

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

NOP Drafts Guidance
for Calculating Percentage
of Organic Ingredients 1

LITIGATION

Fourth Circuit Affirms
FDA's Authority to Issue
Contamination Warnings. 2

Brazilian Beverage Co. to Pay
Professional Beer Taster for
Job-Related Alcoholism 2

Court Denies Stay for FDA
"Natural" Guidance in Kraft
Artificial Coloring Case 3

Bumble Bee Foods Exec Pleads
Guilty to Price-Fixing Scheme. 3

Newman's Own Faces Putative
Class Action Litigation
over Natural Claims. 4

Missouri Plaintiff Challenges
"Fruit" in Kellogg's Fruit & Yogurt
Special K® 4

SCIENTIFIC/TECHNICAL ITEMS

RAND Study Targets Caloric
Content of Kids' Menu Items 5

Study Analyzes Food and
Beverage Industry Responses
to Product Reformulation 5

LEGISLATION, REGULATIONS AND STANDARDS

NOP Drafts Guidance for Calculating Percentage of Organic Ingredients

The U.S. Department of Agriculture's National Organic Program (NOP) has proposed guidance "for calculating the percentage of organic ingredients in multi-ingredient products." Intended for accredited certifying agents and handling operations, the draft guidance responds to a National Organic Standards Board (NOSB) request for correction and clarification of the requirements codified at 7 CFR 205.302(a), which defines the method of calculating the percentage of organically produced ingredients as "[d]ividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product."

Per NOSB's recommendations, the draft guidance corrects this language "to clarify that organic percentages should be calculated by dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total net weight (excluding water and salt) of all ingredients," as opposed to "the weight of the 'finished product' because most products lose weight during processing." In addition, NOP (i) describes "how to calculate the organic percentages of a multi-ingredient product that contains ingredients that are themselves composed of more than one ingredient"; (ii) clarifies "when to exclude salt and water from ingredients"; (iii) offers guidance on "how to calculate raw agricultural product and processed single ingredient ingredients"; and (v) develops "self-calculating forms on items related to the organic percentage of each ingredient and the exclusion of salt and water."

The agency will accept comments on the draft guidance on or before February 6, 2017. *See Federal Register*, December 6, 2016.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 625 | DECEMBER 9, 2016

LITIGATION

Fourth Circuit Affirms FDA's Authority to Issue Contamination Warnings

The Fourth Circuit Court of Appeals has upheld a lower court's determination that the U.S. Food and Drug Administration (FDA) had the discretion to issue an incorrect contamination warning about *Salmonella*-tainted tomatoes, which devalued a tomato farmer's crop by \$15 million. *Seaside Farm v. United States*, No. 15-2562 (4th Cir., order entered December 2, 2016). Details about the lower court's decision appear in Issue [588](#) of this *Update*.

The lawsuit stemmed from FDA's warning against eating raw tomatoes in 2008 following an outbreak of *Salmonella* that was later traced to jalapeno and Serrano peppers. Seaside Farm filed suit alleging FDA negligently issued the warning, impairing the value of its crop. The trial court found that FDA was acting within its discretion to issue the warning.

Seaside argued that FDA's warning was overly broad and based on insufficient evidence, noting that the agency failed to test any tomatoes before issuing its warning. The court disagreed, finding that Seaside misunderstood FDA's discretion. "The decision to issue a contamination warning, especially in the middle of an escalating salmonella outbreak, clearly implicates the policy considerations which FDA was established to weigh," the court held. "Whether the agency pursued its investigation, interpreted relevant evidence, or balanced policy considerations in what Seaside believes to be an optimal manner does not affect the discretionary function analysis. Seaside essentially invites us to engage in the very judicial second guessing that the discretionary function exception forbids." Accordingly, the court affirmed the lower court's ruling in favor of FDA.

Shook 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 at mboyd@shb.com.

Brazilian Beverage Co. to Pay Professional Beer Taster for Job-Related Alcoholism

A Brazilian appeals court has reportedly affirmed a lower court's order to Ambev S/A to pay a former employee about \$14,800 for moral damages related to his job as a beer taster, which he alleged led to his alcoholism. Ambev argued that it was not liable because the employee's beer-tasting activities were voluntary. The court disagreed, finding that employers have a duty to avoid exposing their employees to the "inherent risks of the job activities," even if voluntary. Ambev failed to demonstrate the

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 625 | DECEMBER 9, 2016

proper care toward the plaintiff's health, the court held, because it did not monitor his health throughout his employment as a beer taster, it did not train him on the symptoms of alcoholism or other related conditions, and it told him that if he was declared addicted he would need to seek treatment himself. *See Superior Council of Labor Justice (Conselho Superior da Justiça do Trabalho)*, November 28, 2016.

Court Denies Stay for FDA "Natural" Guidance in Kraft Artificial Coloring Case

A California federal court has denied Kraft Food Group Inc.'s request to stay class action litigation alleging the company's fat-free cheese product is misleadingly labeled "natural" because it contains artificial coloring, finding that the U.S. Food and Drug Administration's (FDA's) expected guidance on the term "natural" does not affect the issues of the case. *Morales v. Kraft Foods Grp. Inc.*, No. 14-4387 (C.D. Cal., order entered December 6, 2016). A week earlier, the same court denied Kraft's motion for summary judgment on the grounds that triable issues existed in the case, including (i) "whether consumers are likely to believe that 'artificial color' is not an artificial ingredient if it is produced by a natural product"; (ii) "whether such belief is material to customers' purchasing decisions"; and (iii) "whether all artificial colors, regardless of source, are artificial ingredients." Details about the certification of the class appear in Issue [570](#) of this *Update*.

The court was not persuaded that FDA's upcoming "natural" guidance would affect the outcome of the case, departing from the reasoning of several other courts in cases with similar claims. "[T]he question here is not whether Kraft has violated FDA regulations," the court found. "Rather, in this case the question is whether the 'natural cheese' label is deceptive to the reasonable consumer." Further, "[c]ompliance with FDA regulations does not 'automatically shield' Kraft from a claim under the relevant statutes," the court said, noting that its order from the prior week had determined the plaintiffs had presented evidence to support the claim that a reasonable consumer is likely to be deceived by the term "natural cheese."

Bumble Bee Foods Exec Pleads Guilty to Price-Fixing Scheme

Walter Scott Cameron, a former senior vice president of sales at Bumble Bee Foods, LLC has pleaded guilty to combination and conspiracy to fix, raise and maintain the prices of packaged seafood, including canned tuna. *United States v. Cameron*, No. 16-CR-0501 (N.D. Cal., information

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 625 | DECEMBER 9, 2016

filed December 7, 2016). The criminal information accuses Cameron of conspiring with other seafood companies to fix prices of seafood sold in the United States.

“Today’s charge is the first to be filed in the Antitrust Division’s ongoing investigation into price fixing among some of the largest suppliers of canned tuna and other packaged seafood,” said an attorney with the U.S. Department of Justice’s Antitrust Division in a December 7, 2016, press release. “All consumers deserve competitive prices for these important kitchen staples, and companies and executives who cheat those consumers will be held criminally accountable.”

Newman’s Own Faces Putative Class Action Litigation over Natural Claims

A consumer has filed a projected class action alleging Newman’s Own, Inc. misleadingly markets its pasta sauce products as natural despite containing citric acid. *Wong v. Newman’s Own, Inc.*, No. 16-6690 (E.D.N.Y., filed November 30, 2016). The complaint asserts the company “deceptively used the term ‘natural’ to describe a product containing ingredients that have been either extensively chemically processed or fundamentally altered from their natural state and thus cannot be considered ‘minimally processed.’” The plaintiff admits “there is not an exacting definition of ‘natural’ in reference to food,” but cites the *Merriam-Webster Dictionary*, a decision from the National Advertising Division of the Better Business Bureau and the U.S. Department of Agriculture’s 2005 Food Standards and Labeling Policy Book to support his definition. For alleged violations of New York’s consumer-protection statutes, the plaintiff seeks class certification, restitution, damages, an injunction and attorney’s fees.

Missouri Plaintiff Challenges “Fruit” in Kellogg’s Fruit & Yogurt Special K®

A consumer has filed a putative class action alleging Kellogg Co.’s Special K® Fruit & Yogurt cereal is misleadingly labeled with pictures of strawberries and blackberries despite that dried apples are listed as the only fruit contained in the product. *George v. Kellogg Co.*, No. 16-1887 (E.D. Mo., E. Div., removed to federal court December 1, 2016). Asserting that she paid a premium price for the product believing it to contain strawberries and blackberries, the plaintiff argues that the labeling violates the Federal Food, Drug, and Cosmetic Act and its labeling regulations. For an alleged violation of the Missouri Merchandising Practices Act and unjust enrichment, she seeks class certification, damages and attorney’s fees.

SCIENTIFIC/TECHNICAL ITEMS

RAND Study Targets Caloric Content of Kids' Menu Items

The RAND Corp. has published a study claiming that “most kids’ menu items offered by the nation’s top 200 restaurant chains exceed the calorie counts recommended by nutrition experts,” according to a December 5, 2016, press release. Relying on the recommendations of 15 child nutrition experts—including Public Health Institute Advisor Lynn Silver and Rudd Center for Food Policy & Obesity Director Marlene Schwartz—the study authors adopted the following benchmarks: (i) a maximum of 300 calories for the main dishes in children’s meals; (ii) 100 calories for a serving of fried potatoes; (iii) 150 calories for soups, appetizers and snacks; and (iv) 150 calories for vegetables and salads that included added sauces, with the entire meal not to exceed 600 calories.

The study singles out fried potatoes as the item “that most often exceeded the calorie guidelines.” As the authors conclude, “Given the high frequency of children dining away from home, right-sizing portions could have a substantial impact on reducing excess consumption. Restaurants should voluntarily adhere to recommended maximum serving sizes for children’s menu items, to provide foods in portions that will not exacerbate the recalcitrant childhood obesity epidemic. Whereas some parents might be able to take advantage of upcoming calorie labeling to not go beyond the recommended maximum of 600 calories per meal, others would find it easier if default portion sizes were already available and all bundled meals were 600 calories or less.”

Study Analyzes Food and Beverage Industry Responses to Product Reformulation

After analyzing food and beverage industry responses to a 2015 consultation by the U.S. Dietary Guidelines Advisory Committee, researchers with the London School of Hygiene and Tropical Medicine have claimed that product reformulation—“the process of altering a food or beverage product’s recipe or composition to improve the product’s health profile”—“has been largely voluntary.” C. Scott, et al., “Food and beverage product reformulation as a corporate political strategy,” *Social Science & Medicine*, November 2016. Part of a larger research project seeking to explore the “political aspects of product reformulation” to inform the debate about obesity and non-communicable diseases, the study purportedly identifies common themes among respondents, such as messages that focus on “positive” nutrients, companies being “part of the solution and not the problem,” voluntary governance and individual responsibility.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 625 | DECEMBER 9, 2016

ABOUT SHOOK

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.

Shook 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.



In contrast to those who view product reformulation as a “win-win” strategy, the authors suggest that it “may be one part of the industry’s political strategy to pre-empt future policy debates and processes from moving towards mandatory approaches.” Drawing parallels with voluntary product reformulations undertaken by tobacco and alcoholic beverage companies, the authors claim that the consultation provided an opportunity for industry to “cast doubt on the scientific literature about the health effects of their products.”