Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards 110th Congress

[1] Commission Holds Congressional Briefing on Antibiotic Resistance and Farm Animals

The Pew Commission on Industrial Farm Animal Production this week conducted a congressional briefing to examine the alleged link between increasing antibiotic resistance and agriculture. Funded by the Pew Charitable Trusts through the Johns Hopkins Bloomberg School of Public Health, the commission includes ranchers, public health scholars and animal welfare advocates, as well as former USDA Secretary Dan Glickman. This group, which plans to issue a formal report in April 2008, has speculated that the use of antibiotics at concentrated animal feeding operations (CAFO) and other confined livestock outfits has caused bacteria to become resistant to those drugs. "The chance of generating a resistance [to antibiotics] out in a pasture, hypothetically should be less than in a tight, crowded space," the commission's vice-president, Michael Blackwell, was quoted as saying in the first of three public hearings. The commission's perspective apparently backs the efforts of a food safety and environmental coalition known as Keep Antibiotics Working, which in December 2007 asked the Food and Drug Administration to test animals

for the "super bug" methicillin-resistant staphylococcus aureus associated with 18,650 U.S. deaths in 2005. *See Pork Alert*, January 29, 2008; *CQ Healthbeat News*, January 30, 2008.

In a related development, the U.S. Department of Agriculture is reportedly studying whether cattle raised on distilled grains harbor significantly higher levels of *E. coli* bacteria than those on conventional feed. Scientists with the U.S. Meat Animal Research Center in Nebraska are currently tracking 600 cattle, one half of which receive a traditional grain diet and one half of which receive a diet of 40 percent distillers' grains. The research aims to follow up on an earlier Kansas State University study that linked the ethanol-production byproduct to a two-fold increase in the *E. coli* present in cattle. USDA has stated that it does not plan to regulate distilled grains in livestock feed regardless of the study results, which are expected later this year. See The Associated Press, January 26, 2008; Meatingplace.com, January 29, 2008.

Federal Trade Commission (FTC)

[2] FTC Submits Comments on Alcohol Labeling

FTC staff submitted <u>comments</u> on the Alcohol and Tobacco Tax and Trade Bureau's (TTB's) proposal to require certain nutrition and alcohol content information on labels and ads for wines, distilled spirits and malt beverages. The comments





support TTB's proposed rulemaking and recommend "that TTB require labels to disclose pure alcohol content in fluid ounces per serving (rather than in the form of ABV [alcohol by volume]) and specify that this disclosure should appear within the Serving Facts panel." The staff comments also recommend that TTB consider allowing "alcohol marketers to make representations about recommended limitations on alcohol intake, and the availability of federal health guidance on that point." The comments conclude with recommendations for consumer perception testing and an education program to accompany the appearance of new labels on the market. "Regardless of the form in which the disclosures are made, consumers will need help learning how to interpret the disclosures and how to compare the alcohol content of different beverages." The January 27, 2008, comments were not formally approved by FTC's commissioners, but they did authorize the submission. Further details about TTB's notice of proposed rulemaking appear in issue 225 of this Update.

Food and Drug Administration (FDA)

[3] GAO Testifies About FDA's Ability to Inspect Medical Device Makers

The Government Accountability Office (GAO) provided <u>testimony</u> before a House Energy and Commerce subcommittee about the FDA's ability to assure the manufacturing quality of medical devices. According to the GAO, FDA inspectors are unable to meet the agency's biennial inspection requirement for U.S. manufacturing facilities. They apparently inspect high-risk device makers once every three years and medium-risk device makers once every five years. Foreign establishments are visited once

every six years for high-risk devices or 27 years for medium-risk devices. Nor have third-party inspection programs taken up the slack. "The small number of inspections completed to date by accredited third-party organizations raises questions about the practicality and effectiveness of establishing similar programs that rely on third parties to quickly help FDA fulfill its responsibilities," according to GAO's testimony summary. GAO Director of Health Care Marcia Crosse concluded that "FDA's ability to fulfill its regulatory responsibilities is jeopardized, in part, by information technology and human resources challenges." According to a news source, the Subcommittee on Oversight and Investigations is exploring a broad range of issues relating to FDA's ability to meet its statutory responsibilities. See The Wall Street Journal, January 29, 2008.

U.S. Department of Agriculture (USDA)

[4] USDA Seeks Comments on New Salmonella Policies

USDA's Food Safety and Inspection Service (FSIS) has published new policies for the agency's *Salmonella* verification sampling program and related activities in meat and poultry establishments. Created in 1996 with the FSIS final rule on pathogen reduction, hazard analysis and critical control point (PR/HACCP) systems, this program sets *Salmonella* performance standards to ensure that selected food animal processors are consistently "controlling and reducing harmful bacteria in meat and poultry products." After reevaluating the program in response to public comments solicited in 2003 and 2006, FSIS has issued policy changes that authorize: (i) the "publication of completed FSIS verification sample set results for establish-





ments that show inconsistency in their ability to meet *Salmonella* performance standards, beginning with those from young chicken slaughter establishments;" (ii) "a voluntary incentive-based program for meat and poultry establishments that should yield significant data on attribution of human illness to FSIS-regulated products;" and (iii) "increasing the Agency's use of targeted sampling approaches and collaborative serotype and subtype data." FSIS will accept comments on these updates, which take effect March 28, until February 27, 2008.

European Commission

[5] EC Proposes New Food Labeling Scheme

The European Commission (EC) this week proposed draft regulations seeking to "modernize and improve [European Union] food labeling rules, so that consumers have, in a legible and understandable manner, the essential information they need to make informed purchasing choices," according to an EC press release. Designed to promote uniformity but preserve flexibility for individual member states, the regulations would require labels on front packaging to display the energy, fat, saturated fat, carbohydrates and sugars, and salt content per 100 ml/g per portion of the product. In addition, the label must be legible, clear and accurate with print that is at least 3 millimeters in height, while any voluntary statements must not detract from the mandatory information. Moreover, the regulations call for current allergen labeling laws, which identify the presence of substances such as peanuts, milk, mustard, or fish, to extend beyond pre-packaged products to all restaurant and unpackaged foods. These labeling requirements also apply to pre-mixed alcoholic beverages, although the EC

may consider after five years of further consultation to include all alcohol under the new system. The regulations currently exempt unprocessed foods and foods sold in packaging with a surface area less than 25 square centimeters. *See EU Morning Bulletin* and *Food Navigator-Europe.com*, January 30, 2008; *Financial Times*, January 31, 2008.

The proposed labeling scheme has drawn fire from some public interest groups, which have faulted the EC for failing to advocate a "traffic light" system favored by the United Kingdom's Food Standards Agency. "We believe the European Commission should have gone a step further and backed mandatory color coded traffic lights on food labels," said a British Heart Foundation spokesperson, claiming that research supports this approach "as more effective than GDA [guideline daily amounts] labels in helping people see what's in the food they buy." The U.K. Food and Drink Federation, however, has applauded the EC efforts for helping "consumers to better understand the relevance of the information provided on the label for their overall diet." See BBC News and The Guardian, January 31, 2008.

Litigation

[6] Challenge to Washington State Restraints on Sale and Distribution of Alcohol Only Partially Successful

The Ninth Circuit Court of Appeals has determined that most of the restraints imposed on the sale and distribution of wine and beer in Washington are not preempted by federal antitrust law. *Costco Wholesale Corp. v. Hoen*, No. 06-35538 (9th Cir., decided January 29, 2008). Costco Wholesale Corp., which operates a chain of





no-frills membership warehouses, challenged the state's liquor control laws claiming they "restrict many of [Costco's] efficient and competitive practices as to wine and beer suppliers and create or facilitate agreement among distributors and among wineries and brewers ('manufacturers') in restraint of competition."

The court upheld restraints requiring (i) uniform pricing, (ii) minimum markups, (iii) a ban on quantity discounts, (iv) a ban on sales of beer and wine on credit, (v) a "delivered price" requirement, (vi) a central warehousing ban, and (vii) a prohibition on retailers selling beer and wine to other retailers. According to the court, the anticompetitive effect, if any, of such laws "is not contingent upon private action, but is simply part-and-parcel of the state-imposed licensing scheme."

A price-posting and hold requirement, however, was stricken as a hybrid restraint of trade not saved by the state immunity doctrine or under the Twenty-First Amendment to the U.S. Constitution. Under this requirement, beer and wine distributors must file "a price posting showing the wholesale prices at which any and all brands of beer and wine" sold by the distributor "shall be sold to retailers within the state," and then they must "hold" to their posted prices for at least 30 days. The court found that pricing agreements among competitors under this scheme are "anti-competitive because they are highly likely to facilitate horizontal collusion among market participants." "Given that the State has failed to demonstrate that the post-and-hold requirement is effective in promoting temperance," a legitimate state interest under the Twenty-First Amendment, the court agreed with the district court that "the state's interests do not outweigh the federal interest in promoting competition under" federal antitrust law.

Media Coverage

[7] Harold McGee, "Dip Once or Dip Twice?," The New York Times, January 30, 2008

"Before you have some dip at a party, look around and ask yourself, would I be willing to kiss everyone here? Because you don't know who might be double dipping, and those who do are sharing their saliva with you." Just in time for "Super Bowl" Sunday and the coast-to-coast food fests that accompany it, New York Times "Curious Cook" Harold McGee quotes a Clemson University professor whose students found that bacteria is left behind by those who "double dip," i.e., dip the same chips, crackers, fruits, or vegetable sticks more than once. Inspired by a 1993 "Seinfeld" episode in which character George Costanza is challenged for repeatedly dipping his food into a communal dip at a funeral reception, Professor Paul Dawson, a food microbiologist, challenged his students to see whether "microbial transfer from mouth to chip to dip" would occur. He was surprised that it did. Apparently, even occasional double dipping can transfer some 50 to 100 bacteria from one person to another with every bite, although the type of dip affected the results. Thicker dips reportedly stick better to chips and leave fewer bacteria behind in the bowl. The research will be published in a forthcoming issue of the Journal of Food Safety.

[8] Larry Copeland, "Animal Rights Groups Pick Up Momentum," *USA Today*, January 28, 2008

"Food producers say the activists aren't just concerned about animal welfare but are trying to win them the same rights as human beings," writes *USA Today* journalist Larry Copeland in this article examining the surging popularity of groups such as





People for the Ethical Treatment of Animals (PETA), which has compared its campaign to "a social justice movement (similar to) suffrage and civil rights." Copeland notes that these animal rights activists have recently targeted large-scale agriculture, urging consumers to avoid certain products such as eggs from chickens kept in wire crates. For example, PETA has pressured a Trappist monastery in Moncks Corners, S.C., to stop the egg-harvesting business that has kept the abbey running for the last 50 years, according to Copeland. In addition, 330 colleges have stopped using or reduced the use of "battery cage" eggs, although one spokesperson for the industry group Animal Agricultural Alliance told Copeland that farming practices have "a scientific basis" "supported by the animal science, research and veterinarian communities." This activist movement, however, has already infiltrated the legal sphere, with more than 90 American Bar Association-approved law schools now offering courses in animal law. "'There's been an explosion of interest' in animal welfare issues," Michigan State law professor David Favre was quoted as saying. "Groups like the Humane Society of the United States and PETA have brought to our social awareness their concerns about animals and all matter of creatures."

Scientific/Technical Items

[9] Researchers Show Higher Rates of Bisphenol A Leaching from Plastic Bottles Exposed to Boiling Liquids

According to University of Cincinnati researchers, plastic bottles that have held boiling water leach the chemical bisphenol A at higher rates than those that are used to store water at room temperature. Hoa Le, et al., "Bisphenol A is released from polycar-

bonate drinking bottles and mimics the neurotoxic actions of estrogen in developing cerebellar neurons," Toxicology Letters, 2007. This effect was the same regardless whether the bottles were new or used, and the increased release (55 times more quickly) occurred even after the bottles with boiling water in them had cooled. The authors conclude, "Exposure to elevated temperatures above those typically used for washing by consumers, but not outside normal household practice (e.g. boiling to sterilize infant feeding bottles), or outdoor applications (addition of very hot or boiling water or beverages to drinking bottles) greatly elevated the rate of [bisphenol A] migration. The exposures anticipated from the [bisphenol A] drinking bottles are likely one of the many sources of [bisphenol A] contamination that contributes to the total amount of endocrine disrupting compounds to which some individuals are exposed."

[10] Pesticides in Children Linked to Consumption of Conventionally Grown Produce

A study funded by the Environmental Protection Agency and appearing in a National Institute of Environmental Health Science publication shows that switching children from eating conventionally raised fruits and vegetables to organic fruits, vegetables and juices reduces the levels of pesticides in their urine and saliva to non-detectable levels.

Chensheng Lu, et al., "Dietary Intake and Its Contribution to Longitudinal Organophosphorus Pesticide Exposure in Urban/Suburban Children," Environmental Health Perspectives, January 15, 2008. Twenty-three children ages 3-11 from the Seattle, Washington, area participated in this year-long study. They switched to organic diets for five consecutive





days in the summer and fall. When they consumed conventionally raised produce, their urine and saliva contained metabolites for malathion, chlorpyrifos and other organophosphate pesticides, which are known to cause neurological effects in humans at high-exposure levels. By showing that the levels disappeared when organic foods were introduced into the children's diets, the researchers were able to demonstrate that "dietary intake of OP pesticides represents the major source of exposure in young children." The study did not assess any possible health implications from such exposure. Lead researcher Chensheng Lu reportedly noted, however, that recent animal research has shown that rats sustained persistent cognitive impairment after chronic dietary exposure to chlorpyrifos. See Seattle Post-Intelligencer, January 30, 2008.

[11] Caffeine Raises Blood Sugar Levels in Diabetics

New research shows that diabetics who took caffeine pills that were the equivalent of four cups of coffee a day increased their blood sugar levels by 8 percent. James Lane, et al., "Caffeine Increases Ambulatory Glucose and Postprandial Responses in Coffee Drinkers with Type 2 Diabetes," Diabetes Care, 2008. Duke University Medical Center researchers studied the effects of caffeine on 10 individuals with type 2 diabetes who drink at least two cups of coffee daily and manage their diabetes with diet and exercise alone. They were given caffeine in capsules and monitored throughout the day. According to lead researcher James Lane, PhD, "Our study suggests that one way to lower blood sugar is simply to quit drinking coffee, or any other caffeinated beverages." He reportedly speculated, "It could be that caffeine interferes with the process that moves glucose from the blood and into muscle

and other cells in the body where it is used for fuel. It may also be that caffeine triggers the release of adrenaline – the 'fight or flight' hormone that we know can also boost sugar levels." *See BBC News*, January 28, 2008; *FoodUSAnavigator.com*, January 29, 2008.

Meanwhile, a British consumer group calling itself "Which?" has reportedly found that coffee sold with added ingredients at chain coffee shops such as Starbucks often contain 500 calories, or nearly one-third of the daily recommended caloric intake for women. A British nutrition scientist was quoted as saying, "The latest research suggests that the body is not good at compensating for calories obtained from beverages such as these coffee drinks and may not process them in the same way as food. There is a psychological element in that people are not aware of the calories in these drinks and continue to eat as normal when drinking them. But some researchers are suggesting there is a physiological mechanism that means the body reacts differently to calories obtained from drink to that in food." See Times Online, January 28, 2008.

[12] Study Claims Association Between Meat Consumption and Breast Cancer Risk

A recent study has claimed to support an association between meat consumption and increased breast cancer risk for women who are genetically susceptible to the carcinogens in cooked meat. Rikke Egeberg, et al., "Meat consumption, N-acetyl transferase 1 and 2 polymorphism and risk of breast cancer in Danish postmenopausal women," *European Journal of Cancer Prevention*, February 2008. Researchers identified 378 beast cancer cases, matched with 378 control cases, among the 24,679 postmenopausal women enrolled in the Diet, Health and Cancer cohort study from 1993 to 2000.





The study focused on the effects of polymorphisms in N-acetyl transferase 1 and 2, two genes believed to influence the metabolism of a carcinogen, known as heterocyclic amines, generated during cooking animal proteins at high temperature. The Danish researchers concluded that increased breast cancer risk was confined to women with intermediate/fast N-acetyl transferase acetylators. In addition, the study apparently showed that every 25 gram increase in the daily consumption of total meat, red meat and processed meat corresponded to a 9, 15 and 23 percent increase in breast cancer risk, respectively. These findings, however, reportedly contradict a 1999 Harvard study that discovered no association between the consumption of cooked meat and breast cancer. See Foodconsumer.org, January 8, 2008; PCRM Press Release, January 9, 2008.



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