



FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

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Jones Day Announcements

Health Care and Life Sciences Practice Expands with Arrival of Edgar J. Asebey

Edgar J. Asebey has joined the Firm's Miami Office as a partner in its Health Care and Life Sciences practice. He arrives from Roetzel & Andress in Washington, D.C. and Fort Lauderdale, where he was the Practice Group Manager for Food & Drug Law. Mr. Asebey's practice focuses on foods, medical devices, drugs, dietary supplements, and cosmetics, and he advises clients in these industries on regulatory, registration, importation, and enforcement matters. He also counsels clients on premarket approval submissions and on compliance issues associated with the development, manufacture, marketing, and sale of FDA-regulated products. Mr. Asebey is a leading authority on the Food Safety Modernization Act ("FSMA") and has lectured in forums in Latin America, Japan, and the U.S. on FSMA's impact on U.S. importers, non-U.S. food exporters, and food companies. He has extensive experience with clients in Latin America, and he is an active speaker and writer on FDA and life science matters. Since 2011, he has delivered more than 30 presentations on the impact of FSMA and related topics.

Top News

New Dietary Guidelines Advisory Report Focuses on Reducing Sugar

The Dietary Guidelines Advisory Committee ("DGAC") recently released the Scientific Report of the 2015 Dietary Guidelines for Americans (the

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"Advisory Report") to the Secretaries of the U.S. Department of Health and Human Services ("HHS") and the USDA.

The agencies will rely on the Advisory Report in developing the Dietary Guidelines for Americans, 2015, to be jointly released by HHS and USDA later this year. New dietary guidelines have been published every five years since 1980 and form the basis of federal nutrition policy, education, outreach, and food assistance programs used by consumers, industry, nutrition educators, and health professionals.

■ [Read More](#)

FDA, CDC, and USDA Partner to Develop Improved Method for Identifying Sources of Foodborne Illness

FDA, the Centers for Disease Control and Prevention ("CDC"), and USDA's Food Safety and Inspection Service ("FSIS") recently announced the development of an improved method for analyzing outbreak data to trace the cause of foodborne illness caused by the four major foodborne bacteria: *Salmonella*, *E. Coli*, *Listeria*, and *Campylobacter*. CDC estimates that these four pathogens cause 1.9 million cases of foodborne illness in the United States each year. On February 24, 2015, the three agencies released a [report](#) on the new method, produced by the Interagency Food Safety Analytics Collaboration ("IFSAC"). The agencies anticipate IFSAC's work will enhance their efforts to prevent foodborne illness. Some of the findings of the report include that [more than 80 percent of *E. Coli* illnesses were attributed to beef and vegetables grown in rows](#). The report also traces Salmonella infections to a wider variety of foods, ranging from tomatoes to sprouts to chicken, beef, and pork. The interagency report comes on the heels of [President Obama's](#) and a group of [Democratic senators' and representatives' proposals](#) for a single food safety agency.

FDA Releases Enhanced Web-Based Tool to Assess Food Safety

Last week, [FDA announced](#) the release of an enhanced version of a free web-based tool called [FDA-iRISK 2.0](#) that helps users conduct their own quantitative risk assessments in support of food safety. The tool allows users to rank and compare risks and predict the effectiveness of prevention and control measures. The Joint Institute for Food Safety and Applied Nutrition will host a [webinar](#) on March 11, 2015, to highlight the key features of the enhanced tool.

Other News

[FDA Announces Closure of Comment Period for Fish Consumption Advice](#)

[New Study Suggests Feeding Infants Peanuts Could Prevent Allergies](#)

[Hershey to Ban GMO Ingredients from its Chocolate Products](#)

[FDA Announces Grant to Support Branded Food Products Database to Monitor Sodium Content](#)

[USDA Proposes Loosening Livestock Export Requirements](#)

Regulatory Updates

HHS and USDA Announce Availability of Scientific Report of 2015 Dietary Guidelines Advisory Committee

In the [February 23, 2015, Federal Register](#), HHS and USDA announced the availability of the [Scientific Report of the 2015 Dietary Guidelines Advisory Committee \("Advisory Report"\)](#). The announcement also solicits written comments on the Advisory Report and provides notice of a public meeting to solicit oral comments on the Advisory Report. The report contains nutritional and dietary information and guidelines for the general public. **Comments due April 8, 2015; public meeting to be held March 24, 2015.**

FDA Announces Availability of Grant Funds to Develop Branded Foods Products Database for Public Health

In the [February 24, 2015, Federal Register](#), FDA announced the availability of grant funds for the support of the Agricultural Technology Innovation Partnership's ("ATIP") Branded Food Products Database for Public Health. The funds are available from the Office of Foods and Veterinary Medicine ("OFVM") for the goal of monitoring the sodium content of branded food in the U.S. marketplace. A database that reflects the sodium content of foods will help OFVM research strategies regarding sodium reduction and help the public maintain healthy diets. ATIP has established a public-private partnership with USDA's Agricultural Research Service and the International Life Sciences Institute North America to compile data for the public's benefit. **Applications due April 2, 2015.**

USDA Releases New Web-Based Self-Reporting Tool for Foreign Food Regulatory Systems

In the [February 23, 2015, Federal Register](#), USDA's FSIS released to the public its new Web-Based Self-Reporting Tool ("SRT") that it will send to foreign countries to report information on their food regulatory systems. The purpose of the SRT is to establish that the foreign food regulatory systems are equivalent to those of the United States. FSIS will send SRTs to all countries currently eligible to export meat, poultry, and egg products to the United States on December 1 of each year going forward.

FDA and EPA Close Public Comment Period for Advice About Eating Fish

In the [February 24, 2015, Federal Register](#), FDA and the U.S. Environmental Protection Agency ("EPA") announced the March 26, 2015, closure date of the public comment period for draft fish consumption advice titled "[Fish: What Pregnant Women and Parents Should Know](#)." The draft was released for public comment in the [June 11, 2014, Federal Register](#).

USDA Proposes Revised Regulations Pertaining to Export of Livestock from the United States

In the [February 26, 2015, Federal Register](#), USDA's Animal and Plant Health Inspection Service ("APHIS") issued a proposed rule revising the regulations pertaining to the exportation of livestock from the United States. The proposed rule would remove most of the requirements for export health certifications, tests, and treatments from the regulations, instead directing exporters to follow the requirements of the importing country. The proposal would also provide exporters and APHIS more flexibility in arranging for the export of livestock from the United States. **Comments due April 27, 2015.**

FDA to Co-Sponsor Public Conference on Science Transforming Policy in Food, Drug, and Medical Device Regulation

In the [February 17, 2015, Federal Register](#), FDA announced, in co-sponsorship with the Association of Food and Drug Officials, a public conference entitled "In Motion: Science Transforming Policy in Food, Drug, and Medical Device Regulation" to be held June 20–24, 2015 at the Sheraton Indianapolis Hotel. The conference is intended to provide information about FDA food, drug, and device regulation to the regulated industry. **Registration due May 20, 2015.**

USDA Announces Meeting to Collect Input on Future Codex Committee Meeting on Pesticide Residue

In the [February 24, 2015, Federal Register](#), USDA's FSIS and EPA announced a public meeting to take place on March 16, 2015, to provide information and receive public comments on agenda items and draft United States positions to be discussed at the 47th Session of the Codex Committee on Pesticide Residues of the Codex Alimentarius Commission ("Codex"). The Codex meeting takes place in Beijing, China from April 13–18, 2015.

USDA Announces Meeting to Collect Input on Future Codex Committee Meeting on General Principles

In the [February 25, 2015, Federal Register](#), USDA announced a public meeting that took

place on the same day. The objective of the meeting was to provide information and receive public comments on agenda items and draft United States positions to be discussed at the 29th Session of the Codex Committee on General Principles of the Codex, which takes place in Paris, France from March 9–13, 2015.

Other USDA Announcements

- APHIS Proposes Amendment to Regulations to Allow Importation of Fresh Hass Avocados from Mexican State of Michoacán
- USDA's Agricultural Marketing Service ("AMS") proposes rule on Establishing Proportion of Tart Cherries for Commercial Outlets
- AMS Announces Referendum to be Conducted Among Eligible Sorghum Producers and Importers
- APHIS Amends Regulations to Recognize the State of Sonora as Region in Mexico Free of Fever Ticks
- Federal Crop Insurance Corporation Proposes to Replace Subpart V of General Administrative Regulation

USDA Announced the Following Requests for Information

- Software Vendors of State and Local Management Information Systems and Other Technology Solutions for the National School Lunch and School Breakfast Programs

USDA Announced the Following Information Collections Have Been Revised and/or Extended

- Substantially Underserved Trust Areas

USDA Announced the Following Information Collections Have Been Submitted to OMB

- Importation of Poultry Meat and Other Poultry Products from Sinaloa and Sonora, Mexico
- National Poultry Improvement Plan
- Acreage/Crop Reporting Streamlining Initiative
- Qualified Product List for Wild Land Fire Chemicals

FDA Announced the Following Information Collections Have Been Submitted to OMB

- Guidance on Consultation Procedures: Foods Derived From New Plant Varieties
- Premarket Notification for a New Dietary Ingredient

FDA Issued the Following Draft and Final Guidance Documents

Draft Guidance for Industry: Evaluating the Effectiveness of New Animal Drugs for the Reduction of Pathogenic Shiga Toxin-Producing E. Coli in Cattle. February 24, 2015, *Federal Register*. **Comments due April 27, 2015.**

European Regulatory Updates

EFSA Simplifies Procedure for Exchange of Pesticide Active Substance Documents

Starting on February 24, 2015, the European Food Safety Agency's ("EFSA") [online platform](#) for sharing Draft Assessment Reports, Renewal Assessment Reports, and sanitization of background documents for the EU peer review of active substances will be live. The new platform aims at streamlining and increasing efficiency in the exchange of files with applicants.

EFSA Discusses Effects of Pesticide Exposure on Human Health

EFSA has [met with stakeholders](#) to gather input for its investigations into the possible effects of pesticide exposure on human health. The meeting focused on issues surrounding pesticide epidemiology. In recent years, an abundance of epidemiological studies investigating possible associations between pesticide exposure and human health outcomes have become available in the open literature. In 2013, EFSA published a report on a systematic review of studies published between 2006 and 2012 that showed a

statistically significant association between exposure to pesticides and health outcomes such as liver cancer, breast cancer, type II diabetes, childhood leukemia, and Parkinson's disease.

EFSA Consults On Draft TCC Report

EFSA and the World Health Organization have [published](#) the draft conclusions and recommendations of their joint workshop on the Threshold of Toxicological Concern approach. ***The Agency invites responses to the consultation until March 29, 2015.***

European Agency's 64th Management Board Meeting

EFSA [invites](#) the public to observe the proceedings of the 64th Management Board meeting. The meeting will take place in Parma, Italy, on March 19, 2015. Attendees will have the right solely to observe and will not be able to join the debate. Registrations are open until Friday, March 13, 2015, at 12:00 CET.

Counterfeit Vodka Being Sold in the UK

The UK Food Standards Agency ("FSA") has issued a [warning](#) regarding counterfeit Glen's Vodka on sale in several locations around the UK. According to the FSA's warning, the counterfeit bottles can be identified by several mistakes on the label: (i) the word "bottled" is misspelled as "botteled" and (ii) below the statement "Enjoy Glen's Vodka Responsibly," customers are alerted to the website D-rink Aware.co.uk, whereas genuine bottles read DrinkAware.co.uk. Brand owner Loch Lomond Distillery Co has been made aware of the problem and is helping local authority officers and the FSA with their investigations.

Upcoming Meetings, Workshops, and Conferences

[Fruit and Vegetable Industry Advisory Committee](#), **March 10-11, 2015**, in Washington, D.C.

[FDA-iRISK 2.0 Webinar Sponsored By JFSAN](#), **March 11, 2015**, via webcast.

[USDA Invitation-Only Workshop on Agricultural Coexistence](#), **March 12-13, 2015**, via webcast.

[FDA Meeting on Regulation of Combination Drug Medicated Feeds](#), **March 16, 2015**, in Rockville, MD.

[Public Meetings on U.S. Positions for Codex Committees:](#)

- [Pesticide Residues](#), **March 16, 2015**, in Arlington, VA.
- [Residues of Veterinary Drugs in Foods](#), **March 19, 2015**, in Washington, D.C.

[HHS and FDA Meeting on Scientific Report of the 2015 Dietary Guidelines Advisory Committee](#), **March 24, 2015**, in Bethesda, MD.

[FDA-JIFSAN Dietetics and Nutrition Spring Webinar Series](#), **March 24 and April 20, 2015**, via webcast.

[FDA Public Workshop: The 2015 Office of Regulatory Science and Innovation \(ORSI\) Science Symposium](#), **April 27, 2015**, in Silver Spring, MD.

[FDA and AFDO Conference titled *In Motion: Science Transforming Policy in Food, Drug, and Medical Device Regulation*](#), **June 20-24, 2015**, in Indianapolis, IN.

[EFSA's 2nd Scientific Conference](#), **October 14, 2015**, in Milan, Italy.

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PHARMACEUTICAL & MEDICAL DEVICE REGULATORY UPDATE

Top News

New Dietary Guidelines Advisory Report Focuses on Reducing Sugar

The Dietary Guidelines Advisory Committee ("DGAC") recently released the *Scientific Report of the 2015 Dietary Guidelines for Americans* (the "Advisory Report") to the Secretaries of the U.S. Department of Health and Human Services ("HHS") and the USDA. The agencies will rely on the Advisory Report in developing the *Dietary Guidelines for Americans, 2015*, to be jointly released by HHS and USDA later this year. New dietary guidelines have been published every five years since 1980 and form the basis of federal nutrition policy, education, outreach, and food assistance programs used by consumers, industry, nutrition educators, and health professionals.

Against the backdrop of data showing that over two-thirds of Americans are obese or overweight, DGAC [has eased some of the previous restrictions on fat and cholesterol](#), while at the same time recommending stricter limits on the amount of added sugar. In doing so, DGAC has aligned itself with other major health groups such as the [American Heart Association](#), which recently backed away from dietary cholesterol restrictions, instead focusing on reducing added sugars. In the Advisory Report, DGAC concludes that "a healthy dietary pattern is higher in vegetables, fruits, whole grains, low- or non-fat dairy, seafood, legumes, and nuts; moderate in alcohol (among adults); lower in red and processed meats; and low in sugar-sweetened foods and drinks and refined grains." But the Advisory Report focuses less on individual nutrients and more on overall patterns of eating, highlighting Mediterranean-style and vegetarian diets. DGAC further notes that such [plant-based diets are more environmentally sustainable](#).

Notably, DGAC for the first time recommends that Americans limit their added sugars to no more than 10 percent of daily calories (roughly 12 teaspoons per day) due to the link between added sugar and obesity and chronic disease. Americans currently consume 22 to 30 teaspoons of added sugar daily. Along those lines, DGAC recommends removing sugary drinks from schools and [endorses a proposed FDA rule that would require a distinct line for added sugars on food nutrition labels](#). The Advisory Report also recommends unsaturated fat—found in fish, nuts, and olive and vegetable oils—instead of saturated fat—found primarily in animal foods. The advice against saturated fat has received criticism in light of [several recent studies that cast doubt on the link between saturated fat and heart disease](#).

The Advisory Report is [open for comment](#) until April 8, 2015.

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