Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

GAO Report Criticizes FDA Handling of Irradiation Petitions

The U.S. Government Accountability Office (GAO) recently issued a report criticizing the Food and Drug Administration (FDA) for its handling of irradiated food products.

In response to congressional inquiries, GAO examined current and proposed FDA labeling requirements for irradiated foods, as well as "the extent to which FDA has effectively managed the petition review process for irradiated food." Despite efforts to bolster public acceptance of irradiated products, FDA "has not effectively managed its petition review process, which is the vehicle to potentially allow more food products to be irradiated," according to GAO.

The report describes ionizing radiation as a safe and effective process capable of eliminating "99.999 percent of *E. coli 0157, Listeria* and *Campylobacter*," but notes that the current labeling scheme may suggest "these foods are less safe." It also censures FDA's failure to meet "key statutory and regulatory timeframes" for six currently active and pending food irradiation petitions. Required to complete the review process and issue an order within 180 days, FDA has purportedly taken, on average, 8.5 years to respond to these petitions. In addition, the agency has not documented pertinent decisions nor communicated this information to applicants. As GAO concluded, "These deficiencies limit the ability of petitioners to understand the actions FDA takes, the ability of petitioners to respond appropriately when FDA changes the requirements of the review process, and the transparency of the petition review process."

EPA Issues Toxicological Review of Acrylamide

The U.S. Environmental Protection Agency (EPA) has issued a "Toxicological Review of Acrylamide" in support of information on its Integrated Risk Information System. The chemical, which is formed during the high-temperature heating of starchy foods, is also used in a number of industrial processes and in adhesives and grouts. According to the agency, many laboratory animal studies have indicated degenerative peripheral nerve changes from repeated oral exposures as well as impaired male reproductive performance and genetic damage. The review also notes that the agency characterizes the chemical as "likely to be carcinogenic to humans" on

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the basis of dermal and drinking-water exposure in rats. According to the review, occupational exposure studies "are sufficient to firmly establish neurological impairment as a potential health hazard from inhalation and dermal exposure."

USDA Inspector General Report Finds Gaps in Organic Program Oversight

The U.S. Department of Agriculture's Office of Inspector General (OIG) has published a March 2010 audit **report** recommending several improvements to the National Organic Program (NOP) administered by the Agricultural Marketing Service (AMS). "We conducted the audit because of the size and growth of the organic industry as well as the public's increased interest in purchasing organic products," stated the report, which faulted NOP for failing to enforce program requirements when "serious violations" occurred and for lax implementation of certification standards.

In particular, OIG found that the program (i) did not resolve 19 of 41 complaints "within a reasonable timeframe"; (ii) needs to address ongoing compliance and enforcement issues with California's State Organic Program; (iii) did not implement periodic pesticide residue testing as required by the Organic Foods Production Act of 1990 (OFPA); (iv) did not assemble a peer review panel "to annually evaluate their accreditation process"; (v) did not ensure "consistent oversight of organic operations by certifying agents"; and (vi) did not complete timely onsite reviews for five of the 44 foreign certifying agents because it failed to establish adequate timeframes for these activities. In addition to resolving these issues, OIG has tasked the agency with strengthening enforcement procedures "to determine what actions should be imposed on program violators, including civil penalties, and to timely issue the appropriate actions."

AMS has reportedly agreed to these findings, including the directive to begin spot testing organic produce for residues. According to the agency's response, "NOP is planning to implement periodic residue testing by accredited certifying agents by September 2010." The program director has also requested a written legal opinion from the Office of General Counsel on whether the regulations are consistent with OFPA, noting that NOP will initiate rulemaking in December 2010 if necessary. *See The New York Times,* March 19, 2010.

USDA Sponsors Food Safety Conference; CSPI Calls for Improvements to Outbreak Reporting

During a U.S. Department of Agriculture-sponsored food safety education conference in Atlanta this week, government, industry and academic speakers addressed a range of issues, including the causes of food borne illness, data collection and analysis, consumer behavior, food recalls, and food-service workforce training. Caroline Smith DeWaal, food safety director with the Center for Science in the Public Interest (CSPI), spoke during the March 23-26, 2010, event to **explain** that nearly half the states do a poor job of tracking outbreaks.

Contending that better local and state reporting of food-borne illness outbreaks could hasten life-saving food recalls, Smith DeWaal apparently called for support of the FDA Food Safety Modernization Act, currently pending in the Senate, which

would require the Food and Drug Administration (FDA) to improve the coordination of federal, state and local surveillance systems. The measure, already approved in the House, would also reportedly establish a national testing-laboratory network, improve the epidemiological tools available to the states and integrate food-borne illness surveillance with other bio-surveillance capabilities. *See CSPI Press Release*, March 24, 2010.

USDA Proposes Rule to Enhance Safety of Meat, Poultry Products

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has issued a **proposed rule** designed to enhance the safety of meat and poultry products.

The proposal would require that regulated establishments (i) promptly notify FSIS if any unsafe, unwholesome or "misbranded meat or poultry product has entered commerce"; (ii) "prepare and maintain current procedures for the recall of meat and poultry products produced and shipped by the establishment"; and (iii) "document each reassessment of the establishment's process control plans, that is, its Hazard Analysis and Critical Control Point plans."

According to a March 25, 2010, *Federal Register* notice, the proposed rule is needed because (i) "FSIS believes that prompt notification that adulterated or misbranded product has entered commerce is an important prerequisite for effective action to prevent such product from causing harm"; (ii) "having established procedures will help establishments to conduct effective and efficient recalls, should it be necessary for them to do so" and (iii) "records of reassessments will help establishment and Agency personnel to assess the adequacy and appropriateness of what has been done." Comments are due by May 24, 2010. *See USDA News Release,* March 25, 2010.

U.S. Codex Delegates Schedule Meeting to Discuss Food Labeling

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has **announced** an April 7, 2010, public meeting to discuss draft U.S. positions for the 38th Session of the Codex Committee on Food Labeling (CCFL) slated for May 3-7, 2010, in Quebec City, Canada. Issues to be discussed include (i) "Labeling Provisions in Draft Codex Standards"; (ii) "Implementation of the WHO Global Strategy on Diet, Physical Activity, and Health," which includes consideration of the "List of Nutrients That Are Always Declared on a Voluntary or Mandatory Basis," and the legibility and readability of nutrition labeling; (iii) "Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods"; (iv) "Labeling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/ Genetic Engineering"; and (v) "Discussion Paper on the Need to Amend the General Standard for the Labeling of Prepackaged Foods in Line with the International Organization of Legal Metrology (OIML)." *See Federal Register,* March 25, 2010.

California Schedules Public Forum on Potential Listing of BPA as Reproductive Toxin; Workshop on NOEL Regulatory Changes Also Scheduled

Cal/EPA's Office of Environmental Health Hazard Assessment (OEHHA) has **scheduled** an April 20, 2010, public forum on its proposal to list bisphenol A (BPA) as a reproductive toxin under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). The action was taken in response to a request for a public forum to present oral comments. OEHHA has also decided, in response to a request, to extend the written comment period on the proposal until May 13, 2010. Prop. 65 requires that businesses provide "clear and reasonable" warnings for exposures to listed chemicals before exposure and prohibits their discharge into drinking water sources.

OEHHA has also **announced** that it will conduct an informal public workshop on April 14 to discuss proposed amendments to regulations that "set out the procedures and criteria for determining an exposure level where there would be no observable effect." Under Prop. 65, warnings are not required and the discharge provisions are not applicable "if an exposure one thousand (1,000) times higher than the level that is actually occurring would still not cause any observable effect." Among the changes proposed would be removing a regulatory provision allowing a party to seek court approval of an alternative "no observable effect level" (NOEL) to that established by regulation. Comments should be submitted by April 28.

LITIGATION

Federal Court Dismisses Excess-Giblet Litigation

A federal court in Illinois has dismissed with prejudice the second amended complaint filed in putative class litigation alleging that a chicken processing company violated state consumer fraud and protection laws by selling its whole chickens with the extra giblets that it cannot sell with its cut-up chicken portions or as pet food. *Nieto v. Perdue Farms, Inc.*, No. 08-07399 (U.S. Dist. Ct., N.D. Ill., E. Div., filed March 17, 2010).

According to the complaint, the defendant placed more than one heart, liver, gizzard, or neck in the whole chickens the company sold, thereby increasing the total weight of a whole chicken and "effectively forcing consumers to subsidize [defendant's] costs of disposing of the extra giblets." The named plaintiff also alleged that the company concealed its policy of including the extra offal when communicating with customers "through advertising generally and at the point of sale."

Finding that it had jurisdiction over the claims under the Class Action Fairness Act, the court analyzed the sufficiency of plaintiff's complaint under the heightened pleading standard of *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), and Federal Rule of Civil Procedure 9, which requires that averments of fraud be stated with particularity. According to the court, the plaintiff alleged that the company "knew and fraudulently concealed and/or intentionally failed to disclose . . . that Perdue was passing off its excess giblet waste." Yet, the plaintiff "alleges no facts supporting this claim, rather only stating that her experience—finding extra giblets in one chicken—and

'her attorney's investigation . . . reveal the passing off of extra giblets on consumers is not an isolated event but a policy and/or procedure which is an accepted means of giblet disposal by Perdue.'" Because the plaintiff "failed to plead with specificity the who, what, where, when, and how of the alleged fraud," the court found she failed to state a claim for fraud under state law. With her unjust enrichment claim and request for declaratory relief dependent on her insufficient claims of fraud, the court dismissed these claims as well.

The court dismissed the litigation with prejudice because the plaintiff had been given repeated opportunities to amend and had "failed to remedy the same deficiency." The court stated, "to permit further amendments would be futile."

District Court Orders *Pelman* Parties to Refile Class Certification Pleadings

The U.S. district court judge now presiding over the obesity-related claims in *Pelman v. McDonald's Corp.* has ordered the parties to refile a number of documents previously submitted on motions addressing class certification. *Pelman v. McDonald's Corp.*, No. 1:02cv7821 (U.S. Dist. Ct., S.D.N.Y., order entered March 24, 2010). Among the documents the court has requested are the defendant's motion for an order striking the class allegations in plaintiffs' second amended complaint and plaintiffs' cross motion to certify a class and motion for an order further denying the defendant's motion to strike.

Filed in 2002 and appealed twice to the Second Circuit Court of Appeals, this litigation seeks damages for the obesity-related health conditions of teenagers who contend they were misled by fast food advertising. Claims that the food consumed in defendant's restaurants caused the plaintiffs' health problems are no longer in the case.

Complaint Filed Against Walnut Seller for Omega-3 Health Claims

A New York resident has filed a putative class action against Diamond Foods, Inc. in a California federal court alleging that the company labeled its walnuts with false claims that "consumption of the omega-3 fatty acids in walnuts promotes heart health and lowers the risk of coronary heart disease." *Zeisel v. Diamond Foods, Inc.*, No. CV10-1192 (U.S. Dist. Ct., N.D. Cal., filed March 22, 2010). The plaintiff seeks to certify a nationwide class of consumers who purchased the company's shelled walnut products since March 19, 2006, and claims that he relied on the product labels to make his purchasing decision.

The complaint alleges unlawful, unfair and fraudulent business practices; false advertising; violation of California's Consumers Legal Remedies Act; and unjust enrichment. The plaintiff seeks an order certifying the class, restitution of either the amounts paid to purchase the products or the company's profits from the transactions, an order enjoining further misleading advertisements, attorney's fees, costs, and interest. The complaint alleges that the Food and Drug Administration rejected health claims for walnuts in 2004 and cites the letter the agency sent to the company in February 2010 warning that its products were misbranded. The plaintiff

is represented by law firms different from the one that was soliciting plaintiffs with claims against Diamond; more details about that initiative appear in issue 341 of this Update.

Insurance Carrier Seeks Reimbursement for Defense Costs in Diacetyl Litigation

Old Republic Insurance Co. has filed a lawsuit in a New York state court, seeking a declaration that it is entitled to reimbursement for the costs it has incurred defending a company that distributed diacetyl and has been sued with other companies for personal injuries allegedly sustained from exposure to the butter-flavored chemical. *Old Republic Ins. Co. v. The Travelers Indemnity Co.*, No. 10103533 (N.Y. Sup. Ct., filed March 18, 2010). According to the complaint, some 21 active lawsuits are currently pending against Old Republic's insured, Citrus & Allied Essence, Ltd. The carrier claims that it has successfully defended the company for three years at a cost of more than $1 million in cases where other carriers, including one that is now insolvent, share coverage and defense responsibilities.

EU Settles WTO Dispute with Argentina over Biotech Agriculture

The European Union (EU) and Argentina have apparently reached an agreement in a dispute before the World Trade Organization (WTO) involving genetically engineered products and the application of biotechnology to agriculture. The agreement, which provides for the establishment of a regular dialogue on these issues, follows a similar agreement the EU struck with Canada, which, along with Argentina and the United States, challenged the EU's legislation on biotech products.

The WTO dispute settlement body previously found that the EU violated international agreements by applying a general de facto moratorium on the approval of genetically modified organisms (GMOs) from 1999 to 2003 and imposing undue delays on the approval of 23 product-specific applications. The WTO also found that six member states failed to base their national safeguard measures on appropriate risk assessment.

According to EU Trade Commissioner Karel De Gucht, "This is the second settlement regarding the WTO case on GMOs that is reached. This is certainly a recognition by Canada and Argentina as much as the EU that the best approach to this complex issue is a regular dialogue. I hope the United States, the only remaining WTO complainant in this dispute, will soon come to the same conclusion." An EU press release noted that while the agreement does not affect EU procedures for approving the import of biotech products, an exchange of information is viewed as a way to minimize potential obstacles to trade among countries with different GMO regulatory regimes. *See EU Press Release*, March 18, 2010.

OTHER DEVELOPMENTS

IOM Announces Meeting on Food Labeling, Issues Report on Obesity Prevention Workshop

The Institute of Medicine (IOM) has announced an April 9, 2010, open workshop to continue its review of front-of-package (FOP) nutrition rating systems and symbols. As tasked by the Food and Drug Administration and Centers for Disease Control and Prevention, IOM established a committee to evaluate and report on "the use of symbols, logos, and icons to communicate nutritional information on the front of food labels." At the forthcoming open session, the committee will gather information on both international and domestic nutrition rating systems and symbols. Scheduled speakers include representatives from (i) the U.K Food Standards Agency (FSA), (ii) the American Heart Association, (iii) ConAgra Foods, the General Mills Bell Institute of Health & Nutrition and Unilever, and (iv) Texas A&M University, the University of Maryland, the University of Washington, and the Yale Prevention Research Center. In addition, New York University Professor Marion Nestle will address concerns about nutrition rating systems and other perspectives on FOP labeling. Details about the committee's first public workshop, held February 2, 2010, appear in issue 336 of this Update.

Meanwhile, IOM recently published a **report** summarizing an October 22, 2009, workshop that discussed obesity prevention policies with U.K. and U.S. health experts. Titled "Perspectives from the United Kingdom and United States Policy Makers on Obesity Prevention," the workshop featured representatives FSA, the U.S. Department of Agriculture (USDA) and other government agencies and health organizations. The presenters reportedly "spoke about policies and programs that are addressing the obesity epidemic across sectors, developing partnerships to leverage limited resources, and drawing on available evidence to promote healthy behaviors." They also called for more research and for continued cooperation across public and private sectors, focusing on: (i) the use of government structures currently situated to address obesity; (ii) school meal policies; (iii) physical activity and the built environment and access to healthy foods; (iv) national programs such those implemented by the USDA and FSA; and (v) state and local policies, including menu labeling laws in New York City.

MEDIA COVERAGE

USDA Survey Generates Buzz on Honeybee Health

The U.S. Department of Agriculture's (USDA's) Bee Research Laboratory has released the preliminary **results** of a survey estimating that honeybee colony losses nationwide "were approximately 29 percent from all causes from September 2008 to April 2009," touching off speculation about the fate of the ubiquitous pollinator. Federal investigators reported that only 15 percent of all colonies lost during the 2008/09 winter apparently died of colony collapse disorder (CCD), leading USDA to emphasize "the urgent need for research" on general honeybee health. "It's just gotten so

much worse in the past four years," USDA Research Leader Jeff Pettis was quoted as saying. "We're just not keeping bees alive that long."

According to media sources, apiary experts have blamed the honeybee die-off on a combination of viruses, bacteria and pesticide residues. In particular, beekeepers have cited a March 19, 2010, study published in *PLoS One* that reportedly identified at least one systemic pesticide in three out of five pollen and wax samples from 23 states. Although the U.S. Environmental Protection Agency (EPA) has apparently registered serious concern over the issue, a recent op-ed in *The New York Times* simply urged farmers to cultivate fewer crops that are entirely dependent on domesticated or wild bee pollination. "The paradox is that our demand for these foods endangers the wild bees that help make their cultivation possible," maintain the writers, who explain that there aren't enough domesticated bees to meet agricultural demand while taking up the slack for their wild cousins where it is needed most. "Thus a vicious cycle: Fewer pollinating bees reduce yield per acre—and lower yield requires cultivation of more land to produce the same amount of food." *See The Associated Press,* March 24, 2010; *The New York Times,* March 25, 2010.

SCIENTIFIC/TECHNICAL ITEMS

Study Linking HFCS to Obesity Draws Criticism from Health Experts

A recent study involving both short- and long-term animal experiments has purportedly linked high-fructose corn syrup (HFCS) to significant weight gain in rats. Miriam Bocarsly, et al., "High-fructose corn syrup causes characteristics of obesity in rats: Increased body weight, body fat and triglyceride levels," *Pharmacology, Biochemistry and Behavior,* March 2010. According to a March 23, 2010, Princeton University press release, researchers have "demonstrated that all sweeteners are not equal when it comes to weight gain: Rats with access to high-fructose corn syrup gained significantly more weight than those with access to table sugar, even when their overall caloric intake was the same."

In the short-term experiment, the authors reported that "male rats given water sweetened with [HFCS] in addition to a standard diet of rat chow gained much more weight than male rats that received water sweetened with table sugar, or sucrose, in conjunction with the standard diet." Moreover, the long-term experiment allegedly suggested that when "compared to animals only eating rat chow, rats on a diet rich in [HFCS] showed characteristic signs of a dangerous condition known in humans as the metabolic syndrome, including abnormal weight gain, significant increases in circulating triglycerides and augmented fat deposition, especially visceral fat around the belly." The accompanying press release hypothesized that, due to molecular differences between HFCS and sucrose, "excess fructose is being metabolized to produce fat, while glucose is largely being processed for energy or stored as a carbohydrate, called glycogen, in the liver and muscles."

Meanwhile, several health experts have already questioned the study and its interpretation of the results, highlighting several discrepancies and inconclusive data sets. As New York University Professor Marion Nestle responded in a March 24, 2010, *Food Politics* blog post, "The study is extremely complicated and confusingly described." In particular, she stated that the results of the first experiment, which involved giving male rats access to either sucrose or HFCS for 12 hours per day, were not borne out when rats were fed HFCS for 24 hours per day. These rats, "which should be expected to be fatter," in fact "weighed less (470 grams) than the rats fed sucrose for 12 hours per day," Nestle pointed out. In addition, she noted (i) that the second experiment was not a comparison but "just looked at the effects of HFCS in groups of 8 male rats," and (ii) that researchers could not replicate the outcome of the first experiment using female rats. "So I'm skeptical," she concluded. "I don't think the study produces convincing evidence of a difference between the effects of HFCS and sucrose on the body weight of rats. I'm afraid I have to agree with the Corn Refiners on this one." *See The Los Angeles Times,* March 24, 2010.

In a related development, a recent study has reportedly claimed that fructose can worsen the severity of liver scarring in patients with nonalcoholic fatty liver disease (NAFLD). Manal Abdelmalek, et al., "Increased fructose consumption is associated with fibrosis severity in patients with nonalcoholic fatty liver disease," *Hepatology,* March 2010. Duke University researchers apparently surveyed the dietary intake of 427 NAFLD patients, finding that "only 19 percent of adults with NAFLD reported no intake of fructose-containing beverage, while 52 percent consumed between one to six servings a week and 29 percent consumed fructose-containing beverages on a daily basis." Noting that NAFLD is present in 30 percent of U.S. adults, the lead author claimed to have "identified an environmental risk factor that may contribute to the metabolic syndrome of insulin resistance and the complications of the metabolic syndrome, including liver injury." *See Duke University Press Release,* March 18, 2010.

Study Claims Last Supper Food Portions Grew for 1,000 Years

A new study asserts that the food portions depicted in paintings of the Last Supper as chronicled in the New Testament of the Bible linearly increased for 1,000 years. Brian and Craig Wansink, "The largest Last Supper: depictions of food portions and plate size increased over the millennium," *International Journal of Obesity,* March 23, 2010. Authored by sibling scholars, the study examined 52 of the most artistically significant depictions of the Last Supper between the year 1000 and the year 2000, although Craig Wansink was quoted as saying the period of artwork considered ended about 1900 because few non-parodic Last Suppers have been created since then.

Using the size of the diners' heads as a basis for comparison, the Wansinks determined that the relative sizes of the main course increased by 69.2 percent, bread by 23.1 percent and plates by 65.6 percent. "I think people assume that increased serving sizes, or 'portion distortion,' is a recent phenomenon," Brian Wansink said. "But this research indicates that it's a general trend for at least the last millennium."

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The Wansinks contend that the various versions of the Last Supper in all likelihood offer an accurate peephole into portion size because the artists' attention was on religious themes. "Whether it was an artist working in 1200 or 1600, the main focus is probably not what's on the table," Brian said, adding that the amount of the food and size of the plates are what the artist thinks is appropriate "given the time and context in which he lives." *See U.S. News & World Report* and *Chicago Tribune,* March 23, 2010.

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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.