

FDA Backs Off Denial of Low Benzene Levels in Soda

By Neil Osterweil, Senior Associate Editor, MedPage Today
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ROCKVILLE, Md., April 6 - The FDA has done an about-face and conceded that its own scientists had found the carcinogenic chemical benzene in soft drinks at levels higher than the established safety standard for tap water.

The concession came only a few days after Robert E. Brackett, Ph.D., the director of the FDA's Center for Food Safety and Applied Nutrition, denied the existence of any such evidence.

But the agency was not in full retreat. It continues to maintain there is no public health concern on benzene in soft drinks.

Dr. Brackett had issued a letter to an environmental watchdog group stating in part that "the vast majority of beverages sampled (including those containing both benzoate preservative and ascorbic acid) contain either no detectable benzene or levels below the five parts per billion limit for drinking water, and do not suggest a safety concern."

But now Laura Tarantino, Ph.D., director of the FDA's Office of Food Additive Safety has acknowledged that agency's own researchers had previously turned up evidence of benzene levels in soft drinks above 5 ppb. She said the finding "is not a public health concern."

That statement is in apparent conflicts with the views of the World Health Organization, which states that "benzene is carcinogenic to humans and no safe level of exposure can be recommended."

The controversy arose after staff members of the Environmental Working Group, a non-profit group based in Washington, went on a mining expedition of FDA data, and dug up information from a food safety study showing that 19 of 24 (79%) of diet soda samples tested over from 1995 through 2001 contained benzene levels above 5 ppb.

"The average benzene level was 19 ppb, nearly four times the tap water standard," according to the

environmental group. "The maximum detection was 55 ppb, 11 times the tap water limit. Each test result is from a composite of three individual soda purchases in three different cities that are blended together to make one sample."

A separate study by FDA researchers in Lenexa, Kan., sampled various foods for volatile organic compounds, and found that one cola contained 138 ppb benzene, about 28 times the level generally considered as safe by the EPA. This study appeared in the *Journal of Agricultural and Food Chemistry* in 2003.

Workplace studies have linked benzene exposure to significantly increased risk for acute myeloid leukemia and chronic lymphocytic leukemia, and in animal studies the chemical has been shown to induce chromosomal aberrations in myeloid cells, according to the American Cancer Society.

Dr. Brackett's letter of March 21 was in response to one sent to acting FDA commissioner Andrew C. von Eschenbach, M.D., by Richard Wiles, the senior vice president of the Environmental Working Group.

In his letter, Wiles wrote that "the agency appears to be repeating the same mistakes it made 15 years ago when it decided not to inform the public about this serious health risk, and let the industry 'solve' it voluntarily. The industry clearly has not remedied the problem, yet the FDA again has chosen to hide this information from the public."

According to Wiles, the FDA learned in 1990 that benzene can form under certain conditions in solutions containing ascorbic acid (vitamin C) and the preservatives sodium benzoate and potassium benzoate. The risk appears to be particularly great when soda is stored warm for a prolonged period.

But according to Dr. Brackett, "the presence of benzoates and vitamin C in a product cannot be used to conclude that elevated levels of benzene have or will form. In fact, in our current analyses, the vast majority of beverages containing both benzoate preservative and ascorbic acid contained either no detectable benzene or levels below 5 ppb."

The FDA has gotten in touch with soda manufacturers and industry trade associations, and has received assurances from them "that they are actively assessing whether their products contain benzene and will

take appropriate steps to minimize benzene formation in their products, if elevated levels are found," Brackett wrote.

Reacted Lauren Sucher, a spokesperson for the Environmental Working Group, "I think what we're seeing is that voluntary agreements like that simply don't work."

The United Kingdom's Food Standards Agency has demanded that grocers there stop all sales of four soft-drink products found to contain benzene levels in excess of 1 ppb, the UK's maximum allowable level of the chemical. None is sold in the U.S.

FDA researchers previously showed that in addition to soft drinks, high levels of benzene have been found in everything from cooked ground (average 40 ppb in 12 samples), to raw bananas (132 ppb) to cole slaw (102 ppb).

Action Points

Inform concerned patients that benzene is a known carcinogen, associated with increased risk for acute myeloid leukemia and other hematologic malignancies. The EPA considers 5 parts per billion of benzene as the maximum safe level in tap water.

Caution patients that evidence suggest benzene may form when beverages containing both vitamin C (ascorbic acid) and the preservatives sodium benzoate and/or potassium benzoate combine are stored warm over prolonged periods.

Understand that FDA researchers have identified benzene levels above 5 ppb in many different food products, including cooked ground beef, bananas, and cole slaw.

Primary source: Food and Drug Administration

Additional source: Environmental Working Group