Food Regulatory Update

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by

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I. U.S. ACTIVITIES

A. FDA

NRDC Publishes Report on Potentially Unsafe Chemicals in Food

The Natural Resources Defense Council (NRDC) has published a new report titled, “Generally Recognized as Secret: Chemicals Added to Food in the United States.” The report takes the position that some companies are using products without addressing FDA’s concerns that were communicated after the review of a GRAS (generally recognized as safe) notice. In addition, the report states that approximately 275 chemicals used by 56 companies were never submitted to FDA for review, but appear to be marketed based on a self-GRAS position. NRDC’s report stems from a Freedom of Information Act (FOIA) request with FDA in the fall of 2013, in which the group sought information on four ingredients that still appeared on food ingredient labels after the companies chose not to respond to the Agency’s questions during the GRAS review process, and withdrew them from consideration. NRDC points out that FDA often asks tough questions to companies when the Agency is notified of a substance proposed to be used in food, but a company is not required to answer those questions, and is not restricted from continuing to sell the substance for use in food. It further notes that some companies withdraw their GRAS notice from review to avoid having a public FDA rejection. The NRDC report is available at http://www.nrdc.org/media/2014/140407b.asp.

FDA Publishes Q&A and Blog Post on HARPC Proposal’s Impact on Spent Grains

On April 25, FDA issued two documents to address the impact of the FDA Food Safety Modernization Act (FSMA) animal feed Hazard Analysis and Risk-based Preventive Controls (HARPC) proposal on spent grains and ultimately the impact of the animal feed HARPC proposal to all waste (“co-products”) of human food production that is diverted to animal feed. The first document was a blog post from FDA’s Deputy Commissioner for Foods and Veterinary Medicine, Michael Taylor, regarding spent grains. The second document was a Questions and Answers document that addresses the diversion of spent grains from beer production to animal feed. According to many comments, facilities that would need to comply with the human food HARPC rule will be made to also comply with the animal feed HARPC requirements making the diversion of these co-products a burdensome process that will force companies to divert the co-products to landfills. In both documents, the Agency confirmed that it will clarify in the final rule that the animal feed HARPC requirements are not required above and beyond human food HARPC requirements. FDA plans to provide this clarification when the animal feed HARPC rule is reissued this summer. FDA’s documents can be viewed at http://blogs.fda.gov/fdavoice/index.php/2014/04/getting-it-right-on-spent-grains?source=govdelivery&utm_medium=email&utm_source=govdelivery, and http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm394991.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.
FDA Expands the Use of Spirulina as a Color Additive in Foods

FDA has expanded the use of the color additive Spirulina, a filtered aqueous extract from *Arthrospira platensis* (a type of seaweed) that is a blue to blue-green colored powder or liquid which contains minor amounts of vitamins, minerals and water. The Agency’s recent action is in response to a petition filed by GNT USA, Inc. in September 2012 seeking to amend the list of approved color additives to include Spirulina as a color additive to be used in several foods. FDA had granted the request to allow for the use of Spirulina in only candy and gum, making it the first source of natural blue colorings for food. However, in the recent notice, the Agency has extended the use of Spirulina to be used as a color additive in all of the coloring confections listed in GNT’s petition including candy, gum, frostings, ice cream, frozen desserts, dessert coatings and toppings, beverage mixes and powders, gelatin, custards, puddings, cottage cheese, breadcrumbs and ready-to-eat cereals. The Agency determined that no upper limit was needed because the amount of the extract is self-limiting through the use of good manufacturing practices. See: 79 Fed. Reg. 20095 (Apr. 11, 2014) at https://federalregister.gov/a/2014-08099.

FDA Publishes Draft Guidance on Honey Labeling

FDA has released a new guidance on the labeling of honey and honey products to help the food industry properly label them, and to remind the industry that the products must not be misbranded or adulterated. In the guidance, honey is specifically defined as “a thick, sweet, syrupy substance that bees make as food from the nectar of flowers and store in honeycombs.” If a product contains only honey, it must be labeled “honey,” which is the common or usual name, but can also include the source of the honey, such as “Clover Honey.” The guidance states that no ingredient statement is required on such products since honey is a single-ingredient food. It also includes a list of questions and answers such as how and when to declare the floral source of honey, how to label products that contain honey and a sweetener, or honey and another ingredient such as natural flavors. FDA notes that it has a long standing import alert for surveillance of honey for adulteration with cane or corn sugars. The Agency also mentions that field personnel have been instructed to detain imported honey products that appear to contain residues of chloramphenicol and fluoroquinolones. Comments are due by June 9, 2014. See: 79 Fed. Reg. 19620 (Apr. 9, 2014) at https://federalregister.gov/a/2014-07925, and http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm389501.htm.

Groups Ask FDA to Withdraw Approval for 19 New Animal Drug Applications

FD A has published a notice in response to five sponsors that asked the Agency to withdraw approval for 19 new animal drug applications for medicated feeds and other items because the drugs in question are no longer manufactured or marketed. The sponsors include ADM Alliance Nutrition, Inc., Micro Beef Technologies LTD, Ridley USA d/b/a Ridley Feed Ingredients, Provimi North America, Inc., and Virbac AH, Inc. On April 10, FDA had formally started a 10-day implementation clock for the drugs, which include bambermycins, hygromycin B, lincomycin, pyrantel, tylosin, tylosin and sulfamethazine, and virginiamycin. The notice states that the drugs the companies requested withdrawal for have been identified
as being affected by guidance for industry #213, New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Produce Use Conditions with GFI #209, which was released in December 2013. The guidance urges drug sponsors to notify the Agency within three months if they plan to remove the products, which had been used for growth promotion or other non-therapeutic uses, from current over-the-counter status. Once approvals for use are withdrawn, the drugs cannot be administered to animals without veterinary oversight. See: 79 Fed. Reg. 19814 (Apr. 10, 2014) at https://federalregister.gov/a/2014-08011.

B. CDC

CDC Publishes Study on Foodborne Illness Infections from 2006-2013

The Centers for Disease Control and Prevention (CDC) released its 2013 annual food safety report on foodborne infections, which is based on data in the Foodborne Diseases Active Surveillance Network (FoodNet) and titled, “Incidence and Trends of Infection with Pathogens Transmitted Commonly through Food – Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2006-2013.” FoodNet tracks nine pathogens including Campylobacter, Cryptosporidium, Cyclospora, Listeria, Salmonella, Shiga toxin-producing Escherichia coli (E. coli) (STEC) O157 and non-O157, Shigella, Vibrio, and Yersinia. CDC report found that from 2006 to 2013, FoodNet recorded more than 19,000 infections, 4,200 hospitalizations, and 80 deaths from all nine pathogens. It also found that the rate of annual infections from Salmonella decreased by 9% compared to 2010-2012. However, compared to the 2006-2008 data, the incidence of Vibrio infections was the highest observed in FoodNet to date with a 75% increase, and Campylobacter infections, often linked to dairy products and chicken, also increased by 13%. There were no changes observed for infections from Listeria, STEC O157, or Yersinia compared to the previously reported disease trends. CDC’s report is available at http://www.cdc.gov/foodnet/data/trends/trends-2013.html.

C. USDA

FSIS Publishes Guidance on Allergens

USDA’s Food Safety and Inspection Service (FSIS) published a new guidance that stresses the importance of accounting for allergens in meat and poultry plants that make foods with multiple ingredients. The guidance advises companies to pay close attention to allergen controls in their Hazard Analysis Critical Control Point (HACCP) plans, and warns that allergens can be introduced at any point in the production of a food item. FSIS explains that many recalls caused by undeclared allergens occurred “because of a change in product formulation by the establishment or a change in supplier’s ingredient formulation that was not reflected on the labeling of the finished meat or poultry product in which the ingredient was used.” Therefore, FSIS emphasizes that a thorough evaluation of a plant’s HACCP plan could be the key to avoiding allergen-related recalls. The guidance provides several checklists for plants and inspectors to use to ensure all stages in the food production process where allergens might be introduced, are addressed, and also includes a list of “straightforward, practical steps” an inspector or plant manager can take to identify all
FSIS Adds Eight Items to Safe and Suitable List of Ingredients in Meat and Poultry

On April 14, USDA’s Food Safety and Inspection Service (FSIS) updated Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products. The list is updated quarterly. The updated list features eight new substances, including three items that can be used as salt in meat and poultry products. The substances added to the list include: (1) an aqueous solution of citric hydrochloric acids adjusted to a pH of less than 2.5, for use as an antimicrobial in permeable and impermeable casings of meat and poultry products, applied as a spray, drip or immersion for the casings prior to opening, removal or slicing; (2) & (3) two listings for cetylpyridinium chloride to be used as an antimicrobial; (4) corn hull fiber, a binding agent to be used as a formulation aid or texturizer in beef patties, turkey patties and frankfurter when binders are permitted; (5) sodium acetate and sodium diacetate mixture as a flavoring agent in various meat and poultry products; (6) a mixture of sodium chloride, potassium chloride and sodium gluconate, as a “miscellaneous” ingredient in whole muscle meats and poultry for sodium reduction at levels to achieve desired purpose, listed as “salt, potassium chloride and sodium gluconate” in the product’s ingredient statement; (7) a mixture of sodium chloride, sodium ferrocyanide, potassium chloride, magnesium carbonate, sodium nitrate medium chain triglycerides (MCT) and sodium gluconate, as a “miscellaneous ingredient in whole muscle meats, meat products and poultry products for sodium reduction and curing; and (8) magnesium chloride, potassium chloride and salt, as a “miscellaneous” ingredient for use as a replacement for a portion of salt normally used in meat and poultry products. Directive 7120.1 is available at http://www.fsis.usda.gov/wps/wcm/connect/bab10e09-aefa-483b-8be8-809a1f051d4c/7120.1.pdf?MOD=AJPERES.

Indiana is Now Eligible to Ship Locally Made Products Interstate

The State of Indiana is the fourth state, after Ohio, North Dakota and Wisconsin, that is now eligible to ship locally grown state-inspected meat and poultry products across state lines. These states have become eligible through USDA’s Cooperative Interstate Shipment Program, introduced in the 2008 Farm Bill, which allows states with inspection programs that have demonstrated to be on par with federal mandates and standards to certify plants to produce meat and poultry products that will carry the USDA Mark of Inspection, and permits those products to be sold across state lines. Specifically, the state-inspected facilities must comply with federal requirements in the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA). Additionally, state inspectors who are assigned to eligible plants must be trained in FMIA and PPIA mandates. See: http://blogs.usda.gov/2014/04/08/in-indiana-the-cooperative-interstate-shipment-program-opens-meatier-markets-for-small-processors/.
D. General

**CSPI Releases Report on Foodborne Illness Outbreaks**

The Center for Science in the Public Interest (CSPI) has published an analysis of foodborne illnesses titled, “Outbreak Alert! A review of Foodborne Illness in America from 2002-2011.” The report covers 10,409 foodborne illness outbreaks reported to the Centers for Disease Control and Prevention (CDC) during that time period, including 98,399 illnesses that resulted from 3,933 outbreaks that were “fully solved,” or for which a pathogen and food source were identified. CSPI found that foodborne illness outbreaks were twice more likely to originate in restaurants than in consumers’ kitchens. It also notes that 66.5% of all illness outbreaks were linked to foods under FDA’s jurisdiction, compared to 26% of outbreaks linked to USDA-inspected meat and poultry products, and 7.5% linked to foods inspected by both agencies. With respect to food commodities, CSPI found that produce was at the top of the list as most often associated with the outbreaks, followed by seafood, poultry, beef, and pork. CSPI’s report is available at [https://www.cspinet.org/new/201404071.html](https://www.cspinet.org/new/201404071.html).

**Vermont Legislature Passes GMO Labeling Bill**

Vermont’s House of Representatives has passed legislation (H.B. 112) that would require the labeling of food produced entirely or partially from Genetically Modified Organisms (GMOs) by July 1, 2016. The Vermont Senate approved H.B. 112 on April 15, and Vermont’s Governor, Peter Shumlin, has signed the bill making H.B. 112 law. Two other states, Connecticut and Maine, have already passed laws mandating GMO labeling, however those laws have implementation schemes that are conditioned on other neighboring states passing similar legislation and, thus, are not yet effective. For additional information on Vermont’s legislation is available, please see the alert on our website at [http://www.khlaw.com/Food-and-Drug-Alert_04_25](http://www.khlaw.com/Food-and-Drug-Alert_04_25).

**EWG Plans to Launch New Food Database**

The Environmental Working Group (EWG) has been compiling data on the nutritional value, amount of processing and any hazard concerns in foods sold in grocery stores for a food database soon to be launched. EWG has already gathered information on 80,000 products, 5,000 ingredients and 1,500 brands. The database will rate the foods according to the three factors mentioned above by using dials with red, yellow and green coloring to indicate the level of each factor in a given food. EWG conducted a beta test of its database by searching for azodicarbonamide, an agent added to bread and also used in yoga mats, which was recently in the spotlight after a food blogger called on Subway to eliminate the ingredient from its breads. The beta search returned 500 products that contain the ingredient, which ranged from breads to premade foods, from 130 brands. EWG hopes the new tool will guide consumers to foods that are good for them and the planet. See EWG’s press release on the food database at [http://www.ewg.org/release/ewg-s-ken-cook-announces-new-landmark-food-project-tedxmanhattan](http://www.ewg.org/release/ewg-s-ken-cook-announces-new-landmark-food-project-tedxmanhattan).
II. INTERNATIONAL NEWS

A. Europe

DG SANCO Releases Updated Guidance on Botanical Active Substances Used in Plant Protection Products

The European Commission’s Health and Consumers Directorate General (DG SANCO) has updated a guidance published in 2004 on the agrochemical assessment of botanical active substances. The updated guidance aims to provide practical solutions for how procedures and data requirements can be applied to facilitate active substance approvals at the EU-level and product approvals by member states. It takes account of the greater variation in qualitative and quantitative composition of botanicals compared with synthesized chemicals. In particular, DG SANCO expanded the scope of the guidance after the European Union’s (EU) review of the existing active substances revealed a need to update the data requirements for assessments of plant oils and extracts, whereas the previous document covered only water and ethanol extracts. The updated guidance replaces “plant extracts” with the preferred term, “botanical active substances.” The updated document also covers additional extraction methods such as pressing, milling and crushing. The updated guidance is available at http://bit.ly/1gHHod2.

EFSA Postpones Publication of BPA Assessment

Once again, the European Food Safety Authority (EFSA) has delayed the scheduled date for the publication of a comprehensive risk assessment of the food packaging material bisphenol A (BPA) to the end of this year. The opinion, which was initially scheduled for publication in May 2013, was first pushed back to November 2013. It was then pushed further back to the second quarter of this year, and is now expected to be published at the end of 2014. EFSA explained that the additional time is needed for scientists to assess the scores of comments received during the public consultation on its safety evaluation of the chemical. The Authority received approximately 250 responses on the second part of its draft opinion on the human health risks of BPA during the two-month consultation period initiated in January. EFSA considers it essential that it has a full understanding of these comments before finalizing its risk assessment of BPA. See EFSA’s statement on the delayed scheduled date at http://www.efsa.europa.eu/en/press/news/140409a.htm.