Food & Beverage

LITIGATION UPDATE

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Table of Contents

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Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Backs Safety of Clone-Derived Food Products

FDA this week **announced** the availability of three regulatory documents supporting the agency's conclusion that "meat and milk from the clones of cattle, swine and goats, and the offspring of all clones, are as safe to eat as food from conventionally bred animals." FDA apparently used scientific evidence and public comments solicited by a 2006 draft report in preparing this latest food safety assessment, which nevertheless recommends "that food from clones of species other than cattle, swine and goat (e.g., sheep) not be introduced into the food supply." In addition, the agency stated that it will not require a labeling scheme for food products derived from animal clones and their offspring. Producers wishing to use a "clone-free" claim, however, can submit their requests on a case-by-case basis for agency consideration. FDA has also released a risk management plan to help veterinary health experts develop ethical "standards of care for animals involved in the cloning process," as well as industry guidance directed at clone producers, livestock breeders, and farmers and ranchers purchasing clones. "The guidance states that food products from the offspring of clones from any species traditionally consumed for food are suitable to enter the food and feed supply," according to FDA. *See FDA News Release*, January 15, 2008.

In conjunction with FDA's announcement, the U.S. Department of Agriculture (USDA) has encouraged the cloning industry to observe a voluntary moratorium dating to 2001 that aims to keep cloned products from entering the food supply. "USDA will join with technology providers, producers, processors, retailers, and domestic and international customers to facilitate the marketing of meat and milk from clones," said Bruce Knight, the undersecretary for marketing and regulatory programs, at an agency press conference. While supporting the FDA risk assessment, Knight stressed that producers should observe the moratorium until the agencies can "ensure a smooth and seamless transition to the marketplace for these products." He also reportedly noted that "given the emotional nature of this issue," consumers in the United States and abroad may need more time to accept animal cloning as a viable livestock breeding practice. *See USDA Press Release*, *The Washington Post*, and *Food Navigator-USA.com*, January 15, 2008; *The New York Times*, January 16, 2008.

Critics have since responded to the FDA risk assessment by asserting that scientific data cannot predict the long-term safety effects of cloned livestock. "If we discover a problem with cloned food after it is in our food supply and it's not labeled, the FDA won't be able to recall it . . . the food will

already be tainted," U.S. Senator Barbara Mikulski (D-Md.) was quoted as saying. Representative Rosa DeLauro (D-Conn.), who has introduced legislation to require labeling on clone-derived foods, also opined that "FDA is ignoring the 30,000 comments the agency received from the scientific, economic and public health communities that urged a more cautious approach." Some members of the scientific community, however, have countered that public opinion should not influence FDA approval. "In fact, cloned animals have been studied much more than naturally produced animals," said one researcher from the University of Connecticut, which has analyzed milk and meat from clones. "We have more data on them than for any other animal that we eat." *See The Washington Post*, *Product Liability Law 360°*, and *CQ Healthbeat News*, January 15, 2008.

Meanwhile, several consumer groups have already launched efforts to keep cloned animals and their offspring out of the food supply. Although USDA has counted only 600 animal clones in the United States and anticipates that "few clones will ever arrive in the marketplace," the Center for Science in the Public Interest (CSPI) has urged Congress to "hold hearings on the animal-welfare, ethical and environmental implications of cloning." While CSPI has acknowledged that "consumers should have confidence" in the scientific data behind the FDA assessment, the group has asked food producers to show that the tangible benefits of cloning outweigh the "other objections that make cloned animals controversial." In addition, the activist organization Food & Water Watch, which called the FDA decision "a slap in the face to Congress and consumers everywhere," has initiated a letter-writing campaign calling for legislation to "ban food from clones and their offspring." The Center for Food Safety (CFS) has likewise echoed these sentiments, condemning the FDA action as based on an "incomplete and flawed review that relies on studies supplied by cloning companies," according to CFS Executive Director Andrew Kimbrell. CFS has specifically asked Congress to pass the 2007 Farm Bill, which contains provisions that would delay the release of clones into the food supply. *See CSPI Press Release*, *Food & Water Watch Press Release*, and *Food Law Prof Blog*, January 15, 2008.

Office of the U.S. Trade Representative (USTR)

[2] U.S. Agrees to Delay Imposition of Sanctions Against EU in GMO Dispute

According to a USTR spokesperson, the United States has decided not to impose immediate sanctions on European Union (EU) goods, despite Austria's continuing refusal to allow the cultivation of genetically modified (GMO) crops. The World Trade Organization (WTO) ruled in 2006 that an EU moratorium on the authorization of GMO crops from 1999 to 2004 violated world trade rules, and Austria had until January 11, 2008, to lift its ban. Under WTO rules, the United States could retaliate by placing punitive trade tariffs on the goods of recalcitrant European nations; in the case of Austria, this could involve the soft drink Red Bull, which is made by Red Bull GmbH.

French President Nicolas Sarkozy reportedly announced on January 12 that France would also prohibit the only GMO crop the EU has licensed for cultivation, a move that means French wines could also be the target of U.S. trade sanctions. USTR spokesperson Gretchen Hamel was quoted as saying, "Our goal is to normalize trade in biotech products, not to impose trade sanctions on EU

goods. Accordingly, we have agreed with the EU to suspend for a limited period the proceedings on our WTO request for authority to suspend concessions in order to provide the EU an opportunity to demonstrate meaningful progress on the approval of biotech products." Nevertheless, the trade office indicated its disappointment with the French government's decision and noted that the United States would take "steps necessary under WTO rules to preserve our right in the WTO to suspend trade concessions."

EU farmers have apparently been growing increasing quantities of GMO corn, and many French farmers say they need the crop, which generates a protein that kills a destructive insect, to reduce their costs for pesticides. The European Commission has reportedly indicated that it will challenge the French ban, which was ostensibly imposed because pollen from GMO corn is too readily transmitted to nearby crops and can affect butterflies and worms. *See Xinhua*, January 14, 2008; and *The Wall Street Journal*, January 15, 2008.

State and Local Governments

[3] Snack Food Maker Asks for Safe Use Determination Under Prop. 65

According to California's Office of Environmental Health Hazard Assessment (OEHHA), Frito-Lay Inc. has asked the agency to allow it to sell its corn-based snack foods without a warning under Proposition 65 (Prop. 65), the law that requires warnings on products containing substances known to the state to be carcinogens or reproductive toxicants. Corn crops worldwide are often contaminated by a fungus that produces fumonisin B1. Frito-Lay apparently contends that because the substance, a carcinogen, is "naturally occurring" in corn and Prop. 65 exempts such substances from warning requirements, OEHHA should make a "safe use determination" for corn products containing fumonisin B1. Comments on Frito-Lays' request are due March 11, 2008, when a public **hearing** will be held.

European Commission (EC)

[4] EC to Consider Public Concerns over Animal Cloning

The European Commission (EC) has reportedly responded to public concern over a draft report issued last week by the European Food Safety Authority, which found that "healthy clones and their offspring do not show any significant differences from their conventional counterparts." The EC has stated that it will await the results of a consumer survey, as well as a final EFSA report, before issuing a formal opinion on the matter. EU citizens and public interest groups have until February 25, 2008, to submit comments on cloning, but the Italian farmers' union known as Coldiretti has already threatened to "mobilize strongly" against the EFSA opinion. The group, which also opposes genetically modified foods and biotechnology, has argued that cloning poses an "unacceptable risk" to consumers. The UK's National Farmers' Union (NFU), however, has backed the scientific data behind the cloning assessment. "It's the science that has got to inform policy and this EFSA opinion reflects our views in terms of food safety," a NFU spokesperson was quoted as saying. *See Product Liability Law 360°* and *BBC News*, January 14, 2008.

Soil Association

[5] UK Soil Association Bars Use of Nanotechnology in Organic Products

The Soil Association, the UK organic certifier, has declared that nanotechnology cannot be used in health and beauty products, foods or textiles seeking organic certification. The Soil Association argues in a January 17, 2008, press release that the nanotechnology industry, which invests $9 billion per year globally, has infiltrated popular consumer products that are not required to carry warning labels. "Yet there is little scientific understanding about how these substances affect living organisms, indeed initial studies show negative effects," contends the organization. In addition, the Soil Association faults the British government for failing to heed scientists who three years ago advised that the release of nanoparticles should be "avoided as far as possible." Consumer interest groups have credited the organization in the past for its role in prohibiting genetically modified crops in the organic food supply. "The Soil Association is the first organization in the world to ban nanoparticles," said Policy Director Gundula Azeez. "As we saw with GM, the government is ignoring the initial indications of risk and giving the benefit of the doubt to commercial interest rather than the protection of human health." *See ETC Group News Release* and *FoodProductionDaily-Europe.com*, January 16, 2008.

Litigation

[6] Consumer Files Diacetyl Lawsuit Against Popcorn Maker

Represented by the attorney who successfully brought "popcorn workers' lung" lawsuits against a Joplin, Missouri, microwave popcorn manufacturer, a Colorado man has filed a lawsuit in federal court alleging that his exposure to fumes from artificial butter flavoring in the popcorn he microwaved each day for six years caused severe damage to his respiratory system. *Watson v. Dillon Cos., Inc.*, No. n/a (U.S. Dist. Ct., D. Colo., filed January 15, 2008). Plaintiff Wayne Watson gained media attention in 2007, when doctors diagnosed him with a rare lung condition linked to flavoring chemical diacetyl. Because he ate two to three bags of popcorn a day and often inhaled the buttery aroma "because he liked it so much," a pulmonary specialist who treated Watson notified the Food and Drug Administration (FDA) about his case. Further details about the FDA letter appear in issue 230 of this Update.

The complaint against Inter-American Products, Inc., which purportedly made the popcorn Watson consumed, and its parent companies Dillon Cos. and The Kroger Co., alleges negligence, strict liability for design defect and failure to warn, violation of Colorado's Uniform Deceptive Trade Practices Act, and loss of consortium. Watson and his wife allege damage in excess of $75,000 and seek compensatory and punitive damages. According to plaintiffs' lawyer, Kenneth McClain of Independence, Missouri, it was "not surprising that someone like Mr. Watson could be at risk," given that Joplin workers "whose only job was to pop microwave popcorn in the quality control department got sick." Tests in Watson's kitchen reportedly showed diacetyl levels only slightly lower than those measured in the factory. *See Associated Press*, January 15 and 16, 2008.

In a related development, North America's largest hotel, restaurant and kitchen workers union has

reportedly called on cooking spray and oil manufacturers to stop using diacetyl in their products. UNITE HERE, which represents 450,000 workers, apparently issued the diacetyl statement in response to an article appearing in a Seattle, Washington, newspaper reporting the results of testing for diacetyl levels in commercial kitchens. Issue 243 of this Update has additional details about that study. Several Democratic congressional committee leaders also cited the newspaper study in a January 10, 2008, **letter** delivered to the director of the National Institute of Occupational Safety and Health, calling on the agency to "conduct a systematic evaluation of 1) where diacetyl-containing flavorings are being used; 2) the industries and operations where workers are being exposed; and 3) health effects that workers may be suffering." *See The Seattle Post-Intelligencer*, January 13, 2008; *The Pump Handle*, January 15, 2008.

[7] Sale of Topps' Assets in Bankruptcy Leaves Little for *E. coli* Claimants

According to a news source, a federal bankruptcy judge has approved the sale of Topps Meat Co. assets. The company, which declared bankruptcy in 2007 after recalling millions of pounds of meat linked to an *E. coli* outbreak, was one of the largest ground beef producers in the United States. Because most of the proceeds will be used to satisfy a bank debt, only about $107,000 will be available for Topps' 5,000 unsecured creditors, including those seeking damages due to the outbreak, which sickened about 40 people in eight states. The bankruptcy trustee reportedly indicated that the injured may be able to obtain additional damages through litigation or via claims to Topps' insurance carriers. The company's Elizabeth, New Jersey, plant will apparently remain partially open until the U.S. Department of Agriculture completes an ongoing investigation. *See Product Liability Law 360*, January 15, 2008.

Scientific/Technical Items

[8] Researchers Claim That Bisphenol Is More of a Threat to Infants

According to researchers exposing neonatal mice to trace amounts of bisphenol A, because the young mammals lack a liver enzyme found in adults that breaks the chemical down into an inactive form, the amounts injected or consumed can be measured at similar levels in their blood. The scientists conclude that the chemical is far more dangerous for human infants than for adults, noting that humans share the mouse liver trait. They call such findings "extremely scary" because bisphenol A is used in plastic baby bottles and infant formula cans. Their study, which has reportedly been shared with Health Canada for its current bisphenol A safety review, will be published in a forthcoming issue of *Reproductive Toxicology*. Formula makers reportedly dismissed any health concerns, citing the Food and Drug Administration's approval of the chemical in food packaging. The American Chemistry Council further discounted the findings, noting that injection studies do not replicate oral exposures because they bypass the detoxification process. *See The Globe and Mail*, January 11, 2008.

[9] Study Links Regular Chocolate Consumption to Weak Bones

A recent study has reportedly suggested that regular chocolate consumption could lead to lower bone density in women ages 70-85. J. M. Hodgson, et al., "Chocolate consumption and bone density in older women," *American Journal of Clinical*

Nutrition, January 2008. The researchers asked 1,001 women in this age group to take either an oral calcium supplement or a placebo and to record how often they ate chocolate or cocoa-based brinks. The study, which did not distinguish between dark and other types of chocolate, concluded that women who consumed chocolate on a daily basis exhibited 3.1 percent lower bone density compared to women who consumed chocolate less than once per week. One researcher has apparently speculated that despite having flavonoids and calcium to promote bone strength, chocolate also contains oxalate and sugars that inhibit calcium absorption and promote calcium excretion. "Additional studies are needed to confirm these observations, but confirmation of these findings could have important implications for prevention of osteoporotic fracture," stated the authors. *See Food Navigator-USA.com*, January 15, 2008.

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