

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Federal Trade Commission (FTC)

[1] FTC Target of Merger Challenge Proclaims Proposed Rule Changes Unfair

Whole Foods Market, Inc., which is currently litigating the FTC's challenge to its merger with Wild Oats Markets, has submitted [comments](#) on the commission's proposed merger rule changes and is urging others to join its "Ad Hoc Committee for FTC Fair Play" to do so as well. Apparently, the FTC will allow comments for only 30 days, which Whole Foods characterizes as "unusually short," and has proposed (i) setting evidentiary hearings five months from the date of the complaint in merger cases, regardless of complexity, (ii) giving the commission the authority to decide "all dispositive pre-hearing motions," (iii) giving the commission or an individual commissioner the authority to preside over discovery, and (iv) providing that "the norm should be that the Part 3 case can proceed even if a [federal] court denies preliminary relief."

Whole Foods contends, "The proposed regulatory changes collectively will create an antitrust double standard by exacerbating the procedural differences between the Department of Justice and the FTC. If a company happens to be under FTC jurisdiction, it will face a rushed administrative hearing, without a

truly independent ALJ [administrative law judge], that carries serious risks of due process violations." The company asks, "Why should unmitigated due process rights be afforded to companies in the airline, financial institution, steel and other industries that are subject to DOJ merger review, but not to supermarkets and companies in other industries subject to FTC merger review?" The company is also seeking an extension to the comment deadline. *See Federal Register*, October 7, 2008; *Whole Foods Press Release*, October 27, 2008.

U.S. Department of Agriculture (USDA)

[2] USDA Proposes Amendments to Livestock Provisions of Organic Program

The USDA has issued a proposed [rule](#) that will amend the livestock provisions of the National Organic Program by providing greater detail about pasture and ruminant animals and "clarify the replacement animal provision for dairy animals." Comments must be submitted on or before December 23, 2008.

The *Federal Register* notice provides a history of the rule's development and summarizes the content of the thousands of comments the agency received on an advanced notice of proposed rulemaking published in 2006. According to the agency, "[s]upport for strict standards and greater detail on the role of pasture in organic livestock production was nearly unanimous with just 28 of the over 80,500 comments opposing changes to the pasture requirements."



Among the changes are (i) defining “crop” to include pastures, sod and cover crops; (ii) defining “livestock” as “Any bee, cattle, sheep, goats, swine, poultry, equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; fish used for food; wild or domesticated game; or other nonplant life”; (iii) specifying livestock feed standards; (iv) detailing livestock living conditions; and (v) requiring organic livestock operators to maintain auditable records, including “a functioning management plan for pasture.”

The Cornucopia Institute is apparently concerned that because the changes incorporate “major policy proposals that have never been reviewed by the industry, or, as Congress mandated, by the National Organic Standards Board,” they have the potential to “crash the other needed changes” and “indefinitely delay enforcement.” See *Federal Register*, October 24, 2008; *Food Law Prof Blog*, October 26, 2008.

Food and Drug Administration (FDA)

[3] Advisory Panel Issues Draft Peer Review Criticizing FDA’s Bisphenol A Exposure Assessment

A subcommittee of FDA’s Science Board has [released](#) its peer review of the agency’s draft assessment of bisphenol A (or BPA) for use in food contact applications. The FDA’s draft assessment concluded, on the basis of industry-funded studies, that “an adequate margin of safety exists for BPA at current levels of exposure from food contact uses.” Further information about the draft assessment appears in issue 272 of this Update.

According to the peer review, scheduled to be reviewed by FDA’s Science Board on October 31,

2008, the FDA properly focused on dietary exposures to children, “because they are likely to have both greater exposures and susceptibility than adults as a function of food consumption patterns, metabolism, vulnerability of developing systems and other factors.” The peer review then criticizes the agency’s assessment for its lack of “an adequate number of infant formula samples” and reliance “on mean values rather than accounting for the variability in samples.” The panel scientists also concluded, (i) “The draft FDA report does not articulate reasonable and appropriate scientific support for the criteria applied to select data for use in the assessment”; (ii) the agency should include other studies in its assessment, including several “published after the draft assessment was finished”; (iii) “the assessment lacks an adequate characterization of uncertainties in its estimates of both exposure and effects”; and (IV) “the Margins of Safety defined by FDA as ‘adequate’ are, in fact, inadequate.”

The FDA responded by agreeing that “additional research would be valuable,” but continued to assert that consumers should not be concerned, stating, “Consumers should know that, based on all available evidence, the present consensus among regulatory agencies in the United States, Canada, Europe, and Japan is that current levels of exposure to BPA through food packaging do not pose an immediate health risk to the general population, including infants and babies.” Still, the agency notes, “Parents who, as a precaution, wish to use alternatives for their bottle-fed babies can use glass and other substitutes for polycarbonate plastic bottles; avoid heating formula in polycarbonate plastic bottles; and consult their pediatrician about switching to powdered infant formula.”

Bisphenol A is widely used in plastic bottles and lines metal cans, including those used for infant



formula. Recent studies have purportedly linked the chemical to diabetes, heart disease, memory loss, learning impairments, depression, prostate and breast cancer, reproductive disorders, and developmental problems. The Judicial Panel on Multidistrict Litigation is currently considering whether to transfer the 24 pending federal cases involving bisphenol A to a single court for pre-trial proceedings. See *FDA Statement*, October 28, 2008; *Product Liability Law* 360, October 29, 2008.

Codex Alimentarius Committee

[4] USDA and FDA Announce Public Meeting to Discuss Codex Food Import Agenda

The U.S. Department of Agriculture (USDA) and Food and Drug Administration (FDA) have [announced](#) a November 4, 2008, public meeting to consider agenda items coming before the 17th Session of the Codex Alimentarius Committee on Food Import and Export Inspection and Certification Systems (CCFICS). Slated for November 24-28 in Cebu, Philippines, the Codex session will address (i) the proposed draft “Principles and Guidelines for the Conduct of Foreign On-Site Audits and Inspections;” (ii) the proposed draft “General Model Health Certificate;” and (iii) the annex to the “Guidelines for Design, Production, Insurance and Use of Generic Official Certificates.” In addition, the committee will discuss “the need for guidance for national food inspection systems, the need for further guidance on traceability and product tracing, and the development of guidance on the prevention of international contamination of food,” according to USDA. Codex was formed in 1963 by the United Nations, the Food and Agriculture Organization and the World Health Organization to develop food standards in the interest of public health and fair food trade practices.

Litigation

[5] Washington Cattleman Sues USDA Over COOL Regulations

A rancher in eastern Washington has reportedly sued the U.S. Department of Agriculture (USDA) in federal court, seeking changes to its country-of-origin labeling (COOL) rules for beef products. According to a news source, Easterday Ranches claims that the regulations are adding to costs for the U.S. beef industry and consumers. Apparently, cattle born in other countries must be segregated from domestic animals and cannot be slaughtered on the same day; extensive records must be kept and buyers must keep the meat separate in processing plants. Easterday’s president reportedly claims that commercial buyers are paying far less per head for Canadian or Mexican cattle, and there is no premium price being paid for U.S. cattle. He also contends that the regulations do nothing for food safety and contradict the North American Free Trade Act. See *Tri-City Herald* and *meetingplace.com*, October 28, 2008.

Other Developments

[6] Food Companies Adopt New Labeling Standards to Aid Consumers

Several of the nation’s largest food and beverage companies have reportedly agreed to market their products under a common nutritional standard and logo designed to lessen consumer confusion at the supermarket. The “Smart Choices Program” allows participating manufacturers to display a “check mark” logo alongside calorie and serving size information on the front of products that meet specific nutritional thresholds set by a coalition of scientists, retailers and industry experts and based on federal



dietary recommendations. These products cannot exceed the program's limits for total fats, saturated fats, added sugars, or sodium. In addition, they must contain several "nutrients to encourage" that include calcium, potassium, fiber, magnesium, vitamin A, vitamin C, and vitamin E. Fruits and vegetables, whole grain, and low- or no-fat dairy products are also eligible for the marketing claim. "It's simple, it's easy-to-use, it's consensus based, it's science based," said one spokesperson for Unilever PLC. "We would hope it would become the front-of-package labeling standard in the United States." See *The Associated Press*, October 27, 2008; *The New York Times*, October 28, 2008.

Meanwhile, an October 29, 2008, article in *The New York Times* discussed the impact of New York City's menu labeling regulations on restaurant offerings and consumer habits. Now required to list calorie content on their menus, some major chains have apparently modified their products in response to customer demand for healthier options. Moreover, patrons interviewed in the article specifically cited the availability of nutritional information as a factor in their decisions. "Counting calories is so 1980s," one diner was quoted as saying. "But when it's right there, it's kind of hard to ignore."

[7] **Obesity Survey Shows Changing Attitudes About Responsibility**

Nielsen's *Consumer Insight Magazine* [reports](#) that rising rates of obesity in the United States can be attributed not only to increasing calorie consumption and less exercise, but also to "pure demographics." According to the report, "The population is older than ever before and Americans tend to be fatter when older. Women are heavier, and because they live longer than men, they make up a higher share of the older population. Lastly, Hispanics—the fastest growing immigrant group in

the U.S.—tend to have higher obesity rates." The report, titled "A Widening Market: The Obese Consumer in the U.S.," also notes that the average American consumes 15-20 more pounds of fat each year than he did 100 years ago.

As to assessing responsibility for weight gain, more than 80 percent of consumers admit they are to blame, about the same as those agreeing in 2006 that weight gain is attributable to eating too much and not exercising enough. In 2006, however, only 2 percent of consumers surveyed placed the most blame for obesity on food companies and 6 percent on fast food restaurants. In 2008, nearly three quarters of those surveyed "believe that people are encouraged to eat less-healthy food by advertising, and that these companies should provide healthier food." Fast food companies and the government "get off surprisingly easy and are not seen as nearly as important a player in the obesity blame game as food companies."

Nielsen suggests its report gives marketers critical information about understanding obese consumers and can help them create products to address the problem. For example, the report notes that consumers embraced Nintendo's Wii Fit®, suggesting that "making weight loss a game" could be a successful approach to addressing the obesity problem. See *Foodnavigator-usa.com*, October 30, 2008.

[8] **University of Arkansas Offers L.L.M. in Agricultural Law**

The University of Arkansas School of Law has announced that it will be accepting applications for graduate studies in agricultural law beginning in fall 2009. The nine-month course, billed as the only one of its kind in the nation, covers a range of issues from farm to fork, including labeling law, food



policy, sustainability, biotechnology, international trade, and environmental issues. Additional information about the program is available at <http://law.uark.edu/llm>. The university also hosts a related [blog](#). See *Food Law Prof Blog*, October 29, 2008.

[9] Australian Industry Group Announces Responsible Children's Marketing Initiative

The Australian Food and Grocery Council (AFGC) recently released a [Responsible Children's Marketing Initiative](#) in response to "community concerns about food and beverage advertising during children's television programs." AFGC developed the initiative after the Australian Communications and Media Authority (ACMA) published its draft *Children's Television Standards 2008*, which did not recommend further government regulation of food and beverage advertising. In agreement with these preliminary findings, AFGC nevertheless stated that industry "is still keen to address community concerns regarding advertising to children."

The initiative covers advertising on free-to-air television, pay television and the Internet; the use of licensed characters; and promotions in children's publications. Companies that publicly commit to the program must institute an action plan focused on six core areas: (i) advertising messaging; (ii) the use of popular personalities and licensed characters; (iii) product placement; (iv) the use of products in interactive games; (v) advertising in schools; and (vi) the use of premium offers. In particular, the marketing code calls on signatories to refrain from advertising products to children under 12 unless "those products represent healthy dietary choices, consistent with established scientific Australian government standards" and the "communication

activities reference, or are in the context of, a healthy lifestyle, designed to appeal to the intended audience through messaging that encourages good dietary habits, consistent with established scientific or government criteria, [and] physical activity." Created in collaboration with the Australian Association of National Advertisers (AANA), the initiative also requires participants to abide by the AANA Code for Advertising & Marketing Communications to Children; the AANA Food & Beverages Advertising & Marketing Communications Code; and the AANA Code of Ethics. "It will be the community's expectation that the scheme will be overseen by an independent arbitrator, to whom perceived breaches can be reported and who can take action to rectify violations; this is also industry's view," stated Chief Executive Kate Carnell in an October 24, 2008, AFGC press release.

[10] Melamine in Animal Feed is Widespread Practice

According to a news source, the Chinese press is reporting that melamine is commonly used in animal feed "to reduce product costs while maintaining protein count for quality inspections." The *Nanfang Daily* apparently calls the practice an "open secret" in the industry. Unnamed industry analysts reportedly said that such news reports constitute "an unusual departure for Chinese officials" and amount to a tacit admission that the scandal, which has affected a range of food products in recent months from milk to eggs, could affect even more parts of the food supply chain. U.S. food safety officials reportedly indicated some months ago that melamine detected in livestock feed did not pose a threat to human health. Details about their conclusions appear in issue 213 of this Update. See *BBC News*, October 31, 2008.



Media Coverage

[11] Faye Flam, "Male Interrupted,"
Philadelphia Inquirer, October 27, 2008

Inquirer staff writer Faye Flam begins her piece on phthalates and possible human health effects by reporting that a Philadelphia surgeon is seeing double the number of baby boys, since he started practice 30 years ago, in need of repairs to their genitalia. Surgeon Howard Snyder hypothesizes that some of them have been exposed to phthalates in the womb. These "hormone-disrupting chemicals" are, according to Flam, found in everything from perfumes, hand and body lotions, nail polishes, deodorants, shower curtains, and children's toys to IV tubing in hospitals. Phthalates apparently "interfere with the synthesis of testosterone," and a study conducted by a University of Rochester researcher involving 134 boys born to women tested for compounds metabolized from phthalates showed that "boys whose mothers were most exposed to certain phthalates were more likely to have undescended testicles and to have smaller penises."

Chemistry trade groups reportedly challenge such research, saying the studies are too small to be valid or involve animal data that may not apply to humans. An American Chemistry Council spokesperson noted that dozens of studies have found no link between phthalate exposure and adult diseases. The director of an environmental advocacy group reportedly said that animal data alone is cause for concern. "There's a huge animal database showing how exposures to phthalates during development can have effects at levels hundreds of times lower than those needed to show any impact on an adult," he was quoted as saying. Other researchers are apparently seeking grants to

test findings already made; at least one suggests that warning labels should be provided for pregnant women.

Scientific/Technical Items

[12] Research Suggests Red-Meat Eaters Primed for *E. Coli*

According to researchers in Australia and the United States, those who persistently eat red meat may be more susceptible to *E. coli* infection. Apparently, the meat contains sugar molecules, Neu5Gc, that accumulate in cells lining the intestines and blood vessels and act as a "magnet" for *E. coli* toxins. The scientists reportedly tested the affinity of the bacteria for Neu5Gc in a lab dish and noted, "The human samples showed the presence of the Neu5Gc toxin binding sites in the gut and the kidney, the two target organs for the disease." Then, they confirmed the results with genetically modified mice that have the gene which produces Neu5Gc suppressed. The research appears in *Nature*, but was not available when the Update was prepared. See *The Australian*, October 30, 2008.

[13] Doctors Report Increase in Pediatric Kidney Stones

Pediatric urologists and nephrologists across the United States have reportedly noted an increase in the number of kidney stones diagnosed in children. An ailment commonly associated with middle-aged men, kidney stones are typically formed when "oxalate, a byproduct of certain foods, binds to calcium in the urine," according to an October 29, 2008, *New York Times* article, which stated that "the two biggest risk factors for this binding process are not drinking enough fluids and eating too much salt." The article also cited "evidence that sucrose,



found in sodas, can also increase risk of stones, as can high-protein weight-loss diets, which are growing in popularity among teenagers.” The incidence of kidney stones has also purportedly risen in women and young adults in their 20s and 30s.

Physicians told *New York Times* reporter Laurie Tarkan that childhood obesity and a diet high in salt are the most likely culprits behind the new cases. They specifically pointed to sources of hidden sodium that include processed meats and canned soup, as well as popular sports drinks. Family history of the disease also appears to be a major risk factor, prompting doctors to recommend that the children of adult stone sufferers avoid high-salt, high-fat foods and drink lots of water. Alicia Neu, medical director of nephrology and the pediatric stone clinic at Johns Hopkins Children’s Center, further observed that increasing water intake “is the most important step in the prevention of kidney stones.”



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