Shook, Hardy & Bacon L.L.P.

ISSUE 424 | JANUARY 27, 2012

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

House Proposal Would Establish Standard for Housing, Treatment of Egg-Laying Hens

Four members of the U.S. House of Representatives have introduced bipartisan legislation (**H.R. 3798**) that would provide "a uniform national standard for the housing and treatment of egg-laying hens." According to the bill's lead author, Representative Kurt Schrader (D-Ore.), the Egg Products Inspection Act Amendments of 2012 would also bring sustainability to the egg industry by avoiding a "problematic patchwork of state laws."

Noting that the proposed measure formalizes a 2011 agreement between the United Egg Producers and The Humane Society of the United States, Schrader said the proposal would require egg producers to nearly double the housing space allotted to egg-laying hens and make other "significant animal welfare improvements" within a 15- to 18-year phase-in period. More specifically, the legislation advocates (i) replacing conventional cages with "enriched colony housing systems" that feature perches, nesting boxes and scratching areas; (ii) labeling on egg cartons that discloses the method used to produce the eggs, such as "eggs from caged hens" or "eggs from hens in enriched cages"; (iii) limiting ammonia levels in henhouses; and (iv) prohibiting the sale and transport of eggs and egg products that do not meet these requirements. *See Press Release of Representative Kurt Schrader,* January 23, 2012.

USDA Revises School Lunch Standards

The U.S. Department of Agriculture (USDA) has issued a **final rule** updating the National School Lunch and School Breakfast Programs "to align them with the Dietary Guidelines for Americans." Effective March 26, 2012, the rule seeks to reduce childhood obesity by requiring schools to (i) "increase the availability of fruits, vegetables, whole grains, and fat-free and low-fat fluid milk in school meals"; (ii) "reduce the levels of sodium, saturated fat and *trans* fat in meals"; and (iii) "meet the nutrition needs of school children within their calorie requirements."

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According to USDA, the new standards reflect the recommendations of an Institute of Medicine expert panel as well as 132,000 public comments. Estimated to add $3.2 billion to school meal costs over five years, the final rule only partially implements the Healthy Hunger-Free Kids Act (HHFKA) of 2010, which also includes a mandate to set nutritional standards for foods and beverages sold in vending machines and other venues on school campuses.

Nevertheless, USDA Secretary Tom Vilsack praised the new school meal standards as "a critical step" in HHKFA's mission to improve childhood nutrition. "When it comes to our children, we must do everything possible to provide them the nutrition they need to be healthy, active and ready to face the future—today we take an important step towards that goal," he said. *See USDA Press Release*, January 25, 2012.

Meanwhile, a recent study has questioned the alleged association between childhood weight gain and the sale of soft drinks, candy bars, chips, and other competitive foods in schools. Jennifer Van Hook and Claire Altman, "Competitive Food Sales in Schools and Childhood Obesity: A Longitudinal Study," *Sociology of Education*, January 2012. Using data from the Early Childhood Longitudinal Study, Pennsylvania State University researchers reportedly concluded that "children's weight gain between fifth and eighth grades was not associated with the introduction or the duration of exposure to competitive food sales in middle school."

Noting that these findings "did not vary significantly by gender, race/ethnicity, or family socioeconomic status," the study's authors speculated that not only are dietary patterns "firmly established before adolescence," but that "middle school environments may dampen the effects of competitive food sales because they so highly structure children's time and eating opportunities." As a result, they concluded that the study despite its limitations "may prove disappointing for those seeking to design school-based interventions to improve children's health."

Codex Meeting Agenda Targets Pesticide Residues in Food, Feed

The U.S. Department of Agriculture's Food Safety Inspection Service and U.S. Environmental Protection Agency have **announced** a February 14, 2012, public meeting in Arlington, Virginia, to provide information and receive public comments on draft U.S. positions to be discussed at the 44th Session of the Codex Committee on Pesticide Residues (CCPR) on April 23-28 in Shanghai, China. CCPR is responsible for establishing maximum pesticide-residue limits in specific food items, food groups or in "certain animal feeding stuffs moving in international trade where this is justified for reasons of protection of human health." *See Federal Register,* January 23, 2012.

European Commission to Reform Data Protection Framework

The European Commission (EC) has **proposed** a new data protection framework seeking to streamline existing directives and strengthen individuals' online privacy rights. Titled "Safeguarding Privacy in a Connected World: A European Data Protection Framework for the 21st Century," the proposed regulations would provide "a single set of rules" within the European Union (EU) and also apply to companies "active in the EU market" that handle personal data abroad.

In particular, the framework would stipulate "increased responsibility and accountability for those processing personal data" such as names, photos, information posted on social networking sites, or computer IP and email addresses. Under the proposed rules, companies must obtain explicit user consent to gather personal data and must report within 24 hours (or as soon as possible) any security breach to a national supervisory authority, which "will be empowered to fine companies that violate EU data protection rules… up to €1 million or up to 2% of the global annual turnover of a company." In addition, the framework would expand consumer rights by granting individuals "easier access to their own data" as well as the ability to "transfer personal data from one service provider to another" or "delete their data if there are no legitimate grounds for retaining it."

"The protection of personal data is a fundamental right for all Europeans, but citizens do not always feel in full control of their personal data. My proposals will help build trust in online services because people will be better informed about their rights and in more control of their information," EU Justice Commissioner Viviane Reding told media sources. "The reform will accomplish this while making life easier and less costly for businesses. A strong, clear and uniform legal framework at the EU level will help to unleash the potential of the digital single market and foster economic growth, innovation and job creation." *See The Wall Street Journal,* January 23, 2012; *EC Press Release, Memo and FAQs,* January 25, 2012; *The Parliament.com,* January 26, 2012; *Guardian Professional,* January 27, 2012.

California Adopts No Significant Risk Level for 4-MEI

California's Office of Administrative Law has **approved** a no significant risk level for the chemical 4-Methylimidazole (4-MEI) proposed by California EPA's Office of Environmental Health Hazard Assessment (OEHHA).

Beginning February 8, 2012, no Proposition 65 warning will be required for exposures to 4-MEI at or below 29 micrograms per day. The action follows a December 2011 court determination that OEHHA complied with the law when it found that 4-MEI, a chemical present in many common foods and beverages, is a carcinogen known to the state to cause cancer. Used in the manufacture of various products such as pharmaceuticals, the chemical is a

by-product of fermentation often found in soy sauce, roasted coffee and the caramel coloring added to colas and beer. Additional information about the court challenge and ruling appears in **Issue 420** of this *Update*.

LITIGATION

SCOTUS Invalidates California Slaughterhouse Law on Preemption Grounds

A unanimous U.S. Supreme Court has determined that the Federal Meat Inspection Act (FMIA) and its regulations preempt a California law that required swine slaughterhouses to humanely euthanize nonambulatory animals and prohibited them from processing, butchering or selling the meat or products of nonambulatory animals for human consumption. ***Nat'l Meat Ass'n v. Harris*, No. 10-224 (U.S., decided January 23, 2012)**. Details about the Ninth Circuit's decision, which the Court reversed, appear in **Issue 344** of this *Update*.

Writing for the Court, Justice Elena Kagan stated that the FMIA includes an express preemption clause which "sweeps widely—and in so doing, blocks the applications of [the California law] challenged here. The clause prevents a State from imposing any additional or different—even if non-conflicting—requirements that fall within the scope of the Act and concern a slaughterhouse's facilities or operations. And at every turn [the California law] imposes additional or different requirements on swine slaughter houses."

The Court explained that federal law does not require all nonambulatory, or "downer," animals to be euthanized. They must be treated humanely and, if not condemned due to a severe disease or condition, are set apart, monitored and slaughtered separately from other livestock. A U.S. inspector decides post-mortem which parts, if any, of the carcass may be processed into food for humans. Noting that the state's proscriptions exceed the FMIA's, the Court also rejected California and The Humane Society's argument that the state law's provisions fall outside the FMIA's scope, "because they exclude a class of animals from the slaughtering process." It was on this ground that the Ninth Circuit upheld California's law.

According to Justice Kagan, states are not free to decide which animals may be turned into meat at the slaughterhouse because "[t]he FMIA's scope includes not only 'animals that are going to be turned into meat,' but animals on a slaughterhouse's premises that will never suffer that fate. The Act's implementing regulations themselves exclude many classes of animals from the slaughtering process."

She also observed that state bans on the slaughter of horses differ from the law at issue here "in a significant respect. A ban on butchering horses for human consumption works at a remove from the sites and activities that the

FMIA most directly governs. When such a ban is in effect, no horses will be delivered to, inspected at, or handled by a slaughterhouse, because no horses will be ordered for purchase in the first instance." In contrast, the state's swine slaughterhouse rules tell it what to do with pigs that "become disabled either in transit to or after arrival at a slaughterhouse" and "thus reach[] into the slaughterhouse's facilities and affect[] its daily activities."

The Court remanded the matter for further proceedings consistent with its ruling.

Seventh Circuit Upholds Indiana Law Regulating Wine Deliveries via Motor Carrier

The Seventh Circuit Court of Appeals has turned aside a challenge to an Indiana law that prevents an alcoholic beverage retailer from shipping wine to its customers via motor carrier. ***Lebamoff Enters., Inc. v. Huskey*, No. 11-1362 (7th Cir., decided January 17, 2012)**. The retailer claimed that the law was preempted by the Federal Aviation Administration Authorization Act of 1994 and that it violated the dormant Commerce Clause of the U.S. Constitution.

Writing for the panel, Judge Richard Posner explained that the Twenty-First Amendment, which confers core powers on the states to regulate the sale of alcoholic beverages, places a thumb on the scale balancing state and federal interests. If the state interests are within those core powers, wrote Posner, there is a "'strong presumption' of validity." According to the court, Indiana requires that drivers employed by liquor retailers be trained in the state's alcohol laws and the recognition of phony IDs to prevent underage drinking. The state also allows the shipment of alcoholic beverages from wineries that have verified their customers' age in person, thus confirming its strong interest in the matter. Because motor carriers' drivers do not undergo such training, the court determined that allowing them to ship wine would "undermine the state's efforts to prevent underage drinking."

The court also rejected the retailer's claim of constitutional infirmity, finding any effects on interstate commerce negligible. A concurring judge would not have employed the "quasi-legislative form of interest-balancing" assessment undertaken by his colleagues. According to Judge David Hamilton, "the Twenty-first Amendment to the Constitution should foreclose those balancing tests when the state is exercising its core Twenty-first Amendment power to regulate the transportation and importation of alcoholic beverages for consumption in the state. The challenged state law here, forbidding some but not all direct deliveries of alcohol by common carriers to consumers, falls within that core power. The law should be upheld even if, as I believe, its actual benefits are minimal and its burdens on federal interests are significant."

Plaintiffs Unable to Enjoin FDA from Enforcing Raw Milk Regulations

A federal court in Iowa has denied a motion seeking to preliminarily enjoin the Food and Drug Administration (FDA) from enforcing regulations prohibiting the interstate sale of raw milk. *Farm-to-Consumer Legal Defense Fund v. Sebelius*, No. 10-4018 (U.S. Dist. Ct., N.D. Iowa, W. Div., decided January 23, 2012). The plaintiffs, who either produce or consume raw milk, filed their motion under the All Writs Act, claiming that FDA has taken enforcement actions against third parties in other jurisdictions while the plaintiffs' lawsuit challenging the validity of the rules is pending and that such action usurps the court's jurisdiction to decide whether the interstate sale of raw milk is legal.

According to the court, "[t]he plaintiffs have not cited, and I have not found, any authority for the proposition that the first federal court to entertain a challenge to a federal regulation has the power to forestall enforcement of that regulation by a federal agency in other jurisdictions and tribunals against non-parties even before the court resolves the legal challenge." Finding that the plaintiffs were unable to show the threat of irreparable harm to themselves and because "[t]he FDA would be unduly hampered, and the public interest would be damaged by enjoining enforcement of still-valid regulations intended to protect the public from food borne illnesses resulting from the consumption of raw milk," the court ruled that no preliminary injunction should issue.

Federal Court Dismisses Challenge to USDA Almond Pasteurization Rule

A federal court in the District of Columbia has determined that the U.S. Department of Agriculture (USDA) had the authority to and properly promulgated a rule "requiring that almonds produced domestically be pasteurized or chemically treated against bacteria." *Koretoff v. Vilsack*, No. 08-1558 (U.S. Dist. Ct., D.D.C., decided January 18, 2012). So ruling, the court granted USDA's motion for summary judgment. Further information about the challenge brought by U.S. almond growers appears in **Issue 274** of this *Update*.

The almond rule was adopted in response to *Salmonella* outbreaks traced to raw almonds in 2001 and 2004. USDA adopted it under the authority of the Agricultural Marketing Agreement Act of 1937 and the California Almond Marketing Order (Almond Order), promulgated in 1950. At issue in the dispute between the U.S. almond growers and USDA was whether safety regulations are encompassed by the law's use of the term "quality," over which USDA specifically has regulatory authority. The court found the term undefined and ambiguous and refused to limit its scope to "only an almond's 'inherent, measurable attribute[s],'" as urged by the plaintiffs.

According to the court, "having rejected plaintiffs' arguments that [the statute] unambiguously forecloses the Secretary's interpretation, the Court is left to decide whether that interpretation is reasonable under *Chevron* step two's 'highly deferential standard.' The Court concludes that it is, and that the *Salmonella* Rule does not exceed the Secretary's authority under the [statute]." Noting that the statute "authorizes the Secretary to intervene in the markets for various agricultural commodities and products in order to ensure their stable and effective functioning," the court found it "apparent that Congress gave the agency the flexibility it needs to respond to both general market conditions and external threats, such as the *Salmonella* outbreaks in 2001 and 2004, which have the potential to cause significant market disruption."

The court also found that USDA was not required to hold a formal rulemaking hearing and producer referendum in promulgating the rule because it did not amend the Almond Order; rather, it was promulgated under the authority of the Almond Order. According to earlier rulings in the case, the *Salmonella* rule eliminated the domestic raw almond market. The producer plaintiffs alleged that "they lost both their expected profits from the premium price paid for raw almonds and the return on investments they had made in production equipment." According to a news source, the plaintiffs are considering whether "there are grounds for continuing this legal battle." *See The Grower*, January 26, 2012.

United States to Appeal WTO Ruling on Dolphin-Safe Labeling of Tuna

The Office of the U.S. Trade Representative has announced that the United States will file an appeal in a dispute with Mexico before the World Trade Organization (WTO) over U.S. labeling provisions that allow producers meeting dolphin-safe requirements to label their products accordingly. One of the U.S. conditions challenged by Mexico provides that this label cannot be used if dolphins are purposefully chased and encircled to catch tuna. In September 2011, WTO handed Mexico a partial victory, finding that the U.S. measures were more trade-restrictive than necessary to achieve a legitimate objective. Additional information about the dispute appears in **Issue 409** of this *Update*.

According to a Trade Representative spokesperson, "Our dolphin-safe labeling measures for tuna products provide information for American consumers as they make food purchasing decisions for their families. Our decision to appeal the WTO ruling in this case demonstrates the commitment of the United States to our dolphin-safe labeling measures." According to a news source, if the United States does not prevail on appeal, its dolphin-safe labeling rules may have to be amended or the country could face Mexican trade sanctions. *See Office of U.S. Trade Representative News Release* and *Thomson Reuters*, January 20, 2012; *InsideCounsel*, January 23, 2012.

Beverage Producer Claims Recycler Sold Rather Than Destroyed Substandard Products

Spike, LLC, a company that makes and distributes energy drinks, has filed a lawsuit against the company it hired to destroy 18 pallets of products that Spike determined should be removed from the marketplace as unfit for sale, claiming that the recycling company failed to destroy the products and, in fact, sold them "thereby undercutting Spike's sales." *Spike, LLC v. Nationwide Recycling, LLC*, No. 12CV00111 (Waukesha County Cir. Ct., Wisconsin, filed January 10, 2012). Seeking compensatory and treble damages, attorney's fees, and interest, the plaintiff alleges conspiracy; breach of contract; property loss through fraudulent misrepresentation; misrepresentation: intentional deceit; misrepresentation: strict responsibility; misrepresentation: negligence; and conversion. According to the complaint, Spike paid the company $10,000 to destroy 13,617 cases of energy drink products, which had a value of about $900,000.

OTHER DEVELOPMENTS

NRC Calls for Coordinated Effort to Address Nanomaterial Safety

A National Academies National Research Council panel has issued a **report** acknowledging the progress made by the National Nanotechnology Initiative in researching the environmental and potential health effects of engineered nanomaterials (ENM), but criticizing an overall failure to link research with strategies to prevent and manage risks.

Headed by Jonathan Samet, who teaches at the University of Southern California Keck School of Medicine and has long researched, written about and crusaded against tobacco smoke and the industry, the panel calls for the development of a strategic research plan "independent of any one stakeholder group, [with] human and environmental health as its primary focus."

The report advocates that four research categories be addressed within five years: "identify and quantify the nanomaterials being released and the populations and environments being exposed"; "understand processes that affect both potential hazards and exposure"; "examine nanomaterial interactions in complex systems ranging from subcellular to ecosystems"; and "support an adaptive research and knowledge infrastructure for accelerating progress and providing rapid feedback to advance research." According to the council panel, the need for a strategic approach is critical given that ENM "are already in industrial and consumer products, including drug-delivery systems, stain-resistant clothing, solar cells, and food additives."

Challenges to assessing risks are identified as (i) a "great diversity of nanomaterial types and variants"; (ii) "lack of capabilities to monitor rapid changes

in current, emerging, and potential ENM applications and to identify and address the potential consequences for EHS [environmental, health and safety] risks"; and (iii) "lack of standard test materials and adequate models for investigating EHS risks, leading to great uncertainty in describing and quantifying nanomaterial hazards and exposures." The report also notes that increased ENM production, "a growing awareness that adequate methods are not available to detect and characterize the materials in the environment" and "recognition that the materials are in products or environments where exposures potentially can occur," have led to increased funding for ENM research. Still, key topics, such as "the effects of ingested ENMs on human health," remain unaddressed by research, according to the report.

SCIENTIFIC/TECHNICAL ITEMS

U.S. Study Identifies Livestock-Associated MRSA in Retail Pork

U.S. researchers have reportedly discovered methicillin-resistant *Staphylococcus aureus* (MRSA) in retail pork samples "at a higher rate than previously identified," raising questions about the organism's "overall ecology and transmission" in the food supply. **Ashley O'Brien, et al., "MRSA in Conventional and Alternative Retail Pork Products," PLoS One, January 2012**. Conducted by the Institute for Agriculture and Trade Policy (IATP) and the University of Iowa College of Public Health, the study examined 395 fresh pork cuts collected from 36 stores in Iowa, Minnesota and New Jersey, in addition to comparing products "from conventionally-raised swine and swine raised without antibiotics."

According to the analysis, researchers isolated *S. aureus* in 256 pork samples (64.8 percent) and MRSA in 26 samples (6.6 percent) but discovered "no significant difference" in prevalence between conventional and alternative pork products. The study notes, however, that 26.9 percent of MRSA isolates were a "livestock-associated" strain known as ST398 (t034, t011) as opposed to human types t002 and t008, which have also been found in live swine. To this end, the authors urge further investigation of potential cross-species transmission, citing Canadian and Dutch studies as well as research covered in **Issue 391** of this *Update* that reported *S. aureus* in 47 percent of 136 meat and poultry samples.

"The latest results are more than double the prevalence found in previous studies of this kind," said IATP Senior Advisor in Science, Food and Health David Wallinga in a January 20, 2012, press release. "At 6.6 percent, pork is four times more likely to be carrying deadly MRSA than the average American, pointing to our food system and industrial farming as an avenue for MRSA to continue to spread."

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FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 424 | JANUARY 27, 2012

Study Claims PFCs Compromise Vaccine Effectiveness

A recent study has reportedly raised concerns about whether exposure to perfluorinated compounds (PFCs) compromises vaccine effectiveness in children. Philippe Grandjean, et al., "Serum Vaccine Antibody Concentrations in Children Exposed to Perfluorinated Compounds," *Journal of the American Medical Association,* January 2012. Approved for use in some food contact applications such as microwavable paper, PFCs "have emerged as important food contaminants," according to the study's authors, who gathered data from 587 participants in a prospective birth cohort study based in the Faroe Islands.

According to a January 24, 2012, Harvard School of Public Health press release, "The results showed that PFC exposure was associated with lower antibody responses to immunizations and an increased risk of antibody levels in children lower than those needed to provide long-term protection." In particular, the authors noted that "a two-fold greater concentration of three major PFCs was associated with a 49% lower level of serum antibodies in children at age 7 years."

"We were surprised by the steep negative associations, which suggest that PFCs may be more toxic to the immune system than current dioxin exposures," said lead author Philippe Grandjean. "Routine childhood immunizations are a mainstay of modern disease prevention. The negative impact on childhood vaccinations from PFCs should be viewed as a potential threat to public health."

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