

ENVIRONMENTAL HEALTH RESEARCH FOUNDATION

A NONPROFIT RESEARCH FOUNDATION SPECIALIZING IN HEALTH AND ENVIRONMENTAL SCIENCE

A REVIEW OF THE SAFETY OF THERMAL PAPER

Executive Summary

The purpose of this review is to examine claims that bisphenol A (BPA) used in making thermal paper could be transmitted to workers or members of the public through skin (dermal absorption) and that this route of exposure could lead to adverse health effects.

Major recent reviews conducted by the U.S. Food and Drug Administration (FDA), Japan's Ministry of Economy, Trade and Industry (METI), the Food Safety Authority of Australia and New Zealand (FSANZ), the European Food Safety Authority (EFSA) and others concluded that products made from BPA, including thermal paper, are safe for consumers and the environment when used as intended.

Specifically regarding thermal paper, there is no evidence to suggest adverse health effects from the small amounts of BPA that may migrate from thermal paper to human skin. Studies have estimated that worst case exposure from thermal paper would be more than 40 times less than current safety regulations, which have a significant margin of safety.

A recent study was reviewed reporting rapid metabolism of BPA in the skin to non-estrogenic metabolites. The authors suggest that the metabolites would be converted back to BPA in the body, but provided no evidence, indicating that this theory is simply speculation.

Another recent study was reviewed claiming high levels of BPA in the urine of pregnant women who worked as cashiers. BPA levels, in fact, were within the normal range of the previous national biomonitoring study.

Full Report

The purpose of this review is to examine relevant studies on the safety of thermal paper used in commerce, specifically in the form of receipts issued in the retail sector. In particular, the review examines claims that bisphenol A (BPA) used in making thermal paper could be transmitted to workers or members of the public through exposure through the skin (dermal absorption) and that this route of exposure could lead to adverse health effects.

It is the conclusion of this review that the BPA used in thermal paper poses no risk to workers or the general public and thus from a practical point of view is safe for use. This conclusion is based on the following facts:

- BPA has been used and extensively studied for many years, including a full risk assessment conducted under the European Union (EU) Existing Substances Directive

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that considered all uses of BPA, including thermal paper.¹ This assessment, completed in 2008, relied on independent scientific experts from the EU Member States. The assessment considered several hundred studies published in recent years, including both small exploratory studies that do not follow established protocols, i.e. studies reporting “low dose effects”, as well as comprehensive, statistically-robust studies following accepted international protocols and standards, such as the Good Laboratory Practices Directive. The studies also covered all potentially affected age groups including infants and small children. This comprehensive EU risk assessment concluded that products made from BPA, including thermal paper, are safe for consumers and the environment when used as intended.

- The leading public health authorities in the United States (FDA),² Japan (METI),³ Australia and New Zealand (FSANZ)⁴, and elsewhere have recently conducted detailed reviews of all relevant studies concerning the potential effect of BPA on human health and affirmed that current uses of products made with BPA pose little risk to public health and thus are safe for continued use.
- The recent review by the European Food Safety Authority (EFSA)⁵ is particularly informative as it:
 - Is the most recent review, published in September 2010.
 - Focuses on new studies published since the previous EFSA review, completed in 2008
 - Considers in detail both the Stump et al. neurobehavioral toxicity study that was a cause for concern to FDA and the biomonitoring studies claimed by some scientists to demonstrate a link between BPA exposure and human health effects.

After considering these new studies, the EFSA panel of independent scientific experts:

- Concluded that the data currently available do not provide convincing evidence of neurobehavioral toxicity of BPA.

¹ http://ecb.jrc.ec.europa.eu/documents/Existing-Chemicals/RISK_ASSESSMENT/ADDENDUM/bisphenola_add_325.pdf

² FDA presented its most recent assessment of BPA use in food contact applications in January 2010 (<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm197739.htm>). While the media coverage characterized FDA's position as a shift on BPA because FDA is conducting additional research on BPA and working with industry to minimize exposure to BPA from infant formula can liners, Dr. Joshua Sharfstein, the FDA principal deputy commissioner, clarified that this did not mean that FDA considers BPA unsafe or had fundamentally changed its position on BPA. As quoted in the *New York Times* (www.nytimes.com/2010/01/16/health/16plastic.html) and other publications, he stated, “If we thought BPA was unsafe, we would be taking strong regulatory action,” which clearly is not the case.

³ The Japanese National Institute of Advanced Industrial Science and Technology, a research agency of the Japanese Ministry of Economy, Trade and Industry (METI), finalized its risk assessment of BPA in November 2005, concluding that “the current exposure levels of BPA will not pose any unacceptable risk to human health.” See: http://unit.aist.go.jp/riss/crm/mainmenu/BPA_Summary_English.pdf

⁴ In March 2009, the Food Safety Authority of Australia and New Zealand issued its most recent opinion on the safety of BPA, stating: “FSANZ has assessed the risk to infants from exposure to BPA and concurred with conclusions reached by US FDA and EFSA (the European Food Safety Agency) that levels of exposure are very low and do not pose a significant health risk.” See: www.foodstandards.gov.au/newsroom/factsheets/factsheets2009/bisphenolabpaandfood4218.cfm

⁵ European Food Safety Authority, <http://www.efsa.europa.eu/en/press/news/cef100930.htm>

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- Noted that human epidemiological studies do not support the conclusion that BPA is the cause of any health effects.
- Concluded they could not identify any new evidence which would lead them to revise the current Tolerable Daily Intake (safe level) for BPA of 0.05 mg/kg body weight set by EFSA in its 2006 opinion and re-confirmed in its 2008 opinion.

In short, the European Food Safety Authority has just reviewed the latest science on BPA and concluded that there is no reason to change its safety standards on BPA.

Thermal Paper

- Specifically regarding thermal paper, there is no scientific evidence to suggest adverse human health effects from the small amounts of BPA that may migrate from thermal paper.
- A significant recent study on dermal absorption (February 2010), by the Centre for Xenobiotic Risk Research at the University of Zurich,⁶ concludes that

“Dermal absorption is at most a secondary absorption route for Bisphenol A. The primary absorption route is still dietary intake. For this route, daily total amounts of BPA around 10,000 times higher are considered harmless for adults.”
- Another important recent study, by Switzerland’s food regulatory authority, published June 2010 in *Analytical and Bioanalytical Chemistry*,⁷ concluded that cashiers or others who might be touching thermal printer paper for as much as 10 hours a day would nevertheless absorb more than 40 times LESS BPA than allowed under current safety regulations, which have a significant margin of safety.

THE METABOLITE THEORY

A recent, widely publicized report, published by Daniel Zalko et al. in the journal *Chemosphere*,⁸ reports for the first time that BPA is efficiently converted to water soluble metabolites in the skin. These metabolites are known to be completely lacking in estrogenic activity⁹ and to be efficiently excreted from the body in the urine. Zalko et al suggest, in the conclusion to their paper, that these metabolites are then converted back into BPA, thus adding to the estrogenic burden on the body. No evidence was provided by the authors to support this theory, suggesting that it is simply speculation.

⁶ <http://www.xerr.uzh.ch/news/bisphenol01.html>. An English translation is available from EHRF.

⁷ Biedermann, S., Tschudin, P. and Grob, K., Transfer of bisphenol A from thermal printer paper to the skin, *Anal. Bioanal. Chem.*, published on-line 11 July 2010

⁸ Zalko, D., Carnine, J., Duplan, H., Bruel, S. and Perdu, E. Viable skin efficiently absorbs and metabolizes bisphenol A, *Chemosphere*, in press 2010.09.058

⁹ Matthers, J.B., Twomey, K. and Zacharewski, T.R., In vitro and in vivo interactions of bisphenol A and its metabolite, bisphenol A glucuronide, with estrogen receptors alpha and beta. *Chem. Res. Toxicol.* 14 (2): 149-157, 2001.

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A RECENT BIOMONITORING STUDY

A further recent study by Braun et al. is a biomonitoring study that measured BPA levels in the urine of 389 pregnant women and looked for statistical associations between various demographic, occupational, dietary and environmental factors.¹⁰ First of all it should be noted that the BPA concentrations measured are total BPA, that is, BPA metabolites as well as an undetermined amount of free BPA. This suggests that the BPA measured in urine is predominately the harmless metabolites that lack any estrogenic activity.

The study reports that the geometric mean BPA levels in the women range from 1.7 micrograms per gram creatinine (at 16 weeks of pregnancy) to 2.0 (at 26 weeks) to 2.0 at birth. The report notes that by occupation, cashiers (who may have had contact with thermal paper) had the highest BPA concentration – recall this is total BPA – 2.8 micrograms per gram creatinine. It should also be noted that there were only 17 cashiers among the 389 study participants, much too small a cohort for any reliable conclusion to be drawn. Nonetheless, cashiers were reported to have the highest BPA level of any of the groups studied.

What the study failed to point out is that this is not an unusually high level of BPA in the urine. In fact, it was the AVERAGE level of BPA in urine in the 2003-2004 U.S. national biomonitoring study,¹¹ where the average, or 50th percentile, value for the total population surveyed was 2.3-2.8 micrograms per gram creatinine.

CONCLUSION

This review found no evidence to support commercial advertising claims that the use of “BPA-free” thermal paper presents any health or safety benefit to workers handling such paper, such as cashiers, or to the general public. Based on this analysis, such claims are clearly erroneous and appear to be a regrettable example of the distortion of science for commercial advantage.

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¹⁰ Braun, J.M. et al., Variability and predictors of urinary bisphenol A concentrations during pregnancy, *Environmental Health Perspectives*, online 8 October 2010.

¹¹ Calafat, A.M., et al. Exposure of the U.S. population to bisphenol A and 4-tertiary-octylphenol: 2003-2004. *Environmental Health Perspectives* 116: 39-44, 2008.