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CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

DeLauro Proposal Would Establish Regulatory Tolerance for Inorganic Arsenic in Rice 1

USDA Seeks Candidates for Grain Inspection Advisory Committee . . . 1

Irish Regulatory Agency Issues Guidance on Use of Food Marketing Terms 1

EFSA Finalizes Caffeine Risk Assessment 2

LITIGATION

Federal Circuit Overturns TTAB Ruling Finding "Pretzel Crisp" Generic 2

StarKist, Consumers Reach $12-Million Settlement in Underfilled-Cans Litigation 3

First Lawsuit Filed in Blue Bell *Listeria* Contamination 3

Abbott Labs Faces Proposed Class Action over "Organic" Infant Formula 4

Heinz Seeks Reversal of TTAB Decision on Smart Balance® Trademark 4

California Winery Challenges HBO's Beer Trademark Application 5

LEGAL LITERATURE

Government Agencies Should Define "Natural" to Avoid Inconsistent Court Decisions, Professor Argues 5

OTHER DEVELOPMENTS

Report Faults EU Regulators for Derailing Debate over Endocrine-Disrupting Chemicals 7

Environmental Groups Release Canada's Environmental Assessment of GM Salmon 7

Sustainability Groups Highlight Water Risks for Food and Beverage Sector 8

LEGISLATION, REGULATIONS AND STANDARDS

DeLauro Proposal Would Establish Regulatory Tolerance for Inorganic Arsenic in Rice

Citing the need to protect the long-term health of children, U.S. Rep. Rosa DeLauro (D-Ct.) has introduced **legislation** (H.R. 2529) that would require the U.S. Food and Drug Administration to set a maximum permissible level for inorganic arsenic in rice and rice products within two years.

"High levels of inorganic arsenic, a known carcinogen, can be found in rice, cereal and other common, everyday foods," DeLauro said. "The federal government needs to step in to make sure that American families are consuming food that is safe."

The proposal has been referred to the Committee on Energy and Commerce and Committee on Agriculture. *See Press Release of U.S. Rep. Rosa DeLauro*, May 21, 2015.

USDA Seeks Candidates for Grain Inspection Advisory Committee

The U.S. Department of Agriculture's (USDA's) Grain Inspection, Packers and Stockyard Administration (GIPSA) is **soliciting** nominations for individuals to fill five pending vacancies on the USDA Grain Inspection Committee. The 15-member group representing grain producers, processors and exporters, among other stakeholders, meets twice a year to guide GIPSA in delivering its mandates under the U.S. Grain Standards Act. *See Federal Register*, May 26, 2015.

Irish Regulatory Agency Issues Guidance on Use of Food Marketing Terms

The Food Safety Authority of Ireland (FSAI) has issued a **guidance note** for industry discussing general legal requirements for use of the descriptors "artisan/artisanal," "farmhouse," "traditional" and "natural."

"Marketing terms are designed to resonate with consumers and are an essential part of business development in the food industry," said Wayne Anderson, FSAI Director of Food Science and Standards. "Consumers need to be confident that the foods they purchase and consume are accurately and truthfully described on the label. Food businesses should also be confident that genuine descriptions of their food are not diluted in the marketplace by undefined marketing terms."

The labeling guidelines apply to products placed on the market after December 2016. *See FSAI News Release*, May 14, 2015.

EFSA Finalizes Caffeine Risk Assessment

The European Food Safety Authority (EFSA) has **published** its final caffeine risk assessment, concluding that "single doses of caffeine up to 200 mg" and "habitual caffeine consumption up to 400 mg per day does not give rise to safety concerns for non-pregnant adults." Following a two-month consultation, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) issued a scientific opinion considering "possible interactions" between caffeine and energy drink constituents, alcohol, *p*-synephrine, and physical exercise. The data evidently indicated no safety concerns when non-pregnant adults consume up to 200 mg of caffeine (i) less than 2 hours before intense physical exercise, (ii) in combination with energy drink ingredients such as taurine or d-glucurono-γ-lactone at typical concentrations, or (iii) in combination with alcohol at doses up to 0.65 g/kg body weight (bw).

"The single doses of caffeine considered to be of no concern for adults (3mg/kg bw per day) may also be applied to children, because the rate at which children and adolescents process caffeine is at least that of adults, and the studies available on the acute effects of caffeine on anxiety and behavior in children and adolescents support this level," notes EFSA. "A safety level of 3mg/kg bw per day is also proposed for habitual caffeine consumption by children and adolescents."

LITIGATION

Federal Circuit Overturns TTAB Ruling Finding "Pretzel Crisp" Generic

The Federal Circuit has reversed and remanded a Trademark Trial and Appeal Board (TTAB) decision invalidating Snyder's-Lance Inc.'s "Pretzel

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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Crisp" trademark after Frito-Lay Inc. challenged the mark as generic. *Princeton Vanguard, LLC v. Frito-Lay N. Am., Inc.*, No. 14-1517 (Fed. Cir., order entered May 15, 2015).

TTAB's decision found that "Pretzel Crisp" is a compound term and not a phrase, so it analyzed "pretzel" and "crisp" separately and found both words to be generic descriptors of Snyder-Lance's pretzel-cracker product. The Federal Circuit disagreed with this method, holding that TTAB had conducted a "short-cut analysis" by not considering "Pretzel Crisp" as a whole phrase, because "the test for genericness is the same, regardless of whether the mark is a compound term or a phrase." At the end of its decision, TTAB noted that "were we to analyze ['Pretzel Crisp'] as a phrase, on this record, our conclusion would be the same, as the words strung together as a unified phrase also create a meaning that we find to be understood by the relevant public as generic for 'pretzel crackers.'" The Federal Circuit further found that this short mention was insufficient analysis and remanded the case for TTB's reconsideration.

StarKist, Consumers Reach $12-Million Settlement in Underfilled-Cans Litigation

StarKist Co. and a class of consumers have filed a proposed settlement agreement for $12 million in a case alleging that the company underfilled its cans of tuna. *Hendricks v. StarKist Co.*, No. 13-0729 (N.D. Cal., motion filed May 14, 2015). Under the agreement, StarKist will pay $8 million in $25-cash increments and provide $4 million in $50-vouchers for StarKist-branded products. The agreement indicates that "tens of millions of purchasers" are members of the class but predicts that "a claim rate of more than 5% will be difficult to achieve." Thus, the amounts of the settlement allow for 80,000 voucher claims and 120,000 cash claims. "This is an excellent result for class members compared to their likely recovery should they prevail at trial," the agreement stipulates.

First Lawsuit Filed in Blue Bell *Listeria* Contamination

Amid ongoing recalls of Blue Bell Creameries' ice cream products, a plaintiff has filed a lawsuit alleging that the company is liable for his severe listeriosis infection he says stems from the consumption of several varieties of contaminated products. *Shockley v. Blue Bell Creameries Inc.*, No. 15-425 (W.D. Tex., filed May 19, 2015). The plaintiff alleges that *Listeria monocytogenes* infected his blood, then brain, resulting in permanent brain damage and leaving him near death.

The complaint documents the recent *Listeria* outbreak subsequently linked to Blue Bell's products by the Centers for Disease Control and Prevention. "Blue Bell utterly failed to design and implement sanitation and safety programs that would have prevented the sort of infestation and contamination that occurred at its facilities over a period of years," the plaintiff asserts. He seeks compensatory, economic and punitive damages for strict product liability, negligence, misrepresentation and breach of warranties.

Abbott Labs Faces Proposed Class Action over "Organic" Infant Formula

A group of consumers has filed a putative class action against Abbott Laboratories, Inc. alleging the company misrepresents its Similac Advance® Organic Infant Formulas because several of the ingredients are banned by federal law from use in food labeled "organic." *Marentette v. Abbott Labs., Inc.*, No. 15-2837 (E.D.N.Y., filed May 15, 2015).

The plaintiffs challenge the products' inclusion of beta carotene, biotin, taurine and lutein, among several other ingredients, and additionally assert that "at least one ingredient in these infant formulas is produced using genetically engineered materials—a practice forbidden in organic foods." The complaint contends that Abbott knew that consumers would pay more for organic products and willfully misled them. The plaintiffs seek class certification, damages and an injunction for alleged violations of New York and California consumer-protection statutes, unjust enrichment and breach of warranty.

Since the complaint was filed, Abbott has begun offering a version of Similac Advance® manufactured without genetically engineered ingredients, citing customer requests, but says it has no plans to entirely phase out the use of such materials in its infant formulas. *See Chicago Tribune*, May 29, 2015.

Heinz Seeks Reversal of TTAB Decision on Smart Balance® Trademark

H.J. Heinz Co. has filed a lawsuit against Boulder Brands USA seeking to vacate and reverse a Trademark Trial and Appeal Board (TTAB) decision finding that the marks representing Heinz's Weight Watchers Smart Ones® and Boulder's Smart Balance® are sufficiently distinct, allowing both to exist. *H.J. Heinz Co. v. Boulder Brands USA, Inc.*, No. 15-0681 (W.D. Penn., filed May 26, 2015).

In its opposition to the Smart Balance® mark, Heinz asserted that the Smart Ones® mark was famous and would be diluted by Smart Balance®, but based on insufficient evidence TTAB disagreed in its March 2015 decision. In addition to the reversal, Heinz seeks a declaration of likelihood of confusion and a declaration of dilution under the Lanham Act and asks the court to direct the U.S. Patent and Trademark Office to invalidate the Smart Balance® mark.

California Winery Challenges HBO's Beer Trademark Application

Franciscan Vineyards has filed an opposition against Home Box Office, Inc.'s (HBO's) 2014 trademark application for "Three-Eyed Raven," a beer collaboration between HBO and Ommegang Brewery based on the network's "Game of Thrones" series. U.S. Trademark Application Serial No. 86309080 (notice of opposition filed May 11, 2015). Franciscan owns trademarks used by Ravenswood Winery, including "Ravens," "Ravenswood" and a drawing of three black ravens forming a circle. The winery asserts that consumers are likely to be confused and challenged HBO's intention to use the "Three-Eyed Raven," alleging that the company had no intention to use the mark and, further, had committed fraud when it told the U.S. Patent and Trademark Office that it did. Ommegang began selling Three-Eyed Raven, its fifth collaboration with HBO, in April 2015.

LEGAL LITERATURE

Government Agencies Should Define "Natural" to Avoid Inconsistent Court Decisions, Professor Argues

In a recent journal article, a Babson College marketing law professor discusses legal disputes over the labeling of food as "natural," noting drawbacks of using courts as public policy developers on the issue. Ross D. Petty, "'Natural' Claims in Food Advertising: Policy Implications of Filling the Regulatory Void with Consumer Class Action Lawsuits," *Journal of Public Policy & Marketing*, Spring 2015.

Petty provides a history of the debate and litigation over use of the terms "natural" and "unprocessed" on food labels, beginning with U.S. Federal Trade Commission (FTC) actions against Sugar in The Raw® and Hawaiian Punch® in the 1970s. The article also details efforts by the U.S. Food and Drug Administration (FDA) and Department of

Agriculture (USDA) to define "natural," "synthetic," "healthy" and "good source." Petty highlights industry self-regulation, such as the processes established by the National Advertising Division of the Council of Better Business Bureaus, as a venue for food companies to challenge their competitors' "natural" claims.

He also discusses consumer class actions against food companies that label their products as "natural," crediting Center for Science in the Public Interest with initiating the current surge of consumer class actions against food companies in the early 2000s after the organization petitioned FDA to take action against food mislabeling. The other catalyst, Petty argues, was likely the "Sugar Wars" that began when the Sugar Association and makers of Equal® sweetener sued the manufacturer of Splenda® for implying in its advertising that its sucralose product is "natural."

Petty criticizes the use of consumer class actions to establish public policy, noting that the single strength of such use is that plaintiff's attorneys are often willing to take on issues that legislatures, regulatory agencies and competitors in the food industry have ignored. He argues, however, that the weaknesses are myriad. Decisions in labeling class actions frequently focus on procedural issues rather than public policy issues, Petty notes, so many of the cases turn on whether FDA has primary jurisdiction or whether proposed class members can prove their membership, paid varying prices or hold differing beliefs about the definition of "natural." Further, judges in trial courts do not typically have any food, advertising or consumer behavior expertise, and perhaps most importantly, Petty argues, the courts are not bound to each other's decisions and reach inconsistent results.

"Because no [consumer class actions] have been litigated to a judicial decision on the merits," Petty states, "a great deal of resources have been expended in the past few years with little substantive progress toward determining when the word 'natural' should appropriately be used in food advertising and labeling." Without regulatory guidance, he says, "natural" has become puffery that companies use without precision. Praising USDA's approach to defining "organic," Petty presses FDA and FTC to develop detailed regulations defining artificial ingredients and delineating what processing techniques are sufficiently minimal to be consistent with a "natural" claim. He criticizes the First Amendment implications of *Consumer Reports*' proposed ban on "natural"

claims and notes that such a prohibition would eliminate a simple claim that consumers value. Finally, Petty calls for more research into what consumers believe about a product with a "natural" claim and what language may be a suitable alternative for properly educating consumers.

OTHER DEVELOPMENTS

Report Faults EU Regulators for Derailing Debate over Endocrine-Disrupting Chemicals

The Corporate Europe Observatory (CEO) has **alleged** that companies used "numerous tactics from the corporate lobbyist playbook" to persuade several European Commission departments to obstruct the Directorate-General of the Environment (DG Environment) in its attempts to regulate endocrine disrupting chemicals (EDCs). In particular, the CEO report claims that groups representing the chemical and plastics sectors not only promoted their own studies "as the only 'sound science,'" but used the threat of economic damage as well as the Transatlantic Trade and Investment Partnership (TTIP) negotiations "as a leverage to prevent any new 'trade barrier.'"

"By early Spring 2013, since DG Environment did not bend under the pressure, the corporate lobby focused on demanding an impact assessment as a delaying tactic," opines the report. "In a culmination of fierce lobbying pressure, DG Environment's proposal for scientific criteria to identify EDCs was finally rejected by the other DGs in the Commission. Moreover, in July 2013 the Secretary-General, Catherine Day, ordered the impact assessment the industry wanted so much. This move meant that the Commission failed to meet the December 2013 deadlines to come up with the scientific criteria, as demanded by EU law." *See CEO Press Release*, May 19, 2015.

Environmental Groups Release Canada's Environmental Assessment of GM Salmon

The Center for Food Safety, Food & Water Watch and Friends of the Earth (FOE) have authored a May 28, 2015, **letter** to the U.S. Food and Drug Administration (FDA), claiming that a draft risk assessment conducted by the Canadian Department of Fisheries and Oceans (DFO) questions the health and welfare of AquaBounty Technologies Inc.'s genetically modified (GM) salmon.

According to FOE, the "never-before-seen" **environmental review** concludes that AquaBounty's GM salmon are not only "more susceptible to *Aeromonas salmonicida,* a type of disease-causing bacteria," but exhibit "diminished growth rates" and "widely varied performance." The assessment also reportedly registers "uncertainty" about the function of the gene construct, in addition to faulting the management and operation of AquaBounty facilities for allegedly failing to supply "internal compliance documentation, such as a daily check-list to ensure that all relevant mechanical barriers are in place and functioning properly." As a result of these findings, the environment groups call on FDA to reject AquaBounty's New Animal Drug Application (NADA).

"The findings from the Canadian risk assessment show that FDA has based its assessment of this totally unnecessary technology on blind trust," said Food & Water Watch Executive Director Wenonah Hauter in a May 28 press release. "It's clear that there are unique safety issues that FDA has failed to consider, which is why we are calling on the agency to terminate its review of GMO salmon." *See Food & Water Watch Press Release*, May 28, 2015.

Sustainability Groups Highlight Water Risks for Food and Beverage Sector

Two new reports from nonprofit advocacy organizations highlight global water risks and urge food and beverage companies to adopt more robust water stewardship practices at every point in the supply chain.

Published by Ceres, ***Feeding Ourselves Thirsty: How the Food Sector Is Managing Global Water Risks*** "ranks the nation's 37 largest food companies on how effectively they are managing precious freshwater supplies." Finding that packaged food and beverage companies outperformed the agricultural sector in their responses to water risks, the report estimates that "only 30 percent of the companies considered water risks as part of major business planning and investment decision-making," while only 16 percent "have sustainable agriculture policies that address water."

To help companies improve water efficiency, Ceres recommends, among other things, that global companies (i) analyze water risks for the entire supply chain, (ii) invest in projects that improve watershed health and (iii) disclose water risks and management plans to investors and other stakeholders. The report also calls on investors to evaluate corporate water risk "in terms of water dependence, security and response."

As Ceres notes, "While most companies in the food sector are not directly involved in agricultural production, many are significantly exposed to agricultural water risks through their suppliers... [C]onsider that risk exposure is shaped by several factors, including the primary agricultural commodities the company buys, the level of water dependence and security associated with those commodities, as well as the sourcing model used by the company to procure agricultural inputs."

Meanwhile, the World Wide Fund for Nature in the United Kingdom (WWF-UK) has released its own water-risk assessment, concluding that "many businesses don't assess their water risk[s], let alone mitigate against them." Titled ***From Risk to Resilience: Does Your Business Know Its Water Risk?***, the study examines how companies approach "the management of the catchments in which they operate or source products from, both domestically and internationally." According to WWF-UK, more than 80 percent by value of UK imports "have a 'moderate' level of water risk when risk is averaged across all sourcing countries," and approximately 40 percent by value "come from countries that have hotspots of high water risk," including China, the United States, Italy and Spain.

Offering recommendations for industry, government and investors, the report singles out the beverage sector for its approach to water-intensive supply chains. "Build 'buy-in' across the company on the business case for water stewardship," states WWF-UK. "Ensure the company is complying with legislation, and implementing best practices related to water management. Without showing leadership with the aspects of water under the company's direct control, there will be a lack of credibility when engaging in the more challenging aspects of water stewardship including with suppliers."

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.