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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

USDA Proposes Updates to GMO, BSE and Bird Flu Measures

The U.S. Department of Agriculture (USDA) has published its **semiannual regulatory agenda** outlining measures currently under development for 2012. Among the agenda items are proposed revisions to the rules that govern "certain genetically engineered organisms [GMOs] in order to bring the regulations into alignment with provisions of the Plant Protection Act." Billed as the first comprehensive review of these regulations since 1987, the undertaking would apparently take into account the agency's accumulated rulemaking experience as well as "advances in genetic science and technology." USDA thus anticipates that any rule changes will affect "persons involved with the importation, interstate movement, or release into the environment of genetically engineered plants and certain other [GMOs]."

In addition, the agenda includes modifications to the rules governing the importation of livestock and poultry at risk of transmitting bovine spongiform encephalopathy (BSE) or highly pathogenic avian influenza. In particular, USDA has suggested (i) amending BSE regulations to classify countries that export bovine and bovine products as either negligible risk, controlled risk or undetermined risk in accordance with World Organization for Animal Health (OIE) guidelines; (ii) amending BSE and scrapie regulations regarding the importation of live sheep, goats, and wild ruminants, and their products and byproducts; and (iii) amending regulations "to prohibit or restrict the importation of birds, poultry, and bird and poultry products from regions that have reported the presence in commercial birds or poultry of highly pathogenic avian influenza other than subtype H5N1." *See Federal Register,* February 13, 2012.

Meanwhile, U.S. Senator Chuck Grassley (R-Iowa) sent a February 13, 2012, **letter** to USDA and the Office of Budget and Management, calling on regulators to consolidate and finalize BSE regulations first proposed in 2004. Signed by 31 members of Congress, the letter asks trade negotiators to help reduce "non-tariff trade barriers" to U.S. beef sales abroad by requiring trading partners such as Mexico "to make science-based decisions" in keeping with

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OIE's recommendations. To this end, the letter also urges the United States to demonstrate that it has taken "the necessary steps to properly address risks related to BSE by adopting a comprehensive rule."

"By having a comprehensive BSE rule in place, the U.S. will show leadership on the global scale and will give USTR [the U.S. Office of the Trade Representative] and USDA a stronger position to press other nations to follow the OIE's guidelines and adopt science-based BSE policies," the letter concludes. "As a result, when nations base their decisions on sound science, we are confident more markets will be expanded or opened to U.S. beef."

USDA Report Critical of France's Proposed BPA Ban

The U.S. Department of Agriculture's (USDA's) Foreign Agriculture Service recently issued a Global Agricultural Information Network (GAIN) **report** concluding that a French proposal to prohibit all food packaging and materials containing bisphenol A (BPA) would "very likely… impact and jeopardize U.S. processed and other food exports to France." Introduced after a French National Agency for Food Safety and Occupational and Environmental Health report questioned BPA's safety, the legislation apparently reflects "strong political pressure from environmental and consumers' groups," as well as public distrust of the regulatory system following "the mad cow scandal, the Mediator diabetes drug scandal and even the PIP breast implant scandal." As a result, the French food industry has evidently expressed concern that a BPA ban is unavoidable "in a short to medium term" even if the current bill is challenged at the EU level.

The GAIN report warns U.S. companies that the proposed measure would require them "to adapt and change the composition of their packaging with a new component at a higher cost," which could prove prohibitive to smaller suppliers who export to France and Europe. The law would primarily affect beverages, "notably the Florida orange and grapefruit juice using plastic container[s]," as well as imported beer, frozen seafood and meat products, dried fruits and legumes, and "any product that contains a plastic packaging or a plastic component."

In particular, USDA cites industry experts who have reportedly criticized the bill for failing to distinguish between direct-contact food packaging and food packaging in general. "No other country is undertaking such drastic legislation such as the one proposed in France," notes the agency report. "The existing proposal seems to include even over-packaging such as films which are not in contact with food. The question of inks containing BPA on food labels was not clarified either."

CSPI Petitions FDA to Set Performance Standards for Shellfish Industry

The Center for Science in the Public Interest (CSPI) has **petitioned** the Food and Drug Administration (FDA) to establish performance standards for the shellfish industry to reduce the threat of a "naturally occurring but deadly contaminant" found primarily in raw or undercooked oysters. According to a CSPI **letter** to FDA Commissioner Margaret Hamburg, *Vibrio vulnificus* (*V-vulnificus*) bacteria in contaminated shellfish is responsible for sickening approximately 30 people and killing 15 annually.

Claiming that an annual "outbreak" occurs between April and November when Gulf Coast water temperatures create an ideal environment for the contaminant to grow, CSPI has urged FDA to "act now" to enforce regulations in 2011's Food Safety Modernization Act requiring performance standards for significant contaminants such as *V-vulnificus*. "If we knew a serial killer were going to kill a dozen people like clockwork each year, the police would spring into action to stop it," said David Plunkett , CSPI's senior food safety attorney. *See CSPI Press Release,* February 9, 2012.

U.S., EU Announce Organic Trade Partnership

The Office of the U.S. Trade Representative (USTR) has **announced** a "historic new partnership" with the European Union that recognizes its organic standards as essentially equivalent to those administered by the U.S. Department of Agriculture (USDA). Effective June 1, 2012, the trade agreement will allow organic products certified by EU or USDA officials to be sold "as organic in either region."

"Previously, growers and companies wanting to trade products on both sides of the Atlantic had to obtain separate certifications to two standards, which meant a double set of fees, inspections and paperwork," explains a February 15, 2012, USTR press release. "This partnership eliminates significant barriers, especially for small and medium-sized organic producers. All products meeting the terms of the partnership can be labeled as certified organic produce, meat, cereal, or wine."

According to USTR, the two parties conducted "thorough on-site audits" to ensure that their organic programs were compatible. Because EU regulations restrict the use of antibiotics to treating infected animals only, the partnership terms will require certifying agents to "verify that antibiotics were not used for any reason" in traded organic products. These items must also bear an export certificate that (i) enables product tracking, (ii) identifies the production location and certifying organization, and (iii) confirms that "prohibited substances and methods weren't used" during production.

"The United States and the European Union will continue to have regular discussions and will review each other's programs periodically to verify that

the terms of the partnership are being met," concludes USTR, which has valued the two organic sectors at $50 billion combined. "The EU and U.S. will also begin to work on a series of cooperation initiatives to promote organic production and tackle important topics such as animal welfare and other issues. Both programs will share technical information and best practices on an ongoing basis to further enhance the integrity of organic crops and livestock production systems."

Joint U.S., Canada Initiative to Develop Coordinated Nanotechnology Rules

According to a news source, the United States and Canada have begun to develop a coordinated model framework to regulate nanomaterials. A draft plan, unveiled during a January 2012 meeting of the U.S.-Canada Regulatory Cooperation Council involving officials with the U.S. Office of Management and Budget (OMB) and Environment Canada, identifies the following as the "deliverable outcome": "Share information and develop common approaches, to the extent possible, on foundational regulatory elements, including criteria for determining characteristics of concern/no concern, information gathering, approaches to risk assessment and management, etc. Develop joint initiatives to align regulatory approaches in specific areas such that consistency exists for consumers and industry in Canada and the US."

Industry officials attending the meeting were reportedly cautiously optimistic about the initiative. They urged government representatives to build on the work already done by European regulators to maintain some consistency, but also suggested that American officials move away from the EU system given its "overwhelmingly precautionary" approach. Environment Canada's Karen Dodds noted that coordination would be effective for setting priorities, assessing and managing risks, collecting commercial information, and sharing resources. OMB's Margaret Malanoski apparently indicated that the framework would follow several key principles: reliance on the best scientific and technical information; consideration of risk, safety benefits and other criteria; communications with stakeholders about risks and benefits; and consistency with existing laws.

Some industry officials called for the agencies to start by defining nanomaterials, claiming that too broad a definition could cover materials that are not nanoscale. A representative of the International Center for Technology reportedly called for the investment of more resources into health and safety testing, noting that since the United States began coordinating nanotechnology efforts in 2005, a mere 4.1 percent of funding has been provided for health and safety research. *See InsideEPA.com*, February 10, 2012.

LITIGATION

Court Enjoins Dairy Farmer from Selling Raw Milk Across State Lines

A federal court in Pennsylvania has granted the U.S. government's motion for summary judgment and permanently enjoined a Pennsylvania dairy farmer from selling raw milk and milk products in interstate commerce. *United States v. Allgyer*, No. 11-02651 (U.S. Dist. Ct., E.D. Pa., decided February 2, 2012).

According to the court, Daniel Allgyer's interstate sales of raw milk were discovered through an undercover investigation that involved placing online orders for the product through a membership-only group. Members were cautioned by the Website to "not share information" about the group with government agencies or doctors. The Food and Drug Administration (FDA) apparently purchased some of the milk for delivery out of state, and independent testing confirmed that it was unpasteurized. FDA warned the farmer to stop violating federal law, but he continued to make deliveries to out-of-state consumers through a different membership organization.

The court rejected the defendant's arguments that summary judgment should not be granted because (i) "his involvement in a private membership cow sharing organization precludes FDA involvement," (ii) the action is quasi-criminal in nature and thus requires probable cause and an official complaint, (iii) "FDA illegally sent him warning letters and failed to answer the mandatory Privacy Act Questions required by the Privacy Act of 1974," and (iv) he had not received the agents' "Oaths of Office." The court did, however, limited the injunction, finding no basis to enjoin the defendant from selling raw milk in Pennsylvania.

Frito-Lay Claims Infringement of Tortilla Chips Design and Packaging

Frito-Lay North America, Inc. has filed a trademark and patent infringement lawsuit in a Texas federal court against a company that purportedly makes a similar tortilla chip product and sells it in similar packaging. *Frito-Lay N. Am., Inc. v. Medallion Foods, Inc.*, No. 12-00074 (U.S. Dist. Ct., E.D. Tex., Sherman Div., filed February 10, 2012). At issue are Frito-Lay's TOSTITOS SCOOPS! ® tortilla corn chips, which have a distinctive shape for use with salsa, guacamole and other dips. According to the complaint, Frito-Lay has registered the shape, brand design, and product and brand names as marks with the U.S. Patent and Trademark Office and holds several patents for the processes and systems used to manufacture the chips. The defendant makes and sells a product called BOWLZ, which Frito-Lay alleges infringes its marks, trade dress and patents.

With counts for federal trademark infringement, trade dress infringement and unfair competition, federal trademark dilution, patent infringement, common law trademark infringement, common law unfair competition, trademark dilution under Texas state law, and unjust enrichment, the complaint includes photos

comparing the two products and packaging and contends that the defendant's product deceives the public, trades on Frito-Lay's goodwill and places its reputation at risk. Frito-Lay seeks a preliminary injunction to stop the defendant from using any mark or trade dress confusingly similar to Frito-Lay's TOSTITOS SCOOPS!®, a permanent injunction, an equitable accounting to determine the defendant's profits for payment to Frito-Lay, enhanced damages, attorney's fees, costs, and interest.

False Advertising Class Action Filed in Georgia Against POM Wonderful

A Georgia resident has filed a complaint in federal court on behalf of a statewide class of consumers allegedly misled about the purported health benefits of POM Wonderful's pomegranate products. *Templeton v. POM Wonderful, LLC*, No. CV412-53 (U.S. Dist. Ct., S.D. Ga., Savannah Div., filed February 16, 2012). According to the complaint, the company promotes its products "as having special health benefits, including but not limited to, the prevention[,] mitigation, and/or treatment of the following: (a) Atherosclerosis; (b) Blood Flow/Pressure; (c) Prostate Cancer, (d) Erectile Function; (e) Cardiovascular Disease; (f) Reduce LDL Cholesterol; (g) and other age-related medical conditions." Citing investigations by the National Advertising Division of the Council of Better Business Bureaus, the U.K.'s Advertising Standards Authority, U.S. Food and Drug Administration, and U.S. Federal Trade Commission, the plaintiff claims that these promotions are not substantiated by medical evidence.

Alleging violations of the Georgia Uniform Deceptive Trade Practices Act and unjust enrichment, the plaintiff seeks compensatory damages, recovery of monies from the company's alleged "overcharging and overreaching," attorney's fees, and costs.

Environmental Group Files Prop. 65 Notice of Violation to Enforce 4-MEI Warnings

The Center for Environmental Health has filed a **notice of violation** under California's Safe Drinking Water and Toxic Enforcement Act (Prop. 65) to inform the manufacturer and retailers of several carbonated soft drinks containing caramel coloring that it will file a citizen enforcement lawsuit against them for violating Prop. 65's warning provision since January 7, 2012, with respect to 4-methylimidazole (4-MEI). According to the notice, "No clear and reasonable warning is provided with these products regarding the carcinogenic hazards associated with 4-MEI exposure."

The notice also states that the lawsuit will be filed unless each "alleged violator enters into a binding written agreement to remedy the violations alleged herein by: (1) recalling products already sold; (2) reformulating such products to eliminate the 4-MEI exposure or taking appropriate measures to otherwise comply with Proposition 65; and (3) paying an appropriate civil penalty based on the factors enumerated" in California's Health and Safety Code. On January 9, California EPA's Office of Environmental Health Hazard Assessment adopted a no

significant risk level for the chemical, which is a by-product of fermentation often found in soy sauce, roasted coffee and the caramel coloring added to colas and beer.

OTHER DEVELOPMENTS

Oxford Academic Wants WHO to Adopt Framework Convention on Alcohol Control

A university lecturer in global health politics at the University of Oxford has called for the World Health Organization (WHO) to use a "vastly underused" mechanism, a legally binding framework convention requiring just a two-thirds vote, to address the health burdens and mortality purportedly attributed to alcohol consumption. In the February 16, 2012, issue of *Nature* journal, Devi Sridhar, D.Phil., points to WHO's Framework Convention on Tobacco Control as one of just two such treaties adopted in more than 60 years. These conventions impose legal requirements on member states, which commit to applying the agreement through national legislation and must report their progress to WHO.

According to Sridhar, "2.5 million deaths a years, almost 4% of all deaths worldwide, are attributed to alcohol—more than the number of deaths caused by HIV/AIDS, tuberculosis or malaria. Alcohol consumption is the world's third-largest risk factor for health burden; in middle-income countries, which constitute almost half of the world's population, it is the greatest risk." She notes that the international community, under a framework convention, would share the responsibility of supporting alcohol control initiatives "by providing financial aid and technical assistance as needed. Informally, ministries of health would have a stronger domestic negotiating position in prioritizing alcohol regulation above economic concerns. Non-governmental organizations would be able to pressure governments, and even bring issues to court."

Sridhar acknowledges that the effects of international law on domestic public health can be overstated, observing that minimal oversight and no strong enforcement mechanisms have made compliance with the tobacco control convention weak. Still, she recommends that the appointment of a commission on global health law headed by an independent expert to focus on strengthening WHO's power and the adoption of a broad framework convention on global health could result in the proactive promotion of health throughout the world by the only body with the authority to do so.

Maine Activists Champion BPA Ban in Baby Food, Canned Foods

Environmental health activists in Maine are reportedly campaigning to extend the state's current ban on bisphenol A (BPA) in baby bottles, sippy cups and reusable food containers to all food containers within three years. Spearheaded by the Alliance for a Clean and Healthy Maine, the effort follows a **chemical analysis** funded by the group that detected BPA in baby and toddler foods.

According to the activists, 15 food containers were sent to a San Francisco independent lab to test for BPA, a packaging chemical used as an epoxy liner inside metal food cans and metal lids of glass jars, that has allegedly "been linked to cancer, obesity, learning disabilities, male infertility, and early puberty in girls." Test results found BPA in 11 of 12 baby food containers manufactured by Beech-Nut, Gerber, Earth's Best Organic, and Shaw's Wild Harvest Brand and in all three canned foods featuring Campbell's Original Disney Princess SpaghettiOs and Dora the Explorer soup, and Chef Boyardee macaroni and cheese.

They are urging the state's Board of Environmental Protection to phase out BPA in food marketed to children younger than age 3, including infant formula, baby foods and "canned foods branded with images of cartoon characters to market to preschoolers." They also call for enforcement action against baby food manufacturers violating state law that require BPA reporting and new legislation that would authorize a phase-out of BPA in all foods. "To protect our kids it's time to get this dangerous and unnecessary chemical out of the foods our children eat," said Megan Rice, spokesperson for Mainely Moms and Dads. *See Alliance for a Clean and Healthy Maine Press Release* and *Maine Public Broadcasting Network,* February 14, 2012.

SCIENTIFIC/TECHNICAL ITEMS

Study Allegedly Links BPA to Insulin Resistance

A recent study has **claimed** that bisphenol A (BPA) exposure causes pancreatic cells to secrete increased amounts of insulin, thereby raising questions about the substance's effect on insulin resistance, type 2 diabetes and obesity. Sergi Soriano, "Rapid Insulinotropic Action of Low Doses of Bisphenol-A on Mouse and Human Islets of Langerhans: Role of Estrogen Receptor β," *PLoS One,* February 2012. Researchers evidently used pancreatic β-cells, which produce insulin, as well as whole islets of Langerhans from human donors to demonstrate that "environmentally relevant doses of BPA (1 nM) stimulated glucose-induced insulin secretion in human islets, giving a response which is almost twice the insulin release elicited by a stimulatory glucose concentration, 8 mM."

According to media sources, the study pinpoints the mechanism by which BPA is thought to influence insulin production in pancreatic cells. "When you eat some-

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thing with BPA, it's like telling your organs that you are eating more than you are really eating," explained one of the study's co-authors in a February 15, 2012, *HuffPost Green* article, adding that the effect could be even more pronounced for developing fetuses. "The fetus is not only exposed to BPA but also to higher levels of insulin from the mother, making the environment for the fetus even more disruptive. This is a very delicate period."

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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.