until October 13, 2015***.

FDA Publishes Certification Fees for Export Certificates of Animal Food
In the September 10, 2015, *Federal Register*, FDA announced the fees for issuing export certifications for animal food, which may reach up to $175 for each certificate. Under the authority of the FSMA, FDA can charge fees to cover costs associated with issuing export certificates. FDA states that for some classes of products including animal food, the certificates cost more than $175 to prepare. ***The fees are effective October 1, 2015***.

FDA Proposes Rule on Emergency Permit Control Regulations
In the September 22, 2015, *Federal Register*, FDA proposed to amend certain regulations pertaining to registration and process filings related to acidified foods and thermally processed low-acid foods packaged in hermetically sealed containers (also known as "low-acid canned foods" or "LACF"). The amendments would reflect new FDA process filing form numbers and would make changes to addresses or locations where such forms can be found or must be sent. Additionally, the amendments would remove obsolete references to the effective dates that occurred years ago, and update a reference to another federal agency. ***Comments are due December 7, 2015***.

FDA Publishes Qualitative Risk Assessments of Risks of Activity/Food and Activity/Animal Food Combinations for Activities Conducted in a Facility Co-Located on a Farm
In the September 17, 2015, *Federal Register*, FDA announced the availability of two Risk Assessments ("RAs"), *see* here and here, titled "Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" and "Qualitative Risk Assessment: Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm," respectively. The purpose of the RAs is to provide a science-based risk analysis of those activity/human and animal food combinations that would be considered low risk when conducted in a food facility co-located on a farm.

FDA Publishes Draft Compliance Policy Guide for Crotalaria Species Seeds in

Grains
In the September 21, 2015, *Federal Register*, FDA announced the availability of a draft Compliance Policy Guide ("CPG") titled "Compliance Policy Guide Sec. 100.101 *Crotalaria* spp. Seeds in Grains." The draft replaces "CPG 7126.15 Crotalaria Seeds in Grains and Feeds," which was revoked in 1994 and inadvertently affected interactions between FDA and USDA's Federal Grain Inspection Service. The draft, when finalized, will provide guidance for FDA staff on the agency's regulatory action criteria for Crotalaria species seeds in grains. ***Comments are due November 20, 2015***.

FSIS Proposes New System of Records for Consumer Complaint Monitoring
In the September 8, 2015, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") proposed under the Privacy Act of 1974, as amended, to establish a new system of records, titled "Consumer Complaint Monitoring System" ("CCMS") II. The CCMS will effectively identify potentially unsafe meat, poultry, or processed egg products regulated by FSIS by recording, sorting, analyzing, and tracking consumer complaints regarding products' potential adverse effects, and by tracking any subsequent analyses and investigations of those complaints. ***Comments are due October 8, 2015. If no comments are received by then, the rule will become effective on above date***.

USDA Requests Comments on Climate Change, Global Food Security, and the U.S. Food System Assessment Report
In the September 8, 2015, *Federal Register*, USDA announced the development of an interagency assessment report titled "Climate Change, Global Food Security, and the U.S. Food System" to support the National Climate Assessment of the U.S. Global Change Research Program, and called for under the President's Climate Action Plan. USDA is requesting input from the public while the final report is being prepared. It will be published on USDA's website when it becomes available***. Comments are due October 8, 2015 and are accepted electronically via http://www.globalchange.gov/notices***.

APHIS Proposes Rule to Amend Scrapie Regulations
In the September 10, 2015, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") proposed to amend regulations regarding scrapie, a degenerative and eventually fatal disease affecting the central nervous systems of sheep and goats, by, among others: (i) changing the risk groups and categories established for individual animals and flocks, (ii) increasing the use of genetic testing as a means of assigning risk levels to animals, (iii) reducing movement restrictions for animals found to be genetically less susceptible or resistant to scrapie, and (iv) simplifying, reducing, or removing certain recordkeeping requirements. These changes would affect sheep and goat producers, persons who handle sheep and goats in interstate commerce, and state governments. ***Comments are due November 9, 2015***.

FSIS Publishes Correction to Proposed Rule on Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products
In the September 10, 2015, *Federal Register*, USDA's FSIS published a correction to the proposed rule published on June 10, 2013 regarding new labeling requirements for raw or partially cooked needle- or blade-tenderized beef products, including beef products injected with a marinade or solution. The correction is to remove ", that do not fall under a regulatory standard of identity" from page 34603, second column, and to add a period after "solution." The phrase was inadvertently included when characterizing which products would be subject to the rule. FSIS indicated the error was evident when reading the phrase as a whole.

APHIS Proposes to Implement Animal Disease Traceability Information System
In the September 16, 2015, *Federal Register*, USDA's APHIS proposed to add to its inventory of records a system of records titled the "Animal Disease Traceability Information System, USDA-APHIS-16," to maintain records of activities conducted pursuant to APHIS's mission and responsibilities authorized by the Animal Health Protection Act, which include disease control, among others. ***Comments are due October 16, 2015, and unless modified to respond to comments the rule will***

become effective October 26, 2015.

AMS Announces Positive Referendum Results Regarding Sorghum Promotion, Research, and Information Program
In the September 25, 2015, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") announced sorghum producers and importers approved, with a majority of the votes in a national referendum from March 23, 2015 through April 21, 2015, the continuation of the Sorghum Promotion, Research, and Information Order. As a result, the Sorghum Checkoff Program, which improves the market position of the covered commodity by expanding markets, increasing demand, and developing new uses and markets, will continue to be funded by a mandatory assessment on producers and importers at the rate of 0.6 percent of net market value of grain sorghum and 0.35 percent of net market value for sorghum forage, sorghum hay, sorghum haylage, sorghum billets, and sorghum silage.

APHIS Requests Comments on Changes to Requirements for Field Testing Regulated Genetically Engineered Wheat
In the September 25, 2015, *Federal Register*, USDA's APHIS requested comments regarding plans to require the authorization of field testing of regulated genetically engineered ("GE") wheat under permit. This will help (i) prevent future compliance issues, (ii) protect plant health and the environment, and (iii) allow for flexibility in the length of the volunteer monitoring period and the specific permit conditions to address how volunteers of GE wheat will be appropriately managed. Currently, GE wheat field trials are authorized under notification. ***Comments are due October 26, 2015***.

Other USDA Announcements
- APHIS Authorizes Importation of Fresh Cranberries from Chile into the U.S.
- APHIS Authorizes Importation of Fresh Peppers from Peru into the U.S. and Territories
- APHIS Authorizes Importation of Citrus from the Entire Country of Peru into the U.S.
- APHIS Authorizes Importation of Kiwi (Actinidia deliciosa and Actinidia chinensis) from Chile into the U.S. Subject to a Systems Approach
- APHIS Announces Availability of Supplement to Environmental Assessment and Finding of No Significant Impact Relative to Oral Rabies Vaccination Field Trial in New Hampshire, New York, Ohio, Vermont, and West Virginia
- USDA's Agricultural Research Service Intends to Grant Exclusive License on Baby Blues to Oregon State

USDA Announced the Following Requests for Information:
- Evaluation of the Food Insecurity Nutrition Incentive Grant Program
- Generic Clearance for Survey Research Studies

USDA Announced the Following Information Collections Have Been Revised, Renewed, and/or Extended:
- Risk Management Education and Targeted States Partnerships Program
- Electronic Mailing List Subscription Form
- Multiple Peril Crop Insurance

USDA Announced the Following Information Collections Have Been Submitted to OMB:
- Advance of Loan Funds and Budgetary Control and Related Burdens
- National Hunger Clearinghouse Database Forms
- PPQ Form 816; Contract Pilot and Aircraft Acceptance
- Foreign Market Development Cooperator Program and Market Access Program

FDA Announced the Following Information Collections Have Been Submitted to OMB:
- Electronic User Fee Payment Request Forms

FDA Announced the Following Collections Have Been Approved by OMB:

- Animal Food Labeling; Declaration of Certifiable Color Additives

FDA Issued the Following Draft and Final Guidance Documents

Draft Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II (Menu Requirements in Accordance with 21 CFR 101.11), September 16, 2015, *Federal Register*. ***Comments are due November 2, 2015***.

European Regulatory Updates

EC Publishes Antimicrobial Guidance for Treatment of Livestock

On September 11, 2015, the EC published Guidelines aimed at preventing the overuse and misuse of antibiotics to avoid antimicrobial resistance ("AMR") in animals. In particular, the Guidelines provides member state authorities, farmers, and veterinarians with practical examples of what other EU member countries have done to promote the prudent use of antimicrobials in veterinary medicine. Additionally, the Guidelines includes species-specific advice. For example, with regards to poultry, the Guidelines state that the EC is concerned about prophylactic treatment of the young and eggs. In addition, antimicrobials should not be used to control salmonella, and the use of third- and fourth-generation cephalosporins should be banned. Additional advice is provided for pigs, cattle, and rabbits. The EC emphasizes the importance of international cooperation in tackling AMR, assessing it causes 25,000 deaths annually and more than €1.5 billion in health care expenses and productivity losses in Europe alone.

Upcoming Meetings, Workshops, and Conferences

Public Meeting of the National Organic Standards Board, **October 13** and **20, 2015**, via webinar.

EFSA's 2nd Scientific Conference, **October 14–16, 2015**, in Milan, Italy.

Public Meeting of the Codex Alimentarius Commission Committee on Food Hygiene, **October 19, 2015**, in Washington, D.C.

Public Meeting titled "FDA Food Safety Modernization Act: Final Rules to Establish Requirements for Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human and Animal Food," **October 20, 2015**, in Chicago, IL or via webinar.

Public Meeting of the Codex Alimentarius Commission Committee of Nutrition and Foods for Special Dietary Uses, **October 27, 2015**, in College Park, MD.

Public Meeting of the National Organic Standards Board, **October 26–29, 2015**, in Stowe, VT.

Jones Day FDA Regulatory & Compliance Counseling Contacts

Edgar J. Asebey
Miami
+1.303.714.9707
easebey@jonesday.com

Cristiana Spontoni
Brussels
+32.2.645.14.48
cspontoni@jonesday.com

Colleen M. Heisey
Washington
+1.202.879.3449
cmheisey@jonesday.com

Jonathan Berman
Washington
+1.202.879.3669
jberman@jonesday.com

Emily K. Strunk
Washington

Katherine M. Llewellyn
Brussels

Aleš Bartl
Brussels

Stephanie L. Resnik
Washington

+1.202.879.3778
estrunk@jonesday.com

+32.2.645.14.47
kllewellyn@jonesday.com

+32.2.645.14.52
abartl@jonesday.com

+1.202.879.5458
sresnik@jonesday.com

Matthew R. Bowles
Washington
+1.202.879.3604
mbowles@jonesday.com

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