Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

NOP Retains Access to Pasture Rules for Ruminant Slaughter Stock

The U.S. Department of Agriculture's National Organic Program (NOP) has evidently **declined** to revisit a final rule published February 17, 2010, that dealt with access to pasture requirements for livestock. In addition to establishing "a pasture practice standard for ruminant animals," the rule established conditions for organic slaughter stock at "finish feeding" operations, where cattle is typically fed grain crops to improve the grade of beef. In particular, NOP exempted these animals from a provision requiring organically raised ruminants to derive "not less than an average of 30 percent of their dry matter intake (DMI) requirement" from grazing. The agency then solicited comments addressing (i) whether NOP should consider infrastructural and regional differences in finish feeding operations; (ii) the length of the finishing period; and (iii) the use of feedlots for finishing organic slaughter stock.

Based on the 500 individual and 14,000 form letters received in response to this request, NOP opted to conduct "two site visits of organic finish feeding operations in December 2010," but ultimately declined "to amend the provision on ruminant slaughter stock." The agency also issued a May 10, 2011, *Federal Register* notice explaining its rationale and discussing the comments it received from organic beef producers, state agencies, animal welfare and consumer organizations, certifying agents, retailers, and a trade association. Further details about the February 2010 final rule appear in **Issue 338** of this *Update*.

FSIS Meetings Target Plan Calling for Mandatory Catfish Inspections

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has **announced** two public meetings on a proposed rule requiring mandatory FSIS inspections of imported and domestic catfish and catfish products. The meetings will be held May 24 in Washington, D.C., and May 26 in Stoneville, Mississippi. The proposed rule was highlighted in **Issue 383** of this *Update*. *See Federal Register,* May 9, 2011.

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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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IOM Meeting to Explore Relationship Between Farm/Food Policy and Obesity

The Institute of Medicine (IOM) has **announced** a May 19, 2011, public session of its Committee on Accelerating Progress in Obesity Prevention. Titled "Farm and Food Policy: The Relationship to Obesity Prevention," the public session is a one-hour information-gathering forum where committee members will hear about "the determinants of food producer, manufacturer, and retailer decision making in the context of obesity prevention," as well as "the current policy and political context in which farm and food policy decisions are made."

According to IOM, "the committee's charge includes: considering relevant information about progress in the implementation of existing recommendations; developing guiding principles for choosing a set of recommendations; identifying a set of recommendations that is fundamental for substantial progress in obesity prevention in the next decade; and recommending potential indicators that can act as markers of progress." IOM has solicited written comments on these topics and **invited** interested stakeholders to give three-minute oral presentations on "relevant information, evidence, and suggestions for the committee to consider as it develops recommendations to accelerate progress in obesity prevention nationwide."

EPA Issues SNUR for Multi-Walled Carbon Nanotubes

The Environmental Protection Agency (EPA) has issued a **significant new use rule** (SNUR) for a multi-walled carbon nanotube under section 5 of the Toxic Substances Control Act (TSCA); it would require manufacturers, importers or processors of the chemical to follow manufacturing and use conditions already reviewed by EPA. The SNUR would require that any chemical manufacturer, importer or processor of the substance identified generically (due to confidentiality claims) as multi-walled carbon nanotubes notify the agency 90 days before seeking to make or use the chemical in a way that differs from those EPA has already reviewed. Section 5 of TSCA gives EPA the authority to review new chemicals before they can be manufactured or imported into the United States. The SNUR exempts from the requirements certain uses of carbon nanotubes, such as when they have been fixed onto a surface or encapsulated in plastic. *See Federal Register*, May 6, 2011.

EFSA Issues Guidance on Engineered Nanomaterial Risks in Food, Feed

The European Food Safety Authority (EFSA) has published its first **guidance document** assessing the risk of engineered nanomaterial (ENM) applications in food and feed. Prepared in response to a European Commission request, the May 10, 2011, guidance comes after a six-week **public consultation** period during which EFSA received 256 comments from 36 organizations, including academia, industry, Member States, international authorities, and non-governmental groups.

The guidance covers potential risks from applications of nanoscience and nanotechnologies across the food supply chain, including food additives, enzymes, flavorings, food contact materials, novel foods, feed additives, and pesticides. Outlining six toxicity testing methods, the guidance stresses the need for ongoing risk assessments in the burgeoning field of engineered nanomaterials and additional data on physical and chemical ENM characteristics in comparison with conventional applications.

"A thorough characterization of the engineered nanomaterials followed by adequate toxicity testing is essential for the risk assessment of these applications," EFSA Scientific Committee Chair Vittorio Silano was quoted as saying. "Yet we recognize uncertainties related to the suitability of certain existing test methodologies and the availability of data for ENM applications in food and feed. The guidance makes recommendations about how risk assessments should reflect these uncertainties for food and feed applications." *See EFSA Press Release*, May 10, 2011.

British ICO Issues Advice on New Data Privacy Rules

The U.K. Information Commissioner's Office (ICO) has issued **advice** for businesses and organizations to ensure compliance with a new EU privacy directive governing the collection of online user data via "cookies" or other technologies that store visitor information on a user's computer or mobile device. ICO has billed the guidance document as a "starting point for getting compliant rather than a definitive guide," and has announced its intention to publish separate guidance on enforcement as the regulations are implemented.

Effective May 26, 2011, the new rules revise the U.K. Privacy and Electronic Communications Regulations 2003 (PECR) in accordance with changes made to the EU Privacy and Electronic Communications Directive. Applicable to cookies, flash cookies and all other technologies designed to store or gain access to information stored "in the device of a subscriber or user," the amended EU directive requires Websites to obtain explicit user consent to store a cookie on a device, whereas the previous regulations allowed Websites to use cookies as long as they stated how the data were used and provided users with the ability to "opt out." The new regulations also provide a "narrow" exception for cookies that are "strictly necessary" to conduct a service requested by the user; for example, cookies used to facilitate the online purchasing process.

With this in mind, ICO has urged businesses and organizations to (i) "check what type of cookies and similar technologies you use and how you use them"; (ii) "assess how intrusive your use of cookies is"; and (iii) "decide what solution to obtain consent will be best in your circumstances." It has also discussed various options for obtaining user consent through the use of

pop-ups, terms and conditions, and similar avenues, as well as accounting for settings-led consent, feature-led consent and third-party cookies. "What is clear is that the more directly the use of a cookie or similar technology relates to the user's personal information, the more carefully you need to think about how you get consent," concludes the ICO. "We are keen to ensure any future guidance we produce in this area reflects real world practice and that it can continue to be used as technologies develop." *See The Parliament.com* and *The Telegraph,* May 10, 2011.

OEHHA Finalizes Prop. 65 Listings for Ethanol in Alcoholic Beverages, Salted Fish

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) recently **finalized** its decision to add ethanol in alcoholic beverages and Chinese-style salted fish to the state's list of carcinogenic chemicals. The listing was effective April 29, 2011. Companies that sell products containing listed chemicals in California are required to notify consumers that their products contain a chemical known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). More information about OEHHA's decision appears in **Issue 385** of this *Update*.

Maryland Legislation Limits Amount of BPA in Infant Formula Containers

Maryland Governor Martin O'Malley (D) has signed a **bill** (H.B. 4/S.B. 151) prohibiting the manufacture, sale or distribution of infant formula containers with a "certain amount" of bisphenol A (BPA). Effective July 1, 2014, the legislation restricts BPA levels in the containers to not more than 0.5 parts per billion and prohibits the state from purchasing containers with BPA levels exceeding that amount. Offenders of the law would be guilty of a misdemeanor and subject to fines as high as $10,000 for each violation.

The law also calls for the Maryland Department of Health and Mental Hygiene to report to lawmakers by September 1, 2012, on BPA federal research findings and regulatory activities and to address the availability and safety of BPA substitutes for infant formula containers. It authorizes the state health secretary to suspend implementation of the BPA restriction on infant formula containers if "the secretary certifies that the safety concerns for bisphenol A are resolved by additional research" or if implementation "would adversely affect the health or well-being of children or adults."

LITIGATION

Taco Bell Appeals Insurance Coverage Case to Ninth Circuit

Taco Bell has requested that the Ninth Circuit Court of Appeals review a district court determination that three insurance companies are not required to provide coverage under commercial liability policies for economic loss allegedly arising from decreased patronage in the wake of a 2006 *E. coli* outbreak. *Nat'l Union Fire Ins. Co. of Pittsburgh, PA v. Ready Pac Foods, Inc.*, No. 09-3220 (U.S. Dist. Ct., C.D. Cal., appeal filed May 11, 2011). The district court reportedly issued an order granting a request for certification of the economic loss claim and stayed its adjudication of other unresolved matters to allow Taco Bell to take an interlocutory appeal to the Ninth Circuit.

According to the lower court, "The lost patronage claim presents a legal issue that is unique and distinct from the other types of loss for which Taco Bell seeks a declaration of coverage . . . such as claims for bodily injury, claims for damages in the form of contaminated food products, and claims for the clean-up of contaminated restaurants." The court also noted that appellate resolution of the issue could "significantly advance the resolution" of an underlying action between Taco Bell and the company that supplied the purportedly contaminated lettuce which led to the outbreak. *See Law360*, May 12, 2011.

POM Wonderful Seeks Review of Adverse Jury Determination on Damages

A federal jury agreed with POM Wonderful LLC that Welch Foods, Inc. developed intentionally confusing and misleading marketing and labeling for its White Grape Pomegranate juice product to take advantage of the market POM created for pomegranate juice, but determined that POM did not lose sales because of Welch's conduct. *POM Wonderful LLC v. Welch Foods Inc.*, No. 09-00567 (U.S. Dist. Ct., C.D. Cal., verdict reached September 13, 2010). More details about the case appear in **Issue 290** of this *Update*.

POM has reportedly asked the Ninth Circuit Court of Appeals to review the verdict, claiming that the lower court's decision to try the case in two phases led the company to refrain from introducing evidence about lost sales during the first phase, which focused on liability. According to a news source, the company requested before the verdict that the court not instruct the jury to decide whether POM had lost sales, but the court refused. The court also apparently refused to re-open POM's case in chief to allow the introduction of lost-sales evidence. *See The National Law Journal*, May 10, 2011.

Court Gives Preliminary Approval to $30M Settlement of Dairy Antitrust Claims

A federal court in Vermont has certified a class of 9,000 to 10,000 dairy farmers who allege that Dean Foods Co. and others engaged in anticompetitive conduct and given preliminary approval to a settlement reached in December 2010. *Allen v. Dairy Farmers of Am., Inc.*, No. 09-00230 (U.S. Dist. Ct., D. Vt., order entered May 4, 2011). Under the settlement, Dean Foods does not admit any wrongdoing, but will create a $30 million settlement fund. Its co-defendants have objected to the settlement, but the court determined that they lack standing to oppose preliminary approval of the Dean settlement. The court also noted that they opposed a settlement provision that has been removed. The court denied several motions to intervene and scheduled a final hearing date for July 18, 2011.

The plaintiffs alleged conspiracies to monopolize, fix prices and restrain trade. Common questions of law and fact included whether the defendants "conspired to fix, stabilize, maintain and/or artificially lower the over-order premiums paid to dairy farmers for raw Grade A milk, and whether Defendants entered into agreements to foreclose those dairy farmers' access to milk bottling and processing plants."

Court Refuses to Transfer Class Action Against Nutella® Maker

A federal court in California has denied without prejudice the motion of Ferrero U.S.A., Inc. to transfer a consolidated consumer-fraud class action involving its Nutella® spread to a New Jersey district court. *In re: Ferrero Litig.*, No. 11-205 (U.S. Dist. Ct., S.D. Cal., decided May 11, 2011). According to the court, the convenience of the parties and witnesses and the interests of justice would best be served by allowing the plaintiffs to remain in their chosen jurisdiction. The court noted that similar litigation is pending in New Jersey, but that case was filed after the California lawsuits, "likely giv[ing] the cases in this district priority." Additional details about the case can be found in Issue 380 of this *Update*.

Citing Insects and Rodent Filth, FDA Seeks to Shutter Food Warehouses

The Food and Drug Administration (FDA) has filed a complaint for permanent injunction against Tennessee-based companies that process food products and ingredients, such as spices, spice blends, herbs, and sauces, claiming they have repeatedly violated the law by selling adulterated foods. *United States v. Am. Mercantile Corp.*, No. 11-02371 (U.S. Dist. Ct., W.D. Tenn., filed May 11, 2011).

According to the complaint, the foods are adulterated because "they have been prepared, packed, and held under insanitary conditions whereby they may have become contaminated with filth." An array of insects and insect

and rodent excreta were allegedly observed on a number of occasions at defendants' facilities, and repeat visits by inspectors showed that the cited violations had not been corrected. Other problems included spilled food, unsatisfactory cleaning, gaps in the building exterior, and expired products.

FDA seeks to permanently enjoin the defendants from "introducing or delivering for introduction into interstate commerce any article of food that is adulterated" and "causing the adulteration of any article of food while such article is held for sale after shipment of one or more of its components in interstate commerce." FDA also seeks to permanently enjoin the defendants from "doing or causing to be done, directly or indirectly, any act that adulterates food." The agency requests that the court order the defendants to cease operations until they comply with the law.

Trademark Rights to "Heart Attack" Designation on Food Menus Contested

A New York City deli has filed a lawsuit in federal court seeking a declaration that it has not infringed the trademark of an Arizona-based restaurant by selling an "Instant Heart Attack Sandwich" and planning to sell a "Triple Bypass Sandwich." ***Lebewohl v. Heart Attack Grill LLC*, No. 11-3153 (U.S. Dist. Ct., S.D.N.Y., filed May 10, 2011)**.

According to the plaintiff, who owns the 2nd Avenue Deli, the Arizona eatery threatened to sue the deli in a March 29, 2011, letter, claiming that the deli's use of these terms for its menu items violated the defendant's Lanham Act rights. The Heart Attack Grill has purportedly registered the trademarks "Heart Attack Grill," "Triple Bypass Burger" and other "Bypass" marks.

The New York deli claims that it has been selling its "Instant Heart Attack Sandwich," which consists of two large potato pancakes with a choice of deli meats, and accompanied by matzo ball soup, since 2004. It also claims that it has been serving quality kosher food to New Yorkers for almost 60 years and has no intention of becoming a medically themed hamburger restaurant and grill, which is how the plaintiff characterizes the defendant's operations. In addition to costs and attorney's fees, the deli seeks a judgment declaring that it has not infringed the defendant's rights and that it did not violate any of the defendant's state or common law claims or rights.

According to news sources, the Heart Attack Grill features female servers wearing scanty nurses' uniforms and sells single, double, triple, and quadruple bypass hamburgers consisting of a stack of beef patties and multiple slices of cheese; they are sold with "flatliner fries" deep fried in pure lard. The grill's owner reportedly complained, "These are desperate times for the unimaginative, but a simple formula has emerged: 1) copy my intellectual property, 2) wait for me to object, 3) file suit against me, for exercising my right to object, in the hopes of garnering media attention for what is otherwise an unremark-

able deli." He was also quoted as saying, "There really is no story here, other than a possible exposé on the abuse of our civil court system for personal gain." *See The New York Daily News*, May 10, 2011; *The Wall Street Journal*, May 11, 2011.

Prop. 65 Lawsuit Seeks Warnings for Acrylamide in Coffee

The Metzger Law Group has filed a lawsuit under the Safe Drinking Water and Toxic Enforcement Act (Prop. 65) on behalf of the Council for Education and Research on Toxics (CERT), seeking an order to require coffee makers and retailers to warn consumers that coffee contains acrylamide, a chemical known to the state to cause cancer. *CERT v. Brad Berry Co., Ltd.*, No. BC461182 (Cal. Super. Ct., Los Angeles County, Cent. Dist., filed May 9, 2011). The defendants include manufacturing companies, coffee shops and major food retailers.

Raphael Metzger and CERT have filed a number of Prop. 65 lawsuits, including claims against fast-food restaurants, for failing to warn consumers about the acrylamide in fried and baked potatoes. Acrylamide, formed when certain foods are roasted, baked or exposed to high-temperature cooking processes other than boiling or steaming, has been listed as a carcinogenic chemical in California since 1990, but was not discovered in many foods until 2002. Information about the Maillard chemical reaction that creates acrylamide in food appears in Issue 2 of this *Update*.

According to the complaint, tests have shown that a single serving of the defendants' coffee "contains anywhere from 4 to well over 100 times more acrylamide than the No Significant Risk Level ('NSRL') for acrylamide established by California's Office of Environmental Health Hazard Assessment ('OEHHA')." CERT contends that the defendants have violated Prop. 65 since June 2002 "by exposing millions of individuals within the State of California to acrylamide without first giving clear and reasonable warnings to said individuals that their coffee contains a chemical known by the State of California to cause cancer."

Among other matters, CERT seeks a declaration that (i) the defendants are legally obligated to provide Prop. 65 warnings "on the containers of the coffee that they sell," (ii) the primary jurisdiction doctrine does not apply to the case, (iii) the court "cannot and ought not defer this action to await potential or pending regulatory action" by OEHHA, and (iv) the plaintiff's Prop. 65 claims are not preempted by federal law. The plaintiff also seeks injunctive relief and civil penalties "not to exceed $2,500 per day for each and every violation by each and every Defendant," as well as attorney's fees and costs.

OEHHA has **adopted** a maximum allowable dose level (MADL) for acrylamide as to its purported reproductive toxicity; the MADL, at 140 micrograms/day, took effect April 29.

OTHER DEVELOPMENTS

New Rudd Center Study Backs Soft Drink Tax

Yale University's Rudd Center for Food Policy and Obesity has **released** a new study claiming that "a penny per ounce" tax on sugar-sweetened beverages "has the potential to reduce consumption and generate significant revenue." Tatiana Andreyeva, et al., "Estimating the potential of taxes on sugar-sweetened beverages to reduce consumption and generate revenue," *Preventive Medicine,* April 2011. To estimate revenues from an excise tax on sugar-sweetened beverages, the study's authors evidently constructed "a model projecting beverage consumption and tax revenues based on best available data on regional beverage consumption, historic trends and recent estimates of the price elasticity on sugar-sweetened beverage demand."

Using this model, the authors described the public health impact of beverage taxes as "substantial," estimating that a penny-per-ounce tax would reduce sugar-sweetened beverage consumption by 24 percent and lower "the daily per capita caloric intake from sugar-sweetened beverages from the current 190-200 cal to 145-150 cal, if there is no substitution to other caloric beverages or food." They also found that a national penny-per-ounce tax "could generate new tax revenue of $79 billion over 2010-2015." The paper concludes that "a modest tax on sugar-sweetened beverages could both raise significant revenues and improve public health by reducing obesity."

MEDIA COVERAGE

John Seabrook, "Snacks for a Fat Planet," *The New Yorker,* May 16, 2011

"Over the course of the past half century, during which PepsiCo's revenues have increased more than a hundredfold, a public-health crisis has been steadily growing along with it. People are getting fatter," opines *The New Yorker's* John Seabrook in this article examining the tension between the ubiquitous snack food empire and its recent foray into "authentic, scientifically advantaged" functional foods designed "for different life stages—snacks for teens, snacks for pregnant women, snacks for seniors." In particular, Seabrook focuses on PepsiCo's recruitment of academics, scientists and former regulators to bolster its new global health agenda, which includes efforts to reduce sodium and sugar in its flagship products, as well as launch "better for you" foods that re-create both the physical and aspirational experience associated with high brand recognition.

"No one I met at PepsiCo better represents the complicated relationship between private food companies and public health than Derek Yach, the company's director of global-health policy," writes Seabrook. An epidemiolo-

gist specializing in non-communicable diseases, Yach "made his name" at the World Health Organization (WHO), where he was "the architect of the Framework Convention on Tobacco Control." But when he turned his attention to "Big Food," Yach allegedly found himself thwarted by industry interests who described his proposals as anti-business. "We were able to paint the tobacco companies as morbidly untouchable," Yach told Seabrook. "They sold one product, and it wasn't good for you—there's no way to make a healthy cigarette. But you can make healthy food."

After leaving WHO, Yach eventually joined PepsiCo and has since publicly defended his decision to work in the private sector, where he has been able to implement many of his nutrition proposals as companywide guidelines. In addition, PepsiCo has apparently hired other consultants like David Kessler, a former Food and Drug Administration commissioner, and George Mensah, an obesity specialist previously with the Centers for Disease Control and Prevention, to work on its obesity, nutrition and health policies. Still, as Seabrook reports, these hires have done little to assuage the suspicions of public health advocates. "The best thing Pepsi could do for worldwide obesity would be to go out of business," New York University Food Studies Professor Marion Nestle was quoted as saying.

SCIENTIFIC/TECHNICAL ITEMS

Study Claims Bt Toxin Found in Human Blood

Canadian researchers have allegedly **detected** the presence of Cry1Ab toxin in human blood, raising questions about whether "pesticides associated to genetically modified [GM] foods (PAGMF)" break down during digestion as previously claimed. Aziz Aris and Samuel Leblanc, "Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada," *Reproductive Toxicology,* 2011. The study apparently focused on 30 pregnant and 39 non-pregnant women with no direct or indirect contact with pesticides. The findings evidently showed Cry1Ab toxin—"an insecticidal protein produced by the naturally occurring soil bacterium *Bacillus thuringiensis* [bt]" and used in GM maize—"in 93% and 80% of maternal and fetal blood samples, respectively and in 69% of tested blood samples from non-pregnant women."

According to the study's authors, these results suggest "(1) that these toxins may not be effectively eliminated in humans and (2) there may be a high risk of exposure through consumption of contaminated meat," since Cry1Ab has also been discovered "in the gastrointestinal contents of livestock fed on GM corn." Moreover, as the authors speculated, "given the widespread use of GM foods in the local daily diet (soybeans, corn, potatoes,…), it is conceivable that the majority of the population is exposed through their daily diet." They have

therefore offered their research as a baseline for further nutrition, toxicology and reproductive studies, "particularly those using the placental transfer approach." *See India Today,* May 11, 2011.

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FOOD & BEVERAGE LITIGATION UPDATE

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.