ENVIRONMENTAL HEALTH RESEARCH FOUNDATION

A NONPROFIT 501(C)(3) RESEARCH FOUNDATION SPECIALIZING IN HEALTH AND ENVIRONMENTAL SCIENCE

Update on Bisphenol A (BPA)

May 23, 2011

Despite the prevalence of recent media articles and blogs about Bisphenol A (BPA), there has been no change in US regulatory policy. Indeed, regulatory authorities have cautioned against the use of small exploratory studies of questionable reliability.

The US Food and Drug Administration (FDA) position on BPA remains unchanged, noting the lack of any credible evidence of risk to human health. It has questioned the applicability, robustness, and consistency of exploratory studies. "FDA does support the use of [baby] bottles with BPA because the benefit of nutrition outweighs the potential risk of BPA," stated Dr. Joshua Sharfstein, the Deputy Commissioner of the FDA in a 2010 press conference, "If we thought it was unsafe we would be taking strong regulatory action."[1]

Most recently, Coca-Cola reaffirmed its decision to use cans with linings made with BPA, based on the expertise of the FDA, and other national regulatory agencies. Muhtar Kent, chairman and chief executive officer of The Coca-Cola Company, assured shareholders at the company annual meeting, "If we had any sliver of doubt about the safety of our packaging, we would not continue to use [BPA]".[2] The Coke website acknowledges the popular controversy, but points out the scientific reality. "In the past couple of years, BPA has become controversial, even though reliable scientific evidence repeatedly reviewed by regulatory authorities indicates that the levels of BPA associated with can linings are safe. While we are very aware of the highly publicized concerns and viewpoints that have been expressed about BPA, our point of view is that the scientific consensus on this issue is most accurately reflected in the opinions expressed by those regulatory agencies whose missions and responsibilities are to protect the public's health."[3] Coke's shareholders were convinced by the company's scientific position and voted by a 3 to 1 margin in favor of continuing to use cans lined with BPA-containing resins.

Similarly, the US Environmental Protection Agency's (EPA) position on BPA is unchanged. The Office of Chemical Safety and Pollution Prevention has only expressed concern over the dearth of data on levels of BPA in the environment. Future regulation on BPA would require more scientific findings than are currently available, including more environmental monitoring and confirmation of the low-dose effects that have been reported in some aquatic species.

Meanwhile, the DfE Alternatives Assessment on BPA in Thermal Paper will be using authoritative studies (WHO[4], US FDA[5], EFSA[6], US NIOSH[7]) to quantitatively evaluate BPA, so there should be no surprises in their evaluation, which is expected to be completed in December of this year.

Meanwhile, there continues to be a steady stream of commentaries and articles confirming the safety of BPA and questioning the safety of alternatives. The American Council on Science and Health (ACSH) continues to support reasonable, risk-based approaches to chemical issues. Science writer Jon Entine's respected voice on BPA and other chemical issues has been featured in a variety of news outlets[8]. Both Entine and noted science writer Trevor Butterworth have improved the caliber of reporting on the science and safety of BPA and have been critical of the failure of other journalists to report accurately on the subject. Butterworth writes:

> "What's missing from this narrative [news] is what happens to the "cascade" [of small exploratory studies suggesting BPA has biological activity] when it is put under critical scrutiny by other scientists. Last month Germany's Society of Toxicology released a scientific review by some of its country's top investigators which looked at 5,000 BPA studies, and which explained — just like the World Health Organization did in November, and the European Union's Food Safety Authority did the same year — why the studies claiming a risk fail the test of replication: wrong methods, poor statistics, lack of rigor. But do the U.S. media report what these critical reviews and risk assessments find? Overwhelmingly, no; instead, tiny studies that lead to huge scary headlines make the daily editorial cut." [9]

Despite the more precautionary approach to chemical policy in Europe, European scientists continue to play a critical role in demonstrating and communicating the safety of BPA. Professor Richard Sharpe of Britain's prestigious Medical Research Council, acknowledged authority on endocrine-disrupting chemicals, has testified on the safety of BPA, noting that the meticulous and thorough multigenerational studies by EPA's Dr. Earl Gray, Rochelle Tyl of RTI International, and others have erased any doubts regarding its safety.[10, 11, 12]

As has been widely noted, the German Society of Toxicology (SOT)[13] recently published the results of a thorough review of the potential hazards or risks posed by BPA. It concluded that BPA does not pose a risk to human health even at levels several orders of magnitude higher than those detected in biomonitoring studies. This review thoroughly analyzed the science on BPA, addressed specific criticisms of previous regulatory studies, and pointed out the flaws and potential reasons for false positives in a number of small, exploratory studies. Given the thoroughness and depth of this SOT review, it carries significant scientific weight and should be an important reference in any further regulatory discussions.

Unfortunately, for reasons related to political or social pressure rather than any new research, the Swedish government has decided to ignore the conclusions of the world's top scientists and health authorities by considering a ban on the use of BPA in food and beverage can linings, children's products, and/or thermal paper. It is nevertheless significant that an "action plan" by Sweden's National Chemical Agency (KEMI) and the National Food Administration (SLV) acknowledges that "the current state of knowledge does not reveal serious risks to human health and the evidence that would be required for general bans or restrictions on the use of BPA is missing."

The Swedish plan requests that in 2011 both domestic and foreign food packaging companies submit plans to substitute BPA-free alternatives. The process for thermal paper is more open-ended. The government will investigate potential exposure from thermal paper and would like to engage with stakeholders on the possibilities of using alternatives to BPA. The Swedish plan may draw heavily from the assessment by EPA's Design for the Environment, expected in December.

Despite the actions under consideration in Sweden, the fact remains that top scientists from WHO, EFSA, US FDA, and other regulatory agencies from around the world (including Sweden) agree that BPA poses negligible concern. Exposure levels fall far below the levels that might cause health effects in humans. There continues to be no evidence from regulatory-caliber studies that demonstrates that BPA has health effects at the trace levels to which people are exposed.

---

[1] http://healthlibrary.epnet.com/GetContent.aspx?token=c5987b1e-add7-403a-b817-b3efe6109265&chunkiid=566903. Accessed 5/16/2100.

[2] http://www.acsh.org/factsfears/newsid.2582/news_detail.asp

[3] http://www.thecoca-colacompany.com/citizenship/challenges_opportunities.html

[4] WHO/FAO. 2010. Summary Report of the Joint FAO/WHO Expert Meeting to Review Toxicological and Health Aspects of Bisphenol A. http://www.who.int/foodsafety/chem/chemicals/BPA_Summary2010.pdf

[5] http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm197739.htm. Accessed 5/1/2011.

[6] http://www.efsa.europa.eu/en/press/news/cef100930.htm. Accessed 5/1/2011.

[7] http://www.cdc.gov/niosh/docs/2011-144/pdfs/2011-144.pdf. Accessed 5/1/2011.

[8] http://www.huffingtonpost.com/jon-entine/toxic-chemicals-debate-_b_831851.html. Accessed 5/1/2011.

[9] http://www.thedaily.com/page/2011/05/16/051611-opinions-column-bpa-butterworth-1-2/ Accessed 5/17/2011.

[10] Ryan, B., Hotchkiss, A., Crofton, K., Gray, E. 2009 In utero and lactational exposure to Bisphenol A, in contrat to ethinyl estradiol, does not alter sexually dimorphic behavior, puberty, fertility, and antanomy of female LE rats. Toxicological Science. 114: 133-48.

[11] http://www.independent.co.uk/life-style/food-and-drink/news/europe-tightens-gender-bender-chemical-rules-2145002.html

[12] Tyl, Myers, Marr, Sloan, Castillo, Veselica, Seely, Dimond, Van Miller, Shiotsuka, Beyer, Hentges, and Waechter. 2008. Two-generation reproductive toxicity study of dietary Bisphenol A in CD-1 (Swiss) Mice. Toxicological Sciences. 104: 362-384.

[13] Hengstler, J., Foth, H., Kramer, P., Lilienblum, W., Schweinfurth, H., Völkel, W., Wollin, K., Gundert-Remy, U. 2011. Critical evaluation of key evidence on the human health hazards of exposure to Bisphenol A. Critical Reviews in Toxicology. 41: 263-91.