Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Intentional Food Adulteration Rule Proposed

The U.S. Food and Drug Administration (FDA) has proposed a rule that will implement those provisions of the Food Safety Modernization Act addressing "hazards that may be intentionally introduced by acts of terrorism." Under the rule, domestic and foreign facilities that manufacture, process, pack, or hold food would be required to register and implement certain measures to protect against the intentional adulteration of food. These facilities, with certain exemptions, would be required, among other things, to "prepare and implement a written food defense plan that includes actionable process steps, focused mitigation strategies, and procedures for monitoring, corrective actions, and verification." The proposal is expected to be published in the December 24, 2013, issue of the *Federal Register*, and will have a 30-day public comment period. *See FDA News Release*, December 20, 2013.

FDA to Revise Proposed FSMA Rules Affecting Farmers

According to U.S. Food and Drug Administration (FDA) Deputy Commissioner for Foods and Veterinary Medicine Michael Taylor, the agency will revise proposed rules under the Food Safety Modernization Act (FSMA) "affecting farmers," who have apparently expressed concern about the potential impact on their livelihoods. Among provisions to be revised and re-published for public comment in early summer 2014 are (i) "sections covering water quality standards and testing," (ii) "standards for using raw manure and compost," (iii) those "affecting mixed-use facilities (such as a farm that has a food-processing operation)," and (iv) "procedures used to withdraw the qualified exemption to these requirements for certain farms." Taylor also noted that the agency continues to review the comments already submitted to the rulemaking docket and may decide to include other changes for public comment. *See FDA Voice*, December 19, 2013.

FDA Extends Comment Period on *Trans* Fat in Processed Foods

The U.S. Food and Drug Administration (FDA) has extended until March 8, 2014, the period for submission of comments and scientific data pertaining to its preliminary determination that partially hydrogenated oils (PHOs), the primary dietary source of artificial *trans* fat in processed foods, are not "gener-

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For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

Mark Anstoetter
816-474-6550
manstoetter@shb.com

or

Madeleine McDonough
816-474-6550
202-783-8400
mmcdonough@shb.com

If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

ally recognized as safe" (GRAS) for use in food. FDA published a notice in the November 8 *Federal Register* announcing this determination and requesting comments on (i) possible alternative approaches; (ii) the time needed for reformulation; (iii) the burden on small businesses; and (iv) other technical challenges to removing PHOs from the food supply. Additional details about FDA's opinion on *trans* fat appear in Issue **503** of this *Update*. *See CFSAN Constituent Update*, December 17, 2013.

FDA Extends Comment Period for Draft Risk Profile on Pathogens and Filth in Spices

The U.S. Food and Drug Administration (FDA) has extended until March 3, 2014, the **period** for submission of comments, scientific data and other information related to its draft document titled, "Draft Risk Profile on Pathogens and Filth in Spices." Originally published in the November 4, 2013, *Federal Register*, the draft risk profile identifies the most commonly occurring microbial hazards and filth in spices and quantifies, where possible, the prevalence and levels of these adulterants at different points along the spice supply chain. It identifies potential sources of contamination throughout the farm-to-table spice supply chain and evaluates the efficacy of current mitigation and control options designed to reduce the public health risk posed by consumption of contaminated spices in the United States. It also describes potential future mitigation and control options and identifies critical data gaps and research needs. FDA invites comments that can help improve the (i) data and information used; (ii) analytical analyses employed; and (iii) clarity and the transparency of the draft risk profile. Additional details about FDA's spice risk report appear in Issue **502** of this *Update*. *See Federal Register,* December 17, 2013.

WHO Reports First Documented Human Case of Avian Influenza A

The World Health Organization (WHO) has **reported** the first documented case of avian influenza A (H10N8) in a human patient from Jiangxi Province, China. Reiterating that no evidence yet indicates human-to-human transmission, WHO noted that the 73-year-old patient visited "a live bird market four days before date of onset" and eventually died from the disease. "Although China has previously detected H10N8 in wild and domestic birds, this is the first ever report of H10N8 isolated from a patient," states the organization's December 2013 fact sheet. "Given the potentially unpredictable behavior of influenza viruses, vigilance and close monitoring is needed… The Chinese government is actively investigating this event and has heightened disease surveillance for early detection, prevention and control measures." *See NBC News,* December 18, 2013.

EC Issues Report on Meat Ingredient Origin Labeling

The European Commission (EC) has published a **report** titled "Origin labelling for meat used as an ingredient: consumers' attitude, feasibility of possible scenarios and impacts" that provides an overview of the potential consequences of mandatory origin labeling of meat used as an ingredient in food.

Based on an independent study completed in July 2013, the report explores three scenarios: (i) maintaining current voluntary origin labeling; (ii) introducing mandatory labeling for EU/non-EU or EU/specific third country indication; and (iii) introducing mandatory labeling indicating the specific EU member state or the specific third country.

Among other things, the findings revealed that (i) overall there is "strong" consumer interest in origin labeling; (ii) a considerable difference exists among European Union (EU) member states on consumer preferences and understanding of origin information as well as on the levels of motivation and reasons for wishing to have such information; and (iii) consumer interest for origin labeling ranks behind price and quality in terms of the most important factors affecting consumer choice. Evidently, strong consumer interest in origin labeling is not reflected in consumers' willingness to pay additional costs. At price increases of less than 10 percent, consumer willingness to pay fell by 60 to 80 percent.

The Commission plans to determine next steps after discussions with EU member states and the European Parliament. *See European Commission News Release*, December 17, 2013.

EC Proposes New Directives to Ban Cloning of Farm Animals

The European Commission (EC) recently **proposed** two draft directives that would prohibit the cloning of farm animals in the European Union (EU) as well as the importation of cloned animals. Designed to address animal welfare concerns and provide "legal certainty in this field," the first directive would temporarily ban cloning techniques and the sale of live animal and embryo clones for commercial purposes, while the second directive would ensure that "food such as meat or milk from animal clones is not placed on the EU market."

At the same time, the Commission has also proposed revising current regulations to centralize the novel food authorization procedure at the EU level "with a view to improving access of new and innovative food to the EU market, while still maintaining a high level of consumer protection." Under these revised rules, the European Food Safety Authority would perform the risk assessment for the novel food application while the Commission would be responsible for managing applicant files and forwarding the authorization of novel foods found to be safe. In addition, the proposal would expedite the

authorization process for foods that are not yet marketed in the European Union but have a history of safe use in other countries.

"Today's initiatives on animal cloning respond to animal welfare concerns as well as consumer perceptions on food from animal clones in a realistic and workable way," EU Health Commissioner Tonio Borg said in a December 18, 2013, press release. "The changes on novel food will create a more efficient system. It will offer EU consumers the benefit of a broad choice of foodstuffs and provides a favorable environment for Europe's food industry." *See European Commission's FAQ on Animal Cloning and Novel Food Proposals,* December 18, 2013.

EC Publishes List of Authorized Smoke Flavorings

The European Commission (EC) has **published** legislation listing the 10 smoke flavoring primary products authorized for use in food. According to Smoke Flavoring Regulation EC No. 2065/2003, these primary products include smoke condensates and tar fractions that can be used directly on foods such as meat and fish to impart a smoky flavor or in the production of derived smoke flavorings, which are then added to a variety of foods and sauces.

Reflecting input from the European Food Safety Authority, the Commission's latest list describes the maximum permitted level for each primary product and the foods to which they can be added. "When authorized smoke flavorings are used in or on food, their use must be in accordance with the conditions of use, including maximum levels, set in the Annex to this Regulation. When authorized smoke flavorings are used in combination, the individual levels should be reduced proportionally," concludes the legislation, which sets a compliance date of January 1, 2015. *See the Official Journal of the European Union,* December 10, 2013; *U.K. Food Standards Agency,* December 13, 2013.

China to Establish Food and Safety 'Blacklist'

The Chinese Food and Drug Administration (CFDA) has announced a public consultation on a draft regulation, "Provisions on the Administration of the 'Black List' System for Food and Drug Safety," that would give regulators the authority to blacklist companies that violate food safety laws. The regulation would allow information on manufacturers that violate laws and regulations concerning food, drugs, medical appliances, and cosmetics management, and receive administrative penalties, to be made public through government Websites. Producers and operators included on the "blacklist" would apparently face increased regulatory supervision.

The draft regulation reportedly also covers food and beverage producers that fail to comply with production license requirements, mislabel products and

do not respond appropriately to food safety incident cases. Companies using fallacious, unsubstantiated or misleading marketing would be ordered to suspend production and, in the case of serious breaches of regulations, have their business licenses revoked. Additions to the "blacklist" would be disseminated by CFDA via publication on the official governmental Website within 15 days of the initial judgment, including such information as: producer/operator name; persons in charge; relevant products; product batch numbers; label approval numbers; and production license numbers. Comments on the draft regulation will be accepted until January 10, 2014. *See CFDA News Release,* December 12, 2013; *ChemLinked.com*, December 17, 2013.

OEHHA Adds Plasticizer to Prop. 65 List

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has **added** diisononyl phthalate—a plasticizer used in food contact materials—to the list of chemicals known to the state to cause cancer. OEHHA's Carcinogen Identification Committee determined that "the chemical was clearly shown, through scientifically valid testing according to generally accepted principles, to cause cancer." The addition, made under the "state's qualified expert" mechanism of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65), takes effect December 20, 2013. OEHHA will next set a safe exposure level for the chemical. *See OEHHA News Release*, December 12, 2013; *Bloomberg BNA Product Safety & Liability Reporter*, December 13, 2013.

Outgoing NYC Mayor Secures Passage of Foam Food-Packaging Law

The New York City (NYC) Council has reportedly adopted legislation that would prohibit the use of foam food containers by 2015, if city sanitation officials determine that recycling the substance is not feasible. Favored by outgoing Mayor Michael Bloomberg, the legislation—referred to as the Styrofoam ban—would include a six-month grace period, during which only warnings would be issued, as well as a hardship exemption for nonprofits and small businesses that could request a one-year renewable waiver. Bloomberg thanked the city council for approving the measure, saying "This legislation not only eliminates a product that cannot be recycled in New York City, it is a giant step forward in the City's effort to recycle organic waste. Foam pollutes the waste stream, making it harder to recycle food waste as well as metal, glass and plastic." *See NYC Mayor Michael Bloomberg News Release* and *Law360*, December 19, 2013.

LITIGATION

Seventh Circuit Says No Duty to Defend Four Loko® Maker

The Seventh Circuit Court of Appeals has determined that Phusion Projects' commercial liability insurance carriers have no duty to defend the company in actions alleging that intoxication attributable to consumption of its Four Loko® alcoholic product caused death and personal injury. ***Netherlands Ins. Co. v. Phusion Projects, Inc.*, No. 12-1355 (7th Cir., decided December 16, 2013)**. Applying Illinois law, the court ruled that the liquor liability exclusions in the relevant insurance contracts unambiguously excluded coverage for bodily injury or property damage when the company "may be held liable by reason of: (1) causing or contributing to the intoxication of any person." So ruling, the court affirmed the lower court's grant of the insurance carriers' motion for summary judgment.

Monster Beverage's Challenge to S.F. Attorney Investigation Dismissed

A federal court in California has dismissed, without prejudice, the action for declaratory and injunctive relief brought against the San Francisco city attorney, seeking to halt his investigation of Monster Beverage's energy drinks and efforts to regulate their formulation, labeling and promotion. *Monster Beverage Corp. v. Herrera*, No. 13-0786 (U.S. Dist. Ct., C.D. Cal., decided December 16, 2013). Additional information about the lawsuit appears in Issue **482** of this *Update*. The matter was before the court on the city attorney's renewed motion to dismiss.

Essentially, the court determined that the *Younger* abstention doctrine, which "counsels federal-court abstention when there is a pending state proceeding," applied because a state action brought by the city attorney is pending, the action implicates important state interests, not all of the city attorney's claims are preempted under federal food-labeling laws, and the state proceedings will be adequate for the consideration of Monster's constitutional claims. Details about the city attorney's lawsuit appear in Issue **483** of this *Update*. While Monster's lawsuit was filed before the city attorney filed his action, the court determined that the "state action" was filed before the court issued an order in August 2013 granting in part and denying in part the city's motion to dismiss the *Monster* action. Details about that ruling appear in Issue **496** of this *Update*.

In August, the court refused to apply the *Younger* abstention doctrine because Monster had removed the city attorney's lawsuit to federal court. A motion for remand was pending at that point, and the court indicated that it could determine whether the doctrine applied if the motion were granted. The city attorney's case was subsequently remanded to state court.

The court also applied the Anti-Injunction Act, finding that issuance of injunctive relief to halt the city attorney's investigation would effectively stay proceedings in a state court, noting "even if the Act does not apply when a request for a federal injunction is made before the state court proceedings are filed, the Court would exercise its discretion in light of the principles of equity, comity and federalism and refrain from granting an injunction that would effectively enjoin the state court proceeding."

Advocacy Groups File Amicus Brief to Support Challenge to Utah "Ag-Gag" Law

Advocacy organizations including the Center for Food Safety and Food & Water Watch have **filed** an *amicus* brief to support an animal-rights organization coalition's challenge to a Utah law that criminalizes undercover investigations of meat and poultry processing facilities. *Animal Legal Def. Fund v. Herbert*, No. 13-0679 (U.S. Dist. Ct., D. Utah, Cent. Div., brief filed December 17, 2013). Contending that the government has failed to prevent illegal animal-handling practices that ultimately threaten consumer safety and that consumers have the right to know how food is produced, the brief calls for the court to decide the challenge to Utah's "ag-gag" law, Utah Code Ann. § 76-6-112, on the merits. Among other matters, *amici* refer to the undercover investigation conducted by the Humane Society of the United States in 2007 of a Hallmark/Westland facility and its conclusion in a U.S. Department of Agriculture ground-beef recall over concerns that the meat "did not receive complete and proper inspection and was therefore unfit for human consumption."

OTHER DEVELOPMENTS

Tort Reform Group Highlights "Big Food" Cases in "Judicial Hellholes" Report

The American Tort Reform Foundation has **published** the 2013-2014 issue of its "Judicial Hellholes" report, placing California, in part for the many lawsuits against food and beverage companies filed there, at the top of the list of jurisdictions with "plaintiff-friendly consumer protection laws" and courts purportedly receptive to such lawsuits.

According to the report, plaintiffs' lawyers "have filed a surge of consumer class actions targeting what they have labeled as 'Big Food'" in California courts. "Some of these claims are brought by veterans of lawsuits against the tobacco industry who are looking for the next deep pocket to sue. About a dozen plaintiffs' law firms have taken to the courts with gusto, filing about 75 class action lawsuits between them in the past few years. By one count, which includes filings from additional firms, more than 100 consumer class actions were filed against food makers in 2012 alone, five times the number filed four years earlier."

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FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 508 | DECEMBER 20, 2013

The report also notes, "Rarely has there been a week in 2013 without a report of another class action filed against a food maker. In some instances, the lawyers bringing the cases do not even bother to find new clients—they recycle the same individuals as lead plaintiffs, over and over again, in lawsuits involving different manufacturers and products."

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
Philadelphia, Pennsylvania
+1-215-278-2555
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400

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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.