Food Regulatory Update

July 2013

by

Melvin S. Drozen
Eve Pelonis
Fatima Aslam

KELLER AND HECKMAN LLP
1001 G Street, N.W.
Washington, D.C. 20001
Phone: (202) 434-4222
Fax: (202) 434-4646
drozen@khlaw.com

FOOD REGULATORY UPDATE

I. U.S. ACTIVITIES

A. FDA

FDA Issues Proposals for Third Party Accreditation and Foreign Supplier Verification

FDA has released two long-awaited proposed rules to implement provisions of the FDA Food Safety Modernization Act (FSMA). Specifically, the agency has issued proposed rules to implement the law's Foreign Supplier Verification Programs (FSVP) for Importers (§ 301) and Accreditation of Third-Party Auditors/Certification Bodies (§ 307). The FSVP proposal will allow FDA to audit importer plans and block importers from shipping foods that do not meet the agency's standards. The proposal defines importers as the U.S. owner of the food, if there is one or the consignee if there is not a U.S. owner at the time of entry. The importer would be required to follow the FSVP for each food it imports, by reviewing the compliance status, such as warning letters, import alerts and new certification requirements, for each food supplier before and after importing the food. Additionally, importers would have to analyze hazards for each food, and trigger verification activities such as onsite audits of suppliers, periodic or lot-by-lot sampling and testing, and review of foreign supplier food safety records or other procedures. The importer would be required to assess their FSVPs at least every three years. The proposal for Accreditation of Third-Party Auditors/Certification Bodies establishes a program for accreditation of third-party auditors of foreign facilities by FDA-recognized bodies. It lays out requirements for the accreditation bodies and third party auditors, including recordkeeping, and the system for FDA to receive reports of third-party audits for certification purposes.

Foreign Supplier Verification Programs (FSVP) for Importers:
See: 78 Fed. Reg. 45729 (July 29, 2013) at, http://www.gpo.gov/fdsys/pkg/FR-2013-07-29/html/2013-17993.htm
FDA overview:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm
Fact Sheet:
http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM362557.pdf

Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications:
See: 78 Fed. Reg. 45781 (July 29, 2013) at, http://www.gpo.gov/fdsys/pkg/FR-2013-07-29/html/2013-17994.htm
FDA overview:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361903.htm
Fact Sheet:
http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM362561.pdf

OMB Publishes FDA's Regulatory Agenda

FDA's regulatory agenda was posted on the White House Office of Management and Budget's (OMB) website on July 3. The following agenda items are among the long-awaited proposed rules the agency expects to publish in the near future:

(1) a proposed rule to revise the nutrition and supplement facts labels (November 2013);
(2) a proposed rule on serving sizes of foods that can reasonably be consumed in one eating occasion; dual column labeling; and modifying the reference amounts customarily consumed (November 2013);
(3) a proposed rule on current good manufacturing practices in manufacturing, processing, packing or holding animal food (April 2014);
(4) a proposed rule on the reports of distribution and sales information for antimicrobial active ingredients used in food-producing animals (April 2014);
(5) a proposed rule to amendment the food facility registration requirements (December 2013);
(6) a proposed rule to change the nutrition label serving size for breath mints to one mint (July 2013);
(7) a proposal to increase the efficiency of the veterinary feed directive program (September 2013); and
(8) a proposal on gluten free labeling of fermented, hydrolyzed, or distilled foods (April 2014).

Under the final rules forecasted, the agency reveals that a final rule on nutrition labeling for food sold in vending machines, and a final rule on nutrition labeling of standard menu items in chain restaurants will be published in September 2013.
For a complete list of actions forecasted by the agency, please see:
http://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0900&Image58.x=44&Image58.y=4

FDA Issues New Compliance Policy Guide for *Salmonella* in Animal Feed

On July 15, FDA released Compliance Policy Guide (CPG) Sec. 690.800 *Salmonella* in Food for Animals. While animal feed containing *Salmonella* has always been considered adulterated, FDA's new policy orders investigators to only focus enforcement on *Salmonella* serotypes that cause disease in the animal species for which the feed is marketed where the animal feed will not subsequently undergo a commercial heat step or other commercial process that will kill the *Salmonella*. The CPG includes the following list of examples of feed and pathogenic pairings: (1) Poultry feed with *Salmonella* Pullorum, *Salmonella* Gallinarum or *Salmonella* Enteriditis; (2) Swine feed with *Salmonella* Choleraesuis; (3) Sheep feed with *Salmonella* Abortusovis; (4) Horse feed with *Salmonella* Abortusequi; and (4) Dairy and beef feed with *Salmonella* Newport or *Salmonella* Dublin. However, FDA asserted that the agency maintains a zero tolerance policy for *Salmonella* in pet food because it can pose risks to human health when people who are "at-risk," such as children and

pregnant women, come into direct contact with contaminated pet food. The CPG specifically says investigators should consider regulatory action if *Salmonella* is present in one or more subsamples of a pet product and it will not be, or information is not available on whether it will be "further processed with a heat treatment or other method during the commercial manufacturing processing to eliminate the *Salmonella.*" FDA has concurrently withdrawn CPG Sec. 690.700 Salmonella Contamination of Dry Dog Food, which describes a zero tolerance for any strain of *Salmonella* in certain animal feed ingredients, even if it was not capable of causing foodborne illness. *See*: http://www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM361105.pdf

FDA Proposes Limits for Arsenic in Apple Juice

On July 12, FDA published its risk assessment and draft guidance on arsenic in apple juice. In its risk assessment titled, "A Quantitative Assessment of Inorganic Arsenic in Apple Juice," FDA employs data from two studies published in 2010, and a 2011 evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JEFCA), to support an action level of 10 parts per billion (10 pbb) for inorganic arsenic in apple juice. Based on FDA's 2011 sampling data, the agency found the modeled urinary tract and lung cancer disease rates at the hypothetical maximum limits ranged from 2.5 to 8.0 cases per million people for the average consumer and 7.7 to 24.9 cases per million for high-level consumers. FDA explains that much of the risk is incurred during childhood because the bulk of exposure is experienced during that period. Based on the findings of its risk assessment, in its "Draft Guidance for Industry: Arsenic in Apple Juice – Action Level," the agency explains that it intends to consider the action level of 10 ppb inorganic arsenic, in addition to other factors, when considering whether to bring enforcement action in a particular case. FDA says it plans to initially analyze apple juice samples for total arsenic, then separate samples containing more than 10 ppb total arsenic to determine inorganic arsenic levels. Comments on the draft guidance and the risk assessment are due by September 13, 2013. *See*: 78 Fed. Reg. 42086 (July 15, 2013) at, https://federalregister.gov/a/2013-16719 and, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm360466.htm

FDA Requests Information for Risk Assessment on *Salmonella* from Tree Nuts

On July 18, FDA published a request for comments, scientific data, and other information for a quantitative assessment the agency plans to conduct on the risk of salmonellosis associated with the consumption of tree nuts. The agency explains "the need for a risk assessment is underscored by outbreaks of human salmonellosis linked to tree nuts over the past decade, by product recalls, and by *Salmonella* isolation from tree nuts during surveys." FDA is specifically seeking information concerning, but not limited to, the following factors: (1) *Salmonella* contamination in different tree nuts sampled at harvest, distribution (including transportation), manufacturing/processing plant (including at times before, during, and after application of treatments designed to reduce bacterial contamination), retail, or anywhere else in the supply chain; (2) *Salmonella* survival, growth or inactivation dynamics in different tree nuts during transportation and storage; (3) current food consumption practices in the U.S.; (4) storage, handling and processing conditions that may affect *Salmonella* survival, growth, or inactivation along the farm-to-fork continuum and the impact of these conditions

on *Salmonella* concentrations on tree nuts; and (5) other comments, including the types of tree nuts that should be evaluated in this risk assessment and information about which types of tree nuts may enter the U.S. market without the application of treatments designed to reduce bacterial contamination. Public submissions will be accepted until October 16, 2013. *See*: 78 Fed. Reg. 42963 (July 18, 2013) at, https://federalregister.gov/a/2013-17211 and, http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm361206.htm

Q&A Fact Sheets on FSMA Provide Guidance for Small Farmers

On July 15, FDA posted new materials on its website to address several concerns raised by industry to clarify certain requirements of the produce safety standards under the Food Safety Modernization Act (FSMA). Among the materials is a fact sheet published in a question and answer (Q&A) format where Deputy Commissioner for Foods and Veterinary Medicine, Mike Taylor, describes "The What You Need to Know About the Produce Safety Rule," and also provides answers to the frequently raised questions thus far. In a separate fact sheet, FDA provides additional information on the agricultural water standards covered under the produce safety rule. The fact sheet expands on the inspections of water systems, testing frequency, testing standards, treatment to reduce microbial loads, and recordkeeping and compliance dates. In his Q&A, Taylor explains that the agency will be coming out with additional materials to explain the proposed requirements, as there are many challenging issues associated with the operations covered under the product safety rule. *See*: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm358090.htm and, http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM360242.pdf

Petition Seeks to Amend Regulation on Carrageenan Use in Infant Formula

On July 19, FDA announced the submission of a citizen petition and a food additive petition (FAP) from Richard Theuer, Ph.D. regarding the use of *Chondrus* extract (carrageenan) in infant formula. Carrageenan, which is made from a particular variety of seaweed, is used as a thickening agent in food and beverages. The petition seeks to amend the regulations at 21 CFR 182.7255 to state that carrageenan can be used in foods except in infant formula. It specifically "requests that FDA reconsider the GRAS [generally recognized as safe] status of carrageenan in light of the conclusion of the Joint FAO/WHO Expert Committee on Food Additives (68th report of JECFA; pp.32-37, 205; 2007) that it is inadvisable to use carrageenan or processed *Eucheuma* seaweed in infant formula intended for infants up to and including 12 months of age. Based on the amount of the substance present in the intestine both directly and based on the concentration in food, the Committee considered all of the margins of exposure to be insufficient to ensure protection of infants fed infant formula containing carrageenan. The Committee concluded "no reports have been identified that address the particular question of effects on the immature intestine and immunity in experimental models or in prospectively designed human studies." In its notice, FDA says it may address the citizen petition and FAP at the same time for reasons of administrative efficiency. *See*: 78 Fed. Reg. 43093 (July 19, 2013) at, https://federalregister.gov/a/2013-17330

FDA Bans BPA from Infant Formula Packaging

On July 12, FDA issued a final rule to bar the use of bisphenol A (BPA) based epoxy resins as coatings in packaging for infant formula because the uses have been abandoned by industry. BPA is a chemical compound found in food contact materials such as packaging as well as in other consumer products. The final rule was issued in response to a petition filed by former Representative Edward Markey (D-Massachusetts) on March 16, 2012, which suggested FDA amend the regulations at 21 C.F.R. 175.300 to revoke the use of BPA in infant formula packaging since all U.S. formula makers have abandoned its use. FDA clarifies that its action is not a ruling on the safety of BPA, and that "BPA-based epoxy resins may be safely used as the food-contact surfaces of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food." This is the second time FDA has amended a regulation based on "abandonment" grounds. *See*: 78 Fed. Reg. 41840 (July 12, 2013) at, https://federalregister.gov/a/2013-16684

B. USDA

OMB Publishes USDA's Regulatory Agenda

USDA's regulatory agenda was posted on the White House OMB's website on July 3. Under the proposed rule stage for USDA's Animal Plant Health and Inspection Service (APHIS), the agency reveals that the proposed amendments to its National Environmental Policy Act implementing procedures will be published in February 2014, with a comment period ending in April 2014. APHIS forecasts an interim final rule on the introduction of organisms and products altered or produced through genetic engineering, which is also commonly referred to as the agency's "biotech overhaul," to be published in November 2013, with a comment period ending in December 2013. APHIS also reveals that future action has yet to be determined for a proposed rule on sharing confidential business information with government agencies regarding the introduction of genetically engineered organisms and products, which was published on February 27 with a comment period ending on April 29, 2013.

Under the actions expected by USDA's Agricultural Marketing Service (AMS), the agency forecasts proposals on: (1) streamlining enforcement related actions under the National Organic Program in February 2014; (2) the 2013 Sunset of Allowances and Prohibitions Contained in the National List in December 2013; (3) Organic Pet Food Standards in December 2013, with a final rule to be published in September 2014; (4) Sunset Review (2012) for Sodium Nitrate in November 2013; (5) Amendments to the National List, Addition Three New Substances (Chlorhexidine, Xylazine, and Excipients) in September 2013, with the final rule expected in May 2014; and (6) establishing a Peer Review Panel, which is expected in October 2013, with the final rule expected in June 2014.

For USDA's Food Safety and Inspection Service (FSIS), some of the actions forecasted include: (1) an interim final rule and supplemental proposed rule for standards for the production of processed meat and poultry products in June 2014; (2) a notice of proposed rulemaking for egg products inspections regulations in June 2014; (3) a proposed rule on the use of the voluntary claim "natural" on the labeling of meat and poultry products in June

2014; (4) a notice of proposed rulemaking on records to be kept by official establishments and retail stores that grind raw beef products in October 2013; (5) a notice of proposed rulemaking on communications with federal agencies, state and foreign government officials, and international organizations is expected in January 2014; (6) a final rule on generic label approval is anticipated in September 2013; and (7) a final rule regarding the modernization of poultry slaughter is expected in September 2013.

For a complete list of expected actions, please see:
http://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0500&Image58.x=31&Image58.y=12

Lawmakers Introduce Bill for Agricultural Research

On July 12, Senator (Sen.) Debbie Stabenow (D-Mich.) and Sen. John Thune (R-S.D.), along with Representative (Rep.) Devin Nunes (R-Calif.) and Rep. Ron Kind (D-Wisc.) introduced The Charitable Agricultural Research Act (S 1280/HR 2671). If enacted, the bill will allow for the development of new charitable, tax-exempt agricultural research organizations (AROs). It will establish the means for agricultural research to be conducted by charitable partnerships between universities and private entities. According to the bill's sponsors, the AROs will complement ongoing public and private research and create the opportunity for under-funded research projects to be fully funded, such as projects that address specialty crops or specific diseases associated with the contamination of agricultural commodities.
See: http://www.stabenow.senate.gov/?p=press_release&id=450
Bill text for S 1280: http://www.govtrack.us/congress/bills/113/s1280
Bill text for HR 2671: http://www.govtrack.us/congress/bills/113/hr2671

NOP Publishes Fact Sheet on List of Allowed and Prohibited Substances

USDA's National Organic Program (NOP) released a two-page fact sheet on the National List of Allowed and Prohibited Substances for organic crop and livestock production. NOP's fact sheet begins with a brief introduction on organic certification, which is governed by USDA's organic regulations and certifying agents who verify farmers and processors are in compliance with the regulations. The fact sheet provides links to the list of synthetic and natural substances allowed and substances that are prohibited from use in organic farming for crops and livestock. The second page of the fact sheet covers the main conditions that must be present for labeling claims such as "100% Organic," "Organic," and "Made with Organic __," along with a disclaimer asserting products that bear these claims cannot be processed with genetically engineered ingredients. It also lists contact information of certifying agents, gives a brief overview of the role of the National Organic Standards Board (NOSB), and provides a link where comments or requested changes to the national list can be submitted.
See:
http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateF&navID=FactSheetslinkNOPNationalOrganicProgramHome&rightNav1=FactSheetslinkNOPNationalOrganicProgramHome&topNav=&leftNav=NationalOrganicProgram&page=NOPFactSheets&resultType=&acct=noppub

FSIS Extends Comment Period for Proposal on Mechanically Tenderized Beef Labels

USDA's Food Safety and Inspection Service (FSIS) has extended the comment period deadline on its proposed rule for labeling mechanically tenderized meat products, which was published in June. The proposed rule would require labeling changes to identify intact muscle cuts which have been needle or blade tenderized as a way to inform consumers that those products must be cooked to an internal temperature of 145 degrees Fahrenheit to kill pathogenic bacteria. Comments on the proposed rule, which were originally due by August 9, are now due by October 8, 2013. *See*:
http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/constituent-updates/archive/2013/ConstUpdate072613

C. General

Codex Commission Releases July Meeting Report

The Codex Alimentarius Commission's meeting report for its July 1-5 meeting in Rome, Italy, reveals that the Commission has approved several hundred new provisions for food additives and maximum residue limits (MRLs) for pesticides. The Commission also created a new Codex Committee on Spices and Culinary Herbs (CCSCH), which will be chaired by India, and will include Arabic, English, French, and Spanish as the working languages. The Commission Codex also adopted 33 other standards at Step 8 or 5/8 in the eight-step Codex approval process and held an additional 10 standards at Step 5 for further consideration; established an electronic working group to consider the feasibility of additional work on a controversial standard for processed cheese, which will be co-chaired by New Zealand and Uruguay with work in English and Spanish; adopted two texts on animal feed; called on the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to consider expanding the donor base for expert scientific review panels, such as the Joint Expert Committee on Food Additives (JEFCA), which provides scientific advice to Codex Committees; and stressed the need for a successor initiative to the Codex Trust Fund, which has supported enhanced participation in Codex work by developing countries. The Commission also adopted a Strategic Plan for 2014-2019, developed by an Executive Committee subcommittee chaired by Vice-Chair Samuel Godefory, which aims to address major changes in the global food supply by adopting four strategic goals that include various objectives and activities to achieve them.
See: www.codexalimentarius.org/meetings-reports/en/

Dr. Pepper Snapple Group Reaches Settlement in Case Against 7UP Products

A settlement has been reached in a lawsuit filed against Dr. Pepper Snapple Group in November 2011. David Green, a Sherman Oaks, California resident, represented by the Center for Science in the Public Interest's (CSPI) litigation director, Steve Gardner, along with New York City-based firm Reese Richman LLP had filed the complaint in the U.S. District Court for the Central District of California, in Los Angeles. The plaintiffs argued that Dr. Pepper Snapple Group was misleading consumers by conveying the message that healthful, natural and antioxidant-rich varieties of its 7UP products were processed with real cherries or berries. The plaintiffs further argued that adding fruit juice and vitamin E to the

carbonated beverages and making labeling claims that the products contained antioxidants was a violation of FDA's fortification policy. Under the settlement, Dr. Pepper Snapple Group has agreed to pay Green $5,000 and $237,500 to other members of the class. The company further acknowledged that all products have been reformulated to remove vitamin E from the products in question and that it will remove all references to antioxidants on the products' labels. The company also agreed that it will not add any vitamin or mineral with a daily recommended intake amount to products, other than vitamins or minerals naturally found in those products, and will not label the products with any references to antioxidants. However, any products with the current labels that already have been produced are allowed to be sold. All parties have agreed not to pursue any further legal action and also waive the right to file similar lawsuits in the future. *See*: http://cspinet.org/new/pdf/7upsettlement.pdf

Naked Juice Files Motion to Settle "All Natural" Suit

On July 2, Naked Juice Company filed a motion to settle a class action suit filed in 2011, which alleges the company violated California's False Advertising Law with its juices and smoothies that stated the following claims: "100% Juice;" "All Natural;" "All Natural Fruit;" "All Natural Fruit + Boosts;" and "Non-GMO." Under the settlement, Naked Juice agrees to pay $9 million to the plaintiffs. It also agrees to modify all future labeling, advertising and marketing to not use "All Natural," "All Natural Fruit," and "All Natural Fruit + Boosts" statements on future product labels. The company further agrees to set up a product verification program through an independent testing organization to substantiate the non-GMO statement on its product labels. The parties agreed to settle after four mediation sessions. A final hearing on the settlement is scheduled for December 2, 2013. *See*: http://articles.law360.s3.amazonaws.com/0455000/455162//mnt/rails_cache/https-ecf-cacd-uscourts-gov-doc1-031117098945.pdf and, http://articles.law360.s3.amazonaws.com/0455000/455162/7.3%20Stipulation.pdf

Codex Develops Electronic Working Groups to Deal with Major Issues

The Codex Alimentarius Commission announced the creation and reauthorization of several electronic working groups (eWGs) to tackle major issues to be discussed in its upcoming meetings for this year and next. The Codex Committee on Contaminants in Foods (CCCF) has announced the creation or reauthorization of eWGs to: (1) work on a draft annex for the "Prevention and Reduction of Aflatoxins and Ochratoxin A in Sorghum;" (2) continue the review of maximum levels (MLs) for lead in fruits, vegetables, milk products and infant formula, follow-up formula and formula for special medical purposes; and (3) develop a discussion paper to prepare a proposed draft revisions of the Code of Practice for Prevention and Reduction of Mycotoxin Contamination in Cereals. The Codex Committee on Pesticide Residues (CCPR) has announced the creation and reauthorization of eWGs to: (1) work on the Committee's Priorities, which was re-established at the last CCPR session; (2) establish the "Performance Criteria for Suitability Assessment of Methods of Analysis for Pesticide Residues;" and (3) work on the revisions of the "Risk Analysis Principles applied by the Codex Committee on Pesticide Residues." Furthermore, the Codex Committee on Milk and Milk Products (CCMMP) announced the establishment of an electronic working group on processed cheese to study the possibility of developing standards for processed cheese and products analogous to processed cheese. *See*:

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/archives/codex-news-july-26-2013

US, Canada, and Mexico Organizations Seek Injunction against COOL Rule

On July 8, several meat and livestock groups filed a complaint against USDA in the U.S. District Court for the District of Columbia, with regards to the agency's final rule on country of original labeling (COOL). USDA published the final rule in March, which went into effect immediately, and requires that labels for meat must specific the production steps of birth, raising and slaughter of the animal, and eliminate the allowance of commingling on the label of meat commodities from different origins. The plaintiffs argue that the final rule (1) violates the U.S. Constitution's First Amendment by "compelling speech" in the form of costly and detailed labels on meat products that do not directly advance a government interest; (2) exceeds the scope of COOL provisions in the 2008 Farm Bill, which does not permit "the kind of detailed and onerous labeling requirements the final rule puts in place;" and (3) is "arbitrary and capricious, because it imposes vast burdens on the industry with little to no countervailing benefit." The plaintiffs have also asked the court to grant a preliminary injunction against the rule in a request filed on July 25, which follows their July 8 complaint and reiterates the three arguments mentioned above. The parties to the complaint include the American Meat Institute, American Association of Meat Processors, Canadian Cattlemen's Association, Canadian Pork Council, National Cattelmen's Beef Association, National Pork Producers Council, North American Meat Association, Southwest Meat Association, and Mexico's National Confederation of Livestock Organizations.
See: http://www.law360.com/articles/460493
Complaint: http://www.law360.com/dockets/documents/51db2e77cccd2f63bd00000b
Preliminary Injunction:
http://www.law360.com/dockets/documents/51f1a91abbec943c5800001c

Delauro Aims to Curb Unhealthy Marketing to Children

On July 25, Representative Rosa DeLauro (D-Connecticut) introduced a bill to "amend the Internal Revenue Code of 1986 to deny any deduction for marketing to children to promote the consumption of food of poor nutritional quality" (HR 2831). The bill notes that foods of poor nutritional quality will be defined as foods that are inconsistent with the latest version of the Dietary Guidelines, and marketing will be defined as "all product and brand advertising and promotional techniques directed at children" under the age of 17. The bill asserts that marketing includes advertising and product placement on television, radio, print and social media websites, as well as product packaging and labeling, advertising linked with a movie, promotional content sent to computer or other personal devices, items given away with the purchase of a product or through a loyalty program, celebrity endorsements or in-school marketing. DeLauro describes her bill as one piece of the multi-faceted approach needed to tackle the complex issue of childhood obesity.
See: http://www.govtrack.us/congress/bills/113/hr2831 and,
http://delauro.house.gov/index.php?option=com_content&view=article&id=1354:delauro-introduces-bill-ending-subsidy-for-marketing-unhealthy-foods-to-children&catid=2:2012-press-releases&Itemid=21

Appellate Court Upholds New York City Soda Ban

On July 30, New York State Supreme Court's Appellate Division unanimously upheld a lower court's ruling that Mayor Michael Bloomberg's proposed "portion cap rule" on non-diet sodas in containers larger than 16 ounces is illegal and overreaches his executive power. Specifically, the appellate court ruled that the Board of Health, which is appointed by Mayor Bloomberg, "violated the state principle of separation of powers." In response, Mayor Bloomberg stated that the appellate court's "decision is a temporary setback," as the Board "plans to appeal this decision" as they "continue the fight against the obesity epidemic." *See*: http://www.nytimes.com/2013/07/31/nyregion/appeals-court-rules-against-bloomberg-beverage-rules.html

II. INTERNATIONAL NEWS

A. Europe

Monsanto to Withdraw its Applications for Biotech Crops in EU

Monsanto Co. recently announced the withdrawal of its applications for the European Union's (EU) approval of new genetically engineered (GE) crops due to the unfavorable opinions and hostile environment towards agricultural biotechnology across Europe. The applications to be withdrawn include five GE corn applications, one soybean and one sugar beet application. However, Monsanto will not withdraw its application to renew the approval for its insect-resistant MON810 corn, which is currently cultivated commercially in Europe. The company plans to focus on growing its conventional seeds business in Europe, as well as securing EU approvals to import its genetically modified crop varieties widely grown in the U.S. The company also plans to invest hundreds of millions of dollars in Europe, in addition to the 225 million euros in corn seed plant expansions that are already under way in France, Hungary and Romania. *See*:
http://www.telegraph.co.uk/earth/environment/10186932/Major-GM-food-company-Monsanto-pulls-out-of-Europe.html
And,
http://www.reuters.com/article/2013/07/17/us-eu-monsanto-gmos-idUSBRE96G16R20130717

EFSA Establishes Timeline for Acrylamide Opinion

On July 15, the European Food Safety Authority (EFSA) announced its 2014-2015 timetable for its draft opinion on acrylamide, which is a chemical compound that forms in starchy food products during high temperature cooking, including frying, baking and roasting. The European Commission's (EC) request for the opinion in February originally asked for the draft opinion to be published by September 2013. However, EFSA's experts aim to complete the full risk assessment and publicly consult on their draft scientific opinion in mid-2014. EFSA reveals it has identified hundreds of scientific studies to consider for the agency's full risk assessment. EFSA has consulted with consumer groups, nongovernmental organizations and the food industry through its Stakeholder Consultative Platform to learn of ongoing and recent research on acrylamide in food. EFSA will also consider related international

developments including work by the Joint FAO/WHO Expert Committee on Food Additives (JEFCA). The feedback received will then assist EFSA's Panel on Contaminants in the Food Chain in finalizing its scientific opinion, scheduled for the first half of 2015. *See*: http://www.efsa.europa.eu/en/press/news/130715.htm

EU and US Pledge to Cooperate on Food Safety, Nutrition, and Nano Standards

On July 18, the European Commission's (EC) Joint Research Center (JRC) announced it has agreed to expand its current scientific cooperation with the National Institute of Standards and Technology (NIST), based in Gaithersburg, Maryland, to include ten different areas to help reach the goal of having compatible standards for food safety, nutrition, and nanotechnology. The new Implementing Arrangement has been agreed to for a period of five years. It expands on the previous collaboration of JRC and NIST for several projects since the signing of the U.S.-EU Agreement on Scientific and Technological Cooperation in 1997. The new agreement will allow for joint access to the scientific infrastructure, exchange of scientific and technological information, exchange of experts and support with the training of scientists, engineers and technical experts. The arrangement is a part of the ongoing negotiations for the Transatlantic Trade and Investment Partnership (TTIP). JRC explains that TTIP aims to remove barriers such as tariffs, unnecessary regulation and restrictions on investments in a wide range of sectors and allow companies to sell and buy goods and invest easier on the other side of the Atlantic. *See*: http://www.nist.gov/jrc_nist_071813.cfm and http://ec.europa.eu/dgs/jrc/index.cfm?id=1410&dt_code=NWS&obj_id=17370&ori=RSS

European Commission Issued a Statement regarding Illegal Additives in Fish Products

The European Commission issued a statement regarding the use of sodium carbonate and potassium carbonate to reaffirm that the carbonates are not permitted for use under European Union (EU) law. The Commission issued its statement at a July 1 meeting of the Standing Committee on the Food Chain and Animal Health after being informed that the additives are marketed for use in the treatment of fresh fish fillets. The Commission reports that the carbonates are used in a blend together with citric acid and sodium citrate for water retention and to protect the filet against oxidation. The additives are dissolved in water and added to the fresh fish either by injection or by submerging the filets in the water solution for a period of 24 to 48 hours. Suppliers of the products have attempted to work around the EUs ban by arguing that under the treatment, the carbonates are used as processing aids as opposed to additives, and therefore do not need to be authorized by EU legislation. However, the Commission rejected that argument by affirming that it "considers the use of sodium carbonate (E 500) and Potassium carbonates (E 501) for the treatment of fresh fish fillets and fisheries products an additive use, as these additives continue to serve a technological purpose in the final food and are expected to become a component of that food." *See*: http://ec.europa.eu/food/committees/regulatory/scfcah/toxic/sum_01072013_en.pdf

EFSA Scientific Opinion Finds Food to be Main Source of BPA

On July 25, the European Food Safety Authority (EFSA) released a draft scientific opinion on exposure to bisphenol A (BPA). This draft opinion is the agency's first review of BPA

exposure since 2006, and the first to cover both dietary and non-dietary sources from other products such as thermal paper, and environmental sources such as air and dust. EFSA's Scientific Panel on Food Contact Materials, Enzymes, Flavorings and Processing Aids (CEF Panel) applied two approaches to derive exposure estimates, exposure modeling and analysis of human bio-monitoring data using urine samples. The exposure modeling involved the assessment of exposure to BPA through food and non-food sources and routes of consumption in the EU population. Urinary bio-monitoring data was used to corroborate the Panel's estimates of overall BPA exposure and to ensure no major source of exposure was missed.

According to the data results, canned food and non-canned meat and meat products were identified as major contributors to dietary BPA exposure for all age groups. For infants and toddlers (ages 6 months-3 years) average exposure from the diet is estimated to amount to 375 nanograms per kilogram of body weight per day (ng/kg bw/day), and the average exposure from diet for the population older than 18 years old is up to 132 ng/kg bw/day. The draft opinion also found that for population groups older than 3 years of age, thermal paper was the second most important source of BPA after diet, potentially accounting for up to 15% of total exposure in some population groups. Scientists further observed that dietary exposure to BPA was the highest among children from ages 3 to 10. The assessment does not look at the toxicity of BPA, or whether the levels of exposure pose a risk to either the public at large or specific population groups such as children and pregnant women. EFSA notes that a second opinion will address potential human health risks of BPA, which will be consulted on next year. EFSA will accept comments on its recently published draft opinion until September 15, 2013. *See*: http://www.efsa.europa.eu/en/press/news/130725.htm