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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

FDA Denies Requests to Prohibit Use of Certain Antibiotics in Food Animals

After a coalition of advocacy organizations filed a lawsuit against the Food and Drug Administration (FDA) seeking an order compelling the agency to rule on 1999 and 2005 petitions that asked the agency to withdraw approval of certain antimicrobial drugs in food animal production, the agency finally acted. Information about the lawsuit appears in **Issue 396** of this *Update*.

According to November 7, 2011, letters addressed to the **Center for Science in the Public Interest** (CSPI) and **Environmental Defense**, "the Agency has decided not to institute formal withdrawal proceedings at this time and instead is currently pursuing other alternatives to address the issue of antimicrobial resistance related to the production use of antimicrobials in animal agriculture."

FDA contends that withdrawal proceedings can be protracted and consume significant agency resources. While the agency notes that it shares the petitioners' "concern about the use of medically important antimicrobial drugs in food-producing animals for growth promotion and feed efficiency indications," it is addressing the issue with draft industry guidance establishing the principle that such drugs "should be limited to those uses that are considered necessary for assuring animal health." Based on stakeholder feedback, "FDA believes that the animal pharmaceutical industry is generally responsive to the prospect of working cooperatively with the Agency to implement" the guideline principles.

CSPI Executive Director Michael Jacobsen expressed disappointment with FDA's response, stating, "The industry's irresponsible use of antibiotics in livestock increases the prevalence of antibiotic-resistant pathogens, and those germs can cause infections in humans that are difficult or impossible to treat. The industry has long failed to cooperate voluntarily, and the FDA should take binding action. Consumers cannot afford another decade of delay." *See CSPI Statement*, November 9, 2011.

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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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California Agency Changes Animal Cancer Conversion Calculation

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) has issued a **notice** addressing its amendment to "the calculation used to convert estimates of animal cancer potency to estimates of human cancer potency, which is used to calculate no significant risk levels for carcinogens listed under Proposition 65."

According to the notice, the amendment took effect November 11, 2011, and will change "the existing regulatory provision to a ratio of human to animal bodyweight to the one-fourth power for interspecies conversion and delete[] the provision giving specific scaling factors for mice and rat data."

OEHHA has also **announced** that its Carcinogen Identification Committee has been asked to consider whether Dibenzanthracenes should be added to the Proposition 65 list. These substances are ubiquitous polyaromatic hydrocarbons that are the product of incomplete combustion, and human exposure may occur from contaminated food or water. Public comments are requested by January 10, 2012.

In other action, OEHHA has **posted** "the comments of three external peer reviewers of the draft public health goal for perchlorate that was released for public comment in January 2011." The comments were submitted by researchers from the Oregon Health & Science University, University of North Texas Health Sciences Center and University of Rochester School of Medicine and Dentistry. Perchlorate exposure in the United States mostly occurs from ingestion of contaminated food or water. The chemical is used in a variety of chemical processes.

European Parliament Adopts Tighter Controls of Antibiotic Use in Livestock Farming

The European Parliament recently **adopted** a resolution calling for a ban on most uses of antibiotics in livestock. Noting that "superbugs" take the lives of approximately 25,000 people in Europe each year, the non-binding resolution urges the European Commission (EC) to "make legislative proposals to phase out the prophylactic use of antibiotics in livestock farming."

The European Union already bans antibiotics to boost animal growth, but the resolution addresses the need to prevent disease by keeping veterinary and human medicines as separate as possible. Among other things, the resolution urges the EC to prevent "last resort" antibiotics from being used in animals and allow the drugs only to be administered under licensed conditions combined with resistance monitoring.

"The growing ineffectiveness of antibiotics is already a serious problem today and a potential health time bomb in the future," said the Parliament's

Public Health Committee Chair Jo Leinen. "We need a clear EU and international strategy to prevent misuse in agriculture and medicine, as well as to encourage the development of new antibiotics." *See European Parliament Press Release,* October 27, 2011.

LITIGATION

Skeptical High Court Could Doom California Downer Livestock Law

Following **oral argument** before the U.S. Supreme Court on the validity of a California law that prohibits slaughterhouses from receiving, processing or selling nonambulatory animals, court watchers are predicting that the law will not survive the National Meat Association's preemption challenge. *Nat'l Meat Ass'n v. Harris*, No. 10-224 (U.S., argued November 9, 2011).

The Ninth Circuit Court of Appeals upheld the law, finding that the states may regulate "what kinds of animals may be slaughtered," despite express preemption language in the Federal Meat Inspection Act. Additional information about the Ninth Circuit's ruling appears in **Issue 344** of this *Update*.

According to news sources, the justices did not appear to accept the fine distinction adopted by the lower court. Under the federal law, federal inspectors are authorized to decide what to do with animals that cannot walk when they reach the slaughterhouse; in some cases, they determine that animals may be revived and slaughtered, and, in others, the inspectors order that animals be kept alive so they can be tested for contagious diseases. The state law is absolute; it requires immediate euthanasia of "downer" animals and bars their slaughter or sale.

Chief Justice John Roberts reportedly said, "When the federal law says you can (sell meat), that pre-empts the rule from the states that says you can't." Justice Stephen Breyer opined that the state law appeared to impose an "additional requirement (on) a federally inspected meat-packing facility." A ruling is expected before the end of the Court's current term, which concludes in June 2012. *See The Washington Post, The New York Times* and *Law360*, November 9, 2011; *San Francisco Chronicle*, November 10, 2011.

Insurers Need Not Defend Egg Producer Embroiled in Antitrust Litigation

The Seventh Circuit Court of Appeals has determined that liability insurers of a major U.S. egg producer have no obligation to defend it in class action lawsuits alleging that the egg producer conspired with others to keep the price of eggs artificially high. ***Rose Acre Farms, Inc. v. Columbia Cas. Co.*, No. 11-1599 (7th Cir., decided November 1, 2011)**.

Rose Acre Farms claimed that the antitrust actions sought damages falling under what the policies call "personal and advertising injury." The court disagreed, noting that the company tried to "connect its advertising to the antitrust suit in [a] convoluted manner." Because the antitrust complaints had nothing to do with trademark infringement, i.e., using another's advertising idea without permission, which is the conduct covered by the "advertising injury" provision, the court affirmed the lower court's ruling denying coverage.

$1.6 Million Awarded to Plaintiffs in GE Alfalfa Litigation

A federal court in California has entered an order granting the motion of conventional alfalfa farmers and environmental groups for an award of attorney's fees and costs in litigation that successfully challenged a U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) decision to de-regulate genetically engineered (GE) alfalfa without conducting an environmental impact statement under the National Environmental Policy Act (NEPA). *Geertson Seed Farms v. Johanns*, No. 06-01075 (U.S. Dist. Ct., N.D. Cal., decided November 8, 2011). While the U.S. Supreme Court ultimately reversed lower court rulings in the case as to the scope of relief granted, the core determination that APHIS had violated NEPA survived the appeal. Due to the "limited" nature of the plaintiffs' success, the court imposed a 10-percent reduction on their request and ordered a total award of $1.6 million. The defendant had argued that the plaintiffs were entitled to $829,422 only.

Asset Managers Seek End to Animal Rights Group Harassment

An asset management company has reportedly filed a lawsuit in a California state court against "Stop Huntingdon Animal Cruelty" (SHAC), an organization apparently dedicated to closing down a life sciences company that tests pharmaceutical, agricultural and veterinary products on animals, alleging that SHAC has targeted its employees for harassment because the company holds shares in a pharmaceutical company that does business with Huntingdon Life Sciences (HLS). According to BlackRock's complaint for injunctive relief, which also named three individuals as defendants, SHAC has held demonstrations at the homes of the money manager's employees, threatened them and terrified their children. SHAC's website purportedly displays images of the protests and "names the targeted employees for all the public to see."

The complaint also apparently contends that one of the defendants "has already been permanently enjoined by a California state court from among other things, any act of violence or making any threat of violence against any employee of the Regents of the University of California or protesting or demonstrating at the homes of such employees." Two other defendants are allegedly "being prosecuted criminally for their animal rights protests at the homes of employees of the University of California at Los Angeles." BlackRock

alleges that the FBI has identified SHAC as a terrorist group that is committed to driving HLS out of business by pursuing "tertiary targets, which are entities that have absolutely nothing to do with HLS but who have done business with one or more of SHAC's secondary targets." *See Courthouse News Service*, November 10, 2011.

OTHER DEVELOPMENTS

NIH Funds Global Center of Excellence on Childhood Obesity

The National Institutes of Health (NIH) has awarded the Johns-Hopkins Bloomberg School of Public Health $16 million "to establish a global center of excellence to address the childhood obesity epidemic." According to a Johns-Hopkins news release, the initiative will involve more than 40 investigators from 15 U.S. and international institutions to integrate basic science, epidemiology, nutrition, medicine, engineering, and environmental and social policy research, among other disciplines. Johns Hopkins University and other institutions will contribute an additional $4 million to the enterprise.

Founding Director Youfa Wang said, "The new Center will address many needs in the prevention and study of childhood obesity. This initiative will help create research and training opportunities that go beyond traditional methods, and on an unprecedented global scale." The center's focus will be on "studying the drivers of the childhood obesity epidemic and environmental and policy interventions," as well as providing "rapid-response grants to investigators in the field worldwide to obtain time-sensitive data on environmental and policy changes relevant to childhood obesity." *See Johns-Hopkins Bloomberg School of Public Health News Release*, November 10, 2011.

Willett & Ludwig Say 2010 U.S. Dietary Guidelines Still Don't Hit the Mark

Walter Willett, Department of Nutrition, Harvard School of Public Health, and David Ludwig, Department of Medicine, Children's Hospital (Boston), have co-authored a **perspective piece** in *The New England Journal of Medicine* titled "The 2010 Dietary Guidelines—The Best Recipe for Health?" While noting that some of the dietary guideline changes represent positive progress, they express concerns about "several components" lacking in "scientific foundation," such as burying a recommendation to limit sugar-sweetened beverages "deep in the guidelines" and continuing to recommend "three daily servings of dairy products, despite a lack of evidence that dairy intake protects against bone fractures and probable or possible links to prostate or ovarian cancers."

Among other matters, the authors suggest that stronger, clear, scientifically sound guidelines require (i) removing primary responsibility for their development from the U.S. Department of Agriculture, which has "conflicts of

interest . . . arising from its institutional mission to promote commodities," to the Centers for Disease Control and Prevention or the Institute of Medicine; (ii) providing more funds to ensure a "comprehensive scientific review"; (iii) conducting all development stages in open meetings; and (iv) writing "guidelines that explicitly state which foods should be consumed less by Americans to reduce risk for chronic disease."

Food Safety News Questions Ultra-Filtered Honey

A November 7, 2011, *Food Safety News* report has questioned the practice of filtering honey to remove pollen, alleging that "more than three-fourths of the honey sold in U.S. grocery stores isn't exactly what the bees produce." According to investigative reporter Andrew Schneider, the ultra-filtering process "is a spin-off of a technique refined by the Chinese" that makes it impossible to determine the honey's source. As a result, the U.S. Food and Drug Administration does not consider ultra-filtered products to be "honey," although it does not check domestic honey for pollen.

Food Safety News sent 60 honey samples bought in 10 states and Washington, D.C., to Texas A&M melissopalynologist Vaughn Bryant for pollen analysis. The results purportedly showed that 76 percent of samples bought at groceries stores had all the pollen removed, while 100 percent of samples from drugstores and 100 percent of individually packaged samples for restaurants contained no pollen. Bryant also reported "that every one of the samples… bought at farmers markets, co-ops and 'natural stores' like PCC and Trader Joe's had the full, anticipated, amount of pollen."

Some producers claiming to source their honey from U.S. and Canadian suppliers evidently told Schneider that ultra-filtering gives consumers "crystal clear" honey as desired, as well as increased shelf life. But American Honey Producers Association President Mark Jensen refuted these arguments, saying that removing pollen from honey "makes no sense" because it is costly and detracts from overall quality. "I don't know of any U.S. producer who would want to do that," he said. "In my judgment, it is pretty safe to assume that any ultra-filtered honey on store shelves is Chinese honey and it's even safer to assume that it entered the country uninspected and in violation of federal laws." *Food Safety News* is produced by plaintiffs' firm Marler Clark.

MEDIA COVERAGE

Are Cupcakes as Addictive as Cocaine?

According to *Bloomberg* reporters Robert Langreth and Duane Stanford, as researchers publish more studies suggesting that processed foods and sugary drinks have drug-like effects on the brain, "the science of addiction could become a game changer for the $1 trillion food and beverage industries."

In their November 2, 2011, article "Fatty Foods Addictive Like Cocaine in Growing Body of Scientific Research," the authors contend that if these types of foods and beverages "are proven to be addictive, food companies may face the most drawn-out consumer safety battle since the anti-smoking movement took on the tobacco industry a generation ago." While industry executives and lobbyists apparently refute these claims, insisting that people do not rob banks "to get the money to buy a candy bar or ice cream or pop," they are facing a growing body of studies suggesting that foods high in fat and sugar affect brain reward circuits in ways similar to drug use.

The article quotes Yale University Rudd Center for Food Policy & Obesity Director Kelly Brownell as saying, "This could change the legal landscape. People knew for a long time cigarettes were killing people, but it was only later they learned about nicotine and the intentional manipulation of it." Outlining the findings of a number of recent studies to support an addiction thesis, the authors note that food and beverage companies have begun offering healthier choices and insisting that voluntary measures are the best way to address obesity. The article concludes, "The same tactic worked for awhile, decades ago, for the tobacco industry, which deflected attention from the health risks and addictive nature of cigarettes with 'low tar and nicotine' marketing."

Meanwhile, *The Wall Street Journal's* Law Blog responded to the article with a reference to a recent *WSJ* story about the growing impact of child obesity on custody battles and asked, "What if those same parents had standing to sue the companies that make the high-sugar, high-fat foods their children ate?" Additional details about the child custody article appear in **Issue 416** of this *Update*. *See WSJ Law Blog*, November 3, 2011.

SCIENTIFIC/TECHNICAL ITEMS

RWJF-Funded Study Questions Impact of Soft Drink Bans in Schools

A recent study funded by the Robert Wood Johnson Foundation (RWJF) has suggested that school soft drink bans do little to curb sugar-sweetened beverage (SSB) consumption among adolescents. Daniel Taber, et al., "Banning All Sugar-Sweetened Beverages in Middle Schools," *Archives of Pediatrics and Adolescent Medicine,* November 2011. Researchers in 2004 and 2007 surveyed approximately 7,000 fifth and eighth graders from public schools in 40 states, concluding that "SSB consumption was not associated with state policy." In middle schools with no SSB policy and those that prohibited only soda sales, close to 30 percent of the students reported purchasing SSBs, including energy or fruit drinks, on campus. Moreover, the study found that state policies banning all SSBs in middle schools "appear to reduce in-school access and purchasing of SSBs but do not reduce overall consumption."

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"We found that banning only sodas does nothing to stop kids from buying sugary drinks at school," said one author with the University of Illinois (UIC) at Chicago's Bridging the Gap program. "Only when sales of all sugar-sweetened beverages—sodas, sports drinks and fruit drinks—were prohibited, did we see fewer students buying such drinks at school."

According to a November 7, 2011, UIC press release, the study authors also noted that additional strategies—"such as sugar-sweetened beverage taxes and regulations of food marketing aimed at children"—were needed to curtail SSB consumption outside school. "This study tells us that it will take comprehensive beverage policies to create a healthier school environment and decrease the amount of sugary beverages students purchase at school," another author was quoted as saying. "At the same time, it underscores the importance of policies that extend beyond schools to discourage consumption of sugary beverages—and encourage children to purchase and drink healthy beverages, like water, low-fat milk and 100% juice." *See The New York Times Well Blog,* November 7, 2011.

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FOOD & BEVERAGE LITIGATION UPDATE

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.