

FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATIONS, REGULATIONS AND STANDARDS

PCAST Calls for More Competitive Research Grants and a Network of Agricultural Institutes

The President's Council of Advisors on Science and Technology (PCAST) has [issued](#) a report urging the federal government to launch "a coordinated effort to boost American agricultural science by increasing public investments in that economically important domain and rebalancing the U.S. Department of Agriculture's research portfolio." According to a press release from the Executive Office of the President, the report also calls for the creation of a network of public-private agricultural "innovation institutes" to leverage the strengths of government scientists and commercial interests.

PCAST concludes that "the United States is the undisputed world leader in agricultural production today, but also cautions that U.S. agriculture also faces a number of challenges that are poised to become much more serious in the years ahead." These challenges include (i) managing new pests, pathogens and invasive plants; (ii) increasing the efficiency of water use; (iii) reducing the environmental footprint of agriculture; (iv) adapting to a changing climate; and (v) accommodating demands for bioenergy—all while continuing to produce safe and nutritious food at home and for those in need abroad.

Based on an analysis of nearly 36 studies focused on the impact of agricultural research on food, feed and energy production and on food safety and nutrition, the report notes that the United States has derived a "substantial societal return on its current investments in agricultural research," with the economy gaining at least \$10 in benefits for every \$1 invested in agricultural research. PCAST, however, identifies two shortcomings in the current approach to U.S. agricultural research enterprises. "First, although competitive grants are widely recognized as having greater innovation potential than grants based on other mechanisms, the proportion of Federal funding for agricultural research allocated through competitive mechanisms is far below the proportion for other fields of research in other science agencies—due in part to longstanding Congressional constraints," states the report. "Second, the current agricultural research portfolio overlaps too much with private-

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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.

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.

sector activities while underfunding areas that are not adequately addressed through private efforts—a situation that calls out for a rebalancing of the research portfolio in favor of greater Federal attention to basic, non-commercial research for the public good and workforce development.”

Focused public investment would not only invigorate agricultural research and create opportunities for new private-sector ventures, but also provide the means to train the next generation of farmers and agricultural researchers to meet the workforce demands of U.S. agriculture in the 21st century, the report concluded. Overall, PCAST recommends that the United States increase its investment in agricultural research by a total of \$700 million per year to nurture a new “innovation ecosystem” that would leverage the best of America’s diverse science and technology enterprises for advancements in agriculture.

“Meeting these challenges will require a renewed commitment to research, innovation, and technology development in agriculture,” said Daniel Schrag, co-chair of the PCAST Agricultural Preparedness Working Group. “If we act strategically today we will gain invaluable benefits tomorrow, including enhanced food security, better nutrition, greener sources of energy, and healthier lives, while we grow the rural economy.”

FTC Finds Apps for Kids Lack Adequate Privacy Disclosures

The Federal Trade Commission (FTC) has [released](#) a December 2012 staff report finding that only 20 percent of the 400 children’s mobile applications under review “contained any privacy-related disclosure on the app’s promotion page, on the developer Website, or within the app.” Titled “Mobile Apps for Kids: Disclosures Still Not Making the Grade,” the report also warned that even when privacy policies were provided, they were often “long, dense and technical” or lacking in “basic details, such as what specific information about a child would be collected, the reason for collecting such information, or what parties would obtain the information.”

According to FTC staff, its testing results evidently revealed that 59 percent of the 400 apps “transmitted some information from a user’s mobile device back to the developer or a third-party,” with 5 percent transmitting the device ID to developers; 56 percent transmitting the device ID to advertising networks, analytics companies or other third parties; and 3 percent transmitting geolocation information to developers and advertising networks, often without disclosing how third parties would use it. The agency also noted “a high incidence of interactive features within the apps that, in most cases, were not disclosed to users.” In particular, the staff reported that only 15 of the apps “indicated the presence of advertising prior to download,” while only 9 percent disclosed links to social networking services before download.

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In light of these conclusions, FTC has called on app stores, developers and third parties that interact with the apps to implement the recommendations made in its recent Privacy Report by (i) "adopting a 'privacy-by-design' approach to minimize risks to personal information"; (2) "providing consumers with simpler and more streamlined choices about relevant data practices"; and (3) "providing consumers with greater transparency about how data is collected, used, and shared." The agency has also apparently indicated that it intends to update the Children's Online Privacy Protection Act (COPPA) in the near future as well as launch non-public investigations "to determine whether certain entities in the mobile app marketplace are violating [COPPA] or engaging in unfair or deceptive practices in violation of the Federal Trade Commission Act."

"While we think most companies have the best intentions when it comes to protecting kids' privacy, we haven't seen any progress when it comes to making sure parents have the information they need to make informed choices about apps for their kids. In fact, our study shows that kids' apps siphon an alarming amount of information from mobile devices without disclosing this fact to parents," said FTC Chair Jon Leibowitz in a December 10, 2012, press release. "All of the companies in the mobile app space, especially the gatekeepers of the app stores, need to do a better job. We'll do another survey in the future and we will expect to see improvement." See *Advertising Age*, December 10, 2012.

FSIS Implements 'Hold and Test' Policy For Poultry and Beef

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) has [announced](#) that, as of February 8, 2013, it will require producers of non-intact raw beef and all ready-to-eat products containing meat and poultry to hold shipments until they pass agency testing for foodborne pathogens. FSIS announced its plan to implement this policy in April 2011.

In the past, FSIS's practice has apparently been "to allow products tested for adulterants to bear the mark of inspection, and to enter commerce, even when test results have not been received." FSIS had asked, but not required, official establishments to maintain control of products tested for adulterants pending test results. According to FSIS, "because establishments, including official import inspection establishments, were not consistently maintaining control of product, despite FSIS's request that they do so, adulterated product was entering commerce." FSIS has reportedly stated that if the new requirement had been in place between 2007 through 2010, 49 of the 251 meat, poultry and processed egg product recalls that occurred during that time could have been prevented.

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The new policy requires official establishments and importers of record to maintain control of products tested for adulterants by FSIS and not allow the products to enter commerce until negative test results are received. FSIS anticipates most negative test results will be determined within two days. The policy applies to non-intact raw beef products or intact raw beef products intended for non-intact use and that are tested by FSIS for Shiga-toxin producing *Escherichia coli*. The policy also applies to any ready-to-eat products FSIS tests for pathogens.

"This new policy will reduce foodborne illnesses and the number of recalls by preventing contaminated products from reaching consumers," said USDA Undersecretary for Food Safety Elisabeth Hagen in an FSIS news release. "Many producers hold products until test results come back. We're encouraging others in the industry to make this a routine part of operations." See *Federal Register*, December 10, 2012.

APHIS Requests Three-Year Extension of Information Collection Activities

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has requested an extension of approval of an information collection associated with the regulations for the introduction of organisms and products altered or produced through genetic engineering.

The regulations set forth "the permit application requirements and the notification procedures for the importation, interstate movement, or release into the environment of a regulated article and necessitate certain information and recordkeeping requirements, including APHIS-issued permits, applicants' field testing records, and the submission of protocols to ensure compliance."

APHIS is asking the Office of Management and Budget to approve its use of these information collection activities for an additional three years. The agency will consider comments received by February 11, 2013. See *Federal Register*, December 11, 2012.

FDA Renews Food Safety Agreement with Chinese Counterpart

The Food and Drug Administration (FDA) has extended for five years a 2007 food safety agreement with the General Administration of Quality Supervision, Inspection, and Quarantine of China (AQSIQ) to "enhance cooperation between the U.S. and China on food and feed safety." The agreement includes provisions enhancing FDA's "ability to identify high-risk food products entering the United States from China," facilitating food facility inspections, focusing on "high-risk foods," and creating processes for FDA to "accept relevant, verified information from AQSIQ regarding registration and certification." See *CFSAN Constituent Update*, December 11, 2012.

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New Russian Regulation on U.S. Pork and Beef Imports

Russian health regulators have announced a new regulation that will require imported meat to undergo testing for and be certified free of ractopamine, a hormone that has reportedly been linked to health concerns. The additive allegedly promotes animal growth and leaner meat and is added to some animal feed in the United States.

According to news sources, because the U.S. Department of Agriculture (USDA) has no mechanism in place certifying meat as "ractopamine free," the Russian requirement could effectively halt U.S. pork and beef exports to the country, profoundly affecting the more than \$500-million market. Some industry analysts reportedly see the move as retaliation for American legislation punishing Russian officials linked to alleged human rights violations.

In a recent press release, U.S. Agriculture Secretary Tom Vilsack stated, "The United States is very concerned that Russia has taken these actions, which appear to be inconsistent with its obligations as a member of the World Trade Organization [WTO]. The United States calls on Russia to suspend these new measures and restore market access for U.S. beef and pork products. The United States sought, and Russia committed as part of its WTO accession package, to ensure that it adhered rigorously to WTO requirements and that it would use international standards unless it had a risk assessment to justify use of a more stringent standard. Especially in light of its commitment to use international standards, this is an important opportunity for Russia to demonstrate that it takes its WTO commitments seriously."

Additional details about a recent report on ractopamine residue in pork appear in Issue [463](#) of this *Update*. See *Agrimoney.com*, December 12, 2012.

New Vending Machine Rules Approved for Some Chicago Buildings

Chicago's City Council has reportedly approved an ordinance that will impose new nutrition rules on most food and drinks sold from 350 vending machines in 94 city buildings, setting restrictions on fat, calories, sugar, and sodium. The new ordinance applies to vending machines in city-owned and -leased buildings and takes effect January 2013. In a recent press release, Mayor Rahm Emanuel (D) said that the changes aim to encourage personal responsibility. "These new vending machines will make it easier than ever before for city employees and the public to make healthy lifestyle choices," he said. "When city employees take their wellness into their own hands, we can reduce health care costs and also serve as a model for the residents of Chicago when it comes to making health choices."

Many health advocates have purportedly said that it makes sense to set standards for machines aimed at children and at city workers whose health care is paid for with taxpayer dollars. But some said the new standards do not go

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far enough. Although most offerings would need to meet health guidelines, 25 percent of each machine could be stocked with sugary drinks or any kind of snack, regardless of nutrition. "It's not appropriate to be selling a harmful product on city property with obesity, diabetes and stroke being such enormous problems in our communities," Center for Science in the Public Interest Executive Director Michael Jacobson was quoted as saying. "We need to be more active in reducing consumption of this major cause of these problems."

Meanwhile, opponents of the new vending machine rules have apparently deemed them overreaching. According to news sources, Cherylyn Harley LeBon, co-chair of Project 21, which is affiliated with the National Center for Public Policy Research, recently said, "We live in a free-market society, not North Korea. ... Adults are capable of making their own decision, and I think it's a problem when the mayor thinks he can define for us what is junk and healthy food."

Chicago Public Schools reportedly improved its food offerings in vending machines a few years ago, but last month the district approved even tighter standards for all food sold outside the cafeteria. Those include limits on fat and sugar in foods and the elimination of all drinks except low-fat milk, juice and water; sports drinks will apparently be restricted to student athletes doing vigorous activity for at least one hour.

A recent *Chicago Tribune* article notes that Chicago Public Health Commissioner Bechara Choucair, who testified in favor of a failed municipal soda tax earlier this year, has said that he believes the city is striking a moderate tone by setting rules yet allowing sales of some less-healthy options. "It's OK to have a treat once in a while," Choucair reportedly said, "But at the end of the day, we are emphasizing for city residents that it's important to make the healthy choice most of the time." He also observed that the new rules restrict high-calorie drinks to 12 ounces and require healthier items to be placed at eye level and priced competitively with less healthy items. *See Chicago Tribune*, December 13, 2012.

LITIGATION

Spurned Expert Asks SCOTUS for Non-Party Right to Appeal

David Egilman, whose expert testimony was deemed inadmissible in proceedings involving a consumer's exposure to the butter-flavoring chemical diacetyl in microwave popcorn, has filed a petition for writ of *certiorari* (No. 12-697) in the U.S. Supreme Court. He asks, "Whether a nonparty to a district court proceeding has a right to appeal a decision that adversely affects his interest, as the Second, Sixth, and D.C. Circuits hold, or whether, as six other circuit courts hold, the nonparty must intervene or otherwise participate in the district court proceedings to have a right to appeal?" He was apparently

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retained by a couple seeking to recover for the lung injury sustained by the husband, but the district court found his testimony inadmissible and granted summary judgment for the manufacturers.

According to Egilman's petition, the district court did not confine itself to a traditional reliability inquiry, but "attacked the character and professionalism of the expert himself. The lower court accused Petitioner of offering 'misleading' testimony based on 'manipulated data.'" He sought to appeal to the Ninth Circuit, "solely for the purpose of striking the offending language from the lower court's opinion." The Ninth Circuit determined that "no matter how damaging the effect of the district court's opinion," Egilman had no right to challenge it because he was not a participant in the district court proceedings. Emphasizing the circuit court split, Egilman requests that the Court review the Ninth Circuit's ruling and resolve the conflict.

MDL Court Certifies Class of Purchasers After Full-Blown *Daubert* Analysis

A multidistrict litigation (MDL) court that is considering pre-trial matters in 91 consolidated antitrust lawsuits alleging that major chocolate manufacturers conspired to implement price increases from 2002 through 2007, has granted the direct-purchaser plaintiffs' motion for class certification. *In re Chocolate Confectionary Antitrust Litig.*, MDL No. 1935 (U.S. Dist. Ct., M.D. Pa., order entered December 7, 2012). The court did so after first determining whether the plaintiffs' expert testimony in support of class certification is reliable under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

The U.S. Supreme Court is currently facing a similar issue, that is, "Whether a district court may certify a class action without resolving whether the plaintiff class has introduced admissible evidence, including expert testimony, to show that the case is susceptible to awarding damages on a class-wide basis." The MDL court, noting that the issue has not yet been decided in the Third Circuit, found persuasive the reasoning of the Fifth and Seventh Circuits, which have found that a full *Daubert* analysis is called for at the Rule 23 certification stage in appropriate situations. Given its role in deciding whether the class claims predominate, the MDL court said, "A court should be hard pressed to conclude that the elements of a claim are capable of proof through evidence common to the class if the only evidence proffered would not be admissible as proof of anything."

The court found the plaintiffs' expert testimony, which was based on econometric modeling and focused on the nature of the chocolate confectionary industry as purportedly conducive to price-fixing, admissible. Then the court certified a class of "All persons and entities who directly purchased standard ('singles') and King size ('King') single serve chocolate candy for re-sale from any Defendant or any predecessor, controlled subsidiary affiliates or division

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of any Defendant, in the United States or for delivery into the United States at any time from December 9, 2002 through December 20, 2007."

Court Directs Litigants to Take Yogurt Dispute to FDA

A federal court in Minnesota has dismissed without prejudice state law-based consumer-fraud claims filed against a company that makes Greek yogurt not by straining it, a process essential to the traditional production of this thickened dairy product, but by adding milk protein concentrate (MPC). *Taradejna v. General Mills, Inc.*, No. 12-993 (SRN/LIB) (U.S. Dist. Ct., D. Minn., decided December 10, 2012). So ruling, the court directed the parties to initiate proper proceedings before the Food and Drug Administration (FDA).

The court recites FDA yogurt-related standard-of-identity initiatives since 1981, culminating in a pending 2009 proposal that would permit the use of "any safe and suitable milk-derived ingredient as an optional dairy ingredient in the manufacture of yogurt." Finding that application of the primary jurisdiction doctrine was appropriate in the matter, the court states, "The underlying issue here is whether MPC is a proper, permitted ingredient in yogurt. The resolution of this question falls squarely within the competence and expertise of the FDA, pursuant to the authority granted to the Agency by Congress. ... The current standard of identity for yogurt, the stayed 1982 limitations, the Agency's subsequent public statement about the standard, and the 2009 Proposed Rule do not constitute a model of clarity. The FDA is in the best position to resolve any ambiguity about the standard of identity for yogurt—a matter requiring scientific and nutritional expertise."

The court also notes that national uniformity in labeling would be ensured if FDA decides the matter, stating in this regard, "The Agency's unique role in ensuring such consistency and uniformity is particularly significant here, as several recently filed yogurt lawsuits throughout the country involve the same or similar issues as found in the instant suit. The increasing volume of this litigation creates the potential for inconsistent judicial rulings. This underscores the importance of promoting uniformity by referral of this matter to the FDA." Finding the issue moot, the court declined to issue a ruling on preemption.

Plaintiff Cannot Sue for "Fake" White Chocolate Products He Did Not Buy

A federal court in California has dismissed in part putative class claims filed by a man who alleges that Ghirardelli Chocolate Co. white chocolate products do not contain the requisite white chocolate ingredients to be labeled and promoted as such. *Miller v. Ghirardelli Chocolate Co.*, No. C 12-04936 LB (U.S. Dist. Ct., N.D. Cal, San Francisco Div., decided December 6, 2012). The court agreed with Ghirardelli that the plaintiff lacked standing to pursue claims relating to four products that he did not purchase. According to the complaint, the plaintiff bought a package of "Ghirardelli Chocolate Premium Baking Chips Classic White" and sought

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recovery on behalf of a class of purchasers of that product as well as white chocolate wafers, ground white chocolate flavor, a mocha mix, and a frappé product.

Noting that controlling authority is lacking on whether plaintiffs have standing for products they did not purchase, the court discussed two lines of cases: one in which federal courts have held that as a matter of law plaintiffs lack standing to assert such claims and the other, the majority of courts, that carefully analyze the question and find that standing can be established to assert claims for unnamed class members if “the products and alleged misrepresentations are substantially similar.” The court found that the products here were not sufficiently similar. Refusing to dismiss the remaining claims pertaining to the baking chips on preemption, insufficient pleading or failure to state a claim grounds, the court gave the plaintiff the opportunity to amend his complaint.

Putative Class Claims Monster Beverage Targets Youth and Miscategorizes Energy Drinks

A plaintiff who claims he began consuming Monster Beverage energy drinks as a teenager, because he was offered free beverages from a truck parked outside his high school, has filed a putative nationwide consumer-fraud class action against the company in a California federal court. *Fisher v. Monster Beverage Corp.*, No. EDCV12-02188 VAP (OPx) (U.S. Dist. Ct., C.D. Cal., filed December 12, 2012). Among other matters, he claims that the company aggressively markets the products to youth and falsely labels them as dietary supplements to avoid regulation under Food and Drug Administration beverage rules. He further contends that the products are addictive.

Alleging violations of California’s Unfair Competition Law, False Advertising Law and Consumers Legal Remedies Act, breach of express and implied warranties, violation of the Magnuson-Moss Warranty Act, and unjust enrichment, the plaintiff seeks actual, statutory and punitive damages; corrective labeling, advertising and marketing; full restitution and disgorgement; and interest.

Worker Exposed to Diacetyl on the Job Loses Before California Jury

According to a news source, the first “popcorn-lung” occupational exposure case tried in California has resulted in a defense verdict. *Velasquez v. Flavor & Extract Mfrs. Ass’n*, No. BC370319 (Cal. Super. Ct., Los Angeles County, verdict reached December 12, 2012). The plaintiff was a former flavoring factory employee who claimed that his exposure to the butter-flavoring chemical diacetyl caused his debilitating lung disease, bronchiolitis obliterans.

His attorney was quoted as saying, “The defense was very effective in confusing the jury,” observing that the defense suggested that the plaintiff’s health problems could have been attributed to acetaldehyde, another chemical flavoring. The lawsuit originally involved 10 defendants, a number of whom settled with the plaintiff before trial. Plaintiff’s counsel has reportedly indicated that the verdict

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will be appealed, citing, among other matters, the trial court's decision to allow the jury to hear that the plaintiff is an illegal immigrant. See *Law360*, December 13, 2012.

Former Beef Processing Worker Sues Jamie Oliver and ABC Anchor

One of the 750 beef processing plant employees who lost his job in the wake of recent negative publicity involving "lean finely textured beef," otherwise referred to in the media as "pink slime," has reportedly filed a lawsuit in a Nebraska state court naming as defendants celebrity chef Jamie Oliver, ABC's Diane Sawyer, a blogger, and 10 unnamed individuals. Bruce Smith, who worked as senior counsel and director of environmental, health and safety at Beef Products, Inc., is apparently seeking \$70,000 in damages on the ground that the company "and its employees were unfairly and unnecessarily maligned and accused of producing a food product that did not exist, a product that critics unfairly labeled 'pink slime.'" The publicity apparently led to the loss of numerous contracts for the product's purchase. See *The Daily Mail*, December 12, 2012.

LEGAL LITERATURE

SHB Attorneys Discuss Preemption Ruling in Nutrient-Content Class Action

Shook, Hardy & Bacon Global Product Liability Attorneys [Frank Cruz-Alvarez](#) and [Talia Zucker](#) have co-authored an [article](#) about a recent federal court ruling that rejected The Hershey Company's preemption-based challenge to a putative class action alleging that the nutrient content claims on its product labels violate the law. Additional information about *Khasin v. The Hershey Co.*, No. 12-1862 (N.D. Cal. 11/9/12), appears in Issue [463](#) of this Update.

Titled "The Food Court Stays Open: Preemption Defense in Food Labeling Class Action Rejected," the article was published on December 12, 2012, in the Washington Legal Foundation's blog "The Legal Pulse." Noting that the ruling was disappointing for food manufacturers, the authors contend that "hope is not lost. Express preemption remains an essential argument for food company defendants in such litigation and though rejected in the *Hershey* case, not all facts lend themselves to such a gloomy conclusion." As an example, they cite a case currently on appeal in the Third Circuit; it was dismissed by a district court which found that the plaintiff was seeking to impose label requirements different than those FDA requires. "And as such, his claims were expressly preempted."

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OTHER DEVELOPMENTS

R-CALF Raises Concerns over Mad Cow Disease in Brazil

The Ranchers-Cattlemen Action Legal Fund (R-CALF USA) sent a December 10, 2012, [letter](#) to the U.S. Department of Agriculture (USDA) requesting the immediate suspension of imports of ruminants and ruminant products from Brazil after the country notified the World Organization for Animal Health (OIE) about a confirmed case of bovine spongiform encephalopathy (BSE) detected in a 13-year-old cow that died two years ago.

R-CALF USA also asked that the suspension “remain in place until [the] agency conducts a thorough and probing investigation to determine the risk of introducing BSE into the U.S. from Brazil,” and noted that “should [the agency] choose to resume such imports from Brazil, [it] must first initiate a public rulemaking with notice and opportunity for comment.”

According to an R-CALF USA [press release](#), Brazilian officials in early 2011 subjected the cow to one of two primary tests for mad cow disease—a histopathological test—that indicated the cow was negative for BSE. In mid-2012, however, a brain sample from the suspect cow was subjected to the second primary test for mad cow disease—the immunohistochemical test—which tested positive.

Officials allegedly claim that the long delay between the two primary tests was due to a combination of a work overload at the testing laboratory and OIE rules that caused Brazil to lower the priority of testing the suspect cow. According to news sources, OIE allows “fallen stock” and cattle “over 9 years” to be classified with a “low diagnosis priority level.”

After the brain sample tested positive in mid-2012, it was sent to the OIE reference laboratory in the United Kingdom, where it again tested positive for BSE on December 6, 2012.

Brazil has reportedly been criticized for the apparent two-year delayed notification. According to R-CALF USA Animal Health Committee Chair Max Thornsberry, the delay is a symptom of the failure of the OIE’s global system that erroneously assumes foreign countries, particularly developing countries, have the same means, commitment and capabilities as the United States to control and eradicate diseases. “This shows that the United States should not be relying on the OIE or on foreign countries to ensure that food imported into the United States is safe,” he said.

Brazilian officials apparently claim that the case was an isolated event and the infected cow had been exclusively grass-fed and had not been given cattle feed containing rendered cow parts—a practice linked to “classical” BSE cases that spread through the United Kingdom in the 1980s and 1990s. In response

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to the recent test results, however, the Japanese government announced on December 8 that it would halt beef imports from Brazil, and, as the world's second-biggest exporter of beef (behind India), Brazil could face significant losses if other nations follow Japan's lead. Officials have reportedly said that Brazil will send missions to the top 20 nations that buy its beef to explain the case.

***Why We Get Fat* Author Launches Initiative to Investigate New Research on Obesity**

Science Writer Gary Taubes, who authored *Why We Get Fat*, writes in *Nature* magazine that obesity is not a matter of energy in-energy out, but is rather a "hormonal, regulatory defect." In his December 13, 2012, article titled "Treat obesity as physiology, not physics," Taubes bases this conclusion on endocrinology and calls for better research into hormonal theories about why we get fat. To that end, he has co-founded the [Nutrition Science Initiative](#), a nonprofit organization "dedicated to reducing the economic and social burden of obesity and obesity-related chronic disease by improving the quality of science in nutrition and obesity research."

Among other matters, the initiative will "fund and facilitate the trials necessary to rigorously test the competing hypotheses, beginning with inpatient feeding studies that will rigorously control dietary interventions for participants so that we know unambiguously the effects of macronutrients—protein, fat and carbohydrates—on weight and body fat." Taubes suggests that it is the "quantity and quality of carbohydrates consumed" that has contributed to the obesity epidemic, not simply excess calories.

SCIENTIFIC/TECHNICAL ITEMS

Scientists Question Use of NHANES Data for Chemical Exposure Studies

A recent research article focusing on bisphenol A (BPA) has questioned the use of National Health and Nutrition Examination Survey (NHANES) datasets "to draw causal inferences regarding environmental chemical exposures and adverse health outcomes." Judy LaKind, et al., "Use of NHANES Data to Link Chemical Exposures to Chronic Disease: A Cautionary Tale," *PLoS One*, December 2012. Using "consistent *a priori* selected methods," researchers analyzed four NHANES datasets to determine whether (i) there was "a consistent association between urinary [BPA] measures and diabetes, coronary heart disease (CHD), and/or heart attacks across surveys"; and (ii) NHANES was "an appropriate dataset for investigating associations between chemicals with short physiologic half-lives such as BPA and chronic disease with multi-factorial etiologies."

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The results evidently revealed no significant associations "between urinary BPA and heart disease or diabetes" for any of the NHANES surveys. Based on these findings, the study's authors opted not to draw "any conclusions regarding whether BPA is a risk factor for these diseases," but instead cautioned that "using cross-sectional datasets like NHANES to draw such conclusions about short-lived environmental chemicals and chronic complex disease is inappropriate." In particular, they noted that "the main limitation of cross-sectional studies such as NHANES is the inability to determine the temporal sequence of exposure and outcome, the main property of a cause-and-effect relation."

"Whether one-time measurements of chemicals with short physiologic half-lives can or should be used to ascertain chronic exposures must be carefully explored on a chemical-by-chemical basis," concluded the authors. "However, it is clear that for many chemicals we cannot be confident that one-time measurements represent long-term exposures. ... We need to expend resources on more appropriately designed epidemiologic studies and toxicological explorations to understand whether these types of chemicals play a causal role in chronic disease."

Cheese the Secret Ingredient in French Cardiovascular Health?

A recent article has speculated that cheese consumption is behind the epidemiological phenomenon known as the "French paradox," that is, "the low rates of cardiovascular mortality which have existed in France for decades despite high saturated fat consumption." Ivan Petyaev and Yurig Bashmakov, "Could cheese be the missing piece in the French paradox puzzle," *Medical Hypotheses*, December 2012. Although previous studies have attempted to link red wine consumption to reduced cardiovascular mortality, the article argues that the "French paradox" "seems to be a multifactorial phenomenon and not due solely to red wine intake."

The authors hypothesize that many cheeses—and particularly molded cheese—contain unique peptides "inhibiting the inflammatory cascade and angiotension-converting enzyme [that] may provide a pharmacological basis for this phenomenon." They also note that in addition to bacteria-ripened varieties, such as Cheddar and Gouda, blue-veined cheeses including Roquefort contain "some important secondary metabolites" produced by *Penicillium roqueforti*, *Penicillium camemberti* or other fungi. These metabolites apparently include "andrastins A-D as well as roquefortine, whose ability to inhibit cholesterol biosynthesis and bacterial growth might be a key mechanism in favoring their therapeutic potential for cardiovascular disease."

"Therefore it is plausible to conclude that cheese consumption might be an important factor in conferring resistance to cardiovascular disease in the French population," write the researchers, who ultimately recommend further

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clinical studies of molded cheese. "This statement is well supported by the fact that other European countries with similarly high cheese consumption (Switzerland, Greece) have a lower incidence of cardiovascular disease and mortality."

Study Examines Effect of Total Fat Intake on Body Weight

A recent World Health Organization-commissioned meta-analysis has reportedly concluded that diets lower in fat can reduce relative body weight by 1.6 kg, BMI by 0.56kg/m² and waist circumference by 0.5 cm. Lee Hooper, et al., "Effect of reducing total fat intake on body weight: systematic review and meta-analysis of randomized controlled trials and cohort studies," *BMJ*, December 2012. After analyzing results from 33 randomized control trials involving 73,589 participants and 10 cohort studies, researchers apparently found "high quality, consistent evidence that reduction of total fat intake has been achieved in large numbers of both healthy and at risk participants over many years."

In particular, the meta-analysis suggested that each 1-percent reduction in energy from total fat "resulted in a 0.19 kg reduction in body weight, compared with not altering total fat intake, in populations with 23-43% of energy from total fat, and in studies of six months to over eight years," according to a concurrent *BMJ* press release. The results also evidently indicated that reductions in fat were associated "with a small but statistically significant reduction in cholesterol and blood pressure, suggesting a beneficial effect on other major cardiovascular risk factors." See *BMJ Press Release*, December 5, 2012.

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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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.

