Shook, Hardy & Bacon L.L.P.

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# FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS



## LEGISLATION, REGULATIONS AND STANDARDS

### FDA Unveils New Nutrition Facts Label

The U.S. Food and Drug Administration (FDA) has **proposed** revisions to the Nutrition Facts label that would emphasize the number of calories and servings per container, among other things. As the agency explained in a February 27, 2014, press release, the new panels would not only display calories per serving in larger, bolder type, but would update serving sizes to reflect "the reality of what people actually eat, according to recent food consumption data." In addition to breaking out the amount of added sugar as a separate item, the labels would make "the number of servings per package… more prominent," with "amount per serving" tied to the actual serving size, e.g., "Amount per cup." FDA has also recommended updating the daily values for various nutrients, listing potassium and vitamin D amounts on the label, and removing "calories from fat" completely.

"Obesity, heart disease and other chronic diseases are leading public health problems," said FDA Center for Food Safety and Applied Nutrition Director Michael Landa. "The proposed new label is intended to bring attention to calories and serving sizes, which are important in addressing these problems. Further, we are now proposing to require the listing of added sugars. The 2010 Dietary Guidelines for Americans recommends reducing calories from added sugars and solid fats."

FDA plans to issue the changes in two proposed rules slated for publication in the *Federal Register* with a 90-day comment period. The first proposed rule will address the updates to the nutrition information as well as the label design, while the second proposed rule will cover changes to serving-size requirements and labeling for certain sizes of packages. Once adopted, the final rules governing the new Nutrition Facts labels would grant industry a two-year compliance period.

The proposal has drawn praise from consumer advocates such as the Center for Science in the Public Interest; former FDA Commissioner David Kessler; and New York University Nutrition Professor Marion Nestle, who nevertheless anticipated that the redesign would be "wildly controversial." At the same time, however, University of North Carolina health researcher Barry Popkin apparently believes the planned changes do not go far enough. "This is a false

victory," he said. "It will affect just a small segment of customers who carefully study nutrition fact panels." *See CSPI News Release, Food Politics* and *The New York Times,* February 27, 2014.

### FDA Refuses to Stay Effective Date for Use of Irradiation

The U.S. Food and Drug Administration (FDA) has **issued** a final rule denying requests for a stay of the effective date and for a hearing on the final rule concerning the use of irradiation in food production, processing and handling. Originally appearing in the August 22, 2008, *Federal Register*, the rule amended food additive regulations to permit the use of ionizing radiation to control food-borne pathogens and extend the shelf life of fresh iceberg lettuce and spinach.

After reviewing objections to the final rule and requests for a hearing, FDA has concluded that "the objections do not raise issues of material fact that justify a hearing or otherwise provide a basis for revoking or modifying the amendment to the regulation," and confirmed August 22, 2008, as the effective date for the final rule.

### WHO/EU Warns That Overweight Children Becoming a "New Norm"

The World Health Organization's Regional Office for Europe (WHO/EU) reportedly warned attendees of a February 25-26, 2014, health conference held by the European Commission and the Greek Presidency of the Council of the European Union that "being overweight is so common that it risks becoming a new norm." According to a February 25, 2014, press release, WHO/EU reported that 27 percent of 13-year-olds and 33 percent of 11-year-olds are now overweight, while 30 percent of boys and girls ages 15 and older "are not getting enough physical activity" in 23 of the 36 countries profiled by the organization.

Although it noted the role of physical inactivity in rising obesity rates, WHO/EU ultimately urged national governments to consider implementing stricter labeling and food product regulations that would require "the food industry to take responsibility."

"We must not let another generation grow up with obesity as the new norm," said WHO/EU Director Zsuzsanna Jakab. "Physical inactivity—coupled with a culture that promotes cheap, convenient foods high in fats, salt and sugars—is deadly." *See GR2014 EU Press Release,* February 24, 2014.

### EFSA Announces Follow-Up Meeting on BPA

The European Food Safety Authority (EFSA) has **announced** an April 23, 2014, scientific meeting to discuss its draft opinion on the human health risks of bisphenol A (BPA) for consumers. Developed by the EFSA Panel on

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Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), the draft opinion also includes a re-evaluation of the tolerable daily intake for BPA, which the agency temporarily recommended lowering from 50 µg/kg bw/day to 5 µg/kg bw/day over concerns that exposure to the substance is likely to pose health risks. Additional details about EFSA's draft assessment of consumer exposure to BPA appear in Issue 511 of this *Update*.

The meeting seeks to discuss comments received during the draft opinion's consultation period, which ends March 13. Before adopting its final opinion the CEF Panel will take into account these comments and meeting discussions, as well as issue a separate report that outlines these proceedings. EFSA has asked "scientific experts in the field of food safety and interested parties who have contributed to the public consultation" to register for the conference by March 14.

### EFSA Issues Opinion on Vitamin D for Bones and Teeth

Following an application to claim that vitamin D is important to normal bone and teeth development in infants and children, the European Food Safety Authority's (EFSA's) Panel on Dietetic Products, Nutrition and Allergies has issued an opinion affirming that vitamin D contributes to normal development of bones and teeth. The panel noted previous favorable assessments of vitamin D and the maintenance of normal bones and teeth in the general population, concluding that "the role of vitamin D in bone and tooth mineralisation and homeostasis applies to all ages, including infants and young children (from birth to three years)."

### Proposed GE Food Labeling Legislation in California Would Limit Litigation

California Senator Noreen Evans (D-Santa Rosa) has introduced legislation (S.B. 1381) that would require labeling for genetically engineered (GE) foods but also place limits on potential litigation arising from the failure to label such products. Under the California Right to Know Genetically Engineered Food Act, "any raw agricultural commodity or packaged food that is entirely or partially produced with genetic engineering" would need to bear labels stating that the product in question was "Produced with Genetic Engineering" or "Partially Produced with Genetic Engineering." The bill would allow the state attorney general or an injured resident "to bring an action for injunctive relief against a violation of these provisions, as specified."

Unlike previous efforts, however, the current proposal would "authorize a court to award a prevailing plaintiff reasonable attorneys' fees and costs, and would prohibit a court from awarding monetary damages in an action brought under the bill's provisions." It would also protect farmers and retailers from litigation, providing a defense under the law if a retailer relied on a wholesaler's or distributor's disclosure that the food was not produced through genetic engineering.

"California paves the way for federal laws," said a spokesperson for the Center for Food Safety, which helped draft the measure. "Since the U.S. Food and Drug Administration has to date refused to label GE foods, it is up to individual states to lead the way and protect our state's interests, including public health, consumers right to know, and our farmers and agricultural lands." *See CFS Press Release,* February 21, 2014; *Law360,* February 24, 2014.

### OEHHA Extends Comment Period on Nitrite with Amines/Amides

In response to requests from trade associations representing meat industry interests, California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has extended the comment period on its proposal to list nitrite in combination with amines or amides as known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). If these substances are added to the Prop. 65 list, companies making products containing them will be required to provide warnings to California consumers. Comments are now requested by May 8, 2014. *See OEHHA News Release*, February 28, 2014.

Meanwhile, OEHHA has also **issued** the agenda for the March 27, 2014, meeting of the Biomonitoring California Scientific Guidance Panel, which will convene in Oakland; the meeting will be accessible via Webinar. Program and laboratory updates are on the agenda, and the panel will also discuss chromium as a potential designated chemical and review as potential priority chemicals antimony, barium, cesium, cobalt, manganese, molybdenum, platinum, thallium, tungsten, and uranium. A U.S. Environmental Protection Agency representative will discuss that agency's perspectives during a session titled "Best Practices for Biomarker Collection, Analysis, and Interpretation."

## LITIGATION

### MDL Court Finds Chocolate Cos. Did Not Conspire to Increase Prices

A federal multidistrict litigation (MDL) court in Pennsylvania has determined that individual-purchaser plaintiffs and a direct-purchaser class failed to discover evidence that U.S. chocolate companies conspired to increase prices for immediate-consumption products between 2002 and 2007, and, with "nothing more than speculation as to the who, what, when, where, and how of communications that allegedly facilitated the parallel price increases," the court was compelled to grant the defendants' motions for summary judgment on the plaintiffs' Section 1 antitrust claims under the Sherman Act. *See In re Chocolate Confectionary Antitrust Litig.*, MDL No. 1935 (U.S. Dist. Ct., M.D. Pa., decided February 26, 2014).

The litigation involves some 91 lawsuits transferred to the MDL court for pre-trial proceedings. Defendants Nestlé U.S.A., Inc., The Hershey Co., and

Mars, Inc. and Mars Snackfood U.S. LLC control about 75 percent of the U.S. chocolate-products market, and during the relevant time period, which saw prices for cocoa increase 53 percent, raised prices for their products nearly in lockstep three times. To prove a U.S. conspiracy, the plaintiffs sought to rely on actions occurring in the Canadian market at this time resulting in charges by that country's competition bureau of conspiracy to restrict competition and fix prices for chocolate products.

According to the court, the plaintiffs' "cross-border theory has evolved almost beyond recognition." First, they alleged that the overlap of economic, operational and managerial factors between the two markets was so extensive "as to effectively eviscerate the border between the countries, merging the domestic and Canadian chocolate markets into a 'single market.' This theory quickly withered on the vine in the absence of any factual support," the court said.

Next, the plaintiffs claimed that "as a result of 'significantly integrated' cross-border management, senior executives in the United States 'were aware of and condoned' the conspiracy in Canada, making it 'plausible' that 'the same executives' conspired in the United States. . . . In essence, plaintiffs asserted that management simply would not have taken advantage of an opportunity to conspire in one market without also conspiring in the United States. Discovery produced no evidence of 'significantly integrated' cross-border management, and this theory was subsequently jettisoned."

Finally, the plaintiffs presented an "actuation" theory to support their conspiracy claims, offering expert reports and testimony with what the court characterized as the "novel theory" that "the domestic defendants' awareness of the nature and success of the trade spend conspiracy in Canada, may have 'actuated' a domestic price-fixing conspiracy." While the court concluded in the context of Rule 702 motion practice that this theory could support the antitrust claims if supported by record evidence, "[f]actual support never materialized." Thus, "this failure to produce any record evidence of a causal connection between Canadian trade spend conspiracy and plaintiffs' allegations of an American pricing conspiracy is fatal to plaintiffs' antitrust claims."

### Court Imposes Spoliation Sanctions in Wine Infringement Dispute

A federal court in California has granted a motion for sanctions filed by Jackson Family Wines, which brought an infringement action against Diageo North America; an adverse inference instruction will be given to the jury during trial, and the plaintiff will be able to recover the costs of its efforts to secure a Diageo marketing department employee's documents, destroyed while the lawsuit was pending. *Jackson Family Wines v. Diageo N. Am., Inc.*, No. 11-5639 (U.S. Dist. Ct., N.D. Cal., order entered February 14, 2014).

At issue in the litigation is the alleged infringement of Jackson's La Crema wine by Diageo's Crème de Lys wine brand. The employee whose laptop was "imaged" outside the firm after she temporarily left Diageo's employ was, in Diageo's words, "the conduit between Diageo's marketing team and Northstar [Research Partners, LLC], the third-party market research company" that conducted focus groups for the selection of the Crème de Lys brand. In one communication between the employee and Northstar, produced by the latter, the employee asked why the focus group report "didn't include anything about potential confusion with La Crema," confusion that had apparently been voiced by some focus group participants. The laptop image, returned to Diageo in an external hard drive, was destroyed some six months after Jackson served document requests for the production of all documents about the "selection, adoption, and/or use" of the Crème de Lys mark. The imaging and destruction were part of the company's "leaving" procedures, and the employee had never been told that her documents were subject to a litigation preservation order.

The court found Diageo's spoliation of evidence willful in light of its frequent and vociferous protests that its production of the employee's documents was "complete and irreproachable." According to the court, "It is apparent now that those representations were not true. At the hearing, Defendants conceded that the representations made to the Court were false, but argued that they were made unknowingly since they were not yet aware that the hard drive was destroyed. If Defendants were actually not aware that the hard drive had been destroyed when the issue was raised and litigated over several months, Defendants' ignorance was the result of a willful failure to make themselves aware." Given "obvious red flags, Defendants should have investigated the issue of Josephson's custodial file, and any reasonable investigation would have uncovered the erasure of her hard drive."

The court observed that Diageo requested and received on October 30, 2013, backup tapes from the outside vendor that had "imaged" the laptop, but "falsely represented to this Court on *November 1* that there was 'no warrant' for Plaintiffs' request for a Rule 30(b)(6) deposition on preservation of Josephson's documents and that 'Jackson has already received the entire universe of documents and correspondence including Ms. Josephson.' Defendants further noted that 'it is extremely disappointing to Diageo that it is still being forced to combat this preservation issue.' Contrary to Defendants' representations on November 1, they knew Josephson's hard drive had not been preserved, and they knew that the 'entire universe' of Josephson's documents and correspondence had not been produced. What is 'extremely disappointing' is that Defendants concealed those facts from Plaintiffs and the Court." The court further determined that the missing documents included relevant material and that the spoliation prejudiced the plaintiffs.

### Consumer Fraud Claims Against Olive Oil Company Continue

A federal court in New York has denied the motion for summary judgment filed by the defendant in litigation alleging that it mislabeled its industrially processed olive-pomace oil as "100% Pure Olive Oil." *Ebin v. Kangadis Food Inc. d/b/a The Gourmet Factory*, No. 13-2311 (U.S. Dist. Ct., S.D.N.Y., order entered February 25, 2014). Details about the court's grant of the plaintiffs' motion to certify a class appear in Issue **507** of this *Update*.

The court rejected, again, the defendant's argument that its Capatriti olive-pomace oil is, as a matter of law, olive oil. According to the court, "there exists more than sufficient evidence for a trier of fact to determine that Capatriti is not 100% pure olive oil. Capatriti has more trans-fat and fewer antioxidants than virgin olive oil, is tasteless, is made from the seed and skin rather than the flesh of the olive, and undergoes chemical treatment with solvents, rather than a purely mechanical extraction process." The court also disagreed with the defendant that the plaintiffs could not prevail on a breach of express warranty claim because they failed to provide pre-litigation notice. New Jersey law does not impose such a requirement, and, in any event, the civil complaint satisfies any notice requirement.

The court also disagreed that the plaintiffs had not provided sufficient damages evidence. New York and New Jersey law apparently place the burden of ascertaining the amount of damages, "when the existence of damage is known but its extent is opaque, upon the alleged wrongdoer, here Kangadis." In the court's view, the plaintiffs had met their burden by introducing expert reports with several models for calculating damages based on three relevant numbers—the average price of 100 percent pure olive oil, the average price of pomace advertised as such and the average price of Capatriti.

### Methylmercury Strict Liability Claims to Proceed Against Bumble Bee

A federal court in New York has refused to dismiss claims alleging that Bumble Bee Foods is strictly liable for and was negligent in failing to warn about the mercury in its products in a lawsuit alleging personal injury from excessive consumption of the company's tuna products, which contain methylmercury. *Porrazzo v. Bumble Bee Foods, LLC*, No. 10-4367 (U.S. Dist. Ct., S.D.N.Y., order entered February 27, 2014). An earlier ruling in the case is summarized in Issue **413** of this *Update*.

The plaintiff, who apparently consumed one to two cans of tuna daily for more than two years and was diagnosed with dangerously high levels of mercury in his body, also brought claims for breach of implied warranty of merchantability and violations of certain state statutory provisions involving agricultural and business law. The court found that the issues argued in Bumble Bee's motion for summary judgment involved genuine issues of material fact that were for a jury to decide. Among other matters, the

company argued that the level of methylmercury in its tuna was below the U.S. Food and Drug Administration's (FDA's) internal enforcement guideline and that the agency does not require warnings about methylmercury on fish product labels.

As to the latter, the court said, "the FDA's decision not to adopt a warning requirement does nothing to absolve defendants of liability if they breached their common law duty to warn. To hold otherwise would entirely vitiate the failure to warn doctrine, rendering proof of such claim impossible unless a federal agency specifically mandated the missing warning. The Court declines to adopt such unworkable rule."

**Consumer Diacetyl Award Finalized by Settlement**

According to a news source, the plaintiffs and defendants in litigation over a respiratory condition allegedly caused by the daily consumption of microwave popcorn containing the butter-flavoring compound diacetyl have settled the claims following a court's reduction of the jury's $7-million verdict to $5.78 million, including fees and costs. *Watson v. Dillon Cos., Inc.*, No. 08-91 (U.S. Dist. Ct., D. Colo.). Additional details about the litigation appear in Issue 497 of this *Update*. Plaintiffs' counsel Ken McClain reportedly indicated that the settlement terms were confidential. *See Law360*, February 24, 2014.

**Appeals Court Throws Out Prop. 65 Suits over PhIP in Chicken**

A California appeals court has affirmed the dismissal of Proposition 65 (Prop. 65) lawsuits filed against fast-food restaurants by the vegetarian and animal-rights advocacy organization Physicians Committee for Responsible Medicine (PCRM), finding that the organization failed to conduct the requisite investigation into the warning signs posted in the defendants' restaurants before certifying the merit of its 60-day notices to the companies, attorney general and local prosecuting entities. ***PCRM v. Applebee's Int'l, Inc.*, No. B243908 (Cal. Ct. App., decided February 27, 2014)**. At issue were warnings about the chemical PhIP, known to the state to cause cancer, created during the chicken grilling process. Details about the lower court's ruling appear in Issue 450 of this *Update*.

Reciting the lengthy litigation history, which involved a number of amended complaints, the court emphasized the statements that the plaintiff's counsel made during hearings on demurrers to the pleadings and deemed them binding admissions that "PCRM had not conducted a factual investigation regarding warnings before filing the lawsuit. . . . Under the requirements of the statute and regulations, the 60-day notice requires that a plaintiff have sufficient information *at the time of filing suit* to support a reasonable basis for concluding that there is merit to each element of the action on which the plaintiff will have the burden of proof, which includes whether a defendant

posts clear and reasonable warnings." Because PCRM lacked the required information, the appeals court determined that the lower court properly sustained the defendants' demurrers without leave to amend.

According to the court, "PCRM conceded that *when PCRM's counsel executed the certificate of merit before filing suit in 2008,* PCRM did not know what warning signs were posted and how they were posted in 2007. . . . PCRM cannot cure this defect in its notice and certificate of merit by later conducting discovery into the warnings given before the filing of the lawsuit." The court further observed, "A Proposition 65 lawsuit filed without adequate investigation into whether and how defendants post clear and reasonable warnings is susceptible to endless mutations and amendments, leaving defendants like those in this case to answer conflicting and contradictory allegations in each successive iteration of the complaint. The statutory requirements of notice and a supporting certificate of merit are intended to prevent such improvident lawsuits."

**Prop. 65 Violation Claims Leveled Against Alcoholic Beverage Makers**

A three-attorney, Pasadena, California-based law firm has filed numerous 60-day notice letters since March 2013 to companies that make alcoholic beverages, warning that they have failed to comply with a section of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65) by selling without the required warnings (i) "alcoholic beverages, when associated with alcohol abuse," (ii) "ethyl alcohol in alcoholic beverages," and (iii) "ethanol in alcoholic beverages."

The letters, filed on behalf of John Bonilla, Rafael Delgado, Jesse Garrett, and Rachel Padilla, assert that the companies have sold their products in the state without first indicating to consumers under "Title 27, CCR § 25603(e)(1): 'WARNING: Drinking Distilled Spirits, Beer, Coolers, Wine and Other Alcoholic Beverages May Increase Cancer Risk, and, During Pregnancy, Can Cause Birth Defects.'"

According to a news source, four individuals have filed Prop. 65 violation lawsuits in the Los Angeles County Superior Court, alleging that Anheuser-Busch and nearly every other major brewery failed to post proper warnings. There is no indication in state records that the state attorney general or local prosecutors accepted the law firm's invitation to file an enforcement action. *See Courthouse News Service*, February 25, 2014.

## OTHER DEVELOPMENTS

### New Book Focuses on Industries Affecting Health

*New York Times* op-ed writer Mark Bittman, who frequently writes about food-related issues and calls for changes in government policy to address over- or unhealthy-consumption problems, has found an ally in City University of New York School of Public Health Professor Nicholas Freudenberg who has authored a new book titled *Lethal but Legal: Corporations, Consumption, and Protecting Public Health."*

Freudenberg, who serves as faculty director for the **New York City Food Policy Center**, apparently explains how the food and beverage, tobacco, alcohol, firearms, pharmaceutical, and automotive industries have used the playbook created by "the corporate consumption complex" of corporations, banks, marketers, and others that purportedly promote and benefit from unhealthy lifestyles. Freudenberg takes issue with what he perceives as their message that anything restricting rights "to smoke, feed our children junk, carry handguns and so on" is un-American.

According to Bittman, Freudenberg's grouping of these industries "gives us a better way to look at the struggle of consumers, of ordinary people, to regain the upper hand. The issues of auto and gun safety, of drug, alcohol and tobacco addiction, and of hyperconsumption of unhealthy food are not as distinct as we've long believed; really, they're quite similar. For example, the argument for protecting people against marketers of junk food relies in part on the fact that antismoking regulations and seatbelt laws were initially attacked as robbing us of choice; now we know they're lifesavers." Bittman suggests that Freudenberg is at his best by calling for a different approach to the discussion of rights and choice. Freudenberg said, "What we need is to return to the public sector the right to set health policy and to limit corporations' freedom to profit at the expense of health."

The question that needs to be asked, in Bittman's view, is not "Do junk food companies have the right to market to children?" but "Do children have the right to a healthy diet?" Freudenberg opines that "[t]he right to be healthy trumps the right of corporations to promote choices that lead to premature death and preventable illnesses." *See The New York Times*, February 25, 2014.

Meanwhile, in a **post** appearing on the Website of Corporations & Health Watch, which Freudenberg founded, he argues that "Washington's obsession with ObamaCare has made the nation lose sight of other strategies for improving health and reducing health care costs." Claiming that government policies doom "millions of Americans to premature death," Freudenberg writes, "Corporations and their allies claim that choices around food, alcohol and tobacco are a matter of individual responsibility, not public policy."

He calls for (i) "a better balance between the constitutional protection of commercial speech and a corporation's responsibility not to misrepresent the health benefits of their products"; (ii) "[s]trengthening corporations' duty to disclose what they know about the health effects of their products"; (iii) a reversal of the trend restricting "the rights of injured consumers to file class action lawsuits"; and (iv) "turning off the faucets of marketing that produces our flood of chronic disease." See *Corporationsandhealthwatch.org,* re-posted from *The Daily Beast*, February 26, 2014.

### Tobacco Foe Banzhaf Predicts New Onslaught of Big Food Lawsuits

George Washington University Law Professor John Banzhaf, who is known for his anti-tobacco advocacy, contends that recent court rulings involving food company defendants facing consumer-fraud and product-mislabeling allegations have opened "the door even further to a growing wave of such suits." He argues that class action lawsuits over labeling terms such as "natural" and "all natural" will lead to increased transparency in food advertising and a reduction in obesity. He also claims that *The American Lawyer* attributed this exploding wave of litigation to "the movement started by Prof. John Banzhaf several years ago to use legal action as a weapon against the problem of obesity, just as he had earlier done in leading the use of legal action as a weapon against smoking." *See John Banzhaf News Release*, February 27, 2014.

### Johns Hopkins Publication Focuses on Food; Caffeinated Waffles on Prof.'s Agenda

*Johns Hopkins Public Health*, a magazine of the Johns Hopkins School of Public Health, has devoted a special issue to food topics and includes an **article** about Health Policy and Management Professor Stephen Teret, who founded the Johns Hopkins Clinic for Public Health Law and Policy and recently engaged law students in a project addressing caffeinated foods. His students reportedly explained to U.S. Food and Drug Administration (FDA) Deputy Commissioner for Food Policy Michael Taylor that the agency should be focusing on this issue.

While Teret was apparently not concerned initially about any purported health effects of caffeine, he suspected that consumers might eat more waffles than normal if they started "feeling really good from the waffles because of the caffeine." In this regard, he said, "It's the sugar for some of these products or the salt or the fat that will ultimately give you health problems, not the caffeine, but, like nicotine [in cigarettes], the caffeine is what is habituating you . . . I thought that there's something the FDA ought to be doing about it." *See Johns Hopkins Public Health*, February 27, 2014.

## SCIENTIFIC/TECHNICAL ITEMS

### Cooked Meats Allegedly Linked to Increased Alzheimer's Risk

A new study has concluded that advanced glycation endproducts (AGEs), which occur in heat-processed meat and animal products, can cause brain changes similar to those found in Alzheimer's disease or metabolic syndrome, a pre-diabetic state. Weijing Cai, et al., "Oral glycotoxins are a modifiable cause of dementia and the metabolic syndrome in mice and humans," *PNAS,* February 2014. Led by researchers at the Icahn School of Medicine at Mount Sinai, the study reportedly used a mouse model to show that consuming AGE-rich foods "raised the body's level of AGEs, which, among other effects, suppressed levels of sirtuin, or SIRT1, a key 'host defense' shown to protect against Alzheimer's disease as well as metabolic syndrome."

The study's authors noted that mice fed a high-AGE diet not only exhibited high levels of AGE in their brains and low levels of SIRT1 in their blood and brain tissue, but also developed cognitive and motor skill declines, amyloid-β deposits characteristic of Alzheimer's disease, and metabolic syndrome. In addition, a clinical study of humans ages 60 and older purportedly showed that, "over a nine-month period, those subjects with high blood levels of AGEs developed cognitive decline, signs of insulin resistance and SIRT1 suppression, while those with low blood AGEs remained healthy."

"Age-associated dementia or Alzheimer's disease is currently epidemic in our society and is closely linked to diabetes. Our studies of both animals and human subjects confirm that AGE-rich foods are a lifestyle-driven reality with major health implications. The findings point to an easily achievable goal that could reduce the risk of these conditions through the consumption of non-AGE-rich foods, for example, foods that cooked or processed under lower heat levels and in the presence of more water—cooking methods employed for centuries," explained co-author Helen Vlassara in a February 24, 2014, press release. "While more research needs to be done to discover the exact connection of food AGEs to metabolic and neurological disorders, the new findings again emphasize the importance of not just what we eat, but also how we prepare what we eat. By cutting AGEs, we bolster the body's own natural defenses against Alzheimer's disease as well as diabetes." Additional details about Vlassara's previous research appear in Issue 8 of this *Update*.

### U.S. Government Study Revives BPA Debate

A recent study funded by the National Toxicology Program and conducted by researchers with the Food and Drug Administration's National Center for Toxicological Research has reportedly found no evidence linking low doses of bisphenol A (BPA) to adverse estrogenic effects in an animal model. K. Barry Delclos, et al., "Toxicity Evaluation of Bisphenol A Administered by Gavage to

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Sprague Dawley Rats From Gestation Day 6 Through Postnatal Day 90," *Toxicological Sciences,* February 2014. To examine the effects of BPA on Sprague Dawley rats shown to be sensitive to estrogenic compounds, scientists administered the substance to rat dams from the sixth day of gestation through labor and to their pups from the first day after birth through postnatal day 90. These rats received either a low dose of BPA (2.5-2700 µg/kg bw/day) or a high dose (100,000 and 300,000 µg/kg bw/day), with the lower dose reportedly corresponding to approximately 70,000 times the amount ingested by a typical U.S. consumer. For comparison, the study included a naïve control group as well as a group that received two doses of ethinyl estradiol ($EE_2$) "to demonstrate the estrogen responsiveness of the animal model."

"Under the conditions of this study, BPA had clear adverse effects at doses of 100,000 and 300,000 µg/kg bw/day, with the majority of these effects observed in females," noted the study's authors. "In the study-defined 'low BPA' dose range of 2.5-2700 µg/kg bw/day, which was the primary focus of this study, potential effects could not clearly be linked to treatment as they were observed sporadically across the dose groups and did not occur in consistent grouping across organs as did effects of $EE_2$ (0.5 and 5.0 µg/kg bw/day) or 'high BPA' (100,000 and 300,000 µg/kg bw/day)." *See NPR's The Salt,* February 26, 2014.

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