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### LEGISLATION, REGULATIONS AND STANDARDS

### FTC Issues Omega-3 Fatty Acid Warning Letters; Seeks Evidence for Health Claims

The Federal Trade Commission (FTC) has <u>announced</u> that it sent letters to 11 unnamed companies in late January 2010, warning that their promotions and product packaging for Omega-3 fatty acid supplements may violate the law "by making baseless claims about how the supplements benefit children's brain and vision function and development." FTC apparently gave the companies until February 8 to respond and explain what they have done or will do to ensure they are complying with the law, that is, that their health-related claims "are substantiated."

FTC provides as an example of substantiation "well-conducted, clinical cause-andeffect studies demonstrating that the use of the combination of Omega-3 fatty acids provided in Product X, in the same dosage as provided by one serving of the product, improves or promotes brain function, cognitive function, attention span, intelligence, memory, learning ability, and visual acuity in normal children ages 2 years and older." The agency cites a similar investigation it made of Northwest Natural Products, Inc., which advertised and promoted a children's vitamin containing Omega-3 as a product that "boosts, improves, or promotes brain function, brain development, intelligence, or academic achievement in children." According to FTC, the company immediately and voluntarily modified its marketing materials for its Gummy Fish® product to comply with the law.

FTC also solicits contact from consumers "who wish to file a complaint against a company they believe may be deceptively advertising dietary supplements for children, or any other type of product." *See FTC Press Release*, February 16, 2010.

### USDA Issues Final Rule Setting Pasture Requirements for Organic Livestock

The U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service has issued a final rule that amends National Organic Program (NOP) regulations to establish "a pasture practice standard for ruminant animals." Seeking "to satisfy consumer expectations that ruminant livestock animals graze on pastures during the grazing season," the final rule requires producers to (i) "provide year-round access for all animals to the outdoors"; (ii) "recognize pasture as a crop"; (iii) "establish a functioning management plan for pasture"; (iv) "incorporate the pasture manage-



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

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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. ment plan into their organic system plan (OSP)"; (v) "provide ruminants with pasture throughout the grazing season for their geographical location"; and (vi) "ensure ruminants derive not less than an average of 30 percent of their dry matter intake (DMI) requirement from pasture grazed over the course of the grazing season." This rule takes effect June 17, 2010, for operations seeking organic certification by this date. Operations already certified as of the rule's publication must achieve compliance by June 17, 2011.

The rule also requires slaughter stock to have access to pasture during the finishing phase, but exempts them from the 30 percent DMI requirement. Organic farmers and ranchers apparently use finish feeding, which involves grain crops, to improve the grade of beef. According to a February 12, 2010, news release, "USDA received a substantial number of comments on provisions of the rule affecting finish feeding practices of slaughter livestock, and has extended the comment period for this provision for 60 days."

"Clear and enforceable standards are essential to the health and success of the market for organic agriculture," stated USDA Secretary Tom Vilsack. "The final rule published today will give consumers confidence that organic milk or cheese comes from cows raised on pasture, and organic family farmers the assurance that there is one, consistent pasture standard that applies to dairy products." *See Federal Register*, February 17, 2010.

# USDA and FDA to Coordinate Produce Safety Efforts

The U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) have issued a joint <u>statement</u> to announce a collaborative effort to improve the safety and quality of fresh produce.

As part of the announcement, the agencies report that USDA's Agricultural Marketing Service "is in the midst of evaluating a proposed marketing agreement for the leafy green industry," while the FDA "is currently developing a proposed produce safety regulation." The notice calls for feedback and comments from stakeholders, noting that FDA would establish "a docket to receive information about current practices and conditions for the production and packing of fresh produce and practical approaches to improving produce safety." *See FDA News & Events*, February 18, 2010.

# FDA Submits Proposed Animal Drug Information Collection to OMB

The Food and Drug Administration (FDA) has <u>submitted</u> a proposed collection of information involving antimicrobial animal drugs to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act. According to the *Federal Register* notice, a 2008 amendment to the Federal Food, Drug, and Cosmetic Act requires that "the sponsor of each new animal drug that contains an antimicrobial agent submit an annual report to FDA on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals."



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The first report under the law will be due March 31, 2010, and must specify (i) "The amount of each antimicrobial active ingredient by container size, strength, and dosage form"; (ii) "quantities distributed domestically and quantities exported"; and (iii) "a listing of the target animals, indications, and production classes that are specified on the approved label of the product." Enacted to "address the problem of antimicrobial resistance," the legislation was intended to ensure that the agency had the information it needs to "examine safety concerns related to the use of antibiotics in food-producing animals." Written comments on the antimicrobial animal drug distribution reports must be submitted to OMB by March 22, 2010. See Federal *Register*, February 18, 2010.

# FDA Seeks Comments on Proposed Collection of Information on Foods from New Plant Varieties

The Food and Drug Administration (FDA) has published a <u>notice</u> seeking public comments on its proposed collection of information on foods derived from new plant varieties including those created through biotechnology. Comments must be submitted by April 19, 2010.

The types of information that developers of new plant varieties would be required to provide to the agency include (i) a description of the applications or uses of the bioengineered food, (ii) information about the sources, identities and functions of the introduced genetic material, (iii) information about any known or suspected allergenicity and toxicity, and (iv) information relevant to the safety and nutritional assessment of the bioengineered food. Commenters are asked to address whether the proposed collection "is necessary for the proper performance of FDA's functions," the accuracy of the agency's estimate of the burden of the proposed information collection, ways to improve the quality of the information to be collected, and ways to minimize the burdens on respondents. *See Federal Register*, February 18, 2010.

## EPA Extends Comment Deadline on Proposal to Expand Reach of 10X Safety Factor

In response to requests by chemical industry interests, the Environmental Protection Agency (EPA) has <u>extended</u> the deadline for comments on its proposal to apply a 10-fold (10X) safety factor to its pesticide risk assessments in relation to the exposure of agricultural workers and their children in agricultural fields. CropLife America and the American Chemistry Council made the request, noting that the proposal is related to several others, such as new labeling rules to control drift, that have not yet been finalized. Comments must now be received by April 12, 2010.

The industry groups also pointed to studies the agency does not appear to have considered in drafting its policy paper, "Revised Risk Assessment Methods for Workers, Children of Workers in Agricultural Fields, and Pesticides with No Food Uses," and expressed concerns that some supporting materials have not been made public. They urge EPA to consider a National Academy of Sciences report on risk reviews and take an approach based on the best available science. *See Federal Register*, February 5, 2010; *Inside EPA.com*, February 12, 2010.



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# LITIGATION

### Federal Court Denies Request for Delay of COOL Implementation

A federal court in Washington has reportedly denied a feedlot company's request to invalidate or delay implementation of the country-of-origin labeling (COOL) regulations adopted by the U.S. Department of Agriculture (USDA) in 2008. *Easterday Ranches, Inc. v. USDA*, No. n/a (U.S. Dist. Ct., E.D. Wash., decided February 5, 2010). According to news sources, the company argued that the COOL regulations, which do not allow beef imported from Canada or Mexico and slaughtered in the United States to be labeled as a U.S. product, conflicted with U.S. Treasury Department rules, would raise its recordkeeping and operational costs, and deter packers from paying fair prices for Canadian cattle. The Treasury rules apparently provide that beef is deemed a U.S. product if it undergoes "substantial transformation," e.g., slaughter, within this country.

The court refused to postpone USDA's rules and further declined to order the agency to create an exception to COOL allowing cattle imported from Canada and Mexico and slaughtered in the United States to be labeled as a U.S. product. The court reportedly determined that (i) COOL does not deny feedlots a fair price for their cattle; (ii) the Treasury Department rules relate to tariffs and do not conflict with the "retail-oriented" COOL regulations; and (iii) USDA cannot create an exception for beef without violating the COOL requirements Congress included in the Farm Bill. *See Capital Press*, February 14, 2010; *Meatingplace.com*, February 17, 2010.

Meanwhile, a cattle industry trade association reportedly cited the court's ruling in a February 12, 2010, memorandum to the U.S. Trade Representative, arguing that it could "help in the defense of our COOL law against Canada's and Mexico's attack at the WTO [World Trade Organization]." According to an R-CALF USA spokesperson, "Much like the *Easterday* complaint filed in the U.S., both Canada's and Mexico's complaints filed at the WTO are seeking the same protection. And like Easterday, Canada and Mexico want to continue hiding the true origins of their foreign beef in the U.S. marketplace. The actions by Canada and Mexico truly are repugnant to U.S. consumers who deserve to know the origins of their food." *See R-CALF Press Release*, February 15, 2010.

Further details about the WTO dispute appear in issues 304, 322, 323, 325, and 329 of this Update.

### French Court Imposes Fines and Suspended Sentences in Wine Scam

A court in Carcassonne, France, has reportedly found French winemakers and traders guilty of deliberately and repeatedly mislabeling wine as a more expensive grape variety to get a better price from E. & J. Gallo under its Red Bicyclette<sup>®</sup> brand. French customs officials apparently discovered the swindle when they found that the amount of "pinot noir" sold to Gallo far exceeded what the region produced. According to a news source, the scam more than doubled the miscreants' profits, which totaled some €7 million for 18 million bottles. The fines imposed ranged from US\$2,050 to US\$247,050, and the suspended jail sentences ranged from one to six months. The judge was quoted as saying, "The scale of the fraud caused severe



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damage for the wines of the Languedoc for which the United States is an important outlet." A defense attorney reportedly said that no American customers complained about the fraud. *See BBC News*, February 17, 2010.

# OTHER DEVELOPMENTS

#### Legal Commentators Make Predictions About BPA-Related Litigation

According to legal commentators interviewed for an article in *Law 360*, consumer perceptions about the safety of food-packaging chemical bisphenol A (BPA), as well as increasing attention to the chemical in state legislatures, could result in a morass of litigation for years to come. While a \$1 billion lawsuit is already pending in multidistrict litigation court against companies producing products, such as baby bottles, containing BPA, some say that manufacturers rushing to reformulate their packaging or products could inadvertently replace the substance with questionable alternatives. The article explores the scientific uncertainties currently informing the debate before the courts and policy makers and suggests that if the Food and Drug Administration ultimately concluded that BPA poses risks to human health, consumer fears would only be exacerbated. *See Law 360*, February 16, 2010.

In a related development, the 95-2 vote in Wisconsin's Assembly on February 16 has moved a BPA ban closer to approval in the state. The Senate approved an identical version, and the governor is expected to sign it. The bill would prohibit the sale and manufacturer of BPA in baby bottles and cups for children ages 3 and younger. According to a news source, similar bans are in effect in Connecticut, Minnesota, Chicago, and three counties in New York. Proposed bans are apparently pending in seven states and Washington, D.C. Oregon's Senate split 15-15 on that state's proposal, which reportedly means that it will go no further. *See Journal Sentinel* and *The Oregonian*, February 16, 2010.

#### British Newspaper Reports Scheme to Recruit Youth Marketers

"Children are being paid up to £25 a week to promote sugary soft drinks and other products through social networking sites and playground chat," claims a February 15, 2010, report published in the *Daily Mail*. Titled "Child 'Mini-Marketers' Paid by Junk Food Firms to Secretly Push Products Among Their Friends," the article focuses on an advertising Web site, Dubit Insider, that offers vouchers worth £25 and free samples to children who sign on to become "brand ambassadors." The *Daily Mail* alleges that this Web site recruits children ages 7 to 24 to "promote brands, products and services" among their peer group, suggesting that Dubit members can use their experience to enhance their college applications. "Companies are not just stalking kids online," one consumer advocate was quoted as saying. "Close on half a million young people in the UK alone have been enlisted by big youth brands, and that's the figure from just one recruitment agency. Kids are regularly signed up through the Internet to be 'insiders,''informers,' and 'lifestyle representatives' for big corporations."

In addition, the newspaper lambastes the UK Food Standards Agency (FSA) for partnering with Dubit on an initiative to spread the word about the importance of a



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good diet. "This followed disturbing research showing that many teen girls and boys are being starved of key nutrients. They were consuming too much junk, such as sugary soft drinks and snack foods, and more than a third were overweight," opines the report, which also criticizes several food and beverage manufacturers for using Dubit in their word-of-mouth marketing campaigns.

### **Animal Rights Organization Targeted Online**

Anne Landman, who once had the tobacco industry in her sights and now posts for Center for Media and Democracy's *PRWatch.org*, has reported that Washington, D.C.-based industry lobbyist Rick Berman and his Center for Consumer Freedom have launched a <u>Web site</u> "to harass" the Humane Society of the United States. Landman states that Berman "sets up his front groups as 501(c)4 organizations and then carries out his attacks through these groups to avoid disclosing his donors, so we have no way of knowing which industries or companies are funding Berman's attack on the Humane Society. We can probably get a good idea though. Just determine which businesses profit most from animal cruelty, and you'll likely find the funders among them." Further discussion about Berman and his appearance on Rachel Maddow's MSNBC-TV program appears in issues 321 and 322 of this Update. *See PRWatch.org*, February 17, 2010.

### Rudd Center to Hold Soft Drink Tax Webinar

Yale University's Rudd Center for Food Policy and Obesity has <u>announced</u> a March 9, 2010, Webinar to discuss "the rationale, relevant science, and economic and policy considerations of soft drink taxes." The conference will reportedly update participants about the latest developments in state and local policies since July 2009, when director Kelly Brownell presented the center's first Webinar on this topic. The Rudd Center has consistently supported taxes on sugar-sweetened beverages to "improve public health and generate considerable revenue for states, cities, and the nation," according to its Web site.

## MEDIA COVERAGE

# Stephanie Clifford, "A Fine Line When Ads and Children Mix," *The New York Times,* February 15, 2010

This article claims that recent efforts to monitor and regulate marketing to children has had "an interesting side effect," that is, a shift away from traditional tactics to "games, contests and events where the advertiser has only a subtle presence—exactly the opposite of what some of the advocacy groups were aiming for." According to *New York Times* journalist Stephanie Clifford, children's publications have increasingly sought to integrate corporate sponsorships with contests and features that emphasize their content. "Instead of just a straight selling of product, it's all about how we tell the message in the magazine and how we engage with the kids," stated one spokesperson for *National Geographic Kids*, which reported a decline in ad revenue "largely because of the economy but in part because of heightened concern about food advertising."



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"But these kinds of strategies, created in part to sidestep advocates' criticisms, are upsetting them all the more," writes Clifford. Susan Linn, director of the Campaign for a Commercial-Free Childhood, apparently described the sponsorships as "powerful and incredibly insidious," despite strides made by federal regulators and some companies, like those supporting the Children's Food and Beverage Initiative, to set nutritional standards for advertised products. As a result, some magazines have decided to sidestep marketing altogether. "We don't have that potential conflict in the needs of our readers, in the wants and desires of our readers, with those of our advertisers," one publisher was quoted as saying.

# Mark Bittman, "Soda: A Sin We Sip Instead of Smoke?," *The New York Times,* February 12, 2010

"In their critics' eyes, producers of sugar-sweetened drinks are acting a lot like the tobacco industry of old: marketing heavily to children, claiming their products are healthy or at worst benign, and lobbying to prevent change," begins *New York Times* columnist Mark Bittman in this article questioning whether aggressive public health initiatives, like those deployed to discourage smoking, could similarly curb soda consumption. Noting that Americans drink "roughly 50 gallons per person per year," Bittman contests the value of industry claims that "in moderate quantities soda isn't harmful, nor is it addictive." His article goes on to summarize the arguments made by policy makers and advocates in favor of "a special tax on soda, similar to those on tobacco, gasoline and alcoholic beverages." In particular, he cites the Rudd Center's director, Kelly Brownell, who maintains that, "Unless food marketing changes, it's hard to believe that anything else can work."

"In the case of tobacco, the health risks of smoking were clear," opines Bittman. "But the beverage industry contends that science does not back up the assertion that childhood obesity is even partly caused by soda consumption, and has sought to make the discussion about personal choice and freedom." As one research analyst with the Center for Consumer Freedom was quoted as saying, "[There] is no unique link between soda and obesity."

Although Bittman ultimately calls for governments to be more "forceful" in their plans to combat obesity, he concedes that some regulators believe these efforts need not be so contentious. "There are parts of industry that want to be constructive," said Thomas Friedan, the director of the Centers for Disease Control and Prevention. "Big Food doesn't have to become the next tobacco."

#### Sarah Elizabeth Richards, "The Irresistible Baconator," Slate, February 16, 2010

"Chalk it up to the lack of willpower, sway of culture, or love of the processed carb, but humans aren't always rational eaters," argues Sarah Elizabeth Richards in this February 16, 2010, *Slate* article that questions the effectiveness of efforts to make calorie counts more visible on menus and food packaging. Citing numerous recent studies that cast doubt on these labeling practices, Richards maintains that not only are "calorie counts irrelevant for consumers who don't know how many calories they're supposed to be eating in a day," but "[it] can also be hard to take the counts seriously when you're not even sure they're accurate."



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For Richards, although menu labeling and federal initiatives to realign product serving sizes are laudable, it remains difficult for most consumers to implement these tools as part of a sensible diet plan. She particularly focuses on a study published in the February 2010 edition of *Appetite* that found "people had a harder time adhering to diets that seemed complicated than to programs that were simpler to follow." According to Richards, "[The] surest way to control your weight, experts say, is to develop a sense of what's best for your body so you don't have to depend on the government or a corporation to tell you what's OK to eat."

# SCIENTIFIC/TECHNICAL ITEMS

### Persistent Organic Pollutants Reportedly Detected in Food

Researchers studying 31 different types of food purchased from supermarkets in Dallas, Texas, have apparently found a range of persistent organic pollutants, including organochlorine pesticides, at varying levels, although none exceeded Environmental Protection Agency reference doses or EU maximum residue levels for pesticide residues in food. <u>Arnold Schecter, et al., "Perfluorinated Compounds, Polychlorinated Biphenyl, and Orgnaochlorine Pesticide Contamination in Composite Food Samples from Dallas, Texas," *Environmental Health Perspectives*, February 10, 2010.</u>

Noting that a number of the pollutants tested have been banned for some time in the United States, the researchers nonetheless found them in meat products, fish, dairy, vegetable-based foods, and eggs. While uncertain whether some of the chemicals may have migrated from food packaging, the researchers conclude that "US food is contaminated with a wide range of chemicals, including pesticides, PFCs, and PCBs and that expanding the current monitoring beyond pesticides to include emerging pollutants is warranted."The researchers also call for additional research "to determine the toxicological effects of these and other mixtures which exist in food."

### OFFICE LOCATIONS

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## **FOOD & BEVERAGE LITIGATION UPDATE**

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

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.

