Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

IOM Report Faults FDA for Piecemeal Approach to Risk Management

The Institute of Medicine (IOM) has issued a June 2010 report claiming that the Food and Drug Administration (FDA) "continues to be reactive, lacking a systematic focus on prevention." According to a June 8, 2010, press release, IOM has advised FDA to adopt a "risk-based model" that involves increased coordination "with state and other federal agencies that share responsibility for protecting the nation's food supply." The institute has also called on Congress to amend the Food, Drug, and Cosmetic Act "to explicitly provide the authority FDA needs to fulfill its food safety mission."

Enhancing Food Safety: The Role of the Food and Drug Administration apparently provides a blueprint for overhauling FDA, which IOM criticized in a report brief for continuing to address problems "on a case-by-case basis." Its recommendations include integrating food safety programs and public education, enhancing the efficiency of the inspection process, and modernizing legislation in an effort to reorganize the food safety system.

In particular, IOM has urged government to (i) "establish a centralized food safety data center outside the regulatory agencies"; (ii) delegate food facility inspections to the states; (iii) implement national standards for state and municipal safety programs; and (iv) "detail FDA's authorities in facility registration, preventive controls, risk-based inspection, mandatory recall, reporting of adulteration, and banning of food imports if the public's health is at risk." As the IOM report brief concludes, "Until the recommended changes are implemented, the FDA and the federal government will lack the process, capabilities, and structure needed to properly evaluate decisions that will ultimately ensure the safety of the nation's food."

FTC Gets Tough with Kellogg over Immunity Claims; Company Agrees to New Restrictions

The Federal Trade Commission (FTC) last week announced that Kellogg Co. has agreed to resolve an "investigation into questionable immunity-related claims for Rice Krispies cereal."

The agreement reopens a prior order involving Kellogg's® Frosted Mini-Wheats®; the FTC will now require "substantiation for all health claims for any food" based on

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"competent and reliable scientific evidence," defined as "tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results."

According to the concurring statement of Commissioner Julie Brill and FTC Chair Jon Leibowitz, the company was "developing its questionable Rice Krispies campaign last year [while] it was simultaneously negotiating with the FTC to resolve earlier allegations that the company had deceptively marketed Frosted Mini-Wheats as improving children's attentiveness."

The concurring statement also notes, "What is particularly disconcerting to us is that at the same time that Kellogg was making promises to the Commission regarding Frosted Mini-Wheats, the company was preparing to make problematic claims about Rice Krispies." The statement concludes, "We hope that the Commission action announced today communicates to industry that it has an obligation to be honest with the public, and that the FTC will act swiftly to challenge questionable health claims about children's food products. Our kids and parents deserve no less."

The company apparently claimed that Frosted Mini-Wheats cereal was "clinically shown to improve kids' attentiveness by nearly 20%," and then marketed its Rice Krispies cereal as a product that "now helps support your child's immunity." Under the 2009 settlement order, the company was prohibited "from making claims about the benefits to cognitive health, process, or function provided by any cereal or any morning food or snack food unless the claims were true and substantiated." Now any product-related claims involving health benefits must be backed by scientific evidence and not be misleading. *See FTC Press Release*, June 3, 2010.

FTC Seeks Comments on Deceptive Marketing Research

The Federal Trade Commission (FTC) has **announced** that it is submitting to the Office of Management and Budget its intention to study consumer susceptibility to fraudulent and deceptive marketing. The commission plans to conduct an "economic laboratory experiment" with 250 subjects to better target its enforcement actions and consumer education initiatives, and to improve future fraud surveys. The study, which will be conducted by a George Mason University faculty member, was previously announced but failed to generate any public comments.

FTC plans to study whether "several decision-making biases, such as impulsivity, over-optimism, and loss aversion, that can cause inaccurate assessments of the risks, costs, and benefits of various choices," are related to consumers' vulnerability to unfair and deceptive marketing claims. The commission will study the subjects' assessment of potentially deceptive and non-deceptive advertisements and their ability to differentiate between seemingly fraudulent and legitimate advertisements. FTC requests public comments by July 8, 2010. *See Federal Register*, June 8, 2010.

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USDA Announces Ambitious Honey Bee Research Initiative

The U.S. Department of Agriculture (USDA) has announced an ambitious research effort "to determine the prevalence of parasites and disease-causing microorganisms that may be contributing to the decline of honey bee colonies nationwide." According to a June 7, 2010, news release, the agency's Animal and Plant Health Inspection Service (APHIS) and Agricultural Research Service (ARS) will join Pennsylvania State University in surveying 350 apiaries across 13 states: Alabama, California, Georgia, Indiana, Florida, Hawaii, Michigan, New York, Pennsylvania, South Dakota, Tennessee, Texas, and Washington. Scientists will reportedly test the beehives for "specific pests and pathogens," particularly a foreign mite of the genus Tropilaelaps.

Noting that beekeepers currently provide pollination services for more than 90 commercial crops, USDA has registered a precipitous decline in honey bee populations since the 1980s. Researchers have apparently blamed the decline on numerous factors that include colony collapse disorder as well as newly introduced pests and diseases caused by viruses, bacteria and fungi. The survey will help regulators "better understand the factors threatening our honey bees so we can take effective action to protect them and the crops that they pollinate," stated USDA Secretary Tom Vilsack.

APHIS Seeks Comments on GM Sugar Beet Assessment

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has published a **notice** of its intent to prepare an environmental impact statement (EIS) on genetically modified (GM) sugar beets. The agency had previously deregulated sugar beets genetically modified for glyphosate resistance without preparing an EIS and was ordered in September 2009 by a federal court in California to prepare one after its action was challenged by organic seed and nonprofit organizations. The court concluded that the environmental assessment which APHIS prepared failed to consider a number of environmental and related economic impacts of the GM crops.

Thus, APHIS is planning to prepare an EIS and requests public comment by June 28, 2010, on the potential issues and reasonable alternatives it intends to include. Among those issues identified in the notice are data on production levels of organic and conventional sugar beets and other crops by region, state and county; potential impacts of GM sugar beet cultivation on livestock production and on food and feed; weed management practices for organic sugar beet systems; the cumulative impact on the development of glyphosate-resistant weeds; and the potential for gene flow from GM sugar beets to other species. *See Federal Register*, May 28, 2010.

FSIS Seeks Input on Food Safety Standards for Codex Consideration

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has **announced** the 33rd Session of the Codex Alimentarius Commission slated for July 5-9, 2010, in Geneva, Switzerland. FSIS seeks public comments before the meeting on "those standards that are currently under consideration or planned for consideration and recommendations for new standards." The standards that will be put

forward for approval during the commission meeting include those concerned with food contaminants, additives, pesticide residues, analysis and sampling methods, import and export inspections, labeling, hygiene, fish and fishery products, milk and milk products, fats and oils, and processed fruits and vegetables.

Also slated for consideration in Geneva is the status of the Codex Strategic Plan, the impact of private standards and the management of the "Trust Fund for the Participation of Developing Countries and Countries in Transition in the Work of the Codex Alimentarius." Before the general commission meeting, the Codex Executive Committee will meet June 29 to July 2 to conduct a "critical review" of Codex standards, review a study on the speed of the Codex standard-setting process and evaluate issues appearing in Codex committee reports. Information about current U.S. government positions on pending Codex standards can be obtained from FSIS. *See Federal Register*, June 4, 2010.

European Commission Adopts Recommendations for Monitoring Acrylamide in Food

The European Commission (EC) has adopted **recommendations** for member states to monitor acrylamide levels in food as a way to obtain a consistent reduction of the known carcinogen found in a number of food categories.

The recommendations, adopted June 2, 2010, urge member states to provide acrylamide monitoring information to the European Food Safety Authority (EFSA) by June 1 of each year starting in 2011.

The new recommendations call for member states to measure acrylamide levels based on sampling procedures developed in 2007 and suggest that sampling be carried out before products' expiration date and "at market level," which means in supermarkets, smaller shops, bakeries, "French fries outlets," and restaurants "where there is good traceability," or at production sites. The recommendations set the minimum number of samples that each member state should analyze across 10 categories: ready to-eat French fries; potato crisps; pre-cooked French fries and potato products for home cooking; soft bread; breakfast cereals; biscuits, crackers, crisp bread and similar products; coffee and coffee substitutes; baby foods, other than processed cereal based; processed cereal-based foods for infants and young children; and other products. *See Official Journal of the European Union*, June 2, 2010.

Health Canada Says BPA in Canned Foods Poses No Risk; Germany Advises Manufacturers to Find Alternatives

Health Canada's Bureau of Chemical Safety has released a **survey** of bisphenol A (BPA) in canned foods that finds low rates of exposure and no risk to public health. Researchers apparently examined samples from 78 domestic and imported canned food products, including pastas, soups, tomato paste, tuna, and vegetables. The results indicated that canned tuna products and condensed soups had "the highest BPA levels, in general," while tomato paste had levels that were "considerably lower."

According to Health Canada, these findings "are consistent with those of past surveys and are not considered to represent a human health concern." The agency,

however, reiterated its commitment to working with the food packaging industry "to better identify the factors which may influence BPA migration to food, with a goal to limit human exposure to BPA to the greatest extent possible."

In a related development, Germany's environmental agency, Umweltbundesamt (UBA), has advised manufacturers, importers and consumers to find alternatives to BPA "that pose less risk to human health and the environment." Claiming that the substance "acts like the female hormone oestrogen," a June 9, 2010, UBA press release urges the public to avoid BPA "for reasons of precaution" and announces the availability of a background report titled ***Bisphenol A – a chemical with adverse effects produced in large quantities***. The report apparently maintains that "numerous studies" have linked BPA to disruptions in the "hormone system of mammals and aquatic organisms."

Meanwhile, Consumers Union (CU) has welcomed the paper "for declaring that in order to protect human health, the use of [BPA] in certain products should be limited and that consumers should chose [sic] safer alternatives." In a June 9 statement, the U.S. watchdog also noted pending local, state and federal legislation designed to ban BPA in all food and beverage containers. "Consumers Union believes that there is enough scientific evidence to date to warrant a ban on BPA in all food contact products now," said CU Technical Director for Policy Urvashi Rangan.

UK Environment Secretary Endorses GM Crops

The United Kingdom's environmental secretary has reportedly endorsed genetically modified (GM) crops, making the current Department for Environment, Food and Rural Affairs the most supportive of GM crops to date. In contrast to the previous government's unwillingness to back what some apparently fear are "Frankenstein foods," Secretary Caroline Spelman told a news source that she was in favor of GM foods "in the right circumstances." Modifying plant genes could reduce the amount of chemicals needed to raise food crops, she said. "GM can bring benefits in food to the marketplace," Spelman was quoted as saying. "There are benefits to developing countries, like drought resistance or resistance to high salt content in water. The principle of GM technology is [OK] if used well. The technology can be beneficial." *See The Guardian,* June 4, 2010.

OEHHA Withdraws Amendment Proposal on Calculating "Safe Harbor" Levels

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) recently **announced** that it is withdrawing a regulatory proposal to amend several provisions of the Proposition 65 (Prop. 65) implementing regulations that establish procedures for calculating "safe harbor" levels for listed chemicals. The public comment period on the proposal closed May 28, 2010. According to OEHHA, "significant changes will be made to the proposal," thus it is being withdrawn. Chemicals on the Prop. 65 list are those known to the state to cause cancer or pose reproductive health risks. Manufacturers of products containing these chemicals must provide notice to consumers or risk the imposition of penalties.

LITIGATION

Master Recommends Denying Class Certification Motion in Ground Beef *E. Coli* Case

A federal magistrate in New York has recommended that the district court deny the class certification motion filed by plaintiffs who allege either personal or economic injury from the purchase of frozen ground beef products purportedly tainted with *E. coli*. *Patton v. Topps Meat Co.*, No. 07-CV-00654 (U.S. Dist. Ct., W.D.N.Y., recommendation entered May 27, 2010). The defendants include the meat processor and a number of retailers, and the claims are based on a 2007 recall involving more than 20 million pounds of ground beef. Forty cases of *E. coli* infection in eight states were allegedly traced to the product. The plaintiffs sought to certify two nationwide classes of those who consumed the product and have personal injury claims and those who purchased the products subject to the recall and allege economic losses.

Because specific causation, that is, "whether the contaminated meat caused the personal injuries of the individual class members," would require an individualized assessment of the evidence, the master found that the typicality requirement for class certification could not be met as to the personal injury class. According to the master, each plaintiff will have to prove that the meat caused his or her illness, and just because someone experienced diarrhea is insufficient to establish causation. The master also found that the proposed class members could not fairly and adequately protect the interests of the class because each "will be preoccupied with establishing their own individual claims to the detriment of the other class members. Because none of the proposed class representatives tested positive for E. coli, they will likely have to focus more of their efforts at establishing causation than other potential injury class members who may have tested positive for E. coli."

The master disagreed with the plaintiffs that the defendants had insufficient assets or insurance to cover the claims of putative class members and thus, determined that they failed to satisfy their burden of establishing a limited fund. And the master disagreed with the plaintiffs that New York law would apply to their claims. According to the master, the argument that defendants should have been expected to be held liable under New York law, "ignores the expectations of the potential plaintiffs—who span 45 states—as to whether New York law would apply to their claims." The master found that common questions of law and fact did not predominate.

As to certification of the economic injury class, the master noted a split in authority as to whether an out-of-court refund program is a method of adjudication under Federal Rule of Civil Procedure 23 and can be superior to a proposed consumer class. Following authority within the circuit, the master found that the refund program was superior. The parties will have until June 14, 2010, to file any objections to the master's report and recommendation.

MDL Court Limits Discovery in BPA Plastic Products Litigation

The multidistrict litigation (MDL) court before which cases alleging a failure to disclose the possible harmful effects of plastic bottles containing bisphenol A (BPA) have been consolidated for pretrial proceedings has granted in part and denied in

part the plaintiffs' discovery motion. *In re: Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig.,* MDL No. 1967 (U.S. Dist. Ct., W.D. Mo., W. Div., order entered May 26, 2010).

The plaintiffs apparently sought to compel the disclosure of information relating to products other than plastic bottles, such as "plastic eating utensils, plastic plates and other food contact items," and to non-health related information from more than five years before the lawsuit was filed. The court determined that it was too late to amend the complaint to include the manufacturers of the additional products, emphasizing that "this case was not intended to—and will not—become an all-encompassing 'BPA case.'" The court also found that the burden on defendants of complying with these requests could not be justified now that the products liability-related claims no longer remain in the case, stating that defendants' motivations in making competing product lines without BPA "have no bearing on the legal claims asserted in this case." The remaining claims are for unjust enrichment, statutory violations, fraudulent and negligent omissions of material fact, and implied warranty of merchantability.

The court agreed with the plaintiffs that admissible evidence could be discovered by requiring defendants to provide information about their decision to market their more recently-manufactured products as "BPA Free." According to the court, "there is a stark contrast between the manner in which Defendants have announced the *absence* of BPA and the manner in which they announced its *presence.* Plaintiffs are entitled to explore this issue and ascertain Defendants' knowledge and beliefs about appropriate and effective methods of communicating health and safety information to consumers."

Patent Marking Complaint Filed Against Kraft Foods

A Missouri resident has filed a complaint in federal court against Kraft Foods Inc., alleging that it has been marking its Kool-Aid® and Country Time Lemonade® drink mix packages with the U.S. patent numbers for container patents that expired in April 2008. ***Brown v. Kraft Foods Inc.*, No. 4:10-cv-1007 (U.S. Dist. Ct., E.D. Mo., filed June 1, 2010)**.

Claiming that the marking violates 35 U.S.C. § 292, the plaintiff seeks injunctive relief, "a civil monetary fine of $500 per false marking offense," costs, attorney's fees, and interest.

This litigation is one of a recent crop of false marking lawsuits to which the Federal Circuit Court of Appeals apparently opened the door when it ruled that the penalty could be imposed under the law on a per unit basis. Shook, Hardy & Bacon Intellectual Property Partner **Peter Strand** is focusing on false marking issues in his May and June *IpQ* newsletters. The May issue can be accessed **here**.

Settlement Announced in Egg Antitrust Litigation

A plaintiffs' firm has announced a $25 million partial settlement in an antitrust class action "brought on behalf of direct purchasers of shell eggs and egg products." *In re: Processed Eggs Antitrust Litigation,* MDL No. 2002 (U.S. Dist. Ct., E.D. Pa.). According to

Hausfeld LLP, plaintiffs alleged "a near industry-wide, price-fixing conspiracy among egg farmers which raised the price of shell eggs and egg products in violation of the Sherman Antitrust Act." The lawsuit specifically claimed that the United Egg Producers, United States Egg Marketers and other trade associations coordinated a conspiracy "to restrict egg supply through cage space requirements, as well as coordinated molting schedules and hen reductions, and exported eggs at a loss in order to reduce domestic supplies and raise prices."

The three settling defendants—Land O'Lakes, Inc., Moark, LLC, and Norco Ranch Inc.—have reportedly agreed "to provide significant cooperation to the plaintiffs as they pursue their claims against the remaining, non-settling defendants." The settlement has yet to be approved by the court. *See Hausfeld LLP Press Release,* June 7, 2010.

OTHER DEVELOPMENTS

"Big Food" Critic Skeptical of Industry Promises to Make Healthier Products

Public health attorney and author Michele Simon has authored an article that calls disingenuous at least one food company's promise to support first lady Michelle Obama's Let's Move campaign to end childhood obesity. Simon targets PepsiCo, which has publicly supported the campaign and also makes sweetened beverages, energy drinks and salty snack foods. The company's CEO has reportedly indicated that it is investing in new sweeteners and salt-reduction technologies to improve its products. According to Simon, this means "the company is hard at work trying to engineer healthy Cheetos." She concludes, "PepsiCo makes processed food, which is no basis for proper diet in any culture. Nature provides true nourishment in the form of whole grains, fruits, and vegetables, and no corporate mantra can improve on that." *See AlterNet*, June 2, 2010.

Consumer Reports Claims Some Protein Drinks Laden with Lead

Consumers Union (CU) has issued the results of its investigation into protein drinks, concluding that many products are at best superfluous and at worst unsafe. Published in the July 2010 edition of *Consumer Reports,* the findings allegedly support the watchdog's position that Food and Drug Administration (FDA) oversight under the Dietary Supplement Health and Education Act "is inadequate to ensure that protein drinks and other dietary supplements are consistently low in heavy metals and other contaminants."

CU apparently conducted outside laboratory tests on 15 protein powders and drinks purchased in the New York-metro area, in addition to reviewing government documents and interviewing health experts and consumers. According to CU, "All drinks in our tests had at least one sample containing one or more of the following contaminants: arsenic, cadmium, lead, and mercury." In three cases, consumers who drank more than three servings per day purportedly risked exceeding the U.S. Pharmacopeia's exposure limits for arsenic, cadmium or lead. As *Consumer Reports* noted, "The amount of lead in a single daily serving of eight of the protein supplements we

tested would require that the products carry a warning in California."

Further suggesting that multiple toxins could have "synergistic" health effects, the report cites one expert who registered concern about the "pregnant women, children and young adults" targeted by some companies' marketing claims. "For most people, protein drinks are not the only possible source of exposure to heavy metals, but they are an easily avoidable one, since most people can meet their protein needs, help minimize exposure to contaminants, and save money by choosing the right foods," opines CU, which calls on Congress to adopt legislation geared toward improving dietary supplement regulation.

MEDIA COVERAGE

Jim Prevor, "Aggrandizing the FDA Only Distracts from Real Solutions," *The New Atlantis,* May 21, 2010

The man who authors *The Perishable Pundit* blog warns in this article that food safety legislation currently pending in Congress that would give the Food and Drug Administration (FDA) mandatory recall authority fails to address the issues that could have a real impact on addressing the problem of food contamination. He argues that absolute food safety is an unattainable goal given the vagaries of nature and the extreme and costly measures that producers would have to undertake to stop pathogens from entering the system.

He sets forth a six-point plan to improve the government's approach to food safety: (i) "Switch to a Negligence Standard from a Strict Liability Standard, and Switch Primary Liability to the Trade Buyer"—Prevor claims this would give producers the incentive to invest in best practices and force buyers, with "a whole new interest in food safety," a reason to pay more for the safest products; (ii) "Root Out Bribery and Corruption in Food Safety Certification"—Prevor contends that government inspectors are not doing their jobs in the United States; (iii) "Invest in State Health Laboratories"—according to Prevor, too many states do not have labs that can adequately identify food-borne illness; (iv) "Invest in Food Safety Research"; (v) "Revitalize the Ag Extension Service"; and (vi) "Educate Consumers About Food Safety."

As to the latter, Prevor suggests that the best way to reduce food-borne illness is to educate consumers on "how to properly clean, separate, cook, and chill foods." As an example, he notes that potatoes in themselves are almost immune from food safety issues, but when prepared as potato salad, continue to sicken many. He contends that FDA officials continue to make vague and general recommendations as to best practices rather than adopting specific proposals because "the recommendation would be no more than an attempt to juggle our imperfect knowledge of pathogen prevention with the realities of the world's need for not only safe food but also plentiful and affordable food. No matter what standard was set, one day some creature would go under the FDA-specified fence, or over it or through it, leaving the agency itself responsible."

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 352 | JUNE 11, 2010

SHB IN THE NEWS

SHB Attorneys Featured in *Feedstuffs*

The industry newspaper *Feedstuffs* has profiled Shook, Hardy & Bacon's Agribusiness & Food Safety Practice in a June 7, 2010, special report on supply chain management and front-of-package (FOP) labeling. *Feedstuffs* writer Rod Smith interviewed attorneys Mark Anstoetter, Christopher McDonald, Madeleine McDonough, and Sarah Sunday about the firm's litigation background and "considerable expertise in areas critical to the food supply chain, like agroterrorism/crisis management, biotechnology, environmental sustainability, food safety and compliance, legislative and regulatory work."

The article particularly notes the arsenal of engineers, biologists, toxicologists, and other professionals who track these issues on behalf of clients at every link in the food supply chain. "[W]e attempt to help them manage risk from the time a food product is produced until it's consumed," McDonough was quoted as saying. "We connect all the dots—all the expertise."

Sunday discussed regulatory developments in FOP labeling, which has recently come under Food and Drug Administration scrutiny. She suggested "that better models could focus more on calories and serving sizes," according to Smith. "Sunday said FOP labels would be positive for fresh meat and poultry because meat and poultry have positive nutritional profiles—low in carbohydrates, fat and sodium, etc."

To view the special report, please click here.

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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.