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#### LEGISLATION, REGULATIONS AND STANDARDS

#### Schumer Calls for FDA Ban on Powdered Alcohol

Dubbing powdered alcohol "the Kool-Aid of teen binge drinking," Sen. Charles Schumer (D-N.Y.) has called on the U.S. Food and Drug Administration (FDA) to supersede the Alcohol and Tobacco Tax and Trade Bureau (TTB) by banning a product known as Palcohol® before it reaches store shelves. Created by Lipsmark, LLC, Palcohol® first attracted media attention when TTB granted and then temporarily rescinded approval for its labels, citing a technical issue with the amount of powdered alcohol in each package. Additional details about Palcohol® appear in Issue 521 of this *Update*.

Now Schumer has written a May 5, 2014, letter to FDA Commissioner Margaret Hamburg, asking the agency to work with TTB "to assess the potential public health concerns that arise by combining this product with food and beverages." Pointing to a 1976 district court ruling and a memorandum of understanding that saddled both agencies with the responsibility to regulate alcohol, Schumer has urged FDA to investigate Palcohol® before its release, "to avoid hospitalizations and death that are likely to follow, particularly when the product's dangers are largely unknown in the first few months of availability."

"With powdered alcohol on its way to store shelves by this fall, we're sitting on a powder keg. Clearly our food and drug safety experts must step in before this mind-boggling product, surely to become the Kool-Aid of teen binge drinking, sees the light of day," opined Schumer. "Palcohol can be easily concealed and brought into concerts, school dances and sporting events, it can be sprinkled on food and can even be snorted. Given that the federal TTB can only judge and approve new alcohol products based on labeling and taxation, it's clear the FDA must utilize their authority to intervene when alcohol products create significant health risks—as they did with Four Loko and stop this potentially deadly product in its tracks." See Sen. Schumer News Release, May 5, 2014.

#### **USDA Solicits Feedback for New Maple Syrup Grading System**

The U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS) has **proposed** revisions to the U.S. Standards for Grades of Maple Sirup in response to a 2011 petition submitted by the International Maple



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Syrup Institute (IMSI). Arguing that "consumers currently face a patchwork of grading systems in the United States that are confusing," IMSI has reportedly asked AMS to implement new standards under which "the grade of a sample unit of maple syrup would be determined using the factors of color, flavor, odor, damage, and turbidity (cloudiness)."

In addition to changing the spelling of "sirup" to the more common "syrup," the agency would recategorize Grade B syrup "containing no damage or off-flavors" as Grade A "to allow the darker syrup to be sold at the retail level." The revised standards would further divide Grade A into the following flavor and color classes: (i) U.S. Grade A Golden (delicate taste, ≥75.0 percent Tc [light transmittance]); (ii) U.S. Grade A Amber (rich taste, 50.0-74.9 percent Tc); (iii) U.S. Grade A Dark (robust taste, 25.0-49.9 percent Tc); and (iv) U.S. Grade A Very Dark (strong taste, <25.0 percent Tc). Under the proposal, Grade A syrup must also be free from off flavors, odors, fermentation, and turbidity or sediment, while "Processing Grade" syrup "must have fairly good characteristic maple taste, be fairly free of damage, turbidity or cloudiness, and be fairly free from foreign material, such as pieces of bark, soot, dust, and dirt."

Although New York and Vermont have already moved ahead with new regulations for grading maple syrup that take effect January 1, 2015, producers, processors and handlers in other regions often rely on the voluntary federal standard in the absence of state rules and are responsible for ensuring that their grading statements are compliant and accurate. AMS will accept comments on the proposed revisions until July 7, 2014. See Federal Register and AMS Press Release, May 7, 2014.

### FSIS Issues Final Rule for Meat and Poultry Products that Contain "Added Solutions"

With an aim to "improve public awareness of product identities by providing truthful and accurate labeling of meat and poultry products," the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has <u>submitted</u> its final rule for labeling products that contain an "added solution" to the federal Office of Management and Budget for review.

Observing that "without adequate labeling information, consumers [] cannot distinguish between raw meat and poultry product[s] that contain added solutions and single-ingredient meat and poultry products," FSIS proposes that all meat and poultry products, raw or partially cooked, that contain at least a 3-percent saline or other liquid solution or marinade, bear a label stating that the product has been "enhanced" with solution. The agency estimates a one-time total cost to modify all federally inspected meat labels of about \$80 million.



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#### FDA Drafts Industry Guidance on Food Allergen Labeling Exemptions

The U.S. Food and Drug Administration (FDA) has <u>issued</u> draft guidance intended to help the food industry prepare submissions for obtaining exemptions from the labeling requirements for major food allergens.

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) requires that food labels identify products containing major food allergens (milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans). Because an ingredient derived from a major food allergen may be modified to such an extent that it does not contain allergenic protein or does not cause an allergic response that poses a risk to human health, FALCPA apparently provides two processes through which manufacturers can obtain an exemption from this labeling requirement for a specific ingredient.

An ingredient may be exempted through submission and approval of either (i) a petition containing scientific evidence which demonstrates that the ingredient "does not cause an allergic response that poses a risk to human health"; or (ii) a notification containing scientific evidence demonstrating that the ingredient "does not contain allergenic protein" or that a premarket approval process under section 409 of the Food, Drug, and Cosmetic Act (21 U.S.C. 348) has previously determined that the ingredient "does not cause an allergic response that poses a risk to human health." FDA will accept comments about the guidance at any time, but suggests submitting them by September 5, 2014, to ensure consideration before the agency works on the final version. See Federal Register, May 8, 2014.

#### **EFSA Addresses Dietary Iodine**

The European Food Safety Authority's (EFSA's) Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) has **published** a scientific opinion proposing new dietary reference values for iodine. After conducting a public consultation on a draft opinion issued in January 2014, the NDA Panel has established adequate intakes (Als) for infants, children and adults based on a large epidemiological study showing that "goiter prevalence is lowest for a urinary iodine concentration above 100  $\mu$ g/L." With this threshold in mind, the NDA panel has recommended the following Als for iodine consumption: (i) 150  $\mu$ g/day for adults; (ii) 200  $\mu$ g/day for pregnant and breastfeeding women; (iii) 70  $\mu$ g/day for infants ages 7-11 months; and (iv) 130  $\mu$ g/day for children. Additional details about the draft scientific opinion appear in Issue 510 of this *Update*.

#### **EFSA Considers Reduction of Zinc in Animal Feed**

The European Food Safety Authority's (EFSA's) Panel on Additives and Products or Substances Used in Animal Feed (FEEDAP Panel) has <u>proposed</u> reducing the maximum amount of zinc permitted in animal feed "to ensure



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the health, welfare and productivity of the target species." According to the FEEDAP Panel, which reviewed the available literature "as well as data received from national authorities of European countries and from stakeholders," the new maximum levels include: (i) 150 mg of Zinc per kilogram (Zn/kg) complete feed for piglets, sows, rabbits, salmonids, cats, and dogs; (ii) 120 mg Zn/kg complete feed for turkeys for fattening; and (iii) 100 mg Zn/kg complete feed for all other species and categories. In addition, "the use of phytase in feeding piglets, pigs for fattening and sows would allow a further reduction of the newly proposed total maximum contents by 30% (from 150 to 110 mg Zn/kg feed for piglets and sows and from 100 to 70 mg Zn/kg feed for pigs for fattening)."

"The newly proposed maximum contents do not affect consumer safety," concludes the May 5, 2015, scientific opinion. "The FEEDAP Panel expects that the introduction of the newly proposed total maximum contents, provided they are applied in feeding practices, would result in an overall reduction of zinc emissions from animal production of about 20%."

#### EFSA Issues Opinion on Bacillus Species in Animal Feed

The European Food Safety Authority's (EFSA's) Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) has issued an opinion on Bacillus species used in animal production as microbial feed additives or as the source of other feed additives, mainly enzymes.

Noting that the main "concern for humans, and, to a lesser extent livestock, associated with Bacillus is a capacity for toxin production," the FEEDAP Panel cautions that the capacity for toxin production and the nature of the toxins produced is "unevenly distributed over the genus, occurring frequently in some species and more rarely in others."

According to the panel, the selection of strains belonging to the B. cereus taxonomic group for direct use in animal production is considered inadvisable. For other species, "concerns appear to be associated to the production of surfactin like-lipopeptides, although the relation between the presence of these compounds and/or other toxic factors and the risk of illness in humans has not yet been established."

The panel also concluded that "in the absence of animal models shown to be able to distinguish hazardous from non-hazardous strains," it relies on the use of "in vitro cell-based methods to detect evidence of a cytotoxic effect . . . If the strain proves to be cytotoxic it is not recommended for use."

#### **ASA Dismisses Complaint Against Cereal Ads Shown in Cinema**

The U.K. Advertising Standards Authority (ASA) has dismissed a complaint alleging that a cereal advertisement shown at the beginning of a "U-rated"



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film "condoned or encouraged poor nutritional habits or an unhealthy lifestyle in children" and "disparaged good dietary practice." Although Kellogg Marketing and Sales Company (UK) Ltd. included on-screen text stating the sugar content of the product and emphasizing the importance of a varied diet and lifestyle, ASA argued that the Coco Pops Rocks ad in question, which featured brand equity characters and aired before a movie, would appeal to children, "who would not have the reading comprehension skills or relevant knowledge to be able to interpret and understand the information about the sugar content of the product and that it should be eaten as part of a varied diet and active lifestyle."

"We also considered that, in the context of the exciting action in the visuals of the ad, it was unlikely that even those children with the ability to read and understand the on-screen text would pay attention to the information, which was contained in small print at the bottom of the screen," noted ASA. "We considered the information in the small print was unlikely to mitigate the appeal of the product to children in the audience, or make clear to them that the product should only be eaten in moderation."

These caveats notwithstanding, ASA ultimately ruled that the ad "included only one brief shot of two of the characters holding bowls and eating a mouthful of the cereal. There was no suggestion that it was appropriate to consume the product frequently or in excess or that an inactive or sedentary lifestyle was better than physical activity." As a result, the agency found that the ad did not breach CAP Code rules 15.11 and 15.12 (Diet and Lifestyle).

#### **FSANZ IDs Exposures to Acrylamide and Aluminum**

Food Standards Australia New Zealand (FSANZ) has <u>issued</u> the first phase of its Australian Total Diet Study (ATDS), which analyzed chemicals in Australian foods and beverages and concludes that acrylamide and aluminum levels are lower than or consistent with those found in similar foods in other countries. Still, FSANZ CEO Steve McCutcheon said that it was working with industry "to look at ways to reduce acrylamide levels in food, such as encouraging industry to use enzymes that reduce acrylamide formation."

Aluminum levels, which are at their highest levels in cakes, pikelets and pancakes, evidently showed "a slight exceedance for 2-5 year old high consumers." According to FSANZ, this exceedance is unlikely to "represent a public health and safety issue—however, FSANZ is investigating whether the current permissions for aluminum-containing food additives are still appropriate." The second ATDS phase will focus on chemicals such as bisphenol A, phthalates and perfluorinated compounds. See FSANZ News Release, May 1, 2014.



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#### **OEHHA Launches Interactive Biomonitoring Results Database**

California EPA's Office of Environmental Health Hazard Assessment (OEHHA), responsible for implementing the state's Safe Drinking Water and Toxic Enforcement Act of 1986, has <u>launched</u> an interactive database that provides information about the results of biomonitoring testing on various groups, including teachers, children and mothers of Salinas, and firefighters. The database allows searching by project or chemical monitored and provides detailed information about testing results. *See OEHHA Biomonitoring CA Notice*, May 5, 2014.

#### LITIGATION

#### **Court Dismisses Most Claims Against Hershey**

A federal court in California has dismissed all but one claim in a putative consumer-fraud class action against The Hershey Co., finding that, based on his deposition, the plaintiff relied only on the label claims for antioxidants in making his purchasing decisions. *Khasin v. The Hershey Co.*, No. 12-1862 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered May 5, 2014). Information about a prior court ruling that dismissed other claims appears in Issue <u>463</u> of this *Update*.

The court granted the company's motion for summary judgment as to claims made on its Website or in off-label advertising and as to "any claims based on alleged misrepresentations or omissions regarding vanillin, PGPR, serving size and alkalized cocoa powder." The court also granted summary judgment as to claims alleging a failure to make disclaimers on the company's mint products, i.e., that they should not be substituted as an entrée, lunch or meal and that they are not a low-calorie product.

While the plaintiff argued that the court could not rule on a dispositive motion—here a motion for summary judgment—before class certification, the court noted that (i) "[w]hen early resolution of a motion for summary judgment is likely to protect both the parties and the court from needless and costly litigation, it is reasonable to consider such a motion before class certification"; and (ii) "when a defendant moves for summary judgment before the class is certified or notice is sent, the defendant waives the right to have notice circulated to the class and the court's decision binds only the named plaintiffs. . . . Putative class members remain entirely free to file suit against Defendant."

#### Court Transfers Venue of 4-MEI Suit

A federal court in the Southern District of California has transferred to the Northern District a lawsuit filed in January 2014 against Pepsico, Inc., alleging



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that its products violate the state's Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65) because they contain 4-methylimidazole (4-MEI), a chemical included on the Prop. 65 list of substances known to the state to cause cancer, and the company has not provided appropriate consumer warnings. Riva v. Pepsico, Inc., No. 14-0340 (U.S. Dist. Ct., S.D. Cal., order entered April 30, 2014). Eight similar federal lawsuits against Pepsico were filed either in the Northern District or transferred there and are scheduled for a May 29, 2014, case management conference. Finding that transfer to the Northern District would promote the efficient use of judicial resources, the court granted the defendant's motion.

The plaintiffs had argued that under the first-to-file rule, all of the cases should have been transferred to the Southern District, but the court disagreed. According to the court, the inconvenience to the other parties and witnesses would be somewhat greater, because more cases were filed elsewhere and have progressed further than Riva. The court also noted that "all actions, wherever located, are attorney-driven statutory consumer class actions and generally require only limited participation of the individual class representative. No actual individual damages need be demonstrated to prevail in these consumer class actions thereby limiting the role of the named plaintiff." The court further indicated that "the first-to-file rule was not adopted to award the winner of the race to the courthouse with the status of class counsel."

#### Texas Intervenes in Breweries' Alamo Trademark Dispute

Texas has filed a motion to intervene in Alamo Beer Co. LLC's trademark infringement suit against Old 300 Brewing LLC, asserting that the state has the rights to the "Alamo" mark. Alamo Beer Co. LLC v. Old 300 Brewing LLC, No. 14-285 (U.S. Dist. Ct., W.D. Tex., motion filed April 28, 2014). Filed in March 2014, Alamo Beer's original complaint alleged that Old 300 Brewing (doing business as Texian Brewing Co.) infringed on its mark by using the silhouette of the Alamo on Texian beer labels, which image Alamo Beer has used and federally registered as a trademark for beer labeling since 1997.

Texas argues that it has registered and common law rights to the use of the Alamo Mission's likeness in commerce. In 2013, the state began registering the Alamo silhouette in a variety of categories, including blankets, apparel, jewelry, leather goods, digital media, packaged foods, and museum services. In the category nearest to the beer labeling at issue, the bottled water market, Texas filed to register the silhouette on April 22, 2014, asserting that its first use in the market dates back to 2011. Rather than arguing the most common standard for trademark disputes—likelihood of consumer confusion—Texas asserts that the Alamo mark is famous, and use of the mark by anyone else in any category would dilute it. "The Alamo is owned by the people of Texas, and the image is also commercialized for the people of Texas—not for private



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profit," Jim Suydam, press secretary of the Texas General Land Office, told *Law360*. *See* U.S. Trademark Serial No. 86259263 (Registration pending); *Law360*, March 28, 2014 and April 30, 2014.

#### Former Peanut Corp. Manager Pleads Guilty

Samuel Lightsey, who formerly managed the Peanut Corp. of America, which was implicated in a 2008-2009 nationwide *Salmonella* outbreak, has entered a guilty plea to six of 76 criminal charges, including conspiracy, mail and wire fraud, obstruction of justice, and other counts related to the distribution of adulterated or misbranded food. *United States v. Samuel Lightsey*, No. 13-CR-12 (U.S. Dist. Ct., M.D. Ga., Albany Div., plea entered May 7, 2014). Facing a potential sentence of six years in prison, Lightsey has agreed to cooperate with the prosecution. The outbreak sickened more than 700 who consumed products containing tainted peanut paste, and at least nine died.

According to the plea agreement, in September 2008, Lightsey and others shipped a lot of peanut paste from the company's Blakely, Georgia, facility "without ever having submitted a sample from said lot to a laboratory for microbiological testing." This food was misbranded because it was accompanied by a document containing test results "from a previously manufactured lot of peanut paste." It was adulterated because it contained *Salmonella*. The agreement also states that, after the outbreak was traced to the Blakely facility and U.S. Food and Drug Administration inspectors sought production of relevant records, Lightsey and another employee concealed and withheld from the agency a log listing "the sample numbers of all samples of peanut products submitted for microbiological testing during calendar year 2008."

The agreement mentions former owner Stewart Parnell in connection with particular email transmissions about changing peanut-paste specifications for a customer. Information on proceedings about whether Parnell's expert witness's testimony—proffered as to Parnell's ability to form the intent to commit the alleged crimes—is admissible under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), appears in Issue 517 of this *Update*.

#### Kashi and Bear Naked Reach "All Natural" Class Action Settlements

Kashi Co. and its unit Bear Naked Inc. have both settled class actions stemming from their claims that their products are "All Natural" and include "Nothing Artificial." *Astiana v. Kashi Co.*, No. 11-1967 (U.S. Dist. Ct., S.D. Cal., settlement filed May 2, 2014). *Thurston v. Bear Naked Inc.*, No. 11-2890 (U.S. Dist. Ct., S.D. Cal., settlement filed May 2, 2014). The plaintiffs alleged in California federal court that the companies, both part of Kellogg Co., advertised their products as all natural and charged higher prices based on that quality while inserting synthetic material into their foods. A judge certified both



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classes in July 2013 after ruling that the plaintiffs had proved the artificiality of some of the "natural" ingredients, including hexane-processed soy ingredients and pyridoxine hydrochloride. Kashi has agreed to pay \$5 million to California consumers who purchased its products and to alter its labeling and advertising to remove the claims at issue; in a similar settlement, Bear Naked will pay \$325,000. Kashi denies any wrongdoing, but reportedly cites the expense and burden of litigation as a driving force for the settlement. Details on the class action certification appear in Issue 492 of this *Update*. *See Law360*, May 5, 2014.

#### Trader Joe's Allegedly Mislabels Sunflower Seeds

A California resident has filed a putative nationwide class action against Trader Joe's alleging that the company fails to disclose "the dangerously high" sodium content contained in its sunflower kernels and sunflower shells and then markets the products as a "good" or healthy snack. *DiSimone v. Trader Joe's Co.*, No. BC544924 (Cal. Super. Ct., Los Angeles Cnty., filed May 6, 2014).

Claiming that the company deceives consumers by listing a single serving "with Shells" as containing 690 milligrams (mg) of sodium or "29%" of the total daily value established by the U.S. Food and Drug Administration (FDA), the plaintiff contends that the seeds and shells, which are also placed in the mouth, actually contain more than 2,350 mg of sodium, an amount that far exceeds a large order of McDonald's French fries at 350 mg of sodium. The plaintiff further asserts that the average consumer will eat more than one serving and thus "double or triple the FDA recommended daily intake of sodium for the entire day," and, in fact, "[a] consumer eating an entire 8-ounce bag of Sunflower Seeds would consume 9,412 milligrams of sodium."

Alleging violations of the state's Consumers Legal Remedies Act, False Advertising Law and Unfair Competition Law, the plaintiff seeks an order prohibiting the alleged misconduct, attorney's fees and costs.

#### Darigold Faces Proposed Class Action for Alleged Employee and Cow Abuses

Two consumers have filed a putative class action against dairy cooperative Darigold Inc., a subsidiary of Northwest Dairy Association, for false advertising and fraud by concealment, alleging that the company misrepresented the conditions in which its milk is produced. *Ruiz v. Darigold Inc.*, No. 14-2054 (U.S. Dist. Ct., N.D. Cal., May 5, 2014). Yesenia Ruiz and Fernando Dorantes argue that they would not have purchased Darigold's products if they had known about the purportedly poor conditions in which its employees work and its cows are milked. According to the complaint, Darigold employees are denied drinkable water, break periods and lunch rooms, and some of its cows are sick and injured but are milked anyway. The plaintiffs also assert claims under California's Unfair Competition Law; the unjust enrichment laws of California, Washington and Oregon; Washington's Consumer Protection Act; and Oregon's Unlawful Trade Practices Act.



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#### Mister Softee Files Motion for Injunction Against Master Softee

Ice cream truck franchiser Mister Softee Inc. has filed a motion for a preliminary injunction in a lawsuit alleging trademark infringement and violation of a non-compete covenant against former franchisee Dimitrios Tsirkos, who converted his 16 Mister Softee trucks to Master Softee trucks and began selling his own ice cream out of them at the beginning of the 2014 ice cream truck season. *Mister Softee of Queens Inc. v. Tsirkos*, No. 14-1975 (U.S. Dist. Ct., S.D.N.Y., motion filed April 25, 2014). Mister Softee ended Tsirkos' franchise contract after he refused to pay \$74,000 in franchise royalties for his trucks, but Tsirkos allegedly adjusted the logo on his trucks, started his own softserve depot and began selling ice cream in New York City anyway. Tsirkos has filed a motion opposing the injunction, and a hearing is set for May 15, 2014. *See Law360*, May 2, 2014. *See New York Daily News*, May 1, 2014.

#### OTHER DEVELOPMENTS

#### Coffee-Making Motions May Cause "Barista Elbow"

Repeated motions of lifting pitchers, steaming milk and stamping espresso may cause medial epicondylitis—golfer's elbow—or other stress injuries in baristas. A recent *New York Post* article chronicles one woman's experience with a stress injury allegedly resulting from her job duties as a barista. In addition, a former barista in Canberra, Australia, was recently awarded \$600,000 (AUD) in damages after she had a rib removed and was diagnosed with a nerve disorder as a result of the stress from repeatedly holding a 4.4-pound jug of milk while the coffee machine steamed it. According to an informal survey conducted by coffee Website Sprudge, 55 percent of 475 respondents reported they had sustained repetitive stress injuries in their barista work. While treatment can include physical therapy or surgery, a certified hand specialist who spoke to the *Post* said that preventative measures like exercise and better posture can help protect coffee shop employees from injury. *See New York Post*, May 4, 2014.

#### **NYC Food Policy Center to Host Salt Discussion**

The New York City Food Policy Center at Hunter College has announced a May 20, 2014, meeting at the Roosevelt House Public Policy Institute at Hunter College in New York City, to discuss ways of translating conflicting information about salt into public health policy. Professor of Public Health at the City University of New York School of Public Health and Hunter College Nicholas Freudenberg is slated to moderate the panel with participants former Commissioner of Health, New York City Department of Health and Mental Hygiene's Thomas Farley; and Professor and Department Chair of Epidemiology at the Mailman School of Public Health at Columbia University's Sandro Galea Gelman. See NYCFoodPolicy.org, May 7, 2014.

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#### MEDIA COVERAGE

#### **Food Substitute Drinks Capture Media Attention**

Drink mixes intended to replace meals altogether have garnered attention from the media recently as part of a larger trend of "lifehacking," a cultural Silicon Valley export that aims to streamline daily life obligations. A recent New Yorker article by Lizzie Widdicombe profiles Rob Rhinehart, creator of Soylent, a drink mix that purports to provide all the daily nutrients that a human needs. The concoction includes lipids from canola oil, carbohydrates from maltodextrin and oat flour, protein from rice, fish oil from omega-3s, and doses of magnesium, calcium and electrolytes. Rhinehart, who says that he has drunk Soylent for 90 percent of his meals in the past year and a half, describes Soylent not as a meal replacement like many diet mixes currently on the market but rather as a food substitute that a person could subsist on alone. The first 30,000 units of commercially produced Soylent shipped to customers in early May, and Soylent's formula is available for free online, as well as variations and ideas for spicing up the beige "vaguely sweet yeasty bread-drink." Competitor Ambronite, in contrast, tastes "like raw, unsalted almonds," and is made from non-factory-derived ingredients such as herbs, berries and nuts. Like Soylent did before it, Ambronite is using crowd-funding to launch the drink into commercial production, and it aims to be the more natural, upscale food substitute mix. While Ambronite gathers money from its future users, Soylent is receiving \$10,000 in new orders each day, and the U.S. military and space programs have asked to run trials on the product. See Ars Technica, May 5, 2014; The New Yorker, May 12, 2014.

#### SCIENTIFIC/TECHNICAL ITEMS

#### Children's Consumption of Food Dyes Allegedly Increased Five-Fold Since 1950

A recent study has claimed that children consume more artificial food colors (AFCs) than previously thought, raising concerns about potential health effects not addressed by federal guidelines. Laura Stevens, et al., "Amounts of Artificial Food Dyes and Added Sugars in Foods and Sweets Commonly Consumed by Children," *Clinical Pediatrics*, April 2014. In addition to reporting the AFC content of individual brand-name foods and beverages, Purdue University researchers ultimately calculated that the U.S. Food and Drug Administration (FDA) certified 62 mg of AFCs per capita per day in 2010, up from 12 mg per capita per day in 1950. According to the Center for Science in the Public Interest (CSPI), these levels of AFC consumption "are higher than the levels demonstrated in some clinical trials to impair some children's behavior."

"In the 1970s and 1980s, many studies were conducted giving children 26 mg

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of a mixture of dyes," one study author was quoted as saying. "Only a few children seemed to react to the dyes, so many doctors concluded that a dye-free diet was pointless. Later studies using larger doses showed that a much larger percentage of children reacted. But some researchers considered those doses unrealistically high. It is now clear that even the larger amounts may not have been high enough. The time is long past due for the FDA to get dyes out of the food supply or for companies to do so voluntarily and promptly." See CSPI Press Release, May 7, 2014.

#### Study Finding Health Benefits of Omega-3s Had Significant Flaws, **Researchers Say**

A recent review has reportedly identified several flaws in the widely cited 1970s study which found that diets rich in omega-3 fatty acids could help fight coronary artery disease (CAD). George J. Fodor et al., "Fishing' for the origins of the 'Eskimos and heart disease' story. Facts or wishful thinking? A review," Canadian Journal of Cardiology, April 2014. In the original study, Danish researchers examined the diet of Greenland Eskimos and linked the high amount of fish oil to the purportedly low incidence of CAD. A team of researchers has reexamined the original study as well as more recent studies on the Eskimo population and found that Eskimos actually suffer CAD at the same rate as Caucasians. The 2014 study identifies several reasons why the original study's source for CAD rates in the Greenland Eskimos—the annual reports produced by the Chief Medical Officer of Greenland—were likely insufficient, including poor reporting rates, inaccessibility of doctors and inaccurate records. The researchers also found that Eskimos have very high rates of mortality due to strokes. "Considering the dismal health status of Eskimos," said lead researcher George Fodor, "it is remarkable that instead of labeling their diet as dangerous to health, a hypothesis has been construed that dietary intake of marine fats prevents CAD and reduces atherosclerotic burden." See Elsevier, May 1, 2014.

#### Crops Grown in Higher CO<sub>2</sub> Conditions Have Lower Levels of Nutrients

Harvard researchers have found that staple crops grown in environments with levels of carbon dioxide (CO<sub>2</sub>) similar to the levels expected in 2050 had less zinc, iron and protein than crops grown at current CO<sub>2</sub> levels. Samuel S. Myers et al., "Increasing CO<sub>2</sub> threatens human nutrition," *Nature*, May 2014. The researchers conducted field trials of 41 strains of wheat, rice, maize, and soybeans grown in seven locations on three continents, elevating the CO<sub>2</sub> levels from the current average of about 380-390 parts per million (ppm) to the expected levels in 2050 of 545-585 ppm. The wheat, rice and maize grown at the higher CO<sub>2</sub> levels each had about 5 to 10 percent less zinc, iron and protein, while soybeans lost similar amounts of zinc and iron but maintained current levels of protein. The precise biological reason for the declines remains unclear, but researchers reportedly said that the nutrient reduction



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could cause a rise in metabolic syndrome in developed countries and exacerbate the iron and zinc deficiencies already experienced by two billion people around the world. *See The Guardian*, May 7, 2014.

#### Antimicrobial Edible Films Inhibit Pathogens in Meat

Researchers at Penn State University's College of Agricultural Sciences have purportedly found that edible films made from pullulan—a transparent polymer produced by the fungus *Aureobasidium pulluns*, silver nanoparticles, zinc oxide, and oregano and rosemary essential oils—can inhibit foodborne pathogens on meat products. Mohamed K. Morsy, et al., "Incorporation of Essential Oils and Nanoparticles in Pullulan Films to Control Foodborne Pathogens on Meat and Poultry Products," *Journal of Food Science*, April 2014.

Observing that the films inhibited the growth of four pathogens—Staphylococcus aureus, Salmonella Typhimurium, Listeria monocytogenes, and E. coli O157:H7—to varying degrees, the researchers concluded that they could form "the basis of a useful packaging tool to improve the safety of meat products." According to Penn State University Food Science Professor Catherine Cutter, who co-authored the study, the edible films are a "novel but effective way" to deliver antimicrobial agents to meats because the bacteria-killing action lasts longer than the liquid applications traditionally used.

"The results from this study demonstrated that edible films made from pullulan and incorporated with essential oils or nanoparticles have the potential to improve the safety of refrigerated, fresh or further-processed meat and poultry products," said Cutter. "The research shows that we can apply these food-grade films and have them do double duty—releasing antimicrobials and imparting characteristics to protect and improve food we eat." See Penn

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#### **FOOD & BEVERAGE LITIGATION UPDATE**

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.





