Food, Dietary Supplement & Cosmetics Regulatory Update
Issue 19 | December 2014 JONES DAY

Top Stories

FDA Issues Long-Awaited Calorie Labeling Rules for Restaurants and Vending Machines
On December 1, 2014, FDA finalized two rules requiring calorie information to be listed on menus in chain restaurants and similar retail food establishments and to be prominently displayed on most vending machines. The new rules implement requirements that became law under the Patient Protection and Affordable Care Act ("ACA").

The menu labeling rule applies to fast-food and sit-down restaurants as well as other food retailers, such as movie theaters and amusement parks, that are part of a chain of 20 or more locations. Starting December 1, 2015, such establishments must conspicuously display calorie information for standard items on their menus and menu boards, next to the name or price of the entree. Vending machine operators with 20 or more machines will have two years to comply with the vending machine rule, which requires information to be displayed so prospective purchasers can examine an item's calorie content before purchasing it. The rulemaking was particularly contentious among non-restaurant food establishments. In response to public comments, FDA made several changes from its original proposals, including narrowing the scope of foods covered by the rule and providing flexible disclosure policies for multi-serving entrees, such as pizza by the slice. Certain alcoholic beverages are also subject to the menu labeling rule, but most seasonal menu items, daily specials, and condiments are exempt from its requirements.

CONTACTS

Mark Mansour
Washington

Cristiana Spontoni
Brussels

Colleen M. Heisey
Washington

Jonathan Berman
Washington

Emily K. Strunk
Washington

Katherine M. Llewellyn
Brussels

Stephanie L. Resnik
Washington

Brigid C. DeCoursey
Washington

Matthew R. Bowles
Washington

Detailed Contact Information

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In recent years, several state and local governments and some restaurant chains have adopted menu labeling standards. FDA's new rules will impose uniform federal standards and help reduce the need for multistate chains to comply with various state requirements. According to FDA, Americans eat and drink about one-third of their calories away from home. FDA Commissioner Margaret Hamburg described the new rules as "an important step for public health that will help consumers make informed choices for themselves and their families" when visiting restaurants and buying food from vending machines.

FDA Releases Revised Food Facility Registration Q&A, Clarifying Applicability of "Farms" Registration While FSMA Rulemaking Is Ongoing

On November 19, 2014, FDA issued its sixth edition of food facility registration Q&A guidance, providing an updated section that addresses proposed changes to the definition of "farm" for food facility registration purposes. Organized in a question-and-answer format, the guidance document describes facility registration requirements for domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. This updated version discusses part of a proposed rule under the Food Safety Modernization Act ("FSMA") by which a farm would no longer be required to register as a food facility solely because it packs or holds raw agricultural commodities grown on a farm under different ownership. According to the guidance document, FDA does not intend to prioritize enforcing the registration requirement under this circumstance while the rulemaking is pending.

Advocacy Groups Sue FDA to Set Aside Approval of Controversial Animal Feed Additive

Last month, in two related actions, a coalition of public health and environmental groups sued FDA, seeking to overturn the agency's approval of ractopamine as an additive in cattle and pig feed. FDA initially approved ractopamine in 1999 as a beta-agonist used to boost livestock weight. In their complaints, the Center for Food Safety, the Humane Society, and other advocacy groups allege FDA failed to adequately assess significant environmental and health risks associated with ractopamine, the use of which as a food additive has been banned by some countries. The complaints also claim ractopamine is associated with higher stress hormones in livestock, which can lead to increased presence of bacteria such as *E. coli* and *Salmonella*.

European Parliament Committee Votes on Draft Legislation on Bioengineered Crops and Novel Foods

The Environment Committee of the European Parliament ("ENVI") recently took actions to advance multiple draft legislations that would impose a moratorium on the use of nanomaterials in food processing, require labeling of cloned food products, and allow EU Member States to ban bioengineered crops.

In particular, on November 24, 2014, ENVI voted on the European Commission's proposed Novel Foods regulation, which aims at introducing a simplified authorization procedure for novel foods. ENVI introduced amendments to the European Commission's proposal, which require that foods processed with nanomaterials be approved by the European Food Safety Authority ("EFSA") before they are authorized to enter the EU market and that cloned food products be labeled as such. The next step in the legislative process is for the position of the Council of Ministers to be agreed.

Earlier in the month, ENVI backed a separate draft proposal, which would give EU Member States greater flexibility to ban the cultivation of bioengineered crops within their borders even if such crops were previously authorized at EU level. ENVI's plans allow EU Member States to justify such ban on a range of environmental grounds, which was not foreseen by the European Commission's proposal. ENVI's proposal, while informally agreed by Parliament and Council on December 3, 2014, still needs to be formally approved by the entire European Parliament and Council of Ministers before it becomes law.

Other News

FDA Issues Update Explaining Improvements to Cosmetics Color Additive Certificates of

Analysis

EFSA Updates Opinion on Food Allergies for Labeling Purposes

In Settlement, Granola Bar Maker Agrees Not to Make "100% Natural" Claim on Certain Labels

FDA Deputy Commissioner Discusses FSMA with State Officials, Food Producers, and Safety Advocates During New England Tour

House Committee Hearing Explores FDA's Role in Regulating Bioengineered Ingredients

President Obama Signs Sunscreen Innovation Act into Law

EFSA Publishes Outcome of Consultation with Member States on Basic Substance Application for Rheum Officinale

EFSA Publishes Outcome of the Consultation on the Basic Substance Application for Arctium Lappa

EU Report Concludes NIV and Deoxynivalenol Can Be Considered Devoid of Genotoxic Potential

EFSA Publishes Explanatory Note for the Scientific Panel of Food Contact Materials, Enzymes, Flavorings and Processing Aids (CEF) on Food Enzymes

Supporters of Oregon Ballot Measure Sue State Over Procedures of Vote Recount

Regulatory Updates

FDA Issues Final Rule for Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Establishments
In the December 1, 2014, *Federal Register*, FDA issued a final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. Effective December 1, 2015, the final rule will require restaurants and similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items to provide calorie and other nutrition information for standard menu items, including food on display and self-service food. Restaurants and similar retail food establishments not otherwise covered by the law may elect to become subject to these requirements by registering biennially with FDA. The final rule implements provisions of the ACA and is intended to make nutrition information available to consumers in a direct and accessible manner. ***Interested parties may submit comments by December 31, 2014***.

FDA Issues Final Rule on Calorie Labeling of Food in Vending Machines
In the December 1, 2014, *Federal Register*, FDA issued a final rule that will require calorie declarations for food sold from certain vending machines. Enacted pursuant to the ACA, the final rule goes into effect December 1, 2016, and it applies to vending machines operated by a person engaged in the business of owning or operating 20 or more vending machines. FDA aims to ensure that calorie information is available for certain food sold from a vending machine. Specifically, vendors must ensure calorie information is displayed for each product in cases where a prospective purchaser would not be able to examine the Nutrition Facts Panel before purchasing the article. Vending machine operators not otherwise covered by the law may elect to be subject to the requirements by registering with FDA. ***Interested parties may submit comments by December 31, 2014***.

FDA, USDA Set Uniform Compliance Date for 2015–2016 Food Labeling Rules
FDA and USDA recently announced January 1, 2018, as the uniform compliance date for

food labeling regulations issued in calendar years 2015–2016. In the December 10, 2014, *Federal Register*, FDA announced that regulated entities will have until the end of 2017 to comply with new food labeling regulations that are issued between January 1, 2015 and December 31, 2016.

Similarly, in the December 1, 2014, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") designated January 1, 2018, as the uniform compliance date for new meat and poultry product labeling regulations issued in 2015 or 2016. FDA and USDA periodically announce uniform compliance dates for new food product labeling regulations to minimize the economic impact of label changes. ***Comments on USDA final rule due December 31, 2014; comments on FDA final rule due February 9, 2015***.

FDA Issues Updated Q&A Guidance on Food Facility Registrations
In the November 19, 2014, *Federal Register*, FDA announced the availability of a guidance for industry titled *Questions and Answers Regarding Food Facility Registration (Sixth Edition)*. To reflect ongoing rulemakings under the FSMA, the guidance includes a new section on FDA's policy regarding food facility registration for farms that also pack or hold raw agricultural commodities grown on a farm under different ownership. ***Comments on FDA guidance may be submitted at any time***.

USDA Adopts Final Rule Regarding Importation of Birds, Poultry from Avian-Flu Regions
In the December 1, 2014, *Federal Register*, USDA adopted as a final rule, with changes, an interim rule amending the importation regulations for live birds and poultry (including hatching eggs) and bird and poultry products from regions where any subtype of highly pathogenic avian influenza ("HPAI") is considered to exist. The final rule amends the interim rule to allow importation of live zoological birds and poultry that have been vaccinated for avian influenza and satisfied other requirements and to allow, under certain conditions, the importation of HPAI-resistant pigeons, doves, and other designated species. ***The final rule is effective immediately***.

USDA Reopens Comment Period on Proposed Rule on Importation and Interstate Movement of Fruits and Vegetables
In the December 4, 2014, *Federal Register*, USDA announced it is reopening the comment period for a proposed rule to amend regulations on the importation and interstate movement of fruits and vegetables. Originally announced on September 9, 2014, the proposed rule seeks to broaden the existing performance standard with a notice-based approval process for importation or interstate movement of new fruits and vegetables into and within the United States and to remove certain region- or commodity-specific phytosanitary requirements from the regulations. ***Comments now due January 9, 2015***.

FSIS Releases Cost-Benefit Analysis on Implementation of Non-O157 STEC Testing for Raw Beef
In the November 19, 2014, *Federal Register*, USDA's FSIS published an analysis estimating the costs and benefits associated with implementation of non-O157 STEC testing on beef manufacturing trimmings. The analysis includes the agency's responses to comments on the process and also considers costs and benefits associated with potentially expanding the process to other ground beef components. ***Comments due January 20, 2015***.

FDA Solicits Nominations for Food Advisory Committee
In the December 8, 2014, *Federal Register*, FDA issued a notice asking for nominations of nonvoting industry representatives to serve on the Food Advisory Committee for the Center for Food Safety and Applied Nutrition ("CFSAN"). FDA will also receive requests to participate in the selection of such nonvoting industry representative to fill current vacancies. ***Nominations and requests to participate are due in writing to FDA by January 7, 2015***.

USDA Requests Nominations for Advisory Committee on Animal Health
In the December 3, 2014, *Federal Register*, USDA announced it is soliciting nominations

for members to serve for two-year terms on the Agriculture Secretary's Advisory Committee on Animal Health. The Committee advises USDA on strategies, policies, and programs to prevent, control, or eradicate animal diseases. Interested organizations and individuals must submit nomination forms to USDA by ***January 20, 2015***.

NIFA Solicits Nominations for Veterinary Medicine Loan Repayment Program
In the November 19, 2014, *Federal Register*, the National Institute of Food and Agriculture announced it is soliciting nominations of veterinary service shortage situations for its Veterinary Medicine Loan Repayment Program, which provides up to $25,000 each year toward qualified educational loans of eligible veterinarians. The notice initiates a 60-day nomination period for fiscal year 2015 and describes the procedures and criteria by which regions may nominate veterinary shortage situations. ***Comments due January 20, 2015***.

USDA's CCC Issues Final Rule on Export Credit Guarantee Programs
In the November 18, 2014, *Federal Register*, USDA's Commodity Credit Corporation ("CCC") issued a final rule, amending its regulations on the Export Credit Guarantee (GSM-102) Program to incorporate operational changes and administrative revisions implemented since publication of the current rule, and eliminating provisions for the Intermediate Export Credit Guarantee (GSM-103) Program, consistent with the repeal of that program pursuant to the Food, Conservation, and Energy Act of 2008. Export Credit Guarantee Programs support the commercial financing of U.S. agricultural exports. ***The final rule is effective December 18, 2014***.

Agriculture Secretary Appoints Members to National Agricultural Research, Extension, Education, and Economics Advisory Board
In the November 18, 2014, *Federal Register*, USDA announced that the Secretary of Agriculture has appointed members to fill eight vacancies on the National Agricultural Research, Extension, Education, and Economics Advisory Board. The Board is composed of 25 members who serve staggered, three-year terms. The eight vacancies were due to expiring terms.

FDA Publishes Privacy Act Notice About State, Local Officials' Commissioning Records
In the December 8, 2014, *Federal Register*, FDA published notice of a Privacy Act system of records titled "FDA Commissioning of State and Local Officials, HHS/FDA/ORA" System No. 09-10-0022. Required by the Privacy Act of 1974, the notice explains the agency's plans to replace a system of records containing information about state and local officials who have applied for an FDA commission to assist the agency with its regulatory compliance and enforcement efforts. FDA uses such records to assess qualifications, initiate background investigations, and track the status of commissioned officials.

USDA Announces Technical Amendment to National Poultry Improvement Plan
In the December 3, 2014, *Federal Register*, USDA announced a technical amendment to the final rule published on July 9, 2014, which revised provisions of the National Poultry Improvement Plan. Original publication of the final rule incorrectly indicated that table-egg layer flocks may qualify for U.S. H5/H7 Avian Influenza Monitored status if they meet one of three testing and surveillance requirements. This technical amendment clarifies that such flocks must meet all applicable listed testing and surveillance requirements to qualify. It also makes several other minor edits for clarity. For more information on the National Poultry Improvement Plan, see Issue 10 of the Jones Day *Food, Dietary Supplement & Cosmetics Regulatory Update*.

FDA Announces Availability of Environmental Assessment Supporting Food Additive Petition for Use of Ethoxyquin in Vitamin D Formulations
In the November 12, 2014, *Federal Register*, FDA announced the availability of an environmental assessment filed in support of a citizen petition proposing that the food additive regulations be amended to provide for the safe use of ethoxyquin in vitamin D formulations, including 25-hydroxyvitamin D3, used in animal food. Notice of the food additive petition was published on December 23, 2013.

Other USDA Announcements

- USDA Proposes Amending Importation Rules for Orchids in Growing Media from Taiwan
- Agricultural Marketing Service ("AMS") Directs Continuance Referendum for Marketing Order of Avocados Grown in South Florida
- USDA Issues Clarification of Bales Made Available for Shipment by CCC-Approved Warehouses
- USDA Issues Guidance to Federal Financial Assistance Recipients Regarding Civil Rights Act, Title VI Prohibition Against National Origin Discrimination Affecting Persons with Limited English Proficiency
- AMS Amends Process for Establishing Rates Charged for AMS Services
- AMS Proposes Assessment Rate Increase Under Honey Packers and Importers Research, Promotion, Consumer Education, and Information Order

FDA Announced the Opportunity to Comment on the Following Proposed Information Collections

- Comparing Food Safety Knowledge, Attitude, and Behavior Among English-Dominant Hispanics, Spanish-Dominant Hispanics, and Other Consumers
- 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
- Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body
- Substances Prohibited from Use in Animal Food or Feed
- Export of Food and Drug Administration Regulated Products: Export Certificates
- Premarket Notification for a New Dietary Ingredient

FDA Announced the Following Information Collections Have Been Submitted to OMB

- Food Allergen Labeling and Reporting

USDA Announced the Opportunity to Comment on the Following Proposed Information Collections

- Suspension and Debarment and Drug-Free Workplace Certifications
- Direct Loan Servicing-Special

USDA Announced the Opportunity to Comment on the Following Approved, Revised, and/or Extended Information Collections

- Milk and Milk Products Surveys
- Reporting, Herd Monitoring, and Management of Swine Enteric Coronavirus Diseases
- Field Crops Objective Yield
- Importation of Mangoes From Australia

USDA Announced the Following Information Collections Have Been Submitted to OMB

- Plan for Estimating Daily Livestock Slaughter under Federal Inspection
- Foot-and-Mouth Disease; Prohibition on Importation of Farm Equipment
- A Pilot Generic Clearance to Conduct Experimental Economic Research
- Technical Assistance for Specialty Crops Program
- Introduction of Organisms and Products Altered or Produced Through Genetic Engineering
- Organic Survey

European Union Regulatory Updates

EFSA Updates Scientific Opinion on Food Allergens

On November 26, 2014, EFSA published its updated scientific advice on food allergens. The EFSA scientific opinion examines in detail all the allergenic products and substances

whose presence in food must be indicated on labeling under EU law. Covered products include cereals containing gluten, milk, eggs, nuts, peanuts, soybeans, fish, crustaceans, mollusks, celery, lupin, sesame, mustard, and sulphites.

EU Authorizes Health Claim for Fats and Oils
On November 17, 2014, the EU authorized the following the health claim for use on fats and oils: "Replacing saturated fats with unsaturated fats in the diet has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease" subject to the condition that the claim may be used only for food that is high in unsaturated fatty acids, as referred to in the claim HIGH UNSATURATED FAT as listed in the Annex to Regulation (EC) No 1924/2006. Commission Regulation (EU) No 1226/2014 of 17 November 2014 on the authorisation of a health claim made on foods and referring to the reduction of disease risk.

EU Commission Issues Regulation on Vitamin D Claims
On November 17, 2014, Commission Regulation (EU) No 1228/2014 of 17 November 2014 authorising and refusing to authorise certain health claims made on foods and referring to the reduction of disease risk was issued authorizing certain health claims relating to Vitamin D and calcium, subject to certain conditions and rejecting certain other health claims.

EU Commission Rejects Certain Child Development Health Claims
On November 17, 2014, certain health claims relating to children's development and health were rejected by Commission Regulation (EU) No 1229/2014 of 17 November 2014 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.

EFSA Publishes New Scientific Opinions
EFSA recently published a series of Scientific Opinions addressing a range of topics including flavorings, dietary reference values for folate, and health claims for prunes, among others. A list of these recent opinions can be found here.

Upcoming Meetings, Workshops, and Conferences

EFSA Meeting on the Outcome of the Public Consultation on "Acrylamide in Food," **December 10, 2014**, in Brussels, Belgium.

Seventh Meeting of the USDA's 2015 Dietary Guidelines Advisory Committee, **December 15, 2014**, via webcast.

FDA Food Advisory Committee Meeting, **December 16–17, 2014**, in Washington, D.C.

EFSA Info Session on Applications—Technical Meeting with Stakeholders on Agronomic and Phenotypic Characterization of Bioengineered Plants, **December 18, 2014**, in Parma, Italy.

Meeting to Discuss U.S. Positions for Codex Committee on Fats and Oils (Codex Alimentarius Commission), **January 13, 2015**, in College Park, MD.

EFSA Info Session on Applications—FIP Technical Meeting on Food Flavorings Applications, **January 20, 2015**, in Parma, Italy.

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

Enforcement Updates

Recent Product Recalls
Recent food recalls involved undeclared ingredients, potential microbial and fungal contamination,

misbranding, and inadequate pasteurization or inspection, among others.

Undeclared allergens continue to be a major reason behind food recalls, with more than a dozen manufacturers recalling products for this reason in the last six weeks. According to FDA's website, manufacturers and grocery stores recalled products because of undeclared nuts, milk, soy, wheat, sulfites, fish, and egg in a range of products including desserts, raisins, bagels, cheese sticks, and pasta salad. One such product also contained undeclared certified colors (yellow #5 and yellow #6).

Several other products, including cheese enchiladas, brown rice flour, nuts, cheese, soybean sprouts, and smoked salmon were recalled due to potential *Salmonella* or *Listeria* contamination. Additionally, a creamery recalled its yogurt for potential inadequate pasteurization, and a grocery chain recalled organic raw almonds for possible elevated levels of naturally occurring hydrogen cyanide.

A dietary supplement powder was recalled for containing a fungus, and another dietary supplement was recalled for being an unapproved new drug. FDA also posted a recall of pet food for insufficient vitamin levels and excess minerals.

USDA recalls included pork belly product for lack of border inspection and ground beef due potential *E. coli* contamination. USDA also posted recalls of various pork products, pretzel dog products, and pierogi products due to misbranding and undeclared allergens.

View a complete list of product recalls for FDA-regulated products and USDA-regulated products.

Recent Warning Letters
Since we last reported on enforcement actions in October, FDA posted warning letters addressed to canned food processors, seafood processors, shell egg production facilities, infant formula producers, dairies, dietary supplement manufacturers, and other food companies for violations related to CGMP (current good manufacturing practice), commodity-specific regulations, labeling, illegal drug residues, and unapproved drug claims, among others.

FDA warned four food manufacturing facilities for various CGMP violations, including packaging food in insanitary conditions and failure to provide adequate screening against pests. Five canned food processors, one located in Korea and one in India, were warned for various violations of the Acidified Foods, Low-Acid Canned Foods, and Emergency Permit regulations. Thirteen seafood processing facilities, including six overseas, were cited for failing to comply with hazard analysis and critical control points regulations. One of these companies was also found to have CGMP violations for, among other violations, failure to monitor prevention of cross-contamination from insanitary objects. FDA cited one shell egg production facility for violations of the *Salmonella* prevention regulations. FDA also warned nine dairy farms for selling cattle for slaughter adulterated with illegal drug residue.

FDA continues to review product labels for incorrect or incomplete claims. In recent warning letters, the agency cited two cheese manufacturers, one overseas, for various violations, including failure to declare egg as a major food allergen, failure to translate required nutrition information in English, and failure to use the common or usual name of each ingredient. A Spanish manufacturer of a dried tuna product was warned for incorrect serving sizes and other label deficiencies. An infant formula manufacturer was cited because its label and website bore health claims not authorized by FDA. An ice cream manufacturer was cited for using unsafe color additives and other labeling violations, such as failing to state that the product contains artificial coloring or chemical preservatives.

FDA also posted more than a dozen warning letters to dietary supplement manufacturers. FDA warned 15 dietary supplement manufacturers for marketing unapproved drugs because their products promote therapeutic claims, six of which were also cited for CGMP violations. Notably, two of the 15 warning letters were issued jointly by FDA and FTC for marketing supplements and other products for the purposes of preventing or treating the Ebola virus. Such claims make the products unapproved drugs, sold in violation of the FDCA, and also lack adequate substantiation, in violation of the fair advertising provisions of the Federal Trade Commission Act. Several of the warning letters note these products were advertised on various social media sites, including Facebook. An additional four dietary supplement manufacturers were warned for CGMP violations; some of the manufacturers were also warned for failing to label their products as "dietary supplements."

Lastly, in a rare warning letter to a cosmetics manufacturer, FDA warned a skin care products

manufacturer for making therapeutic claims on its website, which renders the products unapproved new drugs.

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

Jones Day FDA Regulatory & Compliance Counseling Contacts

Mark Mansour
Washington
+1.202.879.3883
mmansour@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
+1.202.879.3778
estrunk@jonesday.com

Katherine M. Llewellyn
Brussels
+32.2.645.14.47
kllewellyn@jonesday.com

Stephanie L. Resnik
Washington
+1.202.879.5458
sresnik@jonesday.com

Brigid C. DeCoursey
Washington
+1.202.879.3651
bdecoursey@jonesday.com

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

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EFSA Publishes New Scientific Opinions

The European Food Safety Authority recently published the following Scientific Opinions:

- Scientific Opinion on the safety assessment of the substance, dodecanoic acid, 12-amino-, polymer with ethene, 2,5-furandione, á-hydro-ù-hydroxypoly (oxy-1,2-ethanediyl) and 1-propene
- Scientific Opinion on Dietary Reference Values for folate
- Scientific Opinion on the substantiation of a health claim related to zinc and normal growth pursuant to Article 14 of Regulation (EC) No 1924/2006
- Scientific Opinion on the substantiation of a health claim related to "non digestible oligo and polysaccharides including galacto-oligosaccharides, oligofructose, polyfructose and inulin" and "increase in calcium absorption" pursuant to Article 14 of Regulation (EC) No 1924/2006
- Scientific Opinion on the substantiation of a health claim related to prunes and contribution to normal bowel function pursuant to Article 14 of Regulation (EC) No 1924/2006
- Scientific Opinion on the substantiation of a health claim related to selenium and protection of DNA, proteins and lipids from oxidative damage pursuant to Article 14 of Regulation (EC) No 1924/2006

CONTACTS

Mark Mansour
Washington

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Washington

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- Scientific Opinion on Flavouring Group Evaluation 300 Revision 1 (FGE.300Rev1): One cyclo-aliphatic amide from chemical group 33
- Scientific Opinion on the use of existing environmental surveillance networks to support the post-market environmental monitoring of genetically modified plant
- Scientific Opinion on Flavouring Group Evaluation 11, Revision 3 (FGE.11Rev3): Aliphatic dialcohols, diketones, and hydroxyketones from chemical groups 8 and 10

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