Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

UK Nanotechnology Report Critical of Food Industry

In a development that could have a significant impact on the global food industry, the UK's House of Lords has completed an inquiry into the use of nanotechnology in foods, food packaging and food contact materials. In a January 8, 2010, press release and comprehensive report accompanied by a separate volume of evidence, the Lords' Science and Technology Committee criticizes the food industry for "not publishing or discussing details of its research in this area."

The committee calls for the government "to adequately fund research into potential health and safety risks arising from the use of nanomaterials in the food sector" and recommends that the Food Standards Agency "contribute to consumer confidence in the use of nanomaterials in food by maintaining a publicly available register of food and food packaging containing nanomaterials."

Noting the unavailability to border and port authorities of "tests to check whether imported food contains nanomaterials," the committee "raises concerns about the potential for the illegal importation of food products containing nanomaterials not approved for use in food in the EU." Accordingly, the committee's report suggests that these concerns be addressed "by providing consumers with information about products containing nanomaterials, and by the Government ensuring that practical tests are developed for enforcement authorities to use on imported food."

The committee contends that public distrust over genetically modified (GM) foods was fueled by a lack of transparency. Lord Krebs, who chairs the committee, was quoted as saying, "The food industry must also be more open with the public about research it has undertaken in this area and where it sees nanomaterials being used in food production in the future. The lesson from the public reaction to GM foods is that secrecy breeds mistrust, and that openness and transparency are crucial to maintain public confidence." A YouTube® video of Lord Krebs discussing the committee's recommendations will apparently be made available.

The committee's focus is on food products, additives and supplements; food contact packaging; food manufacturing processes; animal feed; pesticides and fertilizers; and products that may come into contact with food, such as food containers and cooking utensils. Not considered at this time were nanomaterial waste products or potential effects on the environment. The report follows a public inquiry into

nanotechnology undertaken in 2009 to consider (i) "State of the science and its current use in the food sector"; (ii) "Health and safety"; (iii) "Regulatory framework;" and (iv) "Public engagement and consumer information."

CRS Reports on Agencies' Failure to Submit Rules to GAO, Congress

The Congressional Research Service (CRS) has published a report discussing the failure of federal agencies to comply with the Congressional Review Act, which has, since 1996, required that they submit their final rules to both houses of Congress and the Government Accountability Office (GAO) before they can take effect. According to the report, CRS has identified some 1,000 final rules published in the *Federal Register* during seven of the past 10 years and not submitted to GAO and/or Congress.

Among the "missing" rules were (i) a U.S. Department of Agriculture (USDA) rule on national school lunch procurement requirements, (ii) a USDA rule on the Farm Service Agency's direct farm loan programs, (iii) a USDA rule on farm program payment limitations and eligibility under the CCC program, (iv) the Environmental Protection Agency's April 2009 rule on its "Endocrine Disruptor Screening Program," describing the policies and procedures the agency intended to adopt for initial screening, and (v) USDA rules on importation of swine from Eastern Europe and *brucellosis* in cattle.

The 1996 law that required agencies to submit their rules to Congress was enacted "to reestablish a measure of congressional authority over rulemaking." It provides a mechanism for Congress to disapprove agency final rules by means of a joint resolution of disapproval and it specifically provides that "[b]efore a rule can take effect," it shall be submitted to Congress and the GAO. According to the CRS, the law's House and Senate sponsors issued a joint statement after it was enacted to explain that "any covered rule not submitted . . . will remain ineffective until it is submitted." The statement also suggests that courts "might recognize that a rule has no legal effect," if the issuing agency failed to comply with the law.

According to OMB Watch, a government watchdog group, "The revelations in the CRS report do not necessarily mean any regulation will be automatically or quickly undone. But, for better or for worse, many regulations may now be open to legal attack. If parties affected by improperly implemented regulations sue, courts could conceivably suspend regulatory requirements or fault agencies over procedure." *See OMBWatch.org*, January 5, 2010.

FDA Calls Nestlé Products Misbranded

In a letter recently posted to its Web site, the Food and Drug Administration (FDA) has warned Nestlé USA that its Juicy Juice® products are misbranded because their labels include "unauthorized nutrient content claims." According to FDA, the product labels include the claim "Helps support brain development . . . In children under two years old" and also states "no sugar added." Under FDA regulations, these statements cannot be made on products for children younger than age 2.

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

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FDA also states that other Nestlé products have misleading labels because they imply that they contain 100 percent natural fruit juice when they actually contain "Flavored juice blend from concentrate with other natural flavors & added ingredients."

In a separate **letter**, FDA warns that the company's BOOST Kid Essentials Nutritionally Complete Drinks® are also misbranded because they are promoted as a "medical food" to address conditions such as "failure to thrive" and "pre/post surgery, injury or trauma, chronic illness." Without any evidence to show that these conditions have unique nutrient needs, FDA contends that the product is not a "medical food" nor is it a drug, although it is being promoted that way. Without FDA approval, the product cannot be marketed as a drug.

In both letters, the agency calls for a response within 15 days with "the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction."

FDA Warns Airline Food Supplier of "Provisional" Status

The Food and Drug Administration (FDA) has issued a warning **letter** to LSG SkyChefs, an airline catering company, to formally notify the company that its classification has been changed from "Approved" to "Provisional." According to the December 10, 2009, letter, an FDA inspection revealed "significant deviations" from regulatory requirements, including insect infestations, standing water, debris accumulation, and swab samples that tested positive for *Listeria monocytogenes*. The company's food processing facility will be re-inspected in 30 days, and if the conditions have not improved, "then your facility will be classified as 'Use Prohibited' or 'Not Approved.' "

FDA provided copies of its warning letter to the airlines that purchase food from SkyChefs; they will be unable to obtain food from the company if it fails the second inspection.

FDA and Northeastern University Enter Research MOU

The Food and Drug Administration (FDA) has entered a **memorandum of understanding** (MOU) with Boston's Northeastern University to "develop collaboration between the two parties in the areas of education, research, and outreach." Focusing broadly on biotechnology and analytical chemistry, the MOU is intended to "provide opportunities for exchanging of graduate and undergraduate students, faculty, and personnel and for advanced training and outreach; stimulate cooperative research, and information exchange in biological product characterization and regulation with Northeastern University's Barnett Institute of Chemical and Biological Analysis; and develop training programs for FDA and potentially other Government agencies and Industry."

Northeastern University is home to law professor and anti-tobacco activist Richard Daynard who also formed the Public Health Advocacy Institute to address food and obesity issues through legislation and litigation. The law school received a $2.7 million grant from the National Cancer Institute in 2009 to conduct a five-year research project, headed by Daynard, on "how the tobacco industry has used personal responsibility rhetoric to influence courts, legislatures, regulatory agencies and public opinion, and to see to what extent the food and beverage industries have made use of similar strategies." *See Federal Register*, January 5, 2010.

CSPI Issues "Food Labeling Chaos" Report

The Center for Science in the Public Interest (CSPI) has prepared a **report** for the Food and Drug Administration (FDA) that purportedly catalogs "some of the most egregious examples of false claims, ingredient obfuscations, and other labeling shenanigans" on the part of food manufacturers that make nutritional claims about their products. Titled "Food Labeling Chaos," the report discusses health claims made by manufacturers of breakfast cereals, beverages, snacks, and baby food. CSPI praises FDA for taking more aggressive action under the Obama administration against food manufacturers that purportedly mislabel their products, but still calls for a significant overhaul of the nation's food labeling regulations.

EPA Takes Steps to Limit or Ban Phthalates

The Environmental Protection Agency (EPA) has announced that it will take a series of actions on four chemicals that purportedly raise serious health or environmental concerns, including phthalates, which are plasticizers used in a wide array of consumer products. The agency will establish a "Chemicals of Concern" list under the Toxic Substances Control Act and intends to place on the list eight phthalates and a number of polybrominated diphenyl ethers (PBDEs), which are used as flame retardants.

According to EPA, "[i]nclusion on the list publicly signals EPA's strong concern about the risks that those chemicals pose and the agency's intention to manage those risks. Once listed, chemical manufacturers can provide information to the agency if they want to demonstrate that their chemical does not pose an unreasonable risk." The American Chemistry Council (ACC) reportedly responded by claiming that the first target chemicals "seem to have been selected based on little more than their current high-profile nature" than on scientific data. The trade organization's president and CEO has apparently charged the agency with a lack of transparency over its choice of substances and called for EPA to review all scientific studies, including those reaching a different conclusion than those previously considered.

In a statement, the ACC reportedly expressed concern about EPA's new approach to phthalates, saying "While the action plan notes that phthalates are generally detected in biomonitoring data collected by the Centers for Disease Control and Prevention (CDC), EPA fails to note that exposure to phthalates in the general public indicated by the CDC data are below—in most cases, well below—safety limits established by the EPA and the European Union."

EPA also announced that it is considering initiating a rulemaking to limit or prohibit long-chain perfluorinated chemicals (PFCs), which are used in numerous industrial and consumer applications, including "as a processing aid in the manufacture of non-stick and stain-resistant surfaces." EPA has provided more **information** and a fact sheet on the chemicals that it intends to address. *See EPA Press Release*, December 30, 2009; *FoodNavigatorUSA.com*, January 6, 2010.

Meanwhile, a study of Mexican women has reportedly found an association between the concentrations of specific phthalate metabolites in their urine and the incidence of breast cancer. Lizbeth López-Carrillo, et al., "Exposure to Phthalates and Breast Cancer Risk in Northern Mexico," *Environmental Health Perspectives Journal*, December 9, 2009. The lead author has apparently cautioned that the research shows a correlation only and not necessarily a causative relationship. Still, monoethyl phthalate, a metabolite of diethyl phthalate, was found in higher concentrations in the cases (233 women) than in the controls (221 women). *See FoodProductionDaily.com*, December 21, 2009.

DeLauro Urges Labels for Mechanically Tenderized Beef, Pork

Representative Rosa DeLauro (D-Conn.) has responded to the recent recall of 248,000 pounds of blade-tenderized steaks by urging the U.S. Department of Agriculture (USDA) "to require labeling that clearly identifies mechanically tenderized beef and pork products for all processing facilities, retailers and consumers." USDA's Food Safety and Inspection Service (FSIS) issued the Class I recall after concluding that beef products originating from an Owasso, Oklahoma, establishment might be contaminated with *E. coli* O157:H7. Working with the Centers for Disease Control and Prevention, FSIS apparently determined "that there is an association between non-intact steaks (blade tenderized prior to further processing) and illnesses in Colorado, Iowa, Kansas, Michigan, South Dakota and Washington." *See FSIS Recall Notice,* December 24, 2009.

According to DeLauro, however, "USDA has been aware of the *E. coli* risks associated with mechanically tenderized steaks as early as 1999, but has refused to act." She has also chided the Obama administration for failing to appoint an undersecretary for food safety at USDA. "This position has been vacant for far too long and it is preventing the department from acting on critical food safety issues such as this one," said DeLauro in a December 28, 2009, press release. *See USA Today,* December 30, 2009.

Meanwhile, the American Meat Institute (AMI) has disputed the need for labeling mechanically tenderized steaks as such. "Because blade-tenderized steaks have been found to be comparable in safety, we don't believe that special labeling declaring the mechanical tenderization process will provide meaningful or actionable information to consumers," one AMI spokesperson was quoted as saying. *See AMI Press Statement,* December 29, 2009.

U.S. Codex Delegates Schedule Meeting to Discuss Dairy Issues

The U.S. Department of Agriculture's Office of Food Safety and the Agricultural Marketing Service have **announced** a January 13, 2010, public meeting in Washington, D.C., to provide information and receive comments on draft U.S. positions to be discussed at the 9th Session of the Codex Committee on Milk and Milk Products (CCMMP) February 1-5 in Auckland, New Zealand.

Agenda items include discussion of the draft amendment to the fermented milks standard, draft standard for processed cheese and purported inconsistencies in food additive provisions. *See Federal Register,* January 8, 2010.

NIOSH Director Expresses Concerns on Safety of Diacetyl Substitutes

Following a December 16, 2009, National Institute for Occupational Safety and Health (NIOSH) "green" workshop, NIOSH Director John Howard **wrote** to the head of the Occupational Safety and Health Administration to indicate that "many of the chemicals and materials used as alternatives to diacetyl for imparting butter flavor to flavoring mixtures and food products are not known to be less hazardous." Additional information about a NIOSH report on diacetyl substitutes appears in issue 330 of this Update.

Howard's December 23 letter discusses potential diacetyl replacements, including (i) "starter mix," which apparently contains "high concentrations of diacetyl itself"; (ii) acetoin, which has not been completely investigated, but "accompanies diacetyl in many of the workplaces where *bronchiolitis obliterans* occurs in workers who make or use flavorings"; and (iii) 2,3-pentanedione, currently being researched by NIOSH, and purportedly associated with "airway epithelial damage similar to that produced by diacetyl."

WHO Board to Discuss Food Marketing Targeting Kids

The 34-member Executive Board of the World Health Organization (WHO) is scheduled to discuss 12 specific recommendations for protecting children from the marketing of unhealthy food and non-alcoholic beverages at the board's upcoming 126th session slated for January 18-23, 2010, in Geneva. The proposed mechanisms for promoting "responsible" marketing of such fare are contained in the annex to a recent WHO **report** focusing on the prevention and control of noncommunicable diseases.

According to the report's annex, "many countries, including those with restrictions in place, are exposed to food marketing in their country from beyond their borders" and the "global nature of many marketing practices needs to be addressed." Overall, the recommendations strive to provide a comprehensive approach for Member States to draft policies that lessen "the impact on children of marketing of foods high in saturated fats, *trans*-fatty acids, free sugars, or salt." More specifically, they champion (i) Member State cooperation in establishing "the means necessary to reduce the impact of cross-border marketing" for the purpose of enhancing the effectiveness of any national policy and (ii) limitations on marketing in "settings where children gather," such as schools, medical clinics, and sporting events.

LITIGATION

Beef Group Challenges EPA Climate Change Finding

The National Cattlemen's Beef Association has filed a challenge to the Environmental Protections Agency's (EPA's) finding that manmade greenhouse gas emissions (GHGs) endanger human health and the environment. Filed by a coalition of interested parties in the D.C. Circuit Court of Appeals on December 23, 2009, the petition calls for the court to determine that the agency lacked an adequate basis to make its finding. The finding apparently provides the foundation for EPA to regulate GHGs regardless of action that could be taken by Congress on pending climate change legislation.

According to an association press statement, "EPA's finding is not based on a rigorous scientific analysis; yet it would trigger a cascade of future greenhouse gas regulations with sweeping impacts across the entire U.S. economy," said Tamara Thies, chief environmental counsel. "Why the Administration decided to move forward on this type of rule when there's so much uncertainty surrounding humans' contribution to climate change is perplexing," Thies said. She contends that if EPA ultimately imposes limitations on GHGs, farmers could be forced to cease operations. Livestock farms apparently emit carbon dioxide from their machinery and trucks, and cattle waste emits methane. *See NCBA News Release*, December 24, 2009.

In a related development, Agriculture Secretary Tom Vilsack has **requested** that USDA's chief economist work with EPA to review assumptions in the model the environmental agency used to calculate the effects of proposed climate legislation on agriculture. Vilsack is calling for the model to be updated and for the development of options on best avoiding unintended consequences for agriculture. According to Vilsack, "I am aware that the results of the FASOM model have caused considerable concern within the farm and ranch community as a result of the model's projections on afforestation over the next several decades. If landowners plant trees to the extent the model suggests, this would be disruptive to agriculture in some regions of the country."

U.S. Attorney Announces Plea Deal in Tomato Industry Corruption Case

A U.S. attorney in Sacramento, California, has announced that a former purchasing manager for Safeway Inc. has agreed to plead guilty to two counts of wire fraud "in connection with an ongoing federal investigation into various illicit activities in the tomato processing industry." According to the announcement, Michael Chavez has admitted that "while working at Safeway, he received personal bribery payments" from a sales broker and director of SK Foods L.P. to steer contracts for processed tomato products to that company rather than industry competitors. Purchasing managers at other major food companies have also pleaded guilty to receiving illicit payments from the SK Foods broker.

U.S. Attorney Benjamin Wagner further noted that the Justice Department's investigation into SK Foods "has uncovered wide-ranging fraud with respect to the quality of tomato product that was produced, purchased and sold by the company."

Apparently, "SK Foods regularly shipped products which, while not a health threat, contained mold count levels that were above the federal regulatory threshold, or which bore altered dates of production or other falsified information." *See DOJ Press Release*, January 6, 2010.

Federal Appeals Court Denies Class Certification in Pet Food Litigation

The Ninth Circuit Court of Appeals has determined that pet food mislabeling claims should not be certified as a class action because the named plaintiff failed to satisfy the predominance requirement of Federal Rule of Civil Procedure 23(b)(3). ***Kennedy v. Natural Balance Pet Foods, Inc.*, No. 08-56378 (9th Cir., decided January 6, 2010) (not for publication)**. The plaintiff alleged that dog and cat food products labeled with "Made in the USA" were mislabeled because they contained ingredients from China and sought to certify a class of individuals from a number of states.

While the court upheld the district court's class certification ruling because the plaintiff failed to show which consumer protection law would apply to the class claims, it reversed the court's order dismissing the action for lack of subject-matter jurisdiction. According to the court, the case, which had been removed from state to federal court, should have been returned to the San Diego Superior Court. The Ninth Circuit ordered the lower court to remand the action.

OTHER DEVELOPMENTS

New York Times Questions Safety of Ammonia-Treated Beef

The New York Times recently published an investigative **report** that questions the safety of beef processed with ammonia to kill *E. coli* and *Salmonella*. According to the article, the U.S. Department of Agriculture (USDA) has exempted one company, Beef Products Inc. (BPI), from routine testing requirements since 2007 because the processor apparently claimed that its ammonia treatment destroyed pathogens "to an undetectable level."

A supplier for fast-food chains and the school lunch program, BPI also purportedly indicated that its ammoniated trimmings, when mixed with untreated meat, would sterilize ground beef. "Given the technology, we firmly believe that the two pathogens of major concern—E. coli O157:H7 and salmonella—are on the verge of elimination," BPI founder Eldon Roth allegedly told USDA in 2001.

"But government and industry **records** obtained by *The New York Times* show that in testing for the school lunch program, E. coli and salmonella pathogens have been found dozens of times in Beef Products meat," maintains the report, noting that "Since 2005, E. coli has been found 3 times and salmonella 48 times, including back-to-back incidents in August in which two 27,000-pounds batches were found to be contaminated."

The Times uses the BPI case to highlight a "schism" between the main Agriculture Department and its school lunch program, which in cases of contamination barred the product from schools but failed to notify other USDA officials, thus allowing the

meat to infiltrate the general market. The report states that, in addition to revoking BPI's testing exemption, "Agriculture Secretary Tom Vilsack has since directed school lunch officials to share information about their suspensions with the department's meat safety division."

The article further criticizes regulators for not requiring BPI to list ammonia as an ingredient despite one Agriculture Marketing Service memo concluding that the "product should be labeled accordingly." Because customers did not anticipate the ammonia odor, BPI has reportedly fielded several complaints about the taste and smell of the beef and has since acknowledged creating a less alkaline version to improve palatability. As USDA subsequently told *The Times,* the agency has "determined that 'at least some of BPI's product was no longer receiving the full lethality treatment'" and has pledged to ensure that future industry innovations "are scientifically sound and protect public health." *See The New York Times,* December 31, 2009.

Meanwhile, Representative Rosa DeLauro (D-Conn.) has echoed the report's call for government intervention. "It is the USDA's responsibility to keep our nation's food supply safe, and steps need to be taken to ensure that this goal is met," stated DeLauro, further urging the agency "to meet to this goal by re-examining this questionable treatment and discontinuing all government contracts with Beef Packers, Inc., and to improve their internal coordination." *See DeLauro Press Release,* December 31, 2009.

CPC Applauds Ban of rBGH Milk and Adulterated Meat

The Cancer Prevention Coalition (CPC) is praising a recent **policy statement** issued by the American Public Health Association's Governing Council, opposing the continued sale and use of genetically engineered hormonal rBGH milk and meat adulterated with sex hormones. CPC is a Chicago-based, non-profit, public-health advocacy organization.

Samuel Epstein, CPC chair and professor emeritus of Environmental and Occupational Medicine at the University of Illinois School of Public Health, claims recombinant Bovine Growth Hormone is injected into about 20 percent of U.S. dairy cows to increase milk production. "While industry claims that the hormone is safe for cows, and the milk is safe for consumers, this is blatantly false," Epstein wrote on December 23, 2009. He also claims that "beef produced in the United States is heavily contaminated with natural or synthetic sex hormones, which are associated with an increased risk of reproductive and childhood cancers."

CSPI Claims Fewer Complete Foodborne Outbreak Investigations Undertaken

The Center for Science in the Public Interest (CSPI) has issued a **report** that claims state health departments completed fewer foodborne outbreak investigations in 2007 than in the previous decade. The consumer watchdog found that states reported 33 percent fewer fully investigated outbreaks to the Centers for Disease Control and Prevention in 2007 than in 2002. Of the nearly 1,100 outbreaks reported in 2007, only 378 cases identified both a food and the pathogen, the mark of a complete investigation.

"The decline in fully-investigated outbreaks could reflect a serious gap in state public health spending," Caroline Smith DeWaal, the group's food safety director, was quoted as saying in a December 23, 2009, press release. CSPI analyzed a total of 4,638 illness

outbreaks linked to specific foods involving 117,136 individual illnesses between 1998 and 2007. The 10-year data analysis showed that eggs dropped out of the top five causes of outbreaks, which CSPI credited to Food and Drug Administration-mandated safety programs by egg producers. The data also indicated that dairy outbreaks increased dramatically after 2004 "due to increased availability of unpasteurized dairy products," according to CSPI.

SHB Recognized for Product Liability Litigation Defense

The American Lawyer has named Shook, Hardy & Bacon as a finalist in the Product Liability category of its Litigation Department of the Year Awards. The firm was recognized "for the breadth of its work, from wins in traditional one-off cases for clients like Kia Motors America, Inc., to its role in managing the massive *Engle* tobacco litigation in Florida for Altria Group, Inc." The legal magazine, which invites the largest U.S. firms to participate in its biannual competition, also cited the firm's pharmaceutical defense work and its attraction of clients through the use of alternative fee arrangements. *See The American Lawyer*, January 1, 2010.

Meanwhile, *Law360* has recognized Shook, Hardy & Bacon as a Product Liability Defense Firm of the Year. The publication cited medical device and pharmaceutical victories that the firm secured for its clients and quoted firm chair John Murphy, who attributes its success to the "Midwestern work ethic that pervades" the firm. Murphy also noted that Shook's litigators rely on a pool of experts on staff with advanced degrees in products-related fields such as biology and chemistry to "take [a] complicated issue and boil it down to where the lawyers understand it and where the juries understand." He referred to collaborations with other law firms as another trend that has led to success in the defense of product liability litigation. "I think we do that very well, and I can't say that's true of all firms," he said. "We tend, as a firm, to play well in the sandbox with others."

MEDIA COVERAGE

Paul Voosen, "Can We Feed the World Without Damaging It?," *Greenwire*, January 4, 2010

In the fifth and final installment of a series about genetically modified (GM) crops, energy and environmental writer Paul Voosen discusses the growing ranks of organic proponents who have begun to embrace GM crops to achieve "sustainable agricultures that can feed the world." Voosen describes a plant scientist who manipulates rice in the lab and is married to an organic farmer. Pamela Ronald and Raoul Adamchak apparently co-authored a book, recently released in paperback, titled *Tomorrow's Table: Organic Farming, Genetics, and the Future of Food*." They contend that current and future generations of GM crops, responsibly managed, would provide for the world's hungry from lands already degraded.

According to Voosen, their work has inspired others, such as Steward Brand, the passionate environmentalist who founded the *Whole Earth Catalog* and is now apparently "full-throated in his defense of GM crops." Brand is quoted as saying, "I daresay the environmental movement has done more harm with its opposition to genetic

engineering than with any other thing we've been wrong about. We've starved people, hindered science, hurt the natural environment, and denied our practitioners a crucial tool." Voosen gives Ronald the final word in his article; she reportedly said, "I think it's important to remind people that most of the arable land has been farmed. There is four-fold less water available per person on Earth than we had 50 years ago. These problems aren't going away."

SCIENTIFIC/TECHNICAL ITEMS

Study Claims Obesity Rivals Smoking as Contributor to "Burden of Disease"

A forthcoming study has reportedly concluded that, in terms of quality-adjusted life years (QALYs) lost, "the overall health burden of obesity among U.S. adults has increased consistently since 1993" and now rivals the overall health burden of smoking. Haomiao Jia and Erica Lubetkin, "Trends in Quality-Adjusted Life Years Lost Contributed by Smoking and Obesity: Does the Burden of Obesity Overweight [sic] the Burden of Smoking?," *American Journal of Preventative Medicine,* February 2010.

Researchers examined "the trend of the health burden of smoking and obesity for U.S. adults from 1993 to 2008 using currently available population-based data" obtained from the Behavioral Risk Factor Surveillance System, which has interviewed more than 3.5 million individuals. Designed to quantify the years gained by a health intervention while adjusting for quality of life, QALYs apparently use "preference-based measurements of health-related quality of life (HRQOL) to provide an assessment of the overall burden of diseases associated with both mortality and morbidity."

For obesity and smoking, the authors calculated the total QALYs lost as "the sum of the QALYs lost due to a decrease in HRQOL score (morbidity) and the future QALYs lost in the expected life-years due to premature deaths (mortality) contributed by the two modifiable risk factors." The results apparently indicated that "because of the marked increase in the proportion of obese people, obesity has become an equal, if not greater, contributor to the burden of disease than smoking." In addition, "[s]moking had a bigger impact on mortality than morbidity, whereas obesity had a bigger impact on morbidity than mortality," wrote the authors, who maintained that their data "might assist in the construction of specified quantitative targets for the *Healthy People 2020* health objectives and setting priorities for prevention in a given population as well as according to sociodemographic subgroups." *See Science Daily,* January 5, 2010.

Researchers Examine Effects of GM Corn on Mammalian Health

French researchers with the Committee of Independent Research and Information on Genetic Engineering (CRIIGEN), the University of Rouen and the University of Caen have published a paper allegedly linking genetically modified (GM) corn varieties to "new side effects" in mammals. Joël Spiroux de Vendômois, et al., "A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health," *International Journal of Biological Science,* December 2009. "[A] comparative analysis of blood and organ system data" from industry-sponsored studies, the paper claims that GM corn-fed rats exhibited "sex- and often dose-dependent" side effects "mostly associated with the kidney and

liver, the dietary detoxifying organs," as well as the "heart, adrenal glands, spleen and hematopoietic system." The authors concluded that "these data highlight signs of hepatorenal toxicity, possibly due to the new pesticides specific to each GM corn," adding that "unintended direct or indirect metabolic consequences of the genetic modification cannot be excluded." *See CRIIGEN Press Release,* December 14, 2009.

Welsh Researcher Questions Evidence for Sugar Addiction

A recent study has reportedly questioned the current availability of scientific literature establishing evidence for physical sugar addiction in humans. David Benton, "The plausibility of sugar addiction and its role in obesity and eating disorders," *Clinical Nutrition,* January 2010. David Benton, a psychology professor with the University of Swansea in Wales, apparently reviewed previous research on the role of sugar addiction in obesity and eating disorders. Noting a lack of scientific consensus on the term "addiction," he construed sugar addiction to involve physical craving, tolerance and withdrawal symptoms, meaning that "Fasting should increase food cravings, predominantly for sweet items; cravings should occur after an overnight fast; the obese should find sweetness particularly attractive; a high-sugar consumption should predispose to obesity." Using this definition, Benton apparently found "no support from the human literature for the hypothesis that sucrose may be physically addictive or that addiction to sugar plays a role in eating disorders."

In addition, the author cautioned the general population about drawing conclusions from studies based on animal models, some of which have suggested the plausibility of sugar addiction in rats. "If addition to food can be established in humans there are widespread implications," Benton wrote. "Dieting might not be the optimal response to obesity as it will lead to counter-regulatory mechanisms such as cravings and withdrawal symptoms… There are also potentially widespread implications for food manufacturers and the fast food industry." *See FoodNavigator-USA.com,* January 5, 2010.

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