Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

ISO Nano-Product Labeling Standard with Implications for Food Industry on ANSI Webinar Agenda

The American National Standards Institute (ANSI) has announced a July 9, 2010, Webinar to provide an overview of the current draft of an Organization for Standardization (ISO) document titled "Guidance on the labeling of manufactured nano-objects and products containing manufactured nano-objects."

According to ANSI, "this nano-labeling document will likely have broad implications for a number of U.S. industry sectors, including food safety/industry, cosmetics and chemicals." The draft ISO guidance document is expected to be distributed for a vote by June 18 to national advisory groups participating in the development of international nanotechnology standards. The ANSI-accredited technical advisory group (TAG) that represents U.S. positions before ISO is interested in comments on the draft to develop the U.S. position and vote. Internet reservations are required to participate in the Webinar.

ISO standards and technical materials, developed on an international level, often form the basis for national regulations. They are developed by stakeholders who participate through individual country advisory groups, such as the ANSI-accredited U.S. TAG to ISO/TC 229 Nanotechnologies. The document under consideration is a "technical specification" (TS); the European Committee for Standardization (CEN) Technical Committee 352 Nanotechnologies leads this TS development activity.

Dietary Advisory Committee Calls for Dietary Improvements, Food Environment Changes

The Dietary Guidelines Advisory Committee has released its recommendations to the secretaries of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA), outlining proposed changes to the 2005 Dietary Guidelines for Americans. This report recommends 2010 guideline revisions that will implement "a lifestyle approach including a total diet that is energy balanced and nutrient dense."

Recognizing that Americans, a majority of whom are obese or overweight, eat too few vegetables, fruits, high-fiber whole grains, low-fat milk and milk products, and seafood, while consuming too many added sugars, solid fats, refined grains, and sodium, the advisory committee endorses a shift to healthful patterns of eating,

such as the Dietary Approaches to Stop Hypertension and certain Mediterranean-style diets.

The committee also recommends a coordinated strategic plan to improve the overall food environment that "includes all sectors of society, including individuals, families, educators, communities, physicians and allied health professionals, public health advocates, policy makers, scientists, and small and large businesses (e.g., farmers, agricultural producers, food scientists, food manufacturers, and food retailers of all kinds)." The Center for Science in the Public Interest lauded this aspect of the report, observing that "at long last" policymakers are recognizing that a national strategy to help people improve their diets will require "ramping up nutrition education, expanding access to fruits and vegetables, and getting industry to provide more healthful products." HHS and USDA have **requested** public comments by July 15, 2010; a public meeting for the receipt of oral comments will be held July 8.

Food and nutrition experts responded to the new report with little enthusiasm, claiming that the dietary recommendations are nearly identical to those first appearing in guidelines published in 1980. Marion Nestle cited her work and that of Michael Pollen; both have said for years, in essence, eat less, exercise more, consume more plant-based foods, and cut out junk food. Noting that the guideline process "is fraught with politics," Nestle reports that a number of industry interest groups have asked HHS and USDA to provide access to the research materials on which the advisory committee relied. According to *Food Chemical News*, the organizations stated, "Without access to the data from which the [advisory committee] drew its conclusions and recommendations, the public may not be able to provide meaningful comments." *See Federal Register*, *CSPI News Release,* and *Food Politics*, June 15, 2010.

Nebraska-Based Organics Certifier Suspended from Operating in China

The U.S. Department of Agriculture's National Organics Program (NOP) has **announced** a settlement agreement with one of the nation's leading organic certifiers, which had allegedly allowed inspections of Chinese organic food operations by auditors with a conflict of interest. Under the agreement, Nebraska-based Organic Crop Improvement Association (OCIA) will be prohibited from certifying organic operations in China for one year and can be approved for re-accreditation as a certifying agent in China only if it hires inspectors with no connection to governmental or quasi-governmental entities.

According to a press report, OCIA allowed government-affiliated inspectors to inspect farms operated on government-owned land and failed to properly oversee the inspectors' activities. NOP apparently discovered the conflict during an August 2007 onsite OCIA audit and proposed revoking OCIA's accreditation in China in July 2008. The agreement does not affect OCIA's accreditation as an organic certifier in the United States, Canada and Latin America. According to NOP's notice, the agency "is expanding its oversight of foreign certifying agents and organic operations." *See NOP Press Release*, June 14, 2010.

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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If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

APHIS Meetings to Target Animal Disease Traceability

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has announced two public **meetings** for stakeholders to offer input on a new framework for animal disease traceability. Specific details for a proposed animal disease traceability rule will be discussed on June 24, 2010, in Salt Lake City, Utah, and July 1 in Fort Worth, Texas. Written comments will be accepted until July 30, 2010. Additional meetings will be announced in a future *Federal Register* notice. *See Federal Register*, June 14, 2010.

FDA, NOAA Enhance Efforts to Ensure Safety of Seafood in Gulf of Mexico

The Food and Drug Administration (FDA) and the National Oceanic and Atmospheric Administration (NOAA) have announced joint efforts to secure the safety of Gulf of Mexico seafood in the wake of the April 20, 2010, oil spill. "It is important to coordinate seafood surveillance efforts on the water, at the docks and at seafood processors to ensure seafood in the market is safe to eat," FDA Commissioner Margaret Hamburg said in a joint press release.

The agencies plan a "multi-pronged approach" that includes precautionary closures of fishing areas, increased seafood testing inspections and a "re-opening protocol" for affected Gulf waters. NOAA has apparently created a "seafood sampling and inspection plan" and is using "ongoing surveillance to evaluate new seafood samples to determine whether contamination is present" outside closed fishing areas. If the samples have elevated levels of oil compounds, NOAA said it will consider expanding the closed areas.

FDA, which initially plans to increase sampling of oysters, crab and shrimp because they retain contaminants longer than finfish, will target seafood processors who buy directly from the harvester as a way to monitor this first step in the distribution chain. A June 14 FDA **letter** to the fish and fishery products industry outlines regulations and policies regarding the food safety hazards of environmental chemical contaminants. *See FDA Joint News Release*, June 14, 2010.

FDA Seeks Input on Changes to Food and Color Additive Petition Submissions

The Food and Drug Administration (FDA) has called for **comment** on "the information collection provisions of FDA's regulations for submission of petitions, including food and color additive petitions (including labeling) and generally recognized as safe (GRAS) affirmations." As required by the Office of Management and Budget, the agency has invited comments on the following: (i) "Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility"; (ii) "the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used"; (iii) "ways to enhance the quality, utility, and clarity of the information to be collected"; and (iv) "ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology."

FDA has also requested feedback on revisions to Form FDA 3503 for food additive petitions (FAPs) and Form FDA 3504 for color additive petitions (CAPs). To facilitate electronic and multi-use submissions, the agency has altered Form FDA 3503 "to accept submissions for both FAP and CAP, thus making Form FDA 3504 redundant… Therefore, FDA is eliminating Form FDA 3504." Comments will be accepted until August 13, 2010.

MEPs Reject Traffic Light System in Favor of Uniform Labeling Laws

Members of European Parliament (MEPs) have apparently voted in favor of draft legislation that would require listing energy, fat, saturated fat, sugar, and salt content on the front of food packages. Doing so, they rejected a traffic light system that sought to further emphasize the levels of salt, sugar and fat in processed foods, and opposed parallel schemes run by national regulators.

According to a June 14-17, 2010, plenary session **report**, MEPs approved mandatory front-of-pack (FOP) nutritional information accompanied by guideline daily amounts "expressed with per 100g or per 100ml values." They also supported (i) stating the amount of protein, fiber and *trans* fats "elsewhere on the packaging"; (ii) extending country-of-origin labeling regulations to all meat, poultry, dairy, and other single-ingredient products; (iii) labeling meat slaughtered without stunning; (iv) specifying country of origin for "meat, poultry and fish when used as an ingredient in processed food"; and (v) retaining the "'nutrient profiles' from existing EU nutrition and health claims legislation." Non-prepackaged foods, handcrafted food products made by "microenterprises," and alcoholic beverages would remain exempt from nutritional labeling requirements.

"Once the legislation is adopted, food businesses will have three years to adapt to the rules. Smaller operators, with fewer than 100 employees and an annual turnover under €5 million, would have five years to comply," concludes the plenary session report, which anticipates that the draft will return to Parliament for a second reading after renegotiation with the European Council. *See The Independent,* June 15, 2010.

California Agency Responds to Objections to Expedited Prop. 65 Procedure on Fumonisin B^1

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has **withdrawn** its proposal to establish a "safe harbor level" under Proposition 65 (Prop. 65) for fumonisin B^1, a substance produced by several mold species that occur mostly in corn, wheat and other cereals. The Grocery Manufacturers Association (GMA) objected to the agency's use of an expedited procedure. According to OEHHA's notice, "[t]o evaluate the need for a conventional risk assessment, OEHHA would have to conduct a detailed review of the data submitted by GMA along with other relevant information that may be identified through an extensive literature search." Because OEHHA would have been unable to timely complete its rulemaking process, it withdrew "its proposal to establish a specific level posing no significant risk using expedited methodology for fumonisin B^1."

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LITIGATION

Settlement Reached in One GM Rice Suit; Court Issues Order in Another

The Bayer defendants and several plaintiffs in multidistrict litigation (MDL) before a federal court in Missouri have filed a joint motion to dismiss their case, because the parties have settled claims that Bayer's genetically modified (GM) rice contaminated plaintiffs' conventional crops, which were exported to Europe. *In re: Genetically Modified Rice Litig.*, MDL No. 1811 (U.S. Dist. Ct., E.D. Mo., E. Div., motion filed June 3, 2010). According to a news source, Bayer agreed to pay $5.8 million to Riviana Foods Inc. and its affiliates. Said to be a first in this MDL proceeding, the settlement is not intended to affect any other litigation currently pending against Bayer and does not resolve claims that Riviana expects to pursue against Bayer should its European customers prevail in litigation against both Bayer and Riviana. *See Product Liability Law 360*, June 4, 2010.

Meanwhile, on June 7, the MDL court issued an order that addresses the motions for summary judgment filed in a GM rice case set for trial June 21, involving two groups of Louisiana-based plaintiffs. The court has limited to negligence the claims that will be tried and will not allow any of defendants' expert witnesses to contradict its finding as a matter of law that "regulations under the Plant Protection Act do not allow for low level or adventitious presence of regulated genetically modified rice in the commercial rice supply." Among matters that will be litigated are certain agency and joint venture liability issues, as well as "share-rent landlord damages." The court also granted defendants' motion for summary judgment on plaintiffs' claims for punitive damages, finding them unavailable under applicable state law.

JPML Denies Request to Consolidate Yo-Plus® Health Claims Cases

The Judicial Panel on Multidistrict Litigation (JPML) has denied a request to transfer four pending federal lawsuits to a multidistrict litigation court, finding that the common factual questions about General Mills's alleged nationwide marketing claims for its Yo-Plus® yogurt products are not sufficiently complex or numerous to justify consolidation. *In re: General Mills, Inc., Yoplus Yogurt Prods. Mktg. & Sales Practices Litig.*, MDL No. 2169 (JPML, order filed June 14, 2010).

Putative class actions, challenging the company's claimed probiotic digestive benefits, are currently pending in federal courts in California, Florida, New Jersey, and Ohio. They involve statewide classes that the court found "will likely not overlap significantly." The Florida action, already certified, is pending on interlocutory appeal before the Eleventh Circuit, and the California court stayed its class certification hearing pending the JPML's ruling. According to the panel, "Because all plaintiffs are represented by mostly common counsel and General Mills is the sole defendant, the parties have every ability to cooperate and minimize the possibilities of duplicative discovery and/or inconsistent pretrial rulings." *See Product Liability Law 360*, June 15, 2010.

California Advocacy Organization Files Prop. 65 Violation Notices over Lead in Fruit Products

The Environmental Law Foundation has **notified** more than four dozen food manufacturers and retailers that they are in violation of California's Proposition 65 Toxics Right to Know law (Prop. 65) after testing purportedly indicated the presence of lead in numerous fruit and fruit juice products.

According to the foundation, "apple juice, grape juice, packaged pears and peaches (including baby food), and fruit cocktail" products contained "enough lead in a single serving that they require a warning" under Prop. 65, and the companies, since June 9, 2009, "have exposed and continue to expose consumers of their food products to lead" every day. California's attorney general, city attorneys and county district attorneys received copies of the notice. The foundation declares in the notices that it intends "to bring suit in the public interest" against the listed companies in 60 days to correct the Prop. 65 violations.

A foundation news release indicates that the notices are based on tests involving 398 samples of 146 different branded products purchased throughout the state. The types of foods chosen for testing represented "food product categories that children like and eat often and which the data showed had widespread presence of lead." The foundation cites research indicating particular risks for children and fetuses exposed to lead. *See Environmental Law Foundation News Release*, June 10, 2010.

Raw Milk Dairy Challenges Restrictions on Sales in Wisconsin

A Wisconsin organic farm was reportedly scheduled to argue in court this week that state restrictions on the sale of raw milk do not apply where the sales are made to consumers who are part owners of the farm. While the legislature recently attempted to change a law that regulators contend allows incidental raw milk sales only, the state calls the farm's sales in excess of $80,000 yearly to consumers, who each own a $10 share in the farm, well beyond what the law allows. Wisconsin's governor vetoed the popular bill, which would have allowed on-farm raw milk sales, apparently concerned that *E. coli* outbreaks purportedly linked to consumption of the unpasteurized product could affect the state's entire dairy industry. Raw milk proponents dispute that any such link exists.

Meanwhile, public health officials investigating a recent *E. coli* outbreak that has allegedly sickened eight Minnesota residents including school-aged children and an infant, reportedly associated the *E. coli* strain with dairy products from a farm that sells raw milk. *See msnbc.com*, June 11, 2010; *StarTribune.com*, June 13, 2010.

OTHER DEVELOPMENTS

Cornucopia Institute Urges Public Nomination Process for Organic Board

An organic industry watchdog has released a June 7, 2010, **letter** that urges the U.S. Department of Agriculture (USDA) to increase the transparency of the National Organic Standards Board (NOSB) appointment process.

"The Cornucopia Institute, and other organic advocates, have long been concerned that representatives from corporate agribusiness have obtained a disproportionate influence on rulemaking at the USDA," states a June 8 press release, which claims that in the past, "many eminently qualified candidates…did not have the political clout to be appointed."

According to Cornucopia, USDA has continued "the Bush administration policy of keeping secret the nominees and the related corporations or organizations they work for or represent." The group alleges that NOSB positions reserved for consumers or organic farmers have previously gone to specialists employed by corporate agribusiness or only the largest organic marketers. It has thus asked USDA to make public "the name of the individual and the slot of which they are applying," as "[m]any in the organic community would welcome the opportunity to provide constructive feedback on the potential appointees and help ensure that the best and most qualified individuals are the focus of the final appointment process."

In addition, Cornucopia has requested "a modest stipend for NOSB members who are not affiliated with a corporate entity or well-funded nonprofit organization," to help ease the financial burden on independent farmers participating in these activities. "Without denigrating Whole Foods, and their commitment to organics, you have to question why this giant corporation again has a seat on the board, whereas the approximately 275 consumer-owned cooperatives, with hundreds of thousands of members and shoppers, have again been shut out," one organic dairy farmer was quoted as saying.

AMA Adopts Policies on *Trans* and Saturated Fat Labeling, Obesity Reduction

The American Medical Association (AMA) has adopted new public health policies concerning the reporting of fats on nutrition labels and obesity reduction. During its June 14, 2010, annual meeting, AMA urged the Food and Drug Administration (FDA) to adopt more "precise processes" to measure *trans* and saturated fat content in foods. Under current FDA guidelines, *trans* and saturated fat content can be listed on nutrition labels as zero if the food product contains less than 0.5 grams per serving. AMA claims that products labeled "*trans* fat free" or "zero trans fat" could supply in one serving as much as 25 percent of the recommended daily allowance of *trans* fats. Claiming that "it's difficult to make dietary changes if food labels are unclear," AMA board member Edward Langston urged FDA to use "clear, concise and uniform labeling" and list the most accurate information.

AMA also adopted a policy supporting efforts to make healthful foods more affordable than "nutrition-poor" foods. "Consuming unhealthy, high fat and high calorie foods increases the risk for obesity and its health consequences," Langston said. "When the price difference between unhealthy and healthy foods puts healthy options out of reach, it's clear that something must be done to close the price gap and make healthy food options available to everyone." *See AMA Press Release*, June 14, 2010.

Author Questions Whether Umami Is the "Fifth Taste"

Book author Anneli Rufus recently explored claims made about food ingredients that stimulate the purported "fifth taste" promoted by, among others, Ajinomoto, a Japanese company that manufactures monosodium glutamate (MSG), which was created in the early 1900s as the essence of ingredients that purportedly give food a richness and savoriness identified as umami. Ajinomoto-funded researchers have apparently fueled a food fad that has been gathering steam over the past decade by claiming that umami stimulates particular taste buds, much as sweet, sour, salty, and bitter do.

Rufus discusses ongoing debates about the safety of MSG; anecdotal evidence allegedly shows that MSG in foods can cause migraines, obesity, asthma, and brain damage. While the Food and Drug Administration requires that food producers include MSG on product labels, the agency does consider MSG as GRAS (generally recognized as safe). Still, other ingredients, such as yeast extract and hydrolyzed vegetable protein also contain MSG. The Codex Alimentarius Commission apparently considers the propanols in some hydrolyzed proteins carcinogenic and genotoxic. Thus, one umami critic "tells everyone who will listen, at least one source of umami causes cancer." *See AlterNet.com*, June 12, 2010.

Andreasen to Chair ABA Agricultural Management Committee

SHB Of Counsel **Jim Andreasen** has been appointed by the ABA Section of Environment, Energy, and Resources leadership to chair the section's Agricultural Management Committee. His one-year term will begin at the conclusion of the section's 2010 annual business meeting to be held August 8 during the ABA's annual meeting in San Francisco. As committee chair, Andreasen will be responsible for appointing committee vice chairs, developing a committee action plan and leading the vice chairs in implementing the plan. He previously served as the committee's programs vice chair. To view the committee's Web page, please click **here**.

MEDIA COVERAGE

Mike Steinberger, "What's in the Bottle?," *Slate,* June 14, 2010

This investigative report by *Slate's* wine columnist, Mike Steinberger, examines the retailer allegedly at the center of a multimillion dollar fraud rippling throughout the rare wine world. Manhattan-based Royal Wine Merchants apparently provided its clientele with highly desirable wines that were later deemed fakes and traced back to Hardy Rodenstock, a supplier suspected of creating counterfeits such as "the so-called Thomas Jefferson bottles." A lawsuit filed by one collector has since highlighted the connection between the two enterprises, revealing that "Rodenstock shipped 818 bottles of wine to Royal between 1998 and 2008." According to Steinberger, "Many industry insiders… believe that the Rodenstock invoices prove that the rare wine business has indeed been polluted by fraud."

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Steinberger meticulously details the voyage of one fake vintage in particular – a magnum of 1921 Château Pétrus – which changed hands several times and left a glut of litigation in its wake. Although a court of law has not yet proven guilt, Steinberger questions how Royal obtained so many rare bottles in the first place and echoes "the deep skepticism" voiced by other key players in the industry. "It now appears that Royal dumped a lot of counterfeit wines on the market over the last two decades," he writes, adding that one consultant who worked for Christie's in the mid-1990s described the retailer as "the most consistent problem in the supply chain."

Steinberger also suggests that Rodenstock and Royal courted the good opinion of wine expert Robert Parker to help move their stock. The journalist maintains that both outfits hosted several events attended by Parker, who sampled and publicly praised some of the false vintages later pawned off on unsuspecting buyers. As Steinberger concludes, Parker "may have unwittingly had a role in corrupting the fine wine market, which would be a bitter irony for a critic who claimed Ralph Nader as his inspiration and who has long presented himself as the consumer's advocate."

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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.