

CONTENTS

Legislation, Regulations and Standards

EPA Asks Congress to Overhaul Toxic Substances Control Act1
EPA, EU Launch Research Strategies for Nanotechnology1
FSIS Announces New General Food Defense Plan2
Food Producers Raise Concerns over Proposed Prop. 65 Warnings

Litigation

Class Action Alleges Hazardous Preparation Instructions on Frozen Pot Pies	3	
CSPI Sues Quorn Foods over Alleged Allergic Reaction to Meat Substitute	3	
Workplace Exposure Claims Against		

Legal Literature

Adam Burrows, "Palette of Our Palates: A Brief History of Food Coloring and Its Regulation," *Comprehensive Reviews in Food Science & Food Safety*, Vol. 8, 2009. .4

Other Developments

м

Soft Drink Tax Could Generate \$10 Billion Annually, Says CSPI5
CSPI Report Critical of Salt Content in Canadian Packaged Foods, Restaurants .5
Investigative Report Traces Pollutants from Sea to Sashimi6
edia Coverage

Consumers Confused About "Natural" and "Organic" Food Labels7

Tara Parker-Pope, "Probiotics: Looking Underneath the Yogurt Label," *The New York Times*, September 29, 2009......8



ISSUE 321 | OCTOBER 2, 2009

LEGISLATION, REGULATIONS AND STANDARDS

EPA Asks Congress to Overhaul Toxic Substances Control Act

Environmental Protection Agency (EPA) Administrator Lisa Jackson has urged Congress to pass sweeping legislative reform of the country's chemical management law and announced plans to review the controversial food-packaging chemical bisphenol A and the perfluorinated chemicals used in nonstick cookware.

In a September 29, 2009, <u>speech</u> at the Commonwealth Club in San Francisco, Jackson claimed that the Toxic Substances Control Act (TSCA) has "fallen behind the industry it's supposed to regulate. It's been proven an inadequate tool for providing the protection against chemical risks that the public rightfully expects," she said, declaring that as "more and more chemicals are found in our bodies and the environment, the public is understandably anxious and confused."

Legislation to strengthen TSCA is expected to be introduced soon. The Obama administration has <u>issued</u> "Essential Principles for Reform of Chemicals Management Legislation," to aid Congress during the legislative process. The six principles would give EPA the "mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals in commerce."

While Congress considers new chemical-law legislation, EPA has identified an initial list of <u>six chemicals</u> for "possible risk management action" and plans to post a set of four action plans in December 2009 with additional chemical action plans in four-month intervals thereafter. *See EPA Press Release*, September 29, 2009.

EPA, EU Launch Research Strategies for Nanotechnology

The Environmental Protection Agency (EPA) and the European Union (EU) have announced separate plans to study nanotechnology, a field believed to have huge potential in food processing and packaging. EPA's strategy involves studying over the next several years how manufactured nanomaterials may harm human health and the environment. "EPA's role among federal agencies is to determine the potential hazards of nanotechnology and develop approaches to reduce or minimize any risks identified," according to an EPA news release. The research will use a "multidisciplinary approach that examines all aspects of nanomaterials in the environment, from their manufacture and use to their disposal or recycling."



ISSUE 321 | OCTOBER 2, 2009

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. EU plans to develop a strategy on how best to reap the economic benefits of nanotechnology because of its "exceptional importance for being at the forefront of managing the shift to a low carbon, knowledge-based economy," according to an EU news release. "Mastering such technologies lays [a] stable foundation for wellpaid jobs in the EU and allows for sustainable, broadly shared growth. The EU still faces significant obstacles in achieving the wide and timely industrial deployment of these technologies." *See EPA News Release; EU News Release*, September 30, 2009.

FSIS Announces New General Food Defense Plan

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has announced the availability of a new general food defense plan developed by the Office of Data Integration and Food Protection, with input from small and very small establishments. FSIS has notified facilities identified in a 2008 survey as lacking a food defense program about the voluntary general plan, which aims to "reduce the chances of someone intentionally contaminating the food supply in order to kill or hurt people, disrupt [the] economy, or ruin [their] business." Designed to reduce company liability, the general food defense plan includes sections on (i) outside security measures, (ii) inside security measures, (iii) personnel security measures, and (iv) incident report security measures. FSIS will also conduct a second food defense survey in December 2009. *See Meatingplace.com*, September 30, 2009.

Food Producers Raise Concerns over Proposed Prop. 65 Warnings

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) held a "<u>pre-regulatory workshop</u>" on September 25, 2009, to present to stakeholders its proposed warning program for exposures to Proposition 65 (Prop. 65) chemicals in foods sold at retail. According to a news source, industry representatives raised "significant" concerns over the draft proposal, which would require producers to place product-specific warning information on an Internet database and retailers to access the information and select from a "menu" of options to communicate product warnings to the public.

A spokesperson for the California Grocers Association reportedly complained that, as drafted, the existing plan would be impossible to comply with. She claimed that grocery stores should be able to make binders available to shoppers containing warning summaries for different foods. The effect on small grocers is also apparently an issue, and OEHHA counsel called on stakeholders to submit comments on how "small" retailers could be defined. Food industry lobbyists have reportedly argued that the rules should be imposed on the largest grocery chains only. OEHHA has also proposed giving the public access to the Web-based database and making the information searchable by product name, manufacturer, retailer, or chemical substance.

Comments on the proposal must be submitted by October 19, and the agency anticipates proposing a formal regulation in early 2010. Prop. 65 requires warnings for substances known to the state to cause cancer or reproductive harm. OEHHA has been working with stakeholders for two years to develop a retail food warning system. *See Inside Cal/EPA*, October 2, 2009.



ISSUE 321 | OCTOBER 2, 2009

LITIGATION

Class Action Alleges Hazardous Preparation Instructions on Frozen Pot Pies

California residents have filed a putative class action against Pinnacle Foods Group, LLC in federal court, alleging that its frozen food products, if prepared as directed, will not "reach the 'kill step' temperature necessary to destroy dangerous bacteria." *Meaunrit v. The Pinnacle Foods Group, LLC*, No. CV-09-4555 (U.S. Dist. Ct., N.D. Cal., filed September 28, 2009). They also claim that the company's failure "to use appropriate quality control measures within its supply chain," means that "almost every ingredient in these products is a potential carrier of pathogens, according to government and industry officials." According to the complaint, "[s]ince there is no reasonable way to know whether Salmonella or other bacteria has [sic] been destroyed based on the design of these products, Plaintiffs and the class suffered harm due to Pinnacle's conduct."

The named plaintiffs seek to represent a class of either California or U.S. residents, who bought "pot pie products under the Swanson and Hungry Man brand names since January 1, 2008." They allege unlawful and unfair business practices, violation of the Consumers Legal Remedies Act, breach of express and implied warranties, violation of the Magnuson-Moss Warranty Act, unjust enrichment, strict liability, and negligence. Remedies requested include declaratory relief, restitution, compensatory and exemplary damages, costs, and attorney's fees.

CSPI Sues Quorn Foods over Alleged Allergic Reaction to Meat Substitute

The Center for Science in the Public Interest (CSPI) has filed a putative class-action lawsuit in a Connecticut court on behalf of an Arizona woman who allegedly had a severe allergic reaction from eating artificial chicken patties made with a Quorn Foods, Inc. fungus. *Cardinale v. Quorn Foods, Inc.*, No. n/a (Connecticut Super. Ct., filed September 15, 2009). CSPI participated in another lawsuit raising similar allegations against the Connecticut-based company and Whole Foods Markets, Inc. in Texas, but those claims were apparently dismissed.

According to CSPI, more than 1,000 consumers have contacted it to complain that eating foods containing the meat substitute, described in the complaint as "a proprietary processed, vat-grown, soil fungus, combined with flavorings, binders, and other substances," causes nausea, vomiting, diarrhea, hives, difficulty breathing, or anaphylactic reactions. A CSPI press release characterizes the product as a "fibrous, proteinaceous paste."

The named plaintiff in the Connecticut litigation purportedly ate Quorn Chik'n Patties[®] on three occasions in 2008 and each time "became violently ill. The pain was so bad that it felt like the soles of Cardinale's feet were going to come out of her mouth. The last time she ate Quorn, Cardinale vomited seven to eight times within two hours."

The plaintiff alleges violations of the Connecticut Unfair Trade Practices Act and seeks restitution, "money damages" less than \$2,500, an injunction barring the company from continuing to sell its product without providing suitable warnings,



ISSUE 321 | OCTOBER 2, 2009

and attorney's fees. She also seeks to certify a nationwide class of purchasers, and states that the action "does not seek relief for any claims for economic or personal injury that any member of the class asserted, or could assert, against Quorn for any reason." *See CSPI Press Release*, September 17, 2009.

Workplace Exposure Claims Against Diacetyl Makers Dismissed

An Ohio appeals court has dismissed negligence, product liability, fraudulent concealment, and civil conspiracy claims filed against companies that supplied diacetyl to a flavoring company that employed two workers who allegedly contracted bronchiolitis obliterans, a debilitating lung disease, from exposure to the butter-flavoring chemical. *Doane v. Givaudan Flavors Corp.*, No. C-080928 (Ohio Ct. App., 1st Dist., decided September 25, 2009). Affirming the trial court's grant of defendants' motions for summary judgment, the appeals court found, among other matters, that the claims were barred by the statute of limitations and because the employer was a sophisticated purchaser with greater knowledge about the "dangers of diacetyl" than its suppliers.

LEGAL LITERATURE

Adam Burrows, "Palette of Our Palates: A Brief History of Food Coloring and Its Regulation," *Comprehensive Reviews in Food Science & Food Safety*, Vol. 8, 2009

Starting from the premise that consumer enjoyment of food is linked directly to its color, this article discusses the types of substances that have been used over the centuries to change the appearance of food products and how various governments have tried to regulate their use. The earliest food coloring regulations in the United States were developed under pressure by dairy producers who were able, at one time, to persuade the legislatures of five states to pass laws requiring that margarine be dyed pink to compromise its acceptability in the marketplace.

The author traces the history of U.S. laws regulating color additives, noting how debate has raged over the application of strict standards that bar the use of substances with even a 1 in a billion cancer risk to applying what the Food and Drug Administration has championed and called *de minimis* exceptions that would allow the use of color additives with any risk lower than 1 in 1 million.

The author notes that public wariness of synthetic additives has led food and beverage producers to research and use natural colors, some of which have been found to have "nutraceutical" properties. One industry executive is quoted as saying, "It is a very new field for a lot of companies. We are still learning what the specific health benefits are and trying to quantify them. As the food industry works with the health industry, we will see them (natural colors) used more and more, not only for color, but also for the health benefits that could be great for children as well as adults."

The article concludes, "What we use to dye our foods and how we regulate it may continue to change, but there is no end in sight to the timeless practice of coloring our food."



ISSUE 321 | OCTOBER 2, 2009

OTHER DEVELOPMENTS

Soft Drink Tax Could Generate \$10 Billion Annually, Says CSPI

The Center for Science in the Public Interest (CSPI) has issued a **paper** claiming that a state tax on sugar-sweetened beverages "would yield billions of dollars in new revenue and counter the alarming risks of obesity, poor nutrition, and displacement of more healthful foods and beverages." Echoing similar proposals published in the *New England Journal of Medicine* and by the Institute of Medicine, the CSPI report calls for "a modest new (or extra) tax of five cents per 12-ounce serving" that would nationally raise state revenues by "more than \$7 billion annually, ranging from about \$13 million in Wyoming to about \$878 million in California."The paper also includes a chart detailing "inickel-a-drink' state revenue projections, based on national consumption data and pro rated for each state's population."

"President Obama is exactly right when he says kids are drinking too much soda," stated CSPI Executive Director Michael Jacobson in a September 30, 2009, press release that makes note of a recent *Men's Health* interview with the president. "Soda is dirt cheap and promotes expensive and debilitating diseases, which in turn runs up health-care costs at all levels of government. Federal, state and even local governments would be wise to institute or increase taxes on a product that causes so much medical and financial harm."

CSPI Report Critical of Salt Content in Canadian Packaged Foods, Restaurants

The Centre for Science in the Public Interest (CSPI Canada) has issued a <u>report</u> claiming that excess sodium "likely kills more Canadians every year than any other chemical substance" added to food. Titled "Salty to a Fault: Varied Sodium Levels Show Lowering Salt in Processed Foods *IS* Feasible," the report surveyed 318 foods and purportedly found that a majority of Canadian restaurants and perhaps most packaged foods sold in grocery stores contain unhealthy and unnecessarily high levels of sodium. It calls on Health Canada to set category-by-category sodium-reduction targets for foods, alleging that "salt remains largely untouched by food safety laws and is grossly underestimated as a public health risk by government officials who generally direct much more attention to substances that pose rare or more acute risks."

The report apparently found varying degrees of sodium among groups of comparable foods, citing as an example two restaurant french fry orders ranging from a low of 40 milligrams (which left salting to the customer) to a high of 555 milligrams in a standardized serving. "Our scan makes it clear that many companies can and do make foods with much less added salt than their competitors, despite claims they must use lots to make dough rise, preserve food, and give foods acceptable taste and texture," a CSPI official said. "The wide variation in sodium levels in most of the 49 categories of foods featured in the CSPI report helps explain how so many Canadians consume double or triple the 1,500 milligrams of sodium accepted by most experts as an appropriate adult target for consumption." *See CSPI (Canada) Press Release*, September 23, 2009.



ISSUE 321 | OCTOBER 2, 2009

Investigative Report Traces Pollutants from Sea to Sashimi

The Public Education Center's (PEC's) DC Bureau has published a two-part investigative report titled Fish and Paint Chips: The Science and Politics of Ocean Trash, which explores "how plastic and other debris in the world's increasing pollutants could be channeling toxins straight onto our dinner plates through tainted seafood." The first part considers research suggesting that once in the ocean, "small bits of plastic are thought to soak up chemicals from paint chips, old metal and other garbage and eventually end up in the guts of the fish we eat." According to PEC, these floating plastic pellets can act as a "toxic sponge," absorbing chemicals like polychlorinated biphenyls (PCBs), when passing through "five so-called pollution gyres – massive fields of waste collected by wind and ocean currents in the North Atlantic, South Atlantic, North Pacific, South Pacific and Indian oceans." Although some experts are apparently reluctant to extrapolate human health risks from this scenario, the National Oceanic and Atmospheric Administration (NOAA) has reportedly started preliminary studies to better under the potential impact of pollution gyres on the food supply. "While NOAA predicted the existence of pollution gyres as far back as 1988 based on scattered data, there has been little concerted effort to measure their impacts on human health," Holly Bramford, director of NOAA's Marine Debris Program, was quoted as saying.

The second part of *Fish and Paint Chips* examines the "political angle," alleging that both the plastics and seafood industries have hampered environmentalist efforts to reduce waste and educate consumers about ocean pollution. While the American Chemistry Council has purportedly worked to block "even minimal local regulation," seafood restaurants have reportedly refrained from publicizing the problem for fear of tarnishing their "\$55 billion a year" business. In addition, PEC accuses politicians of "not wanting to rock the proverbial boat" by championing a cause with no easy fixes. "What is left now is for researchers to establish whether the plastic and other waste already known to infest the world's oceans poses a health risk to humans, and if so on what scale," concludes the report, which exhorts consumers to "demand to know more about what we eat."

MEDIA COVERAGE

Rachel Maddow Takes Aim at Rick Berman and Center for Consumer Freedom

Noting that Washington, D.C.-based industry lobbyist Rick Berman will be on her MSNBC-TV program during the week of October 5, 2009, Rachel Maddow this week discussed the most recent campaign Berman's Center for Consumer Freedom has undertaken on behalf of the producers of high-fructose corn syrup (HFCS). Maddow showed viewers the clip of a new TV ad that directs those wanting to know more about how sugar and HFCS are the same to a Web site that Maddow said was, "brought to you by something called the Center for Consumer Freedom ... headed by ... Rick Berman, the D.C. public relations guy who runs these operations as nonprofits so they don't have to disclose the names of the companies that fund them."



ISSUE 321 | OCTOBER 2, 2009

Maddow also said that the center "is not just here to convince you to stop worrying about sugar, they also link to their other sites like TransfatFacts.com. Where under a picture of a delicious looking cheeseburger and meatballs, you can learn how—at least according to TransfatsFact.com—*trans* fats are actually good for you." And she stated that, "Berman is also behind FishScam.com, where you can learn that the tiny amounts of mercury in fish aren't harmful at all." *See The Rachel Maddow Show Transcript*, September 29, 2009.

A center spokesperson, discussing the new HFCS advertising campaign, reportedly refuted claims that the sweetener is less healthy than sugar, calling the idea "a viral urban myth." According to senior research analyst Justin Wilson, "A sugar is a sugar and a calorie is a calorie. Period. It's very hard to stop urban myths. We are trying to give some legs to the hard science." While the Corn Refiners Association is not apparently involved in the ad campaign, its president commented on it, saying, "It is refreshing to see the food industry defend high-fructose corn syrup and put to rest the misinformation about this ingredient." *See FoodNavigator-USA.com*, October 1, 2009.

Consumers Confused About "Natural" and "Organic" Food Labels

According to a recent *Orlando Sentinel* article, consumers do not understand the difference between food products labeled as "natural," which, for the most part, is an unregulated term, and those labeled "organic," which carries extensive government regulation and requires certification. Some food producers are apparently taking advantage of consumers' mistaken belief that "natural" is a greener term than "organic"; the natural food market reportedly grew 10 percent between 2007 and 2008 to \$12.9 billion. Foods labeled "natural" are generally sold for less than those labeled "organic," and producers can and do create their own definitions for what is "natural." The article outlines the different rules applying to organic and natural food products. *See Orlando Sentinel*, September 29, 2009.

In a related development, the French agency responsible for regulating competition and fraud has reportedly issued a note establishing requirements for foods sold as "naturel." The document was apparently prepared for inspectors who control food claims. According to the agency, this designation should be used on food products sold in their natural state and subject to mechanical changes only, such as peeling, slicing, drying, or pressing. Products that have undergone cooking, fermentation, pressurization, or roasting, may apparently be labeled "of natural origin." The ingredients of composite products must follow these rules and conform to the definitions, and no flavorings or additives may be used.

While "naturel" and "d'origine naturel" may be used to describe additives and flavorings in France, these products are regulated by separate legislation and are not covered by this document. The Directorate General for Competition, Consumption and Fighting Fraud, which prepared the note, reportedly took the divergent views of consumers, professionals and industry associations into account, but warned that the document does not represent the views of all stakeholders. *See Foodnavigatorusa.com*, September 29, 2009.



ISSUE 321 | OCTOBER 2, 2009

Tara Parker-Pope, "Probiotics: Looking Underneath the Yogurt Label," *The New York Times,* September 29, 2009

"Just as a doctor would prescribe different antibiotics for strep throat or tuberculosis, different probiotic species and strains confer different health benefits," writes *New York Times* columnist Tara Parker-Pope in this article examining food-labeling claims that link *Lactobacillus* and other probiotic families to improved digestive health. According to Parker-Pope, some experts and scientific studies have suggested that specific probiotic strains may reduce diarrhea and the symptoms of irritable bowel syndrome, but researchers have stopped short of a consensus on disease prevention and overall health maintenance. "It's a huge problem for the consumer to try and make heads or tails of whether the products that are out there really work," stated one assistant professor of medicine at Tufts University.

The article notes that recent litigation involving yogurt maker Dannon Co. has also drawn attention to the issue. The company has apparently agreed to list the scientific names of the probiotic strains in its products as part of a \$35 million class-action settlement. *"Lactobacillus* is just a bacterium," Gregor Reid, director of the Canadian Research and Development Center for Probiotics, was quoted as saying. "To say a product contains *Lactobacillus* is like saying you're bringing George Clooney to a party. It may be the actor, or it may be an 85-year-old guy from Atlanta who just happens to be named George Clooney. With probiotics, there are strain-to-strain differences."

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 San Francisco, California +1-415-544-1900 Tampa, Florida +1-813-202-7100 Washington, D.C. +1-202-783-8400

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FOOD & BEVERAGE LITIGATION UPDATE

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.



