Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

Senate Judiciary Chair Wants Answers About Peanut Corp. Investigation

Senator Patrick Leahy (D-Vt.) has **requested** that Attorney General Eric Holder provide an update on the Justice Department's criminal investigation into the 2009 *Salmonella* outbreak involving contaminated peanuts from Peanut Corp. of America (PCA) facilities. As Leahy reminds Holder in his February 22, 2011, letter, the outbreak was linked to the deaths of nine people and purportedly sickened more than 700 others. He also cites his previous request that the department conduct "a full criminal investigation into this matter." PCA declared bankruptcy in 2009, and neither its former CEO nor other executives have been charged to date.

According to Leahy, "Given the PCA investigation, the pistachio recall, and last summer's salmonella outbreak from eggs, my concerns remain that wrongdoers are disregarding the health and safety of American consumers by choosing to sell contaminated products. I hope that there has been a thorough criminal investigation into PCA's conduct at the least, and that if appropriate, criminal charges are aggressively pursued." Leahy also asks Holder to determine whether "the Justice Department needs any additional [legal] tools to protect the American people." *See FoodNavigator-USA.com*, February 24, 2011.

FSIS Proposes Catfish Inspection Rules

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) has issued a **proposed rule** that would address a 2008 Farm Bill mandate making catfish an amenable species under the Federal Meat Inspection Act and therefore requiring all domestic and imported catfish to undergo FSIS inspection. According to a February 18, 2011, press release, FSIS has offered two definitions for "catfish," one limited to all species in the family Ictaluridae and a broader one that covers all species in the order Siluriformes, which includes Ictaluridae, Pangasiidae and Clariidae, the three families "typically found in human food channels."

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The proposed rule would also require, among other provisions, that all catfish "produced in or imported to the United States" bear an FSIS inspection mark or "a mark of inspection from the country from which it was exported." In addition, the agency has suggested plans for (i) inspecting catfish farms, (ii) transporting products from farms to processing plants, (iii) ensuring product safety, and (iv) transitioning the domestic and international markets to the new system. FSIS will accept comments on the rule until June 24, 2011. *See The Federal Register,* February 24, 2011.

The proposed rule has already elicited strong criticism from overseas producers who have reportedly warned that USDA inspections are a trade barrier, while drawing support from the domestic catfish industry, which has backed the Siluriformes definition of catfish because it would bring more products under FSIS purview. "We are extremely pleased that the USDA has recommended stricter regulation of catfish, which will mean greater protection for American consumers," said a spokesperson for the Catfish Farmers of America (CFA). "We are certain that based on the food-safety risks it cites in the draft regulation, USDA will determine that all catfish products—domestic and imported—sold in America should meet the same rigorous standards for quality and safety." *See CFA Press Release* and *SeafoodSource.com,* February 18, 2011.

Meeting Slated for Codex Committee on Fish and Fishery Products

The U.S. Department of Agriculture, the Food and Drug Administration, the Office of the Under Secretary for Food Safety, and the Center for Food Safety and Applied Nutrition have **announced** a March 16, 2011, public meeting in College Park, Maryland, to provide information and receive public comments on draft U.S. positions to be discussed at the 31st session of the Codex Committee on Contaminants on Fish and Fishery Products (CCFFP) on April 11-16 in Tromso, Norway. CCFFP "is responsible for elaborating worldwide standards for fresh, frozen (including quick frozen) or otherwise processed fish, crustaceans, and mollusks."

Agenda items include proposed draft standards for fish sauce, smoked fish, smoke-flavored fish, and smoke dried fish; proposed draft codes of practice for fish and fishery products and scallop-meat processing; proposed methods for determining biotoxins in raw and live bivalve mollusks; and proposed revisions to food-additive standards for fish and fishery products. *See Federal Register,* February 25, 2011.

FDA Relies on Genome Sequencing to Trace *Salmonella* Outbreak Source

The Food and Drug Administration (FDA) recently **announced** that agency analysts turned to next-generation sequencing to test samples collected during a *Salmonella* outbreak that purportedly sickened nearly 300 people

from 44 states and the District of Columbia. The 2009-2010 outbreak was linked to the spice rub used on certain salamis and was ultimately traced to a single food facility. According to FDA, "The findings supported the information gathered in the field phase of the investigation and suggest an important role for this novel tool in augmenting future outbreak investigations." *See FDA Press Release*, February 24, 2011.

EU Considers Changing "Zero-Tolerance" GM Policy for Animal Feed

European Union (EU) member states have reportedly endorsed a draft regulation aiming to "harmonize the implementation of the zero tolerance policy on non-authorized genetically modified (GM) material in feed." According to a February 23, 2011, *Europa* press release, the proposal put forth by the Standing Committee on the Food Chain and Animal Health (SCoFCAH) would allow imported feed to contain up to 0.1 percent unauthorized GM seed, a limit that reflects the lowest level of GM presence considered by the EU GMO Reference Laboratory when validating detection methods.

If adopted by the European Parliament and the Council in the next three months, the draft regulation would apply only to GM feed material "authorized for commercialization in a third country and for which an authorization procedure is pending in the EU or of which the EU authorization has expired." Under these rules, "feed will be considered non-compliant with EU legislation when the presence of this GM feed material is, after due consideration of the margin of error, above the technical zero."

SCoFCAH apparently suggested the policy change to address "the current uncertainty EU operators face when placing on the market feed based on imports of raw materials from third countries," and "ensure that results are consistent in all Member States." But the draft regulation has already met with public criticism from consumer advocacy groups that backed the "zero tolerance" approach. "There is absolutely no reason to allow contaminated food to be fed to animals in Europe. Weakening safety rules to appease the animal feed industry compromises human and environmental safety," said a spokesperson for Friends of the Earth Europe, which noted that only 0.2 percent of all EU soy imports were ever denied entry for GM contamination. *See The Telegraph,* February 22, 2011; *Food & Water Europe,* February 23, 2011.

UK's FSA Welcomes Applications for Meat Research Program

The United Kingdom's Food Standards Agency (FSA) has **announced** that it is commissioning research aimed at modernizing official controls on meat. Noting that "the driving force" behind the Future Meat Controls Research Programme is to "improve public health by adopting a more risk- and evidence-based approach to meat production," FSA said four areas of research will be part of the evidence to support regulatory change.

Areas of research needed are (i) "an evaluation of food chain information, and collection and communication of inspection results for all species"; (ii) "trialling the visual inspection for fatting pigs from non-controlled housing conditions"; (iii) "a qualitative risk assessment of visual inspection of red meat and farmed/wild large game (all ages and species other than swine)"; and (iv) "trialling the use of a plant inspection assistant in approved game handling establishments (small and large wild game)." FSA requests proposals by April 6, 2011.

UK Nutrition Committee Recommends Reducing Red Meat Intake

The U.K. Scientific Advisory Committee on Nutrition (SACN) has issued a February 25, 2011, **Health and Iron Report** recommending that the general population eat no more than 500 grams of red and processed meat per week, or 70 grams per day. At the request of the Committee on Medical Aspects of Food and Nutrition Policy, which in 1998 linked red and processed meat to colorectal cancer risk, SACN undertook "a comprehensive review of the role of iron in human nutrition," including "potential adverse effects both of iron deficiency and of iron excess." It ultimately concurred with the earlier findings that "high consumers of red and processed meat should consider reducing their intakes because of possible links with a risk of colorectal cancer."

SACN particularly noted that adults consuming more than 90 grams of red and processed meat per day "should consider reducing their intakes" to reflect the population average of 70 grams per day (cooked weight), a dietary change that would have "little impact on the proportion of the adult population with low iron intakes." The advisory committee also emphasized the need for more research geared toward updating the dietary reference values for iron, and cautioned that some population groups—toddlers, girls, women of reproductive age, and some adult groups older than age 65—were still at risk for iron deficiency and anemia.

SACN also recommended "a public health approach to achieving adequate iron status based on a healthy balanced diet that includes a variety of foods containing iron." According to the report, "This is a change to current dietary advice that iron-rich foods should be consumed at the same time as foods/drinks which enhance iron absorption (e.g., fruit, meat) but should not be consumed with those that inhibit iron absorption (e.g., tea, coffee, milk)." *See The Telegraph* and *SACN Press Release,* February 19, 2011.

LITIGATION

Latest USDA Approval of GE Sugar Beets Generates Lawsuit

The Center for Food Safety has returned to a federal court in California charging the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) with violations of the law in partially deregulating genetically engineered (GE) sugar beets. *Center for Food Safety v. Vilsack*, No. 11-0831 (U.S. Dist. Ct., N.D. Cal., filed February 23, 2011). Details about the agency's action are included in **Issue 381** of this *Update*.

Seeking declaratory and injunctive relief, the group and several other organizations concerned about the safety of GE crops and their alleged potential to contaminate conventional and organic crops, challenge the February 4, 2011, APHIS decision to approve an environmental assessment prepared in connection with the agency's decision to issue an interim partial deregulation of Roundup Ready® sugar beets. According to the complaint, "The partial deregulation decision purports to allow planting and use of [GE sugar beets] pending the completion by APHIS of an Environmental Impact Statement ('EIS'). This interim partial deregulation decision will authorize permits for the continued commercial production of [GE sugar beet] seed and the commercial planting and production of [GE sugar beet] root crops in 2011."

The complaint recites the history of the litigation that led a district court to order APHIS to complete an EIS before deregulating GE sugar beets and to order the destruction in December 2010 of GE sugar beet seedlings that APHIS had summarily allowed to be planted before completion of the EIS, anticipated to occur sometime in 2012. The Ninth Circuit Court of Appeals, which conducted a February 15 oral argument on the government's appeal, stayed the lower court's order to destroy the seedlings pending the appeal's outcome. The plaintiffs contend that APHIS has failed to comply with a number of laws requiring it to assess environmental, economic and human health effects before deregulating a plant pest and that the agency's decision "completes the remainder of APHIS's interim commercialization plan for [GE sugar beets] during the pendency of the . . . EIS."

Among other matters, the plaintiffs seek a court order enjoining APHIS from allowing any GE sugar beets to be planted before it complies with the National Environmental Policy Act, Plant Protection Act and Food, Conservation, and Energy Act of 2008.

EPA Questions Standing of Food Interests to Bring Lawsuit over Ethanol Blend Waiver

The Environmental Protection Agency (EPA) issued two decisions allowing the sale of ethanol blends above 10 percent, referred to as E15, for use in model year 2001 and newer vehicles. Both decisions have been challenged in

court, and the agency has filed a response to a motion filed by food industry interests asking the court to accelerate the briefing schedule. *GMA v. EPA*, No. 10-1380 (U.S. Dist. Ct., D.C. Cir., opposition filed February 17, 2011). EPA asked the court considering the actions to instead adopt a consolidated briefing schedule that allows both decisions to be addressed, in the interest of preserving judicial resources.

In a footnote, EPA suggests that the food industry parties may lack standing to challenge the agency's E15 waiver. Apparently, EPA regulations give "only fuel and fuel additive manufacturers" the ability to register E15, and they are already represented in a challenge to EPA's action. EPA also notes, "given that several steps would need to occur before E15 is actually introduced into commerce, it is unclear whether the Moving Petitioners have standing to challenge the E15 waiver."

Dairy Farmer Sues British Columbia over Raw Milk Distribution Ban

A British Columbia resident who operates a "cowshare" that produces and distributes raw milk to members has filed a lawsuit against the provincial government challenging a regulation that prohibits the sale of milk that has not been pasteurized. *Jongerden d/b/a Home on the Range v. The Queen*, No. S-111196 (Sup. Ct., British Columbia, filed February 23, 2011). According to the complaint, the plaintiff has been cited for packaging and distributing raw milk for human consumption and was further cited for contempt when she continued to sell the milk after labeling it as "not for human consumption." The plaintiff contends that raw milk has beneficial health effects and that the *ultra vires* regulation has prevented her from obtaining and consuming raw milk from a lawful source.

OTHER DEVELOPMENTS

Rudd Center Legal Director Calls for New FOP Labeling Direction

The director of legal initiatives for Yale University's Rudd Center for Food Policy and Obesity has authored an article on front-of-package (FOP) food and beverage labeling that calls for "new directions for research and regulation." **Jennifer Pomeranz, "Front-of-Package Food and Beverage Labeling: New Directions for Research and Regulation," *American Journal of Preventative Medicine*, March 2011**. Claiming that "food labels have become unwieldy from a consumer, health, and regulatory perspective," Jennifer Pomeranz's article explores the current state of "FOP schemes, health and nutrition claims, and enforcement activity," and makes specific research recommendations for each context. In particular, it notes several areas—such as health and nutrition claims—that appear ripe for regulation and where additional scientific evidence could overrule First Amendment objections.

"When the FDA and industry finalize their FOP schemes, research will be needed to assess their scientific validity, their efficacy for consumer use and comprehension, and whether a mandatory FOP scheme is necessary," concludes the article. "Research is also warranted to reveal the limitations of current laws pertaining to health and nutrition claims to support strengthening the scientific basis and nutritional requirements for making a claim. Finally, groups that identify false, deceptive, and misleading food labels and related advertising should bring these practices to the attention of appropriate government entities."

World Anti-Doping Agency Investigates Tainted Beef from China

The World Anti-Doping Agency (WADA) has reportedly requested information from China concerning the country's use of steroids in raising cattle after some athletes blamed tainted beef for their positive drug tests. Noting that he is awaiting a response from the Chinese minister for a "full explanation of what happens in the industry," WADA director general David Howman said, "there seems to be some evidence that some beef in China may have been stimulated in their growth by the use of steroids."

A WADA-accredited lab in Cologne, Germany, apparently discovered that 22 of 28 returning travelers from China tested positive for low levels of agency-banned clenbuterol, a livestock-bulking substance that builds muscle and burns fat. In related developments, the Spanish cycling federation recently cleared the Tour de France champion who had blamed his positive clenbuterol test on contaminated meat from Spain, and a German table tennis player was cleared after blaming Chinese meat for his positive clenbuterol test. Although WADA dropped an appeal in the German case, Howman was quoted as saying that the agency was waiting to see if the International Cycling Union challenges the Spanish ruling before deciding whether to appeal on its own. *See The Associated Press,* February 22, 2011.

"Super Size Me" Director Tackles Product Placement

According to media sources, documentarian Morgan Spurlock recently screened his latest film about advertising and product placement at the 2011 Sundance Film Festival, with plans for a general audience release in April 2011. Best known for "Super Size Me," a film critical of the fast-food industry, Spurlock's "POM Wonderful Presents: The Greatest Movie Ever Made" apparently "unmasks the marketing process to bring audiences behind closed doors directly into the pitch meetings and marketing presentations which ultimately inform our everyday entertainment decisions," according to a press release issued by film sponsor POM Wonderful®. Financed entirely by product placement, the film reportedly explores the world of co-promotion "with humor and insight," although *Advertising Age* also noted a focus on "advertis-

ing's wrongs," such as "the marketers' hooks in children," and new techniques such as neuromarketing.

"I felt the best way to examine the ever-growing debate of brand integration in film and television was to make a non-fiction film that openly uses brand integration to tell the story," said Spurlock. "The idea was to do the same type of advertising, giveaways and cross-promotion for a documentary that big summer blockbusters do, to create a 'docbuster,' and to try to retain total creative control along the away." *See POM Wonderful Press Release,* January 22, 2011; *Advertising Age,* February 21, 2011.

MEDIA COVERAGE

"Happy Meals" Lawsuit Hype Could Lead to Food Industry Reforms

Highlighting the California lawsuit that seeks to stop McDonald's from marketing "Happy Meals" to children, a March 2011 *Inside Counsel* **article** cautions corporate counsel to pay attention to such litigation, because, frivolous or not, the case marks a growing national focus on health and governmental initiatives to impose reforms on the food industry. Additional information about the case appears in **Issue 375** of this *Update*.

Author and managing editor Ashley Trent quotes Shook, Hardy & Bacon Agribusiness & Food Safety Co-Chair **Madeleine McDonough** who questioned whether the lawsuit could be certified as a class. "There are so many individual issues," she said. "What kind of advertising did [putative class members] actually see? What's the proof that they actually relied on the advertising? What are the reasons they ate at McDonald's? What did they eat? What kind of control did the parents exercise?" Other legal experts questioned the strength of the lawsuit's substantive claims.

The article also discusses a number of regulatory initiatives aimed at youth marketing by the industry, including stalled interagency efforts at the federal level and the ban that San Francisco imposed on the sale of fast-food meals of low nutritional value with toys. Noting that some major industry players are adopting voluntary nutritional reforms, the article closes with a call by McDonough for dialogue outside the courtroom to effect change. "Litigation puts people in such a polarized position that it protracts real advances," according to McDonough. "Common ground can be achieved—and perhaps greater effects in public health and in consumer options—when people sit down at the same table and work something out."

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SCIENTIFIC/TECHNICAL ITEMS

Tufts University Researcher Claims Canadians Confused about BPA

In an academic analysis, a Tufts University researcher has reportedly called for "strong legislation" to protect Canadians from continued exposure to bisphenol A (BPA) in light of Canada last year becoming the first country to declare the chemical a toxic substance. Laura Vandenberg, "Exposure to bisphenol A in Canada: invoking the precautionary principle," *Canadian Medical Association Journal,* February 2011. Although noting that Canadians have half the levels of BPA in their bodies as Americans—reasons for which may include the absence of Canadian BPA production plants—Vandenberg suggests that the lack of a BPA ban in Canada puzzles consumers.

"Health Canada continues to maintain that bisphenol A is safe at current exposure levels and does not pose any risk to the general population; regulations to remove bisphenol A from all food-contact sources, or ban it completely, are not yet forthcoming, presenting a conflict that is likely to confuse the public," Vandenberg wrote. "By invoking the precautionary principle, Health Canada has both the power and responsibility to restrict human exposure to BPA." *See FoodProductionDaily.com,* February 23, 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.