

# Food & Beverage

## LITIGATION UPDATE

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### Table of Contents

#### Legislation, Regulations and Standards

- [1] **President Bush Creates Cabinet-Level Panel to Improve Safety of Imported Foods** .....1
- [2] **Illinois Lawmaker Introduces Food Safety Legislation** .....1
- [3] **Consumer Groups File Complaint over “Organic” Seafood** .....2
- [4] **FSIS Issues Final Rule on BSE-Infected Cattle** .....2
- [5] **APHIS Issues Draft Environmental Impact Statement on GM Organisms** . .3

#### Other Developments

- [6] **Food Marketers Pledge to Limit Youth Advertising and Tighten Nutrition Standards** .....4

#### Media Coverage

- [7] **David Goldstein, “Poison for Profit,” *The Nation*, July 30, 2007** .....4

#### Scientific/Technical Items

- [8] **Studies Link Grapefruit, Western Diet to Increased Breast Cancer Risk** . . .5
- [9] **Study Claims Organic Tomatoes Contain More Flavonoids Than Conventional Varieties** .....5

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# Food & Beverage

## LITIGATION UPDATE

### Legislation, Regulations and Standards White House

#### [1] President Bush Creates Cabinet-Level Panel to Improve Safety of Imported Foods

President George W. Bush this week established an Interagency Working Group on Import Safety, a Cabinet-level panel that will assess U.S. regulations governing food and product imports and recommend measures to improve the overall safety of the food supply. Bush appointed Mike Leavitt, secretary of Health and Human Services, to lead the panel, which will also include the secretaries of State, Treasury, Agriculture, Commerce, Transportation, and Homeland Security, as well as the director of the Office of Management and Budget and the chair of the Consumer Product Safety Commission. The panel has 60 days to assess current importation procedures and offer recommendations “identifying potential means to promote all appropriate steps by U.S. importers to enhance the safety of imported products.” The president has also charged the panel with “identifying best practices by U.S. importers in selection of foreign manufacturers, inspecting manufacturing facilities, inspecting goods produced on their behalf either before export or before distribution in the United States, identifying the origin of products, and safeguarding the supply chain.”

Consumer groups and industry representatives reportedly maintain that additional FDA and USDA funding will be necessary to ensure that the panel’s recommendations are carried out. See *White House News Release*, July 18, 2007; *The Los Angeles Times*, July 19, 2007.

### 110th Congress

#### [2] Illinois Lawmaker Introduces Food Safety Legislation

U.S. Senator Richard Durbin (D-Ill.) has introduced legislation ([S 1776](#)) that would establish a user fee and certification program for countries exporting food to the United States. The Imported Food Security Act of 2007 would apply to all FDA-regulated products and require exporters to pay up to \$20 per line item of food. FDA would use the estimated \$200 million in annual revenue to increase inspections and fund research into food-borne illness and chemical residue detection. The bill also proposes an Imported Food Certification Program to ensure that foreign governments and companies meet U.S. food safety standards. “We just don’t have the resources necessary to inspect the food imports into the United States, which leaves consumers in our country vulnerable,” Durbin said. See *Press Release of U.S. Senator Richard Durbin*, July 12, 2007; *The Washington Post*, July 13, 2007.

Meanwhile, U.S. Representative John Dingell (D-Mich.) is reportedly planning to introduce legislation that would increase FDA funding and



authority to inspect food imports. Dingell, chair of the House Energy and Commerce Committee, apparently told staff investigators at an Oversight and Investigations Subcommittee hearing that the inspection shortfall was “unacceptable – especially in light of the horror stories coming out of China such as poisonous melamine in food products, the antifreeze chemical diethylene glycol in toothpaste, and illegal antibiotics and suspected carcinogens in farm-raised fish and shrimp.” Other committee members called on FDA to promulgate new regulations on detaining imports without physical inspections and to profile foreign food agencies to better understand their limitations. They also criticized FDA for plans to close seven of its 13 laboratories, thus increasing the agency’s reliance on privately-owned laboratories that are neither certified nor regulated by FDA. FDA Commissioner Andrew von Eschenbach responded that the post of assistant commissioner of food protection was created to develop new strategies and that reorganizing the agency would alleviate some budget concerns. *See CQ HealthBeat News*, July 17, 2007; *The Washington Post*, July 18, 2007.

## Department of Agriculture (USDA)

### [3] Consumer Groups File Complaint over “Organic” Seafood

The Center for Food Safety (CFS) has filed a [complaint](#) with USDA alleging that seafood improperly labeled as “organic” violates the Organic Foods Production Act (OFPA) and the Federal Trade Commission Act. USDA has not yet ruled on organic standards for aquaculture, but “a number of foreign seafood imports labeled ‘organic’ have appeared to take advantage of this emerging market,” according to CFS.

Backed by Consumers Union and the advocacy organization Food and Water Watch, the petition asks USDA to “take immediate action to enforce the OFPA and to protect consumers from misleading and mislabeled products.” Specifically, the petition requests that USDA: (i) issue a legal opinion “explaining the scope [of] the National Organic Program’s (NOP’s) enforcement activity concerning use of the term ‘organic’ on product labels and labeling;” (ii) issue a general letter to accredited certifying agents (ACAs) stating that NOP does not currently certify aquaculture as organic; (iii) issue a letter of non-compliance to each ACA that has certified aquaculture as organic; (iv) remove all organic labels and certification seals from seafood products within 90 days; and (v) suspend any ACA found in violation of NOP regulations. In addition, CFS has also asked the agencies to deliver similar letters and suspensions to foreign ACAs that have issued organic certification for seafood products. “USDA’s decision to allow importers to call their products organic when many of them use antibiotics or feed that would not be permitted under U.S. regulations is dishonest. Consumers have the right to know that the labeling on their food is truthful and accurate,” CFS said. *See CFS Press Release*, July 11, 2007.

### [4] FSIS Issues Final Rule on BSE-Infected Cattle

USDA’s Food Safety and Inspection Service (FSIS) has [affirmed](#), with amendments, the interim final rule “Prohibition of the Use of Specified Risk Materials for Human Food and Requirement for the Disposition of Non-Ambulatory Cattle” (the SRM rule). The final rule will “make permanent interim measures implemented by the Agency to minimize human exposure to cattle materials that could potentially contain the BSE agent,” or bovine



spongiform encephalopathy. In affirming the SRM rule, FSIS has designated certain materials from cattle as “specified risk materials,” including the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the tail vertebrae, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia from cattle 30 months of age or older, and the distal ileum of the small intestine and tonsils from all cattle. FSIS has deemed these materials inedible and prohibited their use in human food, requiring cattle slaughter houses and processors to “develop, implement and maintain written procedures for the removal, segregation, and disposition of SRMs.” In addition, FSIS has prohibited the slaughter for human food of non-ambulatory cattle “because surveillance data from European countries in which BSE has been detected indicated that non-ambulatory cattle are among the cattle that have a greater incidence of BSE than healthy slaughter cattle.”

The final rule also amends the interim rule to (i) clarify that FSIS inspection personnel will determine the disposition of cattle that become non-ambulatory after ante-mortem inspection; (ii) clarify that veal calves unable to rise from a recumbent position may be set aside for treatment; (iii) exclude from the SRM definition cattle from countries with a BSE risk status that can reasonably be expected to provide the same level of protection from human exposure to the BSE agent; (iv) require the removal of the spinal cord from the carcass at the establishment where the animal was slaughtered; (v) clarify that an establishment’s procedure for the removal, segregation and disposition of SRMs must address potential contamination of edible materials with SRMs before, during and after entry into the official establishment; (vi) codify requirements for the sani-

tation of equipment used to cut through SRMs; and (vii) specify the conditions under which slaughter establishments may ship carcasses or parts of carcasses that contain vertebral columns from cattle aged 30 months or older to another federally inspected establishment for further processing.

The agency has also affirmed, without amendments, the interim rule “Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter,” which prohibits the use of captive bolt stunning devices that inject air into the cranial cavity of cattle. The agency will accept comments on both final rules until September 11, 2007. *See Federal Register*, July 13, 2007.

#### **[5] APHIS Issues Draft Environmental Impact Statement on GM Organisms**

USDA’s Animal and Plant Health Inspection Service (APHIS) has [released](#) a draft environmental impact statement (EIS) that assesses proposed changes to the regulations governing the importation, interstate movement and environmental release of genetically engineered (GE) organisms. The draft EIS seeks public comments on several key issues currently under evaluation, including whether APHIS should (i) expand its “regulatory scope” under the Plant Protection Act; (ii) utilize a “tiered permitting system” based on environmental risk; and (iii) implement a process for the continued oversight of plants that do not meet deregulation requirements. In addition, APHIS will announce four public meetings to be held in August in Washington, D.C., Missouri and California. APHIS will accept public comments on the draft EIS and its proposed regulatory program until September 17, 2007. *See USDA Press Release*, July 12, 2007.



## Other Developments

### [6] Food Marketers Pledge to Limit Youth Advertising and Tighten Nutrition Standards

Campbell Soup Co., General Mills, Inc. and PepsiCo, Inc. have announced new youth marketing guidelines that will further limit advertising to youth younger than age 12. Campbell Soup Co. has pledged to replace its Chicken Noodle Soup ads with commercials for its reduced-sodium variety, while General Mills has agreed not to market products with more than 12 grams of sugar per serving to children younger than 12. In addition, General Mills has publicized a new line of frozen vegetable products bearing familiar cartoon characters such as SpongeBob SquarePants. PepsiCo has also said that it will only market Baked Cheetos Cheese Flavored Snacks and Gatorade to youth, but has not announced whether it intends to market its “Smart Spot” products, which meet company nutritional standards, to children. “This is the first time a majority of children’s food advertisers have publicly committed, that if they are advertising food to kids, they will be using nutritional information,” said the president-CEO of the National Advertising Review Council. “It is a very strong program and an important voluntary response to industry to the concerns that have been raised.”

Companies making these and similar promises now account for 10 of the 11 companies that control two-thirds of all food advertising dollars aimed at children, according to *Advertising Age*. The announcement has also drawn praise from federal officials and consumer groups like Center for Science in the Public Interest, which lauded the efforts as “great step forward.” “The pledges are a

significant step forward in industry self-regulation,” FTC Chair Deborah Platt Majors was quoted as saying. “While changes in food marketing alone will not solve the nation’s childhood obesity problem, these actions will help make a healthy choice the easy choice for parents and kids.” See *The Wall Street Journal* and *Advertising Age*, July 18, 2007.

## Media Coverage

### [7] David Goldstein, “Poison for Profit,” *The Nation*, July 30, 2007

“Clearly, our regulatory agencies wield neither the resources nor the mandate to enforce adequate standards at home, let alone keep pace with the rapidly globalizing food and drug industries,” opines David Goldstein in this article canvassing the recent safety issues affecting food imports. Goldstein contends that America now imports more than 70 percent of its wheat gluten, 20 percent of its generic and over-the-counter drugs, 40 percent of its active pharmaceutical ingredients, and 80 percent of its seafood – “much of it from developing nations with lax standards and little regulatory enforcement.” In light of these numbers, Goldstein faults USDA and FDA for allegedly “serving” industry’s interest in self-regulation and endangering lives for what he terms “sheer corporate greed.” He specifically notes that “just days after pronouncing that there is ‘no acceptable level’ of melamine and cyanuric acid in human food,” USDA and FDA “suddenly recanted” in a “comically Orwellian joint press release,” which stated there was “no evidence of harm to humans” from eating chicken and hogs exposed to the chemicals. “For decades our government has been dominated by a conservative ideology that claims to despise big government, abhor regulation and adhere to an



unswerving faith in the infinite wisdom of the market,” Goldstein concludes, arguing that “*E. Coli* Conservatism” has killed “ten times the number of Americans who died in the terrorist attacks.”

## Scientific/Technical Items

### [8] Studies Link Grapefruit, Western Diet to Increased Breast Cancer Risk

A study by researchers from the universities of Southern California and Hawaii has reportedly concluded that “women who ate one-quarter of a grapefruit or more every day had a higher risk of breast cancer than those who did not eat the fruit at all.” K.R. Monroe, et al., “Prospective study of grapefruit intake and risk of breast cancer in postmenopausal women: the Multiethnic Cohort Study,” *British Journal of Cancer*, July 2007. The researchers, who surveyed 50,000 post-menopausal women, apparently found that those who consumed one-quarter of a grapefruit daily increased their breast cancer risk by up to 30 percent. They also speculated that because grapefruit is known to boost estrogen, a hormone associated with a higher incidence of the disease, it is “biologically plausible” that regular grapefruit consumption would increase the risk. “This is an interesting study of a large group of post-menopausal women whose diet and health have been followed for many years,” a nutrition scientist at the British Nutrition Foundation was quoted as saying. “However, this study is simply a piece of the jigsaw puzzle that will eventually help us to understand how our diets affect our health.” See *BBC News*, July 16, 2007.

In a related development, a different study claims that post-menopausal Chinese women who ate a Western-style diet rich in meats and sweets showed

an increased risk of developing breast cancer. Xiaohui Cui, et al., “Dietary Patterns and Breast Cancer Risk in the Shanghai Breast Cancer Study,” *Journal of Cancer Epidemiology, Biomarkers & Prevention*, July 2007. Researchers studied the general diets of approximately 3,000 women aged 25 to 64, one-half of whom had been diagnosed with breast cancer. Those who reported consuming a diet of red meat, shrimp, fish, candy, desserts, bread, and milk apparently had a 60 percent greater risk of developing estrogen-driven breast cancer, when compared to those women consuming mostly tofu, vegetables, sprouts, beans, fish, and soy milk. “We saw the clearest effect when we looked at post-menopausal women who were overweight, so it looks like there’s an interaction between a meat-sweet diet and being overweight,” said study co-author Marilyn Tseng. “This gives us a broader sense because it looks at diet as a whole as opposed to targeting one element.” See *The New York Times*, July 11, 2007.

### [9] Study Claims Organic Tomatoes Contain More Flavonoids Than Conventional Varieties

A recent University of California [study](#) claims that organic tomatoes contain nearly twice the amount of flavonoids as conventionally-grown varieties. Alyson Mitchell, et al., “Ten-Year Comparison of the Influence of Organic and Conventional Crop Management Practices on the Content of Flavonoids in Tomatoes,” *Journal of Agriculture and Food Chemistry*, 2007. Researchers, who conducted a 10-year study comparing organic and conventional tomatoes, discovered that levels of the flavonoids quercetin and kaempferol were 79 and 97 percent higher in the organic produce. The team reportedly speculated that the production of flavonoids, which



plants use to ward off pests, might increase in crops not protected by pesticides. “There is accumulating evidence that dietary flavonoids... may in large part explain the cardiovascular disease benefits of increased fruit and vegetable intake,” stated the British Food Standards Agency, which has commissioned a three-year study into flavonoids. *See The London Times*, July 5, 2007; *The New York Times*, July 12, 2007.



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