

CONTENTS

Legislation, Regulations and Standards

U.S. Lawmakers Once Again Propose Creating Single Federal Agency to Oversee Food Safety.....1 U.S. Foodborne Illness Source Attribution Focus of Upcoming Interagency Meeting1

Litigation

D.C. Circuit Upholds False Ad Clain Against POM Wonderful	
Plaintiff's Failure to Define "Natura Dooms Kettle Chip Labeling Suit.	
Claims Trimmed in Bacon-Related Against Hormel	
Claims Cut in 5-Hour Energy MDL	3
Putative Class Action Alleges Muse False Labeling	
Groups Challenge California Pestic Spraying Plan	
"Fat Noodle" Too Similar to "Chubb Noodle," Complaint Says	
California Company to Halt Europe Candy Imports in Agreement with Hershey	

Other Developments

German Groups Convene Nanotechnology Symposium in Berlin6
ENSSER Publishes Statement Challenging Consensus on GMO Safety6

Media Coverage

New Yorker Examines Role of Litigation in Food Safety......7

Scientific/Technical Items

Study Allegedly Links Daily SSB Consumption to Earlier Menarche7 ISSUE 553 | JANUARY 30, 2015



LEGISLATION, REGULATIONS AND STANDARDS

U.S. Lawmakers Once Again Propose Creating Single Federal Agency to Oversee Food Safety

Rep. Rosa DeLauro (D-Conn.) and Sen. Richard Durbin (D-III.) this week introduced **legislation** (Safe Food Act of 2015) that would consolidate food-safety duties currently managed by 15 different agencies to the oversight of a single food-safety authority.

"The fragmented nature of our food safety system has left us more vulnerable to the risk of foodborne illness, it has too often forced citizens to go it alone in the case of outbreak," Durbin said.

Among other things, the proposal would transfer responsibility for inspections, enforcement and labeling to the new Food Safety Administration. DeLauro and Durbin introduced similar legislation in 1999, 2004, 2005 and 2007. *See Press Release of Rep. Rosa DeLauro and Sen. Richard Durbin*, January 28, 2015.

U.S. Foodborne Illness Source Attribution Focus of Upcoming Interagency Meeting

The U.S. Department of Agriculture's Food Safety and Inspection Service, Food and Drug Administration, and Centers for Disease Control and Prevention (CDC) are hosting a February 24, 2015, **public meeting** in Washington, D.C., to update stakeholders and solicit input about the agencies' collaborative initiatives to improve foodborne illness source attribution. The discussion will target the agencies' effort to develop a single approach to creating harmonized foodborne illness source attribution estimates from outbreak data for *Salmonella*, *E. coli* O157, *Listeria*, and *Campylobacter*. Those interested in attending the meeting should register <u>online</u> by February 17. *See Federal Register*, January 28, 2015.

LITIGATION

D.C. Circuit Upholds False Ad Claims Against POM Wonderful

The D.C. Circuit Court of Appeals has <u>affirmed</u> a Federal Trade Commission (FTC) order that found POM Wonderful's advertising to be misleading for claiming that its products treat or reduce the risk of several medical conditions, including prostate cancer and heart disease. *POM Wonderful, LLC v. FTC*,



FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 553 | JANUARY 30, 2015

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.

For additional information on SHB's Agribusiness & Food Safety

capabilities, please contact



816-474-6550 manstoetter@shb.com



816-474-6550 202-783-8400 mmcdonough@shb.com

If you have questions about this issue of the Update or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com). No. 13-1060 (D.C. Cir., order entered January 30, 2015). In 2013, FTC ordered POM to stop making misleading health claims about its product, and POM challenged the ruling.

POM argued that its ads were protected by the First Amendment, but the court dismissed this argument, finding that deceptive and misleading ads have no First Amendment protection. The juice company also asserted that it had clinical studies to support its health claims. The circuit court affirmed FTC's finding that POM had cherry-picked its results when presenting them to the public, which invalidated them as support for the claims. The court agreed with POM, however, that the FTC requirement of two double-blind, randomized, placebo-controlled clinical trials (RCTs) was onerous, but found that one RCT as an across-the-board standard for disease claims would be adequate. Finding that POM still could not meet this lowered threshold, the court upheld the FTC ruling.

"It is in keeping with established law that advertisers who market products for serious health conditions must have rigorous science to back up those claims," said FTC Chair Edith Ramirez in a January 30, 2015, press release. "The court specifically recognized that this applied to food and dietary supplement marketers such as POM. It also held that requiring a randomized, well-controlled human clinical study for future disease benefit claims is an appropriate remedy based on POM's conduct."

Plaintiff's Failure to Define "Natural" Dooms Kettle Chip Labeling Suit

A Missouri federal court has dismissed a lawsuit challenging the "all natural" labels of Cape Cod Chips because the plaintiff failed to provide a suitable definition of "natural." Kelly v. Cape Cod Potato Chip Co., No. 14-119 (U.S. Dist. Ct., W.D. Mo., order entered January 27, 2015). The plaintiff alleged that 16 varieties of Cape Cod Chips were advertised as "all natural" and made without preservatives despite containing 13 artificial and synthetic ingredients.

The court reviewed the definitions of "natural" submitted by the plaintiff and found them each lacking. It first dismissed the dictionary definition, "existing or produced by nature: not artificial," as "not plausible because the Chips are processed foods, which of course do not exist or occur in nature." The definition of "natural" found in an informal advisory opinion from the U.S. Food and Drug Administration (FDA) was not binding, the court found, because the agency "specifically declined to adopt any formal definition of 'natural." The definition from the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service was insufficient as well because it "specifically states that it applies to 'labeling for meat products and poultry products." The plaintiff also proposed the use of FDA's "artificial flavoring" definition, but the court found that none of the contested 13 ingredients was included on FDA's list of flavorings. Finally, the invocation of the USDA's definition of "synthetic" was also inadequate because it applies only to products in the National Organic



ISSUE 553 | JANUARY 30, 2015

Program. Finding no valid definition to support the plaintiff's arguments, the court dismissed the claim that the use of "natural" was misleading under the Missouri Merchandising Practices Act.

The plaintiff's argument against the use of "no preservatives" failed as well, the court found, because although she attached exhibits of the chip labels, none of the provided evidence showed any representation of the phrase "no preservatives" on the packaging. Cape Cod argued that its labels complied with federal regulations by listing each ingredient, and the court agreed. "Plaintiff's assertion that she was deceived by Defendants' labeling is contradicted by the full disclosure of the challenged ingredients by Defendants. Further, if Plaintiff wished to avoid products containing the challenged ingredients, Defendants provided her with all the information she needed to do so. Thus, the Court finds that Defendants' labeling of the Chips is not deceptive or misleading with regards to the ingredients contained therein."

Claims Trimmed in Bacon-Related Action Against Hormel

A Minnesota federal court has granted in part and denied in part a motion to dismiss in a lawsuit alleging that Hormel Food Corp. stole trade secrets and breached contractual agreements in its joint venture to develop new methods of cooking bacon. *Unitherm Food Sys. Inc. v. Hormel Food Corp.*, No. 14-4034 (U.S. Dist. Ct., D. Minn., order entered January 27, 2015).

Unitherm alleged that it created the first viable method for pre-cooking sliced bacon—a process using spiral ovens and super-heated steam—and agreed to develop a commercially viable product with Hormel in June 2007. Unitherm asserted that Hormel disclosed its process, which Unitherm had not yet patented, to a rival company in violation of confidentiality agreements, which constituted an appropriation of trade secrets. The court disagreed, finding that Unitherm's July 2009 patent application precluded its claim of trade secrets because patented processes cannot, by necessity, be trade secrets due to the disclosure of the process on the application. The court also found that the claim of trade secrets appropriation before July 2009 was barred by the three-year statute of limitations and accordingly granted Hormel's motion to dismiss on that count. Claims of unjust enrichment and breach of contract were allowed to proceed after the court determined that Unitherm had provided enough information to properly support the claims.

Claims Cut in 5-Hour Energy MDL

A California federal court has dismissed without leave to amend claims that the makers of 5-Hour Energy—Innovation Ventures LLC, Living Essentials LLC, Manoj Bhargava, and Bio Clinical Development Inc.—falsely advertised their product as boosting its users' energy levels with B-vitamins and amino acids rather than caffeine. *In re: 5-Hour Energy Mktg. & Sales Practices Litig.*, No. 13-2438 (U.S. Dist. Ct., C.D. Cal., order entered January 22, 2015).



ISSUE 553 | JANUARY 30, 2015

The plaintiffs argued that the 5-Hour Energy makers downplayed the caffeine content in favor of attributing the product's energy source to vitamins and other ingredients, and they included descriptions of five commercials containing the allegedly misleading statements. The court found that they failed to show what statements actually misled them, and it was also unpersuaded by the argument that the plaintiffs were exposed to a common message and thus did not need to specify which statements they relied upon to their detriment, so it dismissed without leave to amend the fraud-based claims "to the extent that they are based on any off-label representations." The court also dismissed breach-of-express-warranty claims for the failure to provide adequate notice because the complaint was insufficient to serve as notice.

Putative Class Action Alleges Muscle Milk False Labeling

A group of consumers has filed a putative class action against Cytosport Inc., maker of Muscle Milk, alleging that its powdered and ready-to-drink protein supplements do not contain the ingredients and characteristics advertised on its packaging. *Clay v. Cytosport Inc.*, 15-165 (U.S. Dist. Ct., S.D. Cal., filed January 23, 2015). The plaintiffs argue that independent scientific testing shows that Muscle Milk products contain substantially less protein than the amount represented in the Nutrition Facts panel. They also allege that Muscle Milk labels list L-glutamine amino acids separately from the protein content to falsely imply that the products have additional L-glutamine beyond the content inherent in the protein mix. The complaint further argues that Muscle Milk labels cannot feature the word "lean" because the product does not contain less fat than its competitors. Alleging deceptive advertising, misrepresentation and breach of warranties, the putative class seeks certification, damages, an injunction, and attorney's fees.

Groups Challenge California Pesticide-Spraying Plan

Several organizations, including the Center for Biological Diversity, Environmental Working Group and Center for Food Safety as well as the city of Berkeley, California, have filed a lawsuit against the California Department of Food and Agriculture to contest the agency's approval of a pest management plan that allows pesticide spraying on organic farms, schools and residential yards. *Envtl. Working Grp. V. Cal. Dep't of Food and Agric.*, No. RG15755648 (Super Ct. Cal., Alameda Cnty., filed January 22, 2015).

The groups challenge the alleged lack of evidence supporting the conclusion that the program will have no effect on Californians' health and argue that the plan violates state environmental laws, including the requirement of public notice before spraying pesticides and the requirement to analyze the impacts on human and environmental health. A January 22, 2015, Center for Biological Diversity press release asserts that the agency received 30,000 opposition letters to the program. "What will it take to make the state accountable to



ISSUE 553 | JANUARY 30, 2015

the tens of thousands of individuals who wrote comment letters asking the state to adopt a modern, sustainable pest management approach that would ensure that food and nursery plants are not contaminated by pesticides?," Nan Wishner, a representative of plaintiff California Environmental Health Initiative, reportedly asked.

"Fat Noodle" Too Similar to "Chubby Noodle," Complaint Says

Noodles Raw Catering, owner of Chubby Noodle restaurants, has filed a lawsuit alleging that Saison Group's Fat Noodle restaurant infringes on Noodles Raw's trademark. *Noodles Raw Catering LLC v. Saison Group LLC*, No. 15-316 (U.S. Dist. Ct., N.D. Cal., filed January 22, 2015). The complaint asserts that although Chubby Noodle, which sells "high-quality, well-priced Asianinspired" food, does not yet own a federally registered trademark in its name (because its application is pending), it has received national and international attention since its opening in 2011. Saison has been developing a Fat Noodle restaurant since 2012—as indicated by intent-to-use applications with the U.S. Patent and Trademark Office—but has not yet opened the restaurant, and its website appears to be a placeholder.

Noodles Raw alleges that the logo appearing on the website is too similar to its Chubby Noodle logo because both feature "a simple, black, Asian-style bowl with noodles." Claiming common law trademark infringement, false designation of origin, cybersquatting, and unfair competition, Noodles Raw seeks a permanent injunction, treble damages and attorney's fees.

California Company to Halt European Candy Imports in Agreement with Hershey

Let's Buy British Imports (LBB Imports) has reportedly agreed to stop importing Cadbury chocolate made overseas pursuant to the settlement of a lawsuit in which Hershey Co. alleged that the importer violated the candy company's trademarks and trade dress of Cadbury, Kit Kat® and other products by selling versions produced internationally. *Hershey Co. v. LBB Imports LLC*, No. 14-1655 (U.S. Dist. Ct. M.D. Penn., settlement date unknown). The settlement agreement apparently restricts the importation of all Cadbury chocolate as well as Kit Kat® bars, Toffee Crisps, York peppermint patties, and Maltesers®.

Many consumers have responded negatively to the settlement terms; a campaign to boycott Hershey began on Twitter, and a MoveOn.org petition to protest Hershey's trademark protection actions has garnered more than 25,000 signatures. The protesters reportedly argue that British Cadbury chocolate tastes better because of its ingredients—the British version of Cadbury's Dairy Milk bar contains milk as its first ingredient while the American version's first ingredient is sugar, and the American version apparently contains emulsifiers that reduce the viscosity of chocolate but prolong the shelf life. The British version apparently uses different emulsifiers and contains vegetable





ISSUE 553 | JANUARY 30, 2015

fats. In addition, American chocolate must contain 10-percent cocoa solids to fall within the U.S. definition of chocolate, while the British equivalent must contain 20 percent. Details about the complaint appear in Issue <u>536</u> of this *Update. See The New York Times*, January 23, 2015; *The Independent*, January 26, 2015.

OTHER DEVELOPMENTS

German Groups Convene Nanotechnology Symposium in Berlin

The Federal Institute for Risk Assessment (BfR) and the Fraunhofer Nanotechnology and Food Chain Management alliances have organized a <u>two-day</u> <u>public event</u> on March 5-6, 2015, in Berlin to discuss a range of risk-related issues related to the use of nanomaterials.

Symposium topics will include (i) European Food Safety Agency guidance on nanomaterials, (ii) the <u>NanoDefine</u> project, (iii) migration potential of nanomaterials in food contact plastics, (iv) inhalation toxicology, and (v) public acceptance of nanotechnology.

Charged with "providing information on possible, identified and assessed risks which foods, substances and products may entail for consumers," BfR reports to the Federal Ministry of Food and Agriculture.

ENSSER Publishes Statement Challenging Consensus on GMO Safety

Led by the European Network of Scientists for Social and Environmental Responsibility (ENSSER), a group of independent researchers has released a joint statement in *Environmental Sciences Europe* that challenges "recent claims of a consensus over the safety of genetically modified organisms (GMOs)." According to the January 20, 2015, statement, "the scarcity and contradictory nature of the scientific evidence published to date prevents conclusive claims of safety, or lack of safety, of GMOs."

In particular, the signatories not only argue that scientific agreement on the safety of GMOs is "an artificial construct that has been falsely perpetuated through diverse fora," but suggest that the current regulatory approach to vetting GMOs case-by-case belies any purported consensus. As evidence, they cite "the different research methods employed, an inadequacy of available procedures, and differences in the analysis and interpretation of data," as well as unaddressed concerns raised by independent animal-feeding studies and other research.

"The claim [of consensus] further encourages a climate of complacency that could lead to a lack of regulatory and scientific rigor and appropriate caution, potentially endangering the health of humans, animals, and the environment," opines the statement. "Science and society do not proceed on the basis of a constructed consensus, as current knowledge is always open to well-founded



ISSUE 553 | JANUARY 30, 2015

challenge and disagreement. We endorse the need for further independent scientific inquiry and informed public discussion on GM product safety."

MEDIA COVERAGE

New Yorker Examines Role of Litigation in Food Safety

A February 2, 2015, *New Yorker* **article** following the career of plaintiffs' attorney Bill Marler examines how litigation has shaped the food-safety landscape in the absence of robust regulatory oversight.

Viewing the U.S. inspection and recall system through the lens of a 2013 *Salmonella* Heidelberg outbreak that reportedly sickened an estimated 18,000 people, Wil Hylton interviews Marler as well as current and former federal officials about the complicated evolution and sometimes contradictory mandates of the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA) and other agencies responsible for food safety.

In particular, the article notes that many regulators credited Marler with changing the role of lawsuits in food policy. "Where people typically thought of food safety as this three-legged stool—the consumer groups, the government and the industry—Bill sort of came in as a fourth leg and actually was able to effect changes in a way that none of the others really had," Robert Brackett, former director of the FDA Center for Food Safety and Applied Nutrition, tells Hylton.

Tracking Marler as he moves "from litigation to activism," the article points to his work with consumer groups such as the Center for Science in the Public Interest as well as an online newsletter underwritten by the attorney. As the number of foodborne *E. coli* cases continue to wane since USDA declared the pathogen an adulterant, Marler has evidently turned his attention to chicken producers and products as the agency hashes out new regulations for reducing *Salmonella* contamination.

"Fifteen years ago, almost all the cases I had were *E. coli* linked to hamburger, and now I have maybe two or three," Marler is quoted as saying. "It shows how much progress we've made. You might hate lawyers, you might not want us to make money, but look what the beef industry did. Ground beef has learned its lesson—but chicken is still, in many respects, unregulated. So we have to keep fighting."

SCIENTIFIC/TECHNICAL ITEMS

Study Allegedly Links Daily SSB Consumption to Earlier Menarche

A study allegedly linking daily sugar-sweetened beverage (SSB) consumption to earlier menarche has raised concerns about the long-term implica-



ISSUE 553 | JANUARY 30, 2015

tions for breast cancer risk. J.L. Carwile, et al., "Sugar-sweetened beverage consumption and age at menarche in a prospective study of US girls," *Human Reproduction,* January 2015. Relying on dietary questionnaires completed by 5,583 girls ages 9 to 14 before their first menses, researchers with the Harvard School of Public Health and Brigham and Women's Hospital reported "more frequent SSB consumption predicted a higher rate of reaching menarche" during five years of follow-up.

After controlling for birth weight, maternal age at menarche, physical activity, and other factors, the study claims that girls who consumed more than 1.5 servings of sugar-sweetened soda, non-carbonated fruit drinks or iced tea per day (i) were 26 percent "more likely to reach menarche in the next month relative to girls who reported consuming [less than] 2 servings of SSBs weekly," and (ii) attained menarche 2.7 months earlier, even after adjusting for total energy intake. The study's authors also considered the effect of BMI on age at menarche but apparently found that "BMI explained only 9.2% of the total observed association between SSBs and menarche or BMI and menarche."

"A 1-year decrease in age at menarche is estimated to increase the risk of breast cancer by 5%," concludes the study. "Most importantly, the public health significance of SSB consumption on age at menarche, and possibly breast cancer, should not be overlooked, since, unlike most other predictors of menarche, SSB consumption can be modified."

OFFICE LOCATIONS

Denver, Colorado +1-303-285-5300 Geneva, Switzerland +41-22-787-2000 Houston, Texas +1-713-227-8008 Irvine, California +1-949-475-1500 Kansas City, Missouri +1-816-474-6550 London, England +44-207-332-4500 Miami, Florida +1-305-358-5171 Philadelphia, Pennsylvania +1-215-278-2555 San Francisco, California +1-415-544-1900 Seattle, Washington +1-206-344-7600 Tampa, Florida +1-813-202-7100 Washington, D.C. +1-202-783-8400

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.

FOOD & BEVERAGE LITIGATION UPDATE

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.





