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LEGISLATION, REGULATIONS AND STANDARDS

Members of Congress Send Letter to USDA on COOL Regulations

In a letter signed by 110 members of Congress, U.S. Reps. Jim Costa (D-Calif.) and Rick Crawford (R-Ariz.) have <u>urged</u> Secretary of Agriculture Tom Vilsack and U.S. Trade Representative Ambassador Michael Froman to rescind the country-of-origin labeling (COOL) requirements imposed on imports from Canada and Mexico if the World Trade Organization (WTO) rules against the United States in its investigation of U.S. COOL regulations. The letter reportedly suggested that Congress is working on a permanent solution to the issue, and it warned that a WTO ruling against the United States could result in detriment to the U.S. economy. "Congress must be prepared to act and find a solution that maintains a healthy relationship with our trading partners and protects the American economy," Costa said in a July 31, 2014, statement. The letter echoes a similar argument made by food industry groups in July 2014 correspondence. Additional information on the food industry groups' letter appears in Issue <u>529</u> of this *Update*. The same month, an en banc panel of the D.C. Circuit upheld the COOL rules for the meat industry in a challenge by the American Meat Institute. Further information on the decision appears in Issue **532** of this *Update*.

"Gluten-Free" Standards Take Effect

The U.S. Food and Drug Administration (FDA) this week <u>reminded</u> consumers that "gluten-free" "now means what it says" after a final rule outlining the voluntary labeling standards took effect on August 5, 2014. According to FDA, the new standards stipulate that foods labeled "gluten-free," "without gluten" or "no gluten" can contain gluten in amounts less than 20 parts per million (ppm) only, "the lowest level that can be consistently detected in foods using valid scientific methods."

"This level is consistent with those set by other countries and international bodies that set food safety standards," explained the agency, which gave manufacturers one year to bring products into compliance. Additional details about the final rule appear in Issue 492 of this Update. See FDA Consumer Update, August 5, 2014.



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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com);

FDA Seeks Comments on Estimated Time Burdens Related to Recalls

The U.S. Food and Drug Administration (FDA) seeks public comments on the estimated time burdens relating to the extension of an existing information collection pertaining to the recalls of all FDA-regulated products (including food, animal feed, drugs, animal drugs, medical devices, cosmetics, biological products intended for human use, and tobacco). The estimates are based on the total number of recalls from 2011 to 2013 (11,403) averaged to 3,801 per year and involve the time burdens of complying with the voluntary reporting requirements of the agency's recall regulations. Comments must be submitted by October 3, 2014. See Federal Register, August 4, 2014.

EFSA Rejects Emergency Measure to Ban GM Maize

The European Food Safety Authority (EFSA) has <u>rejected</u> the evidence submitted by France "in support of its request to prohibit the cultivation of genetically modified [GM] maize MON 810 in the EU." As requested by the European Commission, EFSA reviewed the French report but determined that none of the cited studies "would invalidate the previous risk assessment conclusions and risk management recommendations made by the EFSA GMO Panel."

Noting that many of the issues in question were previously addressed by the GMO Panel, EFSA also considered the concerns raised by French authorities "in light of the most recent and relevant scientific data." Based on these findings, the agency ultimately found "no specific scientific evidence, in terms of risk to human and animal health or the environment, that would support the adoption of an emergency measure on the cultivation of maize MON 810 under Article 34 of Regulation (EC) 1829/2003."

EFSA Refines Declarations of Interest Rules

The European Food Safety Authority (EFSA) has **revised** the rules governing "Declarations of Interest" as part of its ongoing effort to increase openness and transparency. Effective September 30, 2014, the updated rules clarify how the agency uses such declarations "to prevent the occurrence of conflicts of interest among the members of its governance bodies and its staff," including those serving on EFSA's Management Board, Advisory Forum, Scientific Committee, Scientific Panels, and Working Groups, as well as external experts, observers, tenderers, and grant beneficiary participants.

Among other things, the new rules specify that a "food safety organization" "must receive more than 50% of its funding from public sources." They also provide "a precise definition of what is meant by family members, namely spouses, registered partners and dependent descendants," in addition to making annual Declarations of Interest "obligatory for all staff members."



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"EFSA is committed to reviewing its policies and procedures to ensure they remain fit for purpose," states the agency in a July 31, 2014, news release. "The next important step in this direction will be the more strategic review of EFSA's Policy on Independence and Scientific Decision-Making Processes, which will begin in 2015."

ASA Dismisses Complaints Against Tesco Milk Ads

The U.K. Advertising Standards Authority (ASA) has <u>dismissed</u> complaints challenging print and TV advertisements that tout Tesco-brand milk as fairly priced and responsibly sourced. In particular, the complaints alleged that (i) "the image of cows in an open field did not accurately represent how the milk was produced or the conditions in which the cows lived" and (ii) only a small proportion of Tesco's milk was sourced through the Tesco Sustainable Dairy Group (TSDG).

According to ASA, Tesco countered that all of its core milk suppliers must meet industry Red Tractor standards as well as Tesco's own Livestock Code of Practice, which focuses on food safety, environmental indicators and "welfare outcome measures such as lameness, mastitis, fertility, and animal health." The retailer also reiterated that core farmers with TSDG "supplied approximately 80% of Tesco's total milk requirements over the course of the year," while seasonal farmers provided additional milk during periods of low production. Tesco explained, however, that "[b]oth Core and Seasonal farmers were part of TSDG and received the full TSDG price for the milk they supplied" regardless of the retail price charged for milk.

Based on these arguments, ASA found that not only were adequate procedures in place "to look after the animals' health and welfare," but that "the figures supplied by Tesco showed that all their own brand fresh and filtered milk (excluding organic, goat and flavored) came through TSDG." As the agency concluded, "We appreciated that the exact conditions in which cows would be kept were likely to vary from one location to another and according to weather conditions and time of year... We noted Tesco's explanation that both [seasonal and core farmers] were paid at the same TSDG rate for the quantity they supplied, and that the rate had been calculated to recognize the cost of producing milk and to include provision for capital investment, which we considered would be significant considerations for consumers deciding whether or not they would buy milk at Tesco in response to the ad."



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LITIGATION

Confidential Dairy Records in Dispute in Yakima Valley

A federal court in Washington has determined that the U.S. Environmental Protection Agency (EPA) did not violate the Freedom of Information Act (FOIA) in responding to requests for information relating to its investigation of nitrate levels in groundwater and residential drinking water wells in the Lower Yakima Valley. *Cmty. Ass'n for Restoration of the Env't, Inc. v. EPA*, No. 13-3067 (U.S. Dist. Ct., E.D. Wash., order entered August 6, 2014). Because the environmental organization (CARE), which is a plaintiff in Resource Conservation and Recovery Act (RCRA) citizen suits against the dairies whose documents are part of the FOIA requests, also alleged Administrative Procedure Act (APA) violations against EPA, the court granted its request to allow the parties to brief the merits of CARE's APA claim.

Meanwhile, the dairies subject to the RCRA actions have filed a lawsuit against EPA, seeking an order prohibiting EPA from disclosing to CARE or other members of the public any of the purportedly confidential information and documents that were allegedly voluntarily produced to the agency as part of negotiations leading to a consent order related to the agency's nitrate investigation and findings in the Lower Yakima Valley region. *Cow Palace, LLC v. EPA*, No. 14-3104 (U.S. Dist. Ct., E.D. Wash., filed July 31, 2014). They claim that the material is protected under Federal Rule of Evidence 408, "which prohibits use of settlement communications to establish liability."

They also contend that in July 2014 EPA issued final determination letters as part of CARE's FOIA requests, finding some of the dairies' material not entitled to confidential treatment, despite a court order issued in March in the RCRA litigation denying CARE's request to remove the "confidential" designation from business information the dairies produced under a stipulated protective order. The RCRA court found that the records constitute confidential information about the dairies' business operations. The dairies claim that "EPA should have denied CARE's FOIA requests for disclosure of information that had previously been determined by the Court to be confidential business information that is not subject to public disclosure." In this regard, they claim that the agency's action was arbitrary and capricious and an abuse of discretion.

According to the dairies' complaint, "CARE's only reason for making its FOIA request to EPA is so it can use the Dairies' internal, confidential documents as part of a public relations campaign to smear the Dairies with allegations of wrongdoing." The dairies further note that CARE does not need duplicative records from EPA to support its RCRA lawsuit, because the organization already "possesses much of the information and documents that are the subject of the Final Determinations."



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Kettle Brand Chips Consumer-Fraud Complaint Narrowed

A federal court in California has granted in part the motion to dismiss filed by Diamond Foods, Inc. in a putative class action alleging that the company misleads consumers by claiming that its Reduced Fat Sea Salt Chips are "40%" reduced fat potato chips" and its Backyard Barbecue Chips are "All Natural," as well as making false and deceptive statements in the company's "promotional materials" and on its "website." Hall v. Diamond Foods, Inc., No. 14-2148 (U.S. Dist. Ct., N.D. Cal., order entered July 31, 2014). An amended complaint, if any, must be filed by August 15, 2014, and the case management conference will be held on October 31.

The court dismissed the reduced fat claims finding them insufficiently pleaded because it was unclear whether the plaintiff read only the statement on the front of the bag, in which case he "would lack standing to argue the statements on the back and bottom of the bag are false and deceptive," or whether he read each label statement, in which case "it is unclear how plaintiff would not have understood the 40% comparison on the front and back was with reference to regular potato chips, given the statement on the bottom of the bag to that effect." The plaintiff was given leave to amend to identify the statement or statements on which he relied to purchase the product. The court also agreed that the plaintiff had not adequately pleaded claims based on promotional materials and Website statements because he failed to allege that he read any such statement before purchasing the products at issue. The plaintiff was given leave to amend his complaint to cure the pleading defect.

As to the "All Natural" claims, the court allowed them to proceed, ruling that the defendant's argument that reasonable consumers would not be misled by these labeling representations was premature. The court also rejected the defendant's argument that no reasonable consumer could be misled because all of the ingredients, including citric acid and paprika extract, were identified in the ingredient list. Citing the Ninth Circuit, the court noted that "reasonable consumers expect that the ingredient list contains more detailed information about the product that confirms other representations on the packaging" and cannot be used as shield for liability for the alleged deception. The court further allowed the seventh cause of action, titled "Restitution Based on Quasi-Contract/Unjust Enrichment," to proceed, finding that, while unjust enrichment itself is not a cause of action, restitution may proceed under a quasi-contract theory.

Wine Counterfeiter Receives 10-Year Prison Sentence

According to New York Southern District U.S. Attorney Preet Bharara, a man who allegedly operated a wine counterfeiting laboratory from his California residence between 2004 and 2012 has been sentenced to 10 years in prison. Rudy Kurniawan apparently became a prominent and prolific U.S. dealer



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of rare and expensive wine that was actually lower-priced wine blended to mimic the taste and character of far better wines. He allegedly purchased empty bottles of rare and expensive wines—some of them from New York City restaurants—poured his mixtures into them, sealed the bottles, and then attached counterfeit labels that he created. The fakes were then sold to wealthy wine collectors through auctions and by direct sales. According to a news source, Kurniawan was eventually caught through misspellings and other packaging errors, including early 20th century dates on some bottles that pre-dated their actual production.

Kurniawan also allegedly fraudulently obtained a \$3-million loan from a New York City financing company that specialized in securing loans with valuable collectibles, including art and wine. The U.S. attorney said, "Kurniawan obtained the loan by providing false information to, and concealing information from, the financing company, including falsely omitting approximately \$7.4 million in outstanding loans, falsely representing his annual expenses, and falsely representing that he was a permanent resident of the United States when he had no legal immigration status in the United States and had, in fact, been ordered by an immigration court to leave the country years earlier."The sentencing court also ordered the 37-year-old to forfeit \$20 million and pay restitution of nearly \$28.5 million. See U.S. Department of Justice Press Release and Courthouse News Service, August 7, 2014.

Putative Class Action Filed Against Organic Milling for Allegedly False "100% Natural" Claims

A plaintiff has accused cereal company Organic Milling of mislabeling its Nutritious Living Hi-Lo brand cereals as "100% natural" despite allegedly containing synthetic and heavily processed ingredients and being produced with genetically modified (GM) crops. *Mirto v. Organic Milling*, No. BC553780 (Super. Ct. Cal., Los Angeles Cnty., filed Aug. 5, 2014). The complaint alleges first that the use of GM crops in the cereal's production precludes the company from using the phrase "100% natural" on its marketing materials, citing definitions from the World Health Organization and Environmental Protection Agency to argue that "GM crops are not 'natural,' and products made from these crops, including [Organic Milling's products], are not '100% natural."

The complaint further argues that Organic Milling's use of canola oil in Hi-Lo cereal is not "100% natural" either because of the heavy processing required to produce the oil. The plaintiff also objects to the use of emulsifier soy protein isolate and sweetener evaporated cane juice in products carrying a "100% natural" label. This alleged mislabeling, she argues, amounts to violations of California's Unfair Competition Law, False Advertising Law, Consumer Legal Remedies Act, and a breach of express warranty. She seeks class certifi-



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cation—for a class defined as California purchasers of Hi-Lo Original Flavor or Strawberry since August 4, 2010—attorney's fees, an injunction, and actual, punitive and statutory damages.

Putative Class Action Accuses Whole Foods of Greek Yogurt Sugar **Content Mislabeling**

A plaintiff has alleged in Massachusetts federal court that Whole Foods Market mislabels its 365 Everyday Value Plain Greek Yogurt as containing 2 grams of sugar per serving despite Consumer Reports tests showing that a serving of the product contains an average of more than 11 grams of sugar. Knox v. Whole Foods Market, No. 14-13185 (U.S. Dist. Ct., D. Mass., filed Aug. 1, 2014). According to the complaint, the plaintiff learned about the alleged labeling discrepancy from Consumer Reports magazine, which tested six samples of 365 Everyday Value Plain Greek Yogurt and apparently found the average sugar content to be nearly six times the amount listed on the label. Whole Foods reportedly responded to the magazine's findings by asserting that it relied on testing results from reputable third-party labs. The plaintiff alleges breach of warranty, unjust enrichment and negligence, and he seeks class certification, compensatory and punitive damages, attorney's fees, an injunction, and court declarations that the yogurt label contained false and misleading nutritional information and that Whole Foods knew or should have known about the false information on the label.

Settlement Approval Requested in Chipotle Illegal Immigrant Case

Chipotle Mexican Grill investors have filed a motion for final approval of a derivative-action settlement in a lawsuit accusing the restaurant chain's executives of breaching fiduciary duties by failing to comply with employee work authorization requirements. Mohammed v. Ells, No. 12-1831 (U.S. Dist. Ct., D. Colo., motion filed July 31, 2014). The case stems from a U.S. Immigration and Customs Enforcement (ICE) investigation of the company that led to the firing of 450 Minnesota employees and 50 Washington, D.C., workers for lack of U.S. work authorization. In July 2012, Chipotle investors accused the company's executives of breaching their fiduciary duties in several lawsuits that were later merged. After "intense, arm's-length negotiations by experienced counsel," the parties reached a settlement that earned preliminary court approval in April 2014. Under the settlement's terms, Chipotle will provide twice-yearly reports to its audit committee, which oversees the company's hiring requirement compliance. In arguing for settlement approval, the investors cited recent improvements that Chipotle has made since the government investigations began—including more comprehensive training and a larger compliance team—as evidence that additional reform is unneeded and noted that none of the plaintiffs in the class have objected to the terms of the proposed settlement.



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OTHER DEVELOPMENTS

Russia Bans Food Imports from United States, European Union

In response to recent sanctions related to the conflict in Ukraine, Russia has prohibited food imports from the United States, European Union, Australia, Norway, and Canada. The ban extends to meat, fish, produce, and milk products and will remain in place for one year. Although alcohol was not included in the announced food import bans, the Russian consumer protection agency, Rospotrebnadzor, has reportedly threatened to prohibit the import of Kentucky Gentleman bourbon, citing potential carcinogens. In July 2014, Russia banned the import of soy products, cornmeal, dairy products, and canned foods from Ukraine and most fruit and vegetables from Poland. Some Russians have been critical of the ban and its projected effects on the Russian food supply. "[L]iterally every [Russian] family will be affected," Yevsey Gurvich, head of Russian company Economic Expert Group, told The Washington Post. Russian bans of food imports have frequently coincided with their political tensions. Information on Rospotrebnadzor's reported lawsuit against Russian locations of McDonald's appears in Issue 532 of this *Update*. See Associated Press, July 31, 2014, The Fiscal Times, August 4, 2014, and The Washington Post, August 7, 2014.

MEDIA COVERAGE

Shook Attorneys Discuss France's Class Action Expansion with Food Navigator

Shook, Hardy & Bacon Partner Marc Shelley and Associate Emily Fedeles recently spoke with Food Navigator about a proposal contained in French Minister of Health Marisol Touraine's National Health Bill that would extend class actions to claims involving injuries to health. According to the August 7, 2014, article, the bill seeks to expand a new consumer law that established class action procedures for consumer-protection and antitrust claims but stopped short of including personal-injury claims.

Noting that the current proposal targets food and beverage manufacturers making product-health claims, Shelley and Fedeles warn that these changes are only the latest in a "troubling" trend that could affect the entire industry as more member states move to expand the scope of their class-action laws. With companies granted only one opportunity to defend against collective claims, Fedeles adds, "[y]ou only get one bite at the apple and of course there's a difference between paying a couple thousand Euros to one plaintiff, and paying a couple thousand Euros to a couple thousand plaintiffs."

"In order to ensure the right types of actions are being brought by the right types of claimants against the right types of companies, you need to have



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clear provisions in the rule to allow the parties and the courts to make that decision," explains Shelley. "The consequence for that is that it can raise prices, it can scare off companies. It can stifle innovation because the fear is you're going to get hit with a class action and it's going to take away from the company and away from their bottom line and their stock prices."

Crickets are the Next Quinoa, NYT Suggests

Crickets and other edible insects may be poised for widespread popularity, according to recent New York Times and NPR stories. Cricket flour—pulverized crickets in powder form—offers several nutritional benefits to consumers, including high levels of protein. The flour is gluten-free and compatible with the Paleo Diet, which eschews carbohydrates in favor of meat and vegetables, and cricket flour production is more environmentally friendly and sustainable than other forms of protein production, proponents say. The problem, edible insect-based food producers say, is the "ick factor," the psychological aversion to eating bugs that many Americans have. According to NPR, marketers have pursued "intelligent cutesiness" to overcome that burden and convince new customers to try insect-based foods, including attempts to rebrand locusts as "sky prawns" to assuage consumer fears. "It tastes like dark toast," as one investor described cricket flour to The New York Times. Another first-time customer praised her bite of a cricket flour-based cookie, telling NPR, "It tastes like coconut. Tastes like food, not like bugs." See The New York Times, August 2, 2014, and NPR, August 7, 2014.

SCIENTIFIC/TECHNICAL ITEMS

Study Claims SSBs Consumed During Adolescence Could Impair Memory

An animal study presented at the Annual Meeting of the Society for the Study of Ingestive Behavior (SSIB) held July 29-August 1, 2014, in Seattle, Washington, has reportedly claimed that "daily consumption of beverages sweetened with high-fructose corn syrup or sucrose can impair the ability to learn and remember information, particularly when consumption occurs during adolescence." According to a July 29, 2014, SSIB press release, University of Southern California researchers reported that, unlike adult rats given daily access to sugar-sweetened beverages (SSBs), rats that consumed SSBs during adolescence "were impaired in tests of learning and memory capability."

"[O]ur findings reveal that consuming sugar-sweetened drinks is also interfering with our brain's ability to function normally and remember critical information about our environment, at least when consumed in excess before adulthood," the lead researcher was quoted as saying. "In addition to causing memory impairment, adolescent sugar-sweetened beverage consumption



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also produced inflammation in the hippocampus, an area of the brain that controls many learning and memory functions... In many ways this region is a canary in the coal mine, as it is particularly sensitive to insult by various environmental factors, including eating foods that are high in saturated fat and processed sugar."

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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.





