

FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

OMB Completes Review of Proposal to Remove Saccharin from Hazardous Substances List

The White House Office of Management and Budget (OMB) has reportedly completed its review of the U.S. Environmental Protection Agency's (EPA's) proposal to take saccharin off its list of hazardous substances and wastes. The action will apparently allow EPA to grant a six-year-old industry petition claiming that scientific data suggest the artificial sweetener is "not as harmful as once thought." EPA, which is expected to seek public comment on its proposed de-listing in April 2010, has apparently found that the "current weight of scientific evidence supports the petitioner's request." The substance was placed on EPA's list when it was created in 1980 because the Food and Drug Administration had previously determined that saccharin was a potential human carcinogen. The National Toxicology Program removed it from its own list of carcinogens in 2000. *See InsideEPA.com*, January 5 and March 10, 2010.

New York Senator Urges Adoption of Dairy COOL Act

U.S. Senator Kirsten Gillibrand (D-N.Y.) has responded to a recent recall of melamine-tainted milk from China by urging her peers to pass country-of-origin labeling (COOL) legislation ([S.B. 1783](#)) for all dairy products sold in the United States. Introduced by Al Franken (D-Minn.) as the Dairy COOL Act of 2009, the bill would extend current labeling requirements for nuts, fruits, vegetables, meats, and seafood to milk, cheese, yogurt, ice cream, and butter. "We must do more to protect consumers and provide a competitive edge to New York dairy farmers," Gillibrand said in a March 3, 2010, press release. "All consumers have the right to know whether the milk, yogurt and cheese that we buy are made in Upstate New York or China." *See Dairy Reporter.com*, March 4, 2010.

The International Dairy Foods Association (IDFA) in 2009 registered opposition to the proposal, which is still under consideration by the Senate Committee on Agriculture, Nutrition, and Forestry. "Imposing additional labeling mandates on dairy products, which are not imposed on other processed foods, will reduce demand for dairy products and encourage food manufacturers to substitute vegetable-based or other protein ingredients instead of dairy ingredients," said one IDFA spokesperson. *See IDFA Labeling & Standards Statement*, October 19, 2009.

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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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DOJ Opens Series of Antitrust Workshops to Consider Concentration in Agriculture Sector

The Department of Justice (DOJ) was scheduled to begin a series of antitrust workshops March 12, 2010, in Iowa, to hear from agricultural interests about consolidation and competition in the industry. The workshops have drawn considerable commentary, with some focusing on the biotechnology giants that control most of the patented soybean and corn seeds in the country and others suggesting that small family farms are being excluded from the proceedings.

The consumer advocacy organization Food & Water Watch launched a petition drive calling on supporters to encourage DOJ to "break the monopolies." According to the organization's outreach director, four companies process more than 85 percent of U.S. beef cattle, two companies sell 50 percent of U.S. corn seed, one company controls 40 percent of the U.S. milk supply, and five companies "dominate the grocery sector."

Focusing on competition in the seed, dairy, poultry, beef, and crop industries, the hearings, which will run through December 2010, have been characterized by *The Wall Street Journal* as an "unusual step" by "Justice's tight-lipped antitrust division." Scheduled to attend the first workshop are Attorney General Eric Holder, his antitrust chief Christine Varney and U.S. Department of Agriculture (USDA) Secretary Tom Vilsack. Varney apparently decided to conduct such hearings when she was nominated for her position and several farm-state legislators expressed concerns about the Bush administration's approach to agricultural mergers. Vilsack was quoted as saying, "Seed technology is pretty heavily consolidated." And while noting that he was not "taking sides," he said, "What I'm really concerned about is farmers getting a fair shake."

According to one news source, Monsanto has been a DOJ target. At least one of its patented genes is used in 90 percent of the soybeans grown in the United States and in about 80 percent of all U.S. corn. Industry groups deny that consolidation leads to price fixing, although some commentators, such as retired rural sociologist Bill Heffernan, who has been focusing on concentration in agriculture for 20 years, suggests that when fewer than five companies control the majority of a food processing sector, "They don't have to go down to the lounge to talk about price fixing," rather they simply follow each others' lead in what they pay farmers and what they charge retailers and consumers.

Meanwhile, a coalition of grassroots groups and nonprofits were reportedly planning to conduct a town hall the day before the first workshop; they claim that "family farmers, consumer advocates, and organized labor are underrepresented on the panels at the DOJ/USDA anti-trust workshop." A fourth generation family farmer was quoted as saying, "The corporate control of our food system by multinationals . . . is devastating to consumers, farmers, workers, and the environment." An advocacy organization known as Pesticide Action Network North America reportedly wrote to Varney on March 8 supporting the workshops, but complaining that "only limited time has been allocated for public comments." The letter also states, "We believe the current agenda severely limits time for the DOJ and USDA to hear viewpoints from communities directly impacted by growing concentration in the seed industry,

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vertical integration, lack of market transparency, and shift in buyer power within the agriculture industry." See *Findlaw.com, Associated Press*, March 8, 2010; *La Vida Locavore*, March 10, 2010; *The Wall Street Journal, Food & Water Watch Alert*, March 11, 2010.

GAO Report Criticizes FDA for Lax Oversight of GRAS Foods

The U.S. Government Accountability Office (GAO) recently released a [report](#) criticizing the Food and Drug Administration's (FDA's) oversight of food ingredients determined to be generally recognized as safe (GRAS). Noting that companies are not required to submit their GRAS determinations to regulators, GAO examined whether FDA can vouch for these substances, which increasingly include nanomaterials. The report apparently concludes that not only does FDA's oversight process fail to ensure the safety of both new and preexisting GRAS determinations, but it allows engineered nanomaterials to enter the food supply without the agency's knowledge.

According to the report, FDA "has not systematically reconsidered GRAS substances since the 1980s," nor has it responded to "concerns about GRAS substances, such as salt and the *trans* fat in partially hydrogenated vegetable oils, that individuals and consumer groups have raised through 11 citizen petitions submitted to the agency between 2004 and 2008." The findings also fault FDA for relinquishing the additional authority needed to directly regulate nanomaterials used in GRAS substances. "In contrast to FDA's approach, all food ingredients that incorporate engineered nanomaterials must be submitted to regulators in Canada and the European Union before they can be marketed," states a parallel GAO summary.

The report makes several recommendations to strengthen the GRAS determination process, urging FDA to adopt several obligatory requirements in lieu of voluntary measures. GAO has specifically called on FDA (i) "to require any company that conducts a GRAS determination to provide FDA with basic information" about the substance's identity and intended uses; (ii) "to minimize potential conflicts of interest" by asking GRAS notices to verify the independence of expert panels; (iii) "to monitor the appropriateness of companies' GRAS determinations through random audits"; (iv) "to finalize the rule that governs the voluntary notification program" first proposed in 1997; and (v) "to ensure the safety of engineered nanomaterials" by requiring companies "to inform FDA if their GRAS determinations involve engineered nanomaterials." In addition, the report tasks officials with treating GRAS reassessments "in a more systematic manner, including taking steps such as allocating sufficient resources to respond to citizen petitions in a timely manner, developing criteria for the circumstances under which the agency will reconsider the safety of GRAS substance, and considering how to collect information from companies on their reconsiderations." See *GAO Summary*, February 3, 2010.

FDA Says Flavoring Maker Knew Product Was Contaminated with *Salmonella*

Food and Drug Administration (FDA) inspectors issued a report March 4, 2010, stating that Basic Food Flavors, Inc., the Las Vegas-based company at the center of a massive and growing food recall, "continued to distribute HVP [hydrolyzed vegetable protein] paste and powder products" for nearly a month after receiving

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the first lab results “indicating the presence of Salmonella in your facility.” While no illness has apparently yet been attributed to the HVP, it is used in dozens of products. As of March 11, FDA had [identified](#) some 150 products containing HVP, including bouillon, dressing and dressing mixes, frozen foods, ready-to-eat meals, sauces and marinades, snacks and snack mixes, soups, soup mixes and dip mix products, and stuffings.

According to some quality management specialists, this outbreak could be particularly challenging because HVP is considered a generic commodity; it can be purchased from many different suppliers, stored without an effective tracking system for particular sources or batches and is generally not listed on food products as an ingredient. While FDA has reportedly indicated that the chances of any consumers getting sick are low because the affected foods are usually cooked before packaging, *salmonella* infection can be fatal for young children and those with weakened immune systems. The U.S. Department of Agriculture has apparently recalled 1.7 million pound of ready-to-eat beef taquito and chicken quesadilla products containing HVP.

Food writer and activist Marion Nestle only recently turned her attention to the recall, “because the FDA seems on the job and nobody is getting sick (as far as we know),” but changed her mind, saying it “looks like another food safety scandal,” because HVP is in everything, the company knew it had a *salmonella* problem, and it took six days for FDA to convince Basic Food Flavors to issue a recall. Nestle said, “Do we need more evidence that the FDA needs the authority to order recalls? And when is Congress going to get around to passing the food safety bill? . . . Undoubtedly, this situation is frustrating for the FDA. But it is downright dangerous to us. It’s time to scream at Congress to act.”

One news source indicates that FDA found out about the contamination through its new reportable food registry, which allows companies to report suspected contamination. One of Basic Food Flavors’ customers apparently made the initial report that prompted FDA’s investigation, which found unsanitary conditions, plant construction that does not “allow floors to be adequately cleaned and kept clean and kept in good repair” and inadequate plumbing. See *The Wall Street Journal*, March 9, 2010; and *USA Today*, *The Washington Post*, *Food Politics.com*, *MSNBC.com*, March 10, 2010.

FSIS Holds Meeting to Discuss *E. Coli* Traceability Standards

The U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) held a March 10, 2010, public [meeting](#) to discuss agency procedures “for identifying suppliers of source material used to produce raw beef product that FSIS has found positive for *Escherichia coli* (*E. coli*) O157:H7.” FSIS announced the meeting as part of its ongoing efforts to evaluate “the effectiveness of its policies and procedures in responding to findings that raw beef is positive for *E. coli* O157:H7.” In particular, FSIS intends to issue “new instructions to Enforcement, Investigations, and Analysis Officers (EIAOs) to conduct additional verification activities at suppliers in response to positive *E. coli* O157:H7 results.” The agency will accept public input on these issues until May 7, 2010. See *FSIS Press Release*, March 3, 2010; *Federal Register*, March 8, 2010.

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U.S. Codex Delegates Schedule Meetings to Discuss General Principles, Contaminants in Food

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has [announced](#) a March 23, 2010, public meeting to discuss draft U.S. positions for the 26th Session of the Codex Committee on General Principles (CCGP) slated for April 12-16, 2010, in Paris, France. Issues to be discussed include (i) "Draft Revised Code of Ethics for International Trade in Foods"; (ii) "Review of the Risk Analysis Policies of Codex Committees"; (iii) "Definition of the Term 'Competent Authority'"; and (iv) "Discussion Paper on the Development of Joint Codex and World Organization for Animal Health Standards."

FSIS has also [announced](#) a March 29, 2010, public meeting to discuss draft U.S. positions for the 4th Session of the Codex Committee on Contaminants in Food (CCCF) slated for April 26-30, 2010, in Izmir, Turkey. Agenda items include proposed draft maximum levels for melamine in food and feed and a priority list of contaminants and naturally occurring toxicants proposed for evaluation by the Joint FAO/WHO Expert Committee on Food Additives. See *Federal Register*, March 5, 2010.

EFSA Issues Opinion on Hundreds of "General Function" Health Claims

The European Food Safety Authority (EFSA) recently published a second series of opinions on a list of "general function" health claims for foods. EFSA's Panel on Dietetic Products, Nutrition and Allergies assessed the scientific data submitted to substantiate more than 400 hundred health claims; its opinions are forwarded to the European Commission and member states, which ultimately decide whether to authorize the claims. Among other matters, the panel generally allowed adequately supported claims related to vitamins and minerals, but rejected "probiotic" and "anti-oxidant properties" claims for lack of information and evidence. EFSA apparently expects to complete its work by 2011, depending on the final number of claims received. See *EFSA News Release*, February 25, 2010.

Swiss Reject Proposal to Appoint Lawyers for Abused Animals

While the city of Zurich reportedly employs a lawyer to represent animals in cases alleging abuse or excessive cruelty to animals, Swiss voters have overwhelmingly rejected a measure that would have expanded the practice throughout the country. Some 70.5 percent of the electorate defeated a proposal that would have required paying 25 or more lawyers to prosecute humans on behalf of abused animals. Some have attributed the outcome to recent press reports that Zurich's animal advocate was involved in prosecuting an angler who boasted that it took him some time to reel in a 22-pound pike. The angler was charged with and prosecuted for causing excessive suffering to the animal, but later acquitted. Although the pike story attracted numerous animal rights fans, many Swiss apparently did not believe that fish need legal representation. See *The Guardian*, March 5, 2010; *The New York Times*, March 8, 2010.

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Battle over Soft Drink Taxes Gains Momentum

Facing budget shortfalls in the upcoming fiscal year, several state and city legislatures are reportedly considering a tax on sugar-sweetened beverages. Kansas Senator John Vratil (R-Leawood) this week proposed a bill ([S.B. 567](#)) that would tax such products, including energy and sports drinks, at the rate of one penny per teaspoon of sugar. According to its proponents, the measure would add a dime to the cost of a typical 12-ounce soft drink and raise approximately \$90 million per year. "The thinking is No. 1, we need money," Vratil was quoted as saying. "But perhaps just as importantly, obesity is a real, growing problem." See *The Kansas City Star*, March 9, 2010.

In addition, Philadelphia Mayor Michael Nutter has introduced a FY 2010-11 [budget](#) that includes a 2-cent-per-ounce tax on the distribution of sugary drinks. Media sources have apparently likened the measure to current excise taxes or the 10 percent "liquor-by-the-drink" tax. "Multiple studies have demonstrated a link between sugar-sweetened beverages and obesity, and if the costs are fully passed on to consumers, consumption is expected to decrease," states Nutter's proposal, which estimates that the levy will raise \$38.6 million annually for city coffers. See *Philly.com*, March 3, 2010.

Meanwhile, New York Governor David Paterson (D) has reiterated the plan outlined in his proposed [FY 2010-11 Executive Budget](#) to raise \$650 million by "imposing a syrup excise tax on unhealthy beverages." According to news sources, the proposal faces opposition but could pass because the legislature must reject the entire budget to kill the tax. "It's not a separate bill that can just be left to die," wrote Monica Potts, an associate editor for *The American Prospect* magazine on March 11, 2010. "Lawmakers would have to come up with alternative revenues or cuts to offset the loss if the proposal is jettisoned—a tough proposition given the existing \$9 billion budget gap." See *Crain's New York Business*, March 9, 2010.

Speaking at a March 8, 2010, symposium sponsored by the New York Academy of Medicine and other state health groups, Paterson also cited the "\$7.6 billion the state spends every year to treat disease from obesity." His appeal has since been echoed by New York City Mayor Michael Bloomberg, who urged legislators to adopt a 1-cent-per-ounce tax. "An extra 12 cents on a can of soda would raise nearly \$1 billion, allowing us to keep community health services open and teachers in the classroom. And, at the same time, it would help us fight a major problem plaguing our children: obesity," opined Bloomberg on his weekly radio program. See *The New York Times*, March 7, 2010; *Reuters* and *The New York Times*, March 8, 2010.

These initiatives, however, have drawn criticism from industry proponents who warn that the tariffs will negatively affect consumers and businesses without reducing obesity rates. In particular, the American Beverage Association (ABA) has warned that the Philadelphia measure "will threaten 2,000 well-paying beverage industry jobs" in the area, as well as hurt local grocers "by driving sales outside the city limits." Moreover, as one ABA spokesperson argued, "Singling out soft drinks and other foods for taxation in order to reduce obesity won't solve this public health problem and could lead to unintended consequences, especially for lower and middle income Americans."

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ABA has specifically criticized a recent study claiming that local, state and federal taxes on soft drinks and pizza “may be effective mechanisms to steer U.S. adults toward a more healthful diet and help reduce long-term weight gain or insulin levels over time.” Kiyah Duffey, et al., “Food Price and Diet and Health Outcomes: 20 Years of the CARDIA Study,” *Annals of Internal Medicine*, March 2010. Researchers apparently relied on dietary information supplied by 5,115 participants in the 20-year Coronary Artery Risk Development in Young Adults (CARDIA) study. Although the study only “examined a small handful of 11 foods and beverages,” according to ABA, it nevertheless concluded that an 18 percent tax on soda and pizza could lead to an average annual weight loss of five pounds per person. A concurrent editorial also noted that revenues from these surcharges could be used to promote health education and awareness initiatives. “Copying a successful tactic of anti-tobacco crusaders, the funds could also be used to counter the lavish advertising of soda and junk food or for ‘marketing’ ordinary tap water,” wrote the editorial authors. See *ABA Press Releases*, March 4 and 8, 2010; *Los Angeles Times* and *Reuters*, March 8, 2010.

New York Assembly Considers Banning Sodium in All Restaurant Foods

New York Assemblyman Felix Ortiz (D-Brooklyn) has reportedly introduced legislation ([A.B. A10129](#)) that would bar restaurants from using salt “in any form” during food preparation. According to the bill, which cites the World Health Organization, “three quarters or more of the sodium intake in the United States comes from processed or restaurant foods.” Proposing to fine restaurants \$1,000 for each violation, the law aims to “give customers the option to add salt after the meal has been prepared for them,” allowing them “more control over the amount of sodium they intake, and... the option to exercise healthier diets and healthier lifestyles.”

Meanwhile, the legislation has drawn swift criticism from consumers, nutritionists, restaurateurs, and chefs, the latter of whom have noted the important chemical role of salt in baked goods and other dishes. “Chefs would be handcuffed in their food preparation, and many are already in open rebellion over this legislation,” said one spokesperson for My Food My Choices, a coalition opposed to government action on the issue. “Ortiz and fellow anti-salt zealot Mayor Michael Bloomberg of New York City seek to undermine the food and restaurant business in the entire state.” See *The New York Times*, March 10, 2010; *My Fox New York* and *Times Union Tablehopping Blog*, March 11, 2010.

OEHHA Extends Public Comment Period on Prop. 65 Listing of Fungicide

California EPA’s Office of Environmental Health Hazard Assessment (OEHHA) has [extended](#) until April 7, 2010, the public comment period on its proposal to add epoxiconazole, a triazole fungicide used on coffee beans and bananas grown outside the United States, to the state’s Proposition 65 (Prop. 65) list of chemicals known to cause cancer or reproductive harm. According to OEHHA, the U.S. Environmental Protection Agency has identified the chemical as likely to be carcinogenic to humans. If the fungicide is added to the list, warnings will have to be provided to California consumers purchasing products containing the substance. See *OEHHA News*, March 8, 2010.

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LITIGATION

Eighth Circuit Finds Some Poultry Processing Facility Losses Not Covered by Insurance

The Eighth Circuit Court of Appeals has determined that certain business expense claims and a personal property claim made by a poultry processor for damages sustained during a break in electrical service caused by an ice storm were not covered by the processor's insurance policy. [*George's Inc. v. Allianz Global Risks US Ins. Co., No. 09-2220 \(8th Cir., decided March 9, 2010\)*](#). The insurer paid the processor's claims for lost business income and extra expenses totaling more than \$300,000, but refused to pay \$155,000 in fixed labor and overhead costs and \$30,000 for chickens that died in the processor's holding shed.

The court agreed with the insurer that the refused claims were subject to exclusions under the insurance policy, rejecting the processor's contentions that (i) its labor and overhead costs were extra expenses because the processor experienced an increase in cost-per-pound when the business disruption caused it to process less chicken relative to its fixed expenses; and (ii) the chickens in the holding shed should be treated as processing stock, subject to a limited work-in-progress exclusion, rather than "animals," which were excluded from personal property coverage altogether.

Some Claims Dismissed in Dispute over Supply-Chain Insurance Coverage

A federal court in California has dismissed without prejudice some of the claims filed by a food supplier in a dispute over insurance coverage in food-contamination litigation. [*Nat'l Surety Corp. v. Pacific Int'l Vegetable Mktg., Inc., No. 09-4898 \(U.S. Dist. Ct., N.D. Cal., decided March 5, 2010\)*](#).

A fast food restaurant was sued for injuries purportedly linked to food-borne contamination, and it filed a third party complaint against the company that supplied the lettuce which allegedly caused the outbreak. The supplier turned to the lettuce grower's insurer to defend it under a policy that was supposed to include the supplier as an additional insured pursuant to an agreement between the supplier and grower. The insurer refused to defend the claims, and the supplier sued the agent purportedly responsible for adding the supplier to the insurance policy for breach of contract, breach of the covenant of good faith and fair dealing, breach of fiduciary duty and other tort duties (negligence, misrepresentation and breach of warranty).

The agent sought to dismiss the claims for misrepresentation, breach of fiduciary duty and breach of warranty. The court dismissed the claims for misrepresentation (including the breach-of-warranty claim) and the claim for fiduciary duty, finding that the former had been pleaded with insufficient specificity and the latter contained insufficient allegations of a fiduciary relationship between the supplier and agent. The supplier apparently indicated that it did not intend at this point to amend its complaint, so the court ordered the agent to respond to the complaint by March 23, 2010, noting that its ruling did not bar the supplier from subsequently seeking leave to reassert the dismissed claims.

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Pelman "Obesity" Lawsuit Reassigned Yet Again

Over the past two years, little has taken place in *Pelman v. McDonald's Corp.*, the putative class action litigation brought in 2002 on behalf of obese and overweight teenagers who alleged that the fast food restaurant is responsible for their weight-related health conditions. On March 10, 2010, the case was reassigned to U.S. District Court Judge Donald Pogue. Since Judge Robert Sweet recused himself in 2008 from the case he had heard through two trips to the U.S. Court of Appeals, the matter has been passed to three different judges. Currently pending before the court is plaintiffs' motion to certify the class. *Pelman v. McDonald's Corp.*, 1:02cv7821 (U.S. Dist. Ct., S.D.N.Y., filed September 30, 2002).

Law Firm Seeks Potential Plaintiffs Who Purchased Foods Targeted by FDA

Lieff Cabraser Heimann & Bernstein, LLP, a national plaintiffs' law firm recognized for its products liability and complex litigation practice, has posted information about the Food and Drug Administration's (FDA's) recent warning letters to food companies about the health-related claims they make for their products. Focusing on Diamond Foods walnuts, POM Wonderful 100% Pomegranate Juice and Nestlé Juicy Juice products, the firm calls for consumers who have purchased the products "based on the claims made" by the companies to submit their complaints for review at no charge. More information about the FDA's letters warning the companies to cease making unsubstantiated health-related claims appears in issue 340 of this Update. See *LieffCabraser.com*.

Jury Awards Arkansas Rice Farmer Damages for GM Crop Contamination

According to a news source, a state court jury has awarded an Arkansas rice farmer more than \$1 million in litigation alleging that a genetically engineered (GE) rice crop contaminated the nation's rice supply, leading to Japanese and European restrictions on U.S. imports and a precipitous drop in rice prices. *Kyle v. Bayer Crop-Science LP*, No. n/a (Woodruff County Cir. Ct., Ark., verdict rendered March 8, 2010). The verdict included both compensatory and punitive damages. A spokesperson for the defendant reportedly indicated that the company disagreed with the decision and is considering its legal options. The company continues to maintain that it acted responsibly and appropriately. See *Arkansas Democrat-Gazette*, March 10, 2010.

EU High Court Adviser Rules Argentine Soy Meal Not Protected by EU Patent on GE Soybeans

A European Court of Justice adviser has determined that Monsanto Co. cannot seek royalties from a company that imported from Argentina soy meal containing residues of Monsanto's patented gene. Case C-428/08, *Monsanto Tech. LLC v. Cefetra BV* (Op. of Advocate Gen. Mengozzi, delivered March 9, 2010). Monsanto has no patent on its Roundup Ready® soy beans in Argentina. In 2005 and 2006, the company had shipments of soy meal from Argentina impounded in Amsterdam harbor, and testing showed that it contained some of the seed traits that Monsanto has patented in the European Union (EU). The company then sued the importers for infringement, and a Dutch court hearing the dispute sought guidance from the EU tribunal.

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Disagreeing with Monsanto, which argued that its EU patent covers the DNA sequence, the adviser opined that under Directive 98/44, “a DNA sequence must be regarded as protected, even as a self-standing product, only where it performs the function for which it was patented.” After harvest, the code is no longer active in its purpose of resisting the application of glyphosate, the pesticide that Roundup Ready® seed is engineered to resist. Because “the patented DNA sequence does not perform any function within the soy meal,” the adviser determined that EU patent protection could not be extended to it, stating, “It seems to me that the interpretation proposed by Monsanto would ultimately lead the holder of a biotechnological patent to be granted too wide a range of protection. . . . [I]t is not possible to say for how long, or up to which stage of the food and derived product chain, traces of the original DNA of the genetically modified plant are still identifiable. Plainly, those sequences no longer perform any function, but their very presence means that an unspecified number of derivative products would come under the control of the person who had patented the DNA sequence of the plant.”

Monsanto reportedly expressed disappointment with the decision; a spokesperson indicated that the company would await the court’s final decision, expected within six months of the adviser’s opinion. According to the company, “The only reason we have this case is because of a very arbitrary and controversial decision 15 years ago to throw out all existing patent applications in Argentina. We have tried to find ways to be properly compensated for quite a while. This was one of those steps.” See *BusinessWeek*, March 9, 2010; *Courthouse News Service*, March 11, 2010.

OTHER DEVELOPMENTS

CSPI Faults Most Food, Entertainment Companies for Food Marketing to Kids

The Center for Science in the Public Interest (CSPI) has issued a [report card](#) that rates 128 companies for their policies on marketing food to children. According to CSPI, most of the food makers, restaurants and entertainment companies failed “either for having weak policies or for failing to have any policies whatsoever.”

Based on research conducted in summer 2009, the report found that industry spends some \$2 billion on youth marketing annually.

Grades in the “Report Card on Food-Marketing Policies” ranged from a B+ for Mars, Inc., for its policy to exclude marketing to children ages 12 and younger, to an F for Denny’s “for marketing to children through its children’s menu, which includes many nutritionally poor items; games on its Web site; and a kid’s birthday club.” In all, seven of the companies earned a D, and 95 received an F.

“Despite the industry’s self-regulatory system, the vast majority of food and entertainment companies have no protections in place for children,” said CSPI’s nutrition policy director in a March 9, 2010, press release. “If companies were marketing bananas and broccoli, we wouldn’t be concerned. But instead, most of the marketing is for sugary cereals, fast food, snack foods, and candy. And this junk food is a major contributor to childhood obesity.”

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SCIENTIFIC/TECHNICAL ITEMS

Study Claims BPA Exposure May Cause Permanent Fertility Defects

Researchers at Yale School of Medicine have reportedly claimed in a new study that exposure to the food packaging chemical bisphenol A (BPA) during pregnancy can cause permanent abnormalities in the uterus of offspring, including altering their DNA. Jason G. Bromer, et al, "Bisphenol-A exposure *in utero* leads to epigenetic alterations in the developmental programming of uterine estrogen response," *Journal of the Federation of American Societies for Experimental Biology* (March 2010).

According to a March 8, 2010, Yale University press release, the study is the first to show that BPA exposure permanently affects sensitivity to estrogen. Using two groups of mice, one exposed to BPA as a fetus during pregnancy and another exposed to a placebo, researchers examined gene expression and the amount of DNA modification in the uterus. Results showed that the mice exposed to BPA as a fetus had an exaggerated response to estrogens as adults, long after the exposure to BPA, and that the genes were permanently programmed to respond excessively to estrogen.

"What our mothers were exposed to in pregnancy may influence the rest of our lives," said lead researcher Hugh Taylor. "We need to better identify the effect of environmental contaminants on not just crude measures such as birth defects, but also their effect in causing more subtle developmental errors."

In another recent BPA [study](#), Swiss researchers examined exposure pathways for nine different consumer groups and reportedly found that infants up to 6 months old were the most exposed. Natalie von Goetz, et al., "Bisphenol A: How the Most Relevant Exposure Sources Contribute to Total Consumer Exposure," *Risk Analysis: An International Journal*, (January 29, 2010). Although the levels were "far below" safety limits set by European regulating authorities, they were of "the same order of magnitude as recently reported concentrations that caused low-dose health effects in rodents," according to the study.

The researchers found exposure to BPA decreased as people got older and called for more study into exposure through food packaging. "Our results suggest that the most important pathways for infants and children are the use of polycarbonate (PC) baby bottles and for adults and teenagers the consumption of canned food," the authors wrote.

Researchers Find Young Children Aware of Popular Brands

A recent psychology study has reportedly suggested that children younger than age 5 "have emerging knowledge of brands that are relevant in their lives." Anna McAllister and T. Bettina Cornwell, "Children's Brand Symbolism Understanding: Links to Theory of Mind and Executive Functioning," *Psychology & Marketing*, March 2010. Noting previous research suggesting that "brand symbolism understanding does not develop until 7 to 11 years of age," the study authors nevertheless found that younger children not only recognize brands, but are already beginning to understand brands "as social systems." McAllister and Cornwell first asked 38 children ages

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3 to 5 to identify brand-name logos for 50 brands across 16 product categories, including fast food. The researchers then interviewed 42 3-to-6 year olds to determine their brand symbolism understanding. "Surprisingly, there were children as young as 3 who were making very strong judgments when comparing McDonald's and Burger King," one author was quoted as saying. "If you have a feeling that your child is very mature socially, you might want to put some more effort into monitoring their TV time or access to advertisements, because those are the kids who are really taking a lot away when they see an ad." See *MSNBC.com*, March 9, 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.

