



Consumers Union's written testimony to FDA on the Draft Assessment of BPA for Use in Food Contact Applications [FDA-2008-N-0038].

Submitted by Urvashi Rangan, Ph.D., Senior Scientist and Policy Analyst, Consumers Union and Rachel Weintraub, Consumer Federation of America

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Consumers Union, the non-profit publisher of *Consumer Reports*, appreciates the opportunity to comment on the Food and Drug Administration (FDA) Draft Assessment of BPA for Use in Food Contact Applications [FDA-2008-N-0038]. Consumers Union reaches approximately 20 million people each month with our independent information. Our sole goal, since 1936, is to help consumers make the most informed decisions in the marketplace.

Consumers Union scientists believe that FDA's draft assessment of BPA for Use in Food Contact Applications does not do a sufficient job of presenting the evidence and risk posed by BPA given the mounting scientific evidence. Consumers Union believes that materials made with BPA should not be used in any food contact application and should be replaced with safer alternatives.

Consumers Union has a long history on this issue. We were one of the first organizations to test consumer products for BPA and published our findings on BPA in baby bottles almost a decade ago, where we warned consumers then about the potential risks.¹ We recently tested “BPA-free” claims on bottles² and have also published advice on how consumers can reduce their direct exposure to BPA.^{3,4,5} We have also supported strong legislation proposed to ban BPA from children's products and food and beverage containers.⁶

¹ Consumers Union. Baby alert: New findings about plastics. *Consumer Reports*, 1999.

² <http://www.consumerreports.org/cro/consumer-protection/recalls-and-safety-alerts-10-08/update-on-bisphenol-a/recalls-update-on-bisphenol-a.htm>

³ Rangan, Urvashi. Plastic worries: What you need to know to keep your family safe. *Consumer Reports' Shoppersmart*, 2008.

⁴ <http://blogs.consumerreports.org/baby/2008/03/ga-baby-bottles.html>

⁵ <http://blogs.consumerreports.org/baby/2008/03/ga-baby-bottles.html>

⁶ Consumers Union et al. Written testimony to Senate hearing on Phthalates and BPA, 2008.

Since our first study, more than a hundred studies have been published showing a wide range of adverse effects in animals at low doses of BPA --doses that approximate current levels circulating in the human population. We are very concerned about this narrow margin of safety. The NOAEL (no observable adverse effect level) of 5mg/kg/d, used in FDA's analysis is sorely outdated and based only on a few large dose studies. This erroneous NOAEL has also factored in FDA's claim that there is a large margin of safety based on current exposure levels. While traditional toxicology with linear dose relationship curves (stemming from the theory "it's the dose that makes the poison") has formed the risk basis for many regulated chemicals, 21st century science demonstrates that not all chemicals follow this linear toxicity, particularly agents that cause hormonal disruption (through cellular receptors and signaling transduction systems), and gene regulation. These agents follow a non-monotonic or inverted-U shaped dose-response curve.

In addition, the range of toxic endpoints considered in this or any safety assessment must be expanded beyond reproductive, teratogenic and carcinogenic endpoints. Toxic endpoints such as diabetes, cardiovascular risk, asthma, neurobehavioral effects should be included as a standard in any safety risk assessment. Consumers Union suggests that the FDA convene independent expert panels with representatives from consumer and unbiased scientific groups to discuss how to include these important, modern-day toxicology tests and results into future risk assessments.

The FDA analysis only included studies that followed good laboratory practices (GLPs) and therefore hundreds of studies were not factored into FDA's quantitative risk assessment. It is difficult to understand how FDA could dismiss consideration of so many studies in a safety assessment. Consumers Union believes that this is a myopic approach to understanding a complicated risk. Two-thirds of the GLP studies did not have positive controls (and one that did, did not have a responsive positive control) which is problematic since some animal models are virtually unresponsive to estrogenic compounds. Moreover, without positive controls, the data cannot be accurately interpreted.

The safety of BPA, at current exposure levels in the US population, has not been demonstrated. BPA has a fast clearance rate and yet constant, elevated levels are circulating in the US population. Those levels seem to have a wide range of effects in animal studies, which Consumers Union believes need to be factored into FDA's calculation of a NOAEL. This shift in the NOAEL would therefore diminish the safety buffer between the levels that cause adverse effects in animals and current human exposure levels--a safety buffer that is typically in place for many chemical and heavy metal risk safety thresholds for human exposure. These factors raise legitimate questions about the safety of BPA that warrant concern and government action.

But the public is hearing contradictory messages from the government about the level of concern of BPA exposure. Moreover, consumers want to know how they can protect themselves, even in the face of scientific uncertainty, and they don't want to be the guinea pigs in the experiment.

While scientists continue to assess the health risks of BPA to consumers, the FDA is taking on a bigger risk in taking no action. We have seen so many examples of potential risks today becoming tomorrow's reality--does the FDA really want to take that gamble in the face of so much mounting evidence? Consumers deserve to buy products that have a proven safety record, not a lack of proven harm. Consumers Union believes that the FDA should exercise precaution and ban the use of materials made with BPA in food contact applications. In the meantime, we will advise consumers on how to avoid ingesting BPA.

**Consumers Union
Headquarters Office**
101 Truman Avenue
Yonkers, New York 10703-1057
(914) 378-2029
(914) 378-2992 (fax)

Washington Office
1666 Connecticut Avenue, NW,
Washington, DC 20009-1039
(202) 462-6262 Suite 310
(202) 265-9548 (fax)

West Coast Regional Office
1535 Mission Street
San Francisco, CA 94103-2512
(415) 431-6747
(415) 431-0906 (fax)

South West Regional Office
1300 Guadalupe, Suite 100
Austin, TX 78701-1643
(512) 477-4431
(512) 477-8934 (fax)