

FOOD & BEVERAGE LITIGATION UPDATE



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FIRM NEWS

McDonough Honored as *NLJ* Litigation Trailblazer & Pioneer

The National Law Journal (*NLJ*) recently recognized Shook, Hardy & Bacon Agribusiness & Food Safety Co-Chair [Madeleine McDonough](#) among the 50 attorneys selected for its inaugural class of [Litigation Trailblazers & Pioneers](#).

"The 'Litigation Trailblazers & Pioneers' list recognizes those professionals who have acted as real agents of change in their field, elevating—and in some cases, redefining—the ways in which litigation is pursued, cases are defended or trials are handled," *NLJ* publisher Tom Larranaga said. "They have raised the bar in several meaningful ways and are establishing important new standards as the legal landscape continues to evolve."

McDonough has represented more than 65 companies regulated by the Food and Drug Administration over her 25-year career at Shook and told *NLJ* that whenever possible she helps clients avoid litigation through anticipatory risk management. "I've learned that a lot of issues can be resolved before trial," she said. "If you have to go to trial, we'll do that. But it's time-consuming, expensive and often not satisfactory—even if you win." Ways of preventing litigation include developing a thorough understanding of the opponents, claims, landscape and "trying to work out something that helps everybody."

McDonough has resolved thousands of claims and cases, often with no or minimal payment by her clients, through establishing strong relationships with opposing counsel, educating counsel and judges about the scientific and medical issues at hand, and developing creative approaches through negotiation, phased litigation techniques, targeted motion practice, and trial, whenever necessary.

LEGISLATION, REGULATIONS AND STANDARDS

House Lawmakers Propose Bill to Reduce Taxes on Craft Brewers

A bipartisan group of U.S. representatives has [proposed](#) legislation that would reduce excise taxes levied on the first two million barrels of beer sold annually by small brewers. Reps. Erik Paulsen (R-Minn.) and Richard Neal (D-Mass.) were joined by Reps. Peter DeFazio (D-Ore.), Earl Blumenauer (D-Ore.), Patrick McHenry (R-N.C.), and Patrick Meehan (R-Penn.) in proposing the "Small Brewer Reinvestment and Expanding Workforce Act" (Small BREW Act) to impose an excise tax rate of \$3.50 per barrel on the first 60,000 barrels and \$16 per barrel on the next 1,940,000 barrels.

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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).

If passed, the law would apply only to brewers that produce six million barrels or fewer each year. "Small brewers—long an important part of American culture and history—have enjoyed a tremendous growth in popularity in recent years," Meehan said in a January 8, 2015, press release. "But while our brewing industry has evolved, our tax code hasn't evolved with it. Outmoded federal excise taxes inhibit the growth of small brewers and make it harder for fledgling businesses to survive and prosper. This legislation will ease the tax burden on small brewers [] and help them expand and create jobs." *See Press Release of Congressman Peter DeFazio*, January 8, 2015.

FDA Releases Draft Environmental Impact Statement for Produce Rule

The U.S. Food and Drug Administration (FDA) has [published](#) a draft environmental impact statement (EIS) for a proposed rule establishing science-based standards for the growing, harvesting, packing and holding of produce for human consumption. The draft EIS reportedly identifies the following rule provisions as potentially significant to the human environment and offers alternatives for consideration: (i) standards directed to agricultural water, (ii) standards directed to biological soil amendments (BSA) of animal origin, (iii) standards directed to domesticated and wild animals, and (iv) general provisions. The agency has also announced a February 10, 2015, public meeting in College Park, Maryland, to discuss the draft EIS. *See Federal Register*, January 14, 2015.

USDA Extends Comment Period for Organic Product Exemption Under Commodity Promotion Law

The U.S. Department of Agriculture's Agriculture Marketing Service has [extended](#) until February 17, 2015, the comment period for a proposed rule that would expand assessment exemptions for commodity promotion activities "to cover all 'organic' and '100 percent organic' products certified under the National Organic Program regardless of whether the person requesting the exemption also produces, handles, or imports conventional or nonorganic products." Under the current rule, the exemption applies only to those who exclusively produce and market products certified as 100-percent organic. Additional details about the original notice appear in Issue [549](#) of this *Update*. *See Federal Register*, January 15, 2015.

U.S. Codex Delegates Schedule Food Additives Meeting

The U.S. Department of Agriculture's Office of the Under Secretary for Food Safety and the Food and Drug Administration have [announced](#) a February 17, 2015, public meeting in College Park, Maryland, to discuss draft U.S. positions for consideration during the 47th Session of the Codex Committee on Food Additives slated for March 23-27 in Xi'an, China.

Agenda items at the February meeting include (i) provisions of food category 14.2.3 "grape wines" and its sub-categories; (ii) potentially replacing Note 161

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with an alternative regarding provisions for sweeteners; (iii) the commercial use of potassium diacetate; and (iv) a proposal revising food category 01.1 “milk and dairy based drinks” and its sub-categories. *See Federal Register*, January 14, 2015.

EFSA Seeks Comments on Caffeine Safety Assessment

The European Food Safety Authority (EFSA) has [opened](#) a public consultation on a draft scientific opinion finding that “single doses of caffeine up to 200 mg and daily intakes of up to 400 mg do not raise safety concerns for adults.” Authored by EFSA’s Nutrition Unit, the draft opinion also concludes that (i) “it is unlikely that caffeine interacts adversely with other constituents of ‘energy drinks’—such as taurine and D-glucurono- γ -lactone—or alcohol”; (ii) “for pregnant women, caffeine intakes of up to 200mg a day do not raise safety concerns for the fetus”; (iii) “for children (3-10 years) and adolescents (10-18 years), daily intakes of 3mg per kg of body weight are considered safe”; and (iv) “single doses of 100mg may increase sleep latency (the amount of time it takes to fall asleep) and shorten sleeping time in some adults.” EFSA has requested comments by March 15, 2015. *See EFSA News Release*, January 15, 2015.

Argentine Import Restrictions Violate WTO Rules, Appellate Body Affirms

The World Trade Organization’s (WTO’s) Appellate Body has affirmed its August 2013 decision condemning Argentina’s broad trade-related restrictions affecting a variety of goods and food products. In one case that the WTO considered, Argentine government officials approved an agreement with a firm that imported Porsche vehicles that would require the company to offset the imports by exporting the same value of wine and olive products each year; in another, Pirelli was required to export \$100 million worth of honey to import its tires.

The Argentine Secretary of Domestic Trade also apparently limited the 2012 importation of finished ham products, especially those from Spain and Italy, to 80 percent of the amount imported the previous year. Affected goods also included clothing, medicine, technology products, and Bibles. “The United States welcomes the WTO’s findings in this dispute,” U.S. Trade Representative Michael Frohman said in a statement. “Argentina’s protectionist measures impact a broad segment of U.S. exports, potentially affecting billions of dollars in U.S. exports each year that support high-quality, middle class American jobs.” *See Press Release of the Office of the U.S. Trade Representative*, January 15, 2015.

European Parliament Approves GMO Cultivation Regulation

Confirming a December 2014 “hand-shake” agreement, the European Parliament has reportedly approved a law giving member states the authority to regulate the cultivation of genetically modified organisms (GMOs) within their

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borders. Until the new rules take effect in spring 2015, EU member states can limit cultivation of approved GMOs only if they present new evidence to the European Food Safety Authority that demonstrates the crop is not safe for consumption.

The new rules allow member states to prohibit GMO growth and cultivation on several grounds, including “town and country planning requirements, socio-economic impact, avoiding the unintended presence of GMOs in other products and farm policy objectives.” The legislation also creates a procedure allowing a GMO crop company to consent to proposed restrictions to avoid a unilateral ban on its product. Additional information about the 2014 political agreement appears in Issue [548](#) of this *Update*. See *European Parliament Press Release*, January 13, 2015.

LITIGATION

Federal Circuit Affirms USDA’s Grape Patents

The Federal Circuit Court of Appeals has affirmed a lower court’s ruling that unauthorized public use of the Scarlet Royal and Autumn King varieties of table grapes does not invalidate the U.S. Department of Agriculture’s (USDA’s) patents on them. *Delano Farms Co. v. Cal. Table Grape Comm’n.*, No. 2014-1030 (Fed. Cir., order entered January 9, 2015).

The appellants, three farming companies, had challenged the patents on the grounds that they were in public use for more than a year before the date of the patent applications. According to the facts determined by a lower court’s bench trial, the mature fruit of grape varieties were exhibited at an experimental variety open house in 2001 at California State University, Fresno. Without authorization, a USDA employee gave a grape grower the plant materials for the unreleased varieties, and that grower in turn gave the materials to his brother and cousin in addition to planting and growing Scarlet Royal and Autumn King himself. The growers later sold the grapes under a different name, but the court noted that those sales occurred less than one year before the filing of the patent applications. The court refused to find that the unauthorized use of the plant varieties constituted a public use that would invalidate the patent, so it affirmed the lower court’s finding that the patents were valid.

Lagunitas Files, Retracts Lawsuit Alleging Sierra Nevada Trademark Infringement

Two days after filing a lawsuit alleging that Sierra Nevada Brewing Co. infringed its stylized label trademark featuring the letters “IPA,” Lagunitas Brewing Co. filed a notice of voluntary dismissal without prejudice in the case and its owner, Tony Magee, publicly commented that he had been “seriously schooled” by the “Court of Public Opinion” following a wave of social media

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backlash. *The Lagunitas Brewing Co. v. Sierra Nevada Brewing Co.*, No 15-153 (U.S. Dist. Ct., N.D. Cal., notice of voluntary dismissal filed January 14, 2015).

The complaint alleged that Sierra Nevada's label for its new Hop Hunter IPA, in a "radical departure" from its typical label designs, infringed the Lagunitas trademark on "large, all-capital, bold, black and centralized 'IPA' lettering." The complaint further argued that "[w]hen Lagunitas began selling its now iconic IPA beer in 1995, there existed only a handful of other brewers who produced an India Pale Ale, and, on information and belief, no other company had marketed or sold its India Pale Ale using the acronym 'IPA.'" The company did not assert the exclusive right to the use of the acronym, but argued that its large blocked "IPA" on the label was distinctive down to the kerning of the letters.

After the complaint received negative publicity on social media, Magee said via Twitter that he had attempted to work out the issue with the founder of Sierra Nevada but had not received a satisfactory response. "Today, January 13th[,] 2015, has been the worst day ever in 23 years of growing my brewery," he wrote. "Today was in the hands of the ultimate court[,] The Court of Public Opinion[,] and in it I got an answer to my Question[:] Our IPA's [trademark] has limits." In a January 14, 2015, interview with the *Chicago Tribune*, Magee defended both the lawsuit and its retraction. "If we'd gone to court I think we would have been successful," he said. "But it would have been a [P]yrrhic victory." Additional information about increasing trademark tensions in the craft brewing market appears in Issue [550](#) of this *Update*. See [@lagunitasT](#), January 13, 2015.

OTHER DEVELOPMENTS

Italian Winemakers Threaten Legal Action Against British Pubs for Selling Prosecco on Tap

A consortium of prosecco manufacturers has reportedly contacted the United Kingdom's Food Standards Agency and Intellectual Property Office to threaten legal action under EU trading regulations against British wine bars and pubs that refuse to stop serving the sparkling wine from a keg. Prosecco sales apparently surpassed those of its rival, champagne, for the first time in 2014, and in the same year the United Kingdom replaced Germany as the top export market for prosecco.

"If prosecco is sold on tap then it is no longer prosecco—it needs to be served directly from the bottle," Luca Giavi, director of the consortium, told *The Telegraph*. The winemakers cite a 2009 European law which states that "prosecco wine shall be marketed exclusively in traditional glass bottles," and the president of the consortium, Stefano Zanettin, asserted that violations can merit fines ranging from €2,000 to €20,000. Michele Anzaldi, a member of the Italian Parliament's agricultural commission, has pledged support for the consortium's efforts. "The government will act immediately, in conjunc-

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tion with the EU, against the United Kingdom and the incorrect serving of prosecco in British pubs," he was quoted as saying. "We will find out if sanctions have already been applied and if not how best we can discourage further violations that are damaging a valuable sector of our economy." See *The Telegraph* and *The Independent*, January 7, 2015.

SCIENTIFIC/TECHNICAL ITEMS**Study Allegedly Links Red Meat Sugar Molecule to Cancer Risk**

Researchers with the University of California, San Diego, have reportedly linked a sugar molecule found in red meat to the development of spontaneous cancers. Annie N. Samraj, et al., "A red meat-derived glycan promotes inflammation and cancer progression," *Proceedings of the National Academy of Sciences*, January 2015. According to a December 29, 2014, press release, N-glycolylneuraminic acid (Neu5Gc) is present in most mammals but not humans, who consume bioavailable forms of the molecule from beef, pork and lamb.

Building on previous work hypothesizing that Neu5Gc can cause chronic inflammation when absorbed by the human body, the study authors fed the sugar molecule to mice genetically engineered to suppress Neu5Gc. The results not only showed that these mice developed antibodies to Neu5Gc that contributed to systemic inflammation, but that the incidence of spontaneous tumor formation increased fivefold, with Neu5Gc accumulating in the tumors.

"Until now, all of our evidence linking Neu5Gc to cancer was circumstantial or indirectly predicted from somewhat artificial experimental setups," said principle investigator Ajit Varki. "This is the first time we have directly shown that mimicking the exact situation in humans feeding non-human Neu5Gc and inducing anti-Neu5Gc antibodies—increases spontaneous cancers in mice." Details about an earlier Neu5Gc study led by the same researchers appear in Issue [280](#) of this *Update*.

BPA/BPS Study Calls on Regulators to Rethink Low-Dose Exposure Assessments

A study claiming that low doses of bisphenol A (BPA) and bisphenol S (BPS) increased brain-cell growth in embryonic zebrafish—which later exhibited hyperactive behaviors as larvae—has urged health authorities to reconsider the use of linear dose-response relationships to set tolerable daily intake levels. Cassandra Kinch, et al., "Low-dose exposure to bisphenol A and replacement bisphenol S induces precocious hypothalamic neurogenesis in embryonic zebrafish," *Proceedings of the National Academy of Sciences*, January 2015.

After exposing embryonic zebrafish to the two substances at levels (0.0068 µM) similar to those found in rivers that supply two major urban centers, University of Calgary researchers reported that BPA and BPS caused "180%

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and 240% increases, respectively, in neuronal birth (neurogenesis) within the hypothalamus, a highly conserved brain region involved in hyperactivity.” This increased neurogenesis apparently relied not on estrogen receptors as predicted, but on “androgen receptor-mediated up-regulation of aromatase.”

Based on these results, the study’s authors concluded that BPA/BPS “can alter the normal developmental timing of this critical neuroendocrine center, the consequences of which can lead to early synaptogenesis and improper fine-tuning of the brain later in development.” As one author explained in a January 13, 2015, press release, “These findings are important because they support that the prenatal period is a particularly sensitive stage, and reveals previously unexplored avenues of research into how early exposure to chemicals may alter brain development.”

In particular, the study warns that many endocrine-disruptors follow “U-shaped dose-response curves, whereby exposure to midrange concentrations activates physiological defense mechanisms against the compounds, but at low-range concentrations, the compound mimics endogenous hormones. Thus, our finding that BPA at a very low dose (0.0068 μM) alters neurogenesis and that a moderate BPA (1 μM) dose did not affect neurogenesis significantly calls for change in government-sanctioned methods of assessing human tolerable intake levels.”

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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.

