

ISSUE 419 | DECEMBER 2, 2011



CONTENTS

Legislation,	Regu	lations	and	Stanc	lards
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FDA Considers Stricter Guidelines for
Arsenic in Apple Juice1
Consumer Groups Support Petition
Calling for Labels on Genetically
Fngineered Food

Litigation

rederal Court Dismisses 100% Natural
Cooking Oil Suit2
"Lazy Cakes" Lawsuit Dismissed

Other Developments

WTO Rebuffs U.S. COOL Regulations $\dots .3$

Media Coverage

NPR Disputes Food Safety News	
Honey Coverage	.4

Scientific/Technical Items

Study Links Canned Soup to	
BPA Spike in Humans	

. .5

LEGISLATION, REGULATIONS AND STANDARDS

FDA Considers Stricter Guidelines for Arsenic in Apple Juice

The Food and Drug Administration (FDA) is evaluating current allowable levels of inorganic arsenic in apple juice in response to consumer groups' demand for tighter restrictions. In a November 21, 2011, Letter to Food & Water Watch and the Empire State Consumer Project, FDA said, "we are seriously considering setting guidance or other level for inorganic arsenic in apple juice and are collecting all relevant information to evaluate and determine an appropriate level."

Earlier this year, Mehmet Oz, M.D., highlighted concerns about arsenic in apple juice during his nationally syndicated TV show, details of which were highlighted in Issue 410 of this *Update*.

According to FDA guidelines, apple juice cannot contain more than 23 parts per billion (ppb) of inorganic arsenic, which is found in pesticides and can be harmful if consumed at high levels over a long period of time. FDA Deputy Commissioner Michael Taylor told a news source that although "apple juice is generally safe," FDA is conducting arsenic studies to "minimize these exposures as much as we possibly can." FDA test <u>results</u> reportedly indicate that of 160 apple juices sampled, approximately 88 percent had fewer than 10 ppb total arsenic, and 95 percent had total arsenic levels below 23 ppb.

Meanwhile, Consumers Union, which publishes *Consumer Reports*, has <u>issued</u> a study calling for arsenic levels of 3 ppb. "We look at apple and grape juice as a poster child for arsenic in the food supply in general," Consumers Union Senior Scientist Urvashi Rangan reportedly said. "Chronic low-level exposure of carcinogen is something we should be concerned about." *See Associated Press*, December 1, 2011.



ISSUE 419 | DECEMBER 2, 2011

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);

Consumer Groups Support Petition Calling for Labels on Genetically Engineered Food

The Consumer Federation of America (CFA) has written a <u>letter</u> to the Food and Drug Administration (FDA) supporting a legal petition that demands required labeling of all genetically engineered (GE) food.

Information about the October 4, 2011, petition filed by the Center for Food Safety appear in <u>Issue 412</u> of this *Update*.

Representing nearly 300 nonprofit consumer organizations concerned with food safety, agricultural biotechnology, food and agricultural policy, and nutrition, CFA claims that current FDA regulations fail to provide consumers with information about GE food despite growing public interest in food content. "Genetically engineered foods are required to be labeled in the 15 European Union nations, Russia, Japan, China, Australia, New Zealand, and many other countries around the world," the November 23 letter states. "U.S. consumers should be provided the same basic information about GE foods as consumers in these other countries."

LITIGATION

Federal Court Dismisses "100% Natural" Cooking Oil Suit

A federal court in California has dismissed without prejudice a proposed class action alleging that ConAgra Foods misrepresented its Wesson cooking oils as "100% Natural" when they contain genetically modified (GM) ingredients. *Briseño v. ConAgra Foods, Inc.*, No. 11-05379 (U.S. Dist. Ct., C.D. Cal., order entered June 28, 2011). Seeking to certify a nationwide class of consumers, the plaintiff sought declaratory and injunctive relief, compensatory damages, restitution, disgorgement, attorney's fees, and costs, as well as an order requiring ConAgra to disclose the presence of GM ingredients and/or remove the "100% Natural" marketing claims from its products. Additional details about the complaint appear in Issue 400 of this *Update*.

Ruling that the complaint failed to satisfy procedural rule requirements, the court found that the plaintiff's general allegations "about when he purchased the product, where he purchased it, and how he was made aware of ConAgra's representations about [sic] do not afford ConAgra adequate opportunity to respond." The court also ruled that ConAgra could not be ordered to disclose GM ingredients because such an order "would impose a requirement that is not identical to federal law," which thoroughly regulates "the manner in which ingredients much be listed on packages."

The ruling also took issue with some of the defendant's arguments for dismissal, noting that the existence of a ConAgra line of products "made



ISSUE 419 | DECEMBER 2, 2011

entirely from non-bioengineered ingredients suggests that some consumers opt not to buy genetically engineered products, no matter how common they may be."Thus, the court could not be persuaded "at this stage of the proceedings" that the plaintiff's claims "are so implausible that they must be dismissed with prejudice."The plaintiff has 20 days from the date of the order to file an amended complaint.

"Lazy Cakes" Lawsuit Dismissed

A federal judge in California has reportedly dismissed a putative class action against the manufacturer of melatonin-laced brownies marketed as a relaxation and sleep aid. According to media sources, the plaintiff alleged that HBB LLC failed to disclose the potential effects of its Lazy Larry® or Lazy Cakes® baked goods, including "extreme fatigue, exhaustion and slurred speech." The products have also come under fire from lawmakers and the Food and Drug Administration, which in August 2011 warned the company that the brownies were adulterated under federal law.

Despite the ongoing debate over whether the brownies are conventional food or a dietary supplement, U.S. District Judge Manuel Real concluded that the product packaging adequately displayed its contents. "It is undisputed that the packaging on the product accurately disclosed the quantity of melatonin in each serving as well as the relevant serving size [and] that the product contained a disclaimer of the potential to cause drowsiness," the judge reportedly told lawyers during a hearing. "Plaintiff fails to demonstrate that a reasonable person would been deceived about the melatonin content and potential side effect of Lazy Cakes." See Law360, November 28, 2011.

Additional details about the ongoing response to melatonin brownies appear in <u>Issues 404</u> and <u>395</u> of this *Update*.

OTHER DEVELOPMENTS

WTO Rebuffs U.S. COOL Regulations

A World Trade Organization (WTO) panel has issued a **ruling** against the United States in a dispute with Mexico and Canada over country-of-origin labeling (COOL) regulations for beef and pork products. According to the November 18, 2011, panel report, Canada and Mexico filed complaints arguing that U.S. COOL regulations enacted in 2008 afford "imported livestock treatment less favorable than that accorded to like domestic livestock." In addition to labeling requirements, the regulations evidently required the segregation of imported livestock before processing, as well as ear tags certifying that the cattle are free of bovine spongiform encephalopathy.



ISSUE 419 | DECEMBER 2, 2011

Although the WTO panel reportedly affirmed the right of the United States to enact COOL regulations, it found that the specific requirements provided less favorable treatment to Canadian and Mexican livestock. "Additionally, the panel determined that the U.S. COOL requirements fail to fulfill their consumer information objective because the information included on the labels is not clear enough in all instances," concluded a November 2011 statement issued by the Office of the U.S. Trade Representative, which could appeal the ruling. Additional details about the WTO investigation appear in Issue 398 of this *Update. See The Associated Press*, November 18, 2011.

MEDIA COVERAGE

NPR Disputes Food Safety News Honey Coverage

"Maybe we're too inclined to believe the worst about supermarket food," writes NPR's Dan Charles in a November 25, 2011, column about a recent Food Safety News report suggesting that most honey sold in the United States does not deserve the name. According to NPR, the article in question implied that producers use a process known as "ultrapurification" to remove pollen from honey, thus preventing "anyone from detecting illicit honey from China."

"Food that doesn't deserve its name, processed beyond recognition, probably adulterated, maybe unsafe, of unknown origin. It sounded so right, plenty of people decided that it just had to be true," opines Charles, who upon further investigation found the entire story "misleading" at best. His research showed that most packers use diatomaceous earth before filtration to eliminate the microscopic particles of pollen, dust and bee parts which otherwise promote crystallization. Moreover, audits of the raw or pretreated honey evidently revealed pollen from India, Vietnam and other legal export countries, but not China.

Charles concludes that adulteration, if it is happening, would occur before export by mixing ultrafiltered Chinese honey with raw product destined for the United States. As one expert explained, however, such honey would apparently have "an unnaturally low concentration of pollen." In any case, Charles adds, "It's worth remembering that Chinese honey is barred from the U.S. not because it's unsafe, but because U.S. officials decided it was too cheap... The European Union is much more fussy about honey quality than the U.S., yet the EU imports lots of honey from China."



ISSUE 419 | DECEMBER 2, 2011

SCIENTIFIC/TECHNICAL ITEMS

Study Links Canned Soup to BPA Spike in Humans

A recent Harvard School of Public Health (HSPH) study has allegedly linked canned soup consumption to increased urinary bisphenol A (BPA) levels in humans. Jenny Carwile, et al., "Canned Soup Consumption and Urinary Bisphenol A: A Randomized Crossover Trial," *Journal of the American Medical Association*, November 2011. According to a November 22, 2011, HSPH press release, researchers analyzed urinary BPA levels in 75 volunteers who first consumed one 12-ounce serving of canned vegetable soup for five days and then one 12-ounce serving of fresh vegetable soup for five days, or vice versa. The results evidently indicated that one serving of canned soup daily "was associated with a 1,221 percent increase in BPA compared to levels in urine collected after consumption of fresh soup."

Although the study authors acknowledged that further research is necessary to determine the duration of the BPA spike, they nevertheless found that "the magnitude of the rise in urinary BPA after just one serving of soup was unexpected" and raised concerns about consumers who regularly eat canned foods. "Previous studies have linked elevated BPA levels with adverse health effects," said lead author Jenny Carwile. "We've known for a while that drinking beverages that have been stored in certain hard plastics can increase the amount of BPA in your body. This study suggests that canned foods may be an even greater concern."

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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.



