FDA's flawed assessment of Bisphenol A safety underscores the need for State and Federal Legislation

August 18, 2008

An Environmental Working Group (EWG) analysis of FDA's draft assessment of BPA revealed a number of critical flaws and built in assumptions that biased the agency's evaluation and ensured that the FDA would find current exposure levels in the population to be safe.

1. The FDA limited its assessment to studies that conformed to rigid, 50 year old study designs that feed animals high amounts of BPA and analyze the animals for overt signs of poisoning and toxicity. FDA admits in their assessment that the studies they use to set the safety level do not adequately address the impacts of early life exposure to the developing brain, behavior and the reproductive system. Notably, the only studies that conformed to these 50 year old study designs, were those funded by industry.

2. By adhering to what it euphemistically calls studies that follow "good laboratory practices," the FDA ignores more than 100 studies, including many funded by the National Toxicology Program, showing toxic effects of BPA at very low doses.

3. FDA's so called 2,000-fold margin of safety evaporates if current exposures are compared to *any* of the low dose studies, particularly the 12 studies the National Toxicology Program highlights in their April 14, 2008 BPA assessment as raising concerns for the safety of infant exposure to BPA.

4. FDA's exposure calculations underestimate infant ingestion. They calculate formula intake for the average infant instead of focusing on babies who eat the most, thus underestimating risks for half of all infants. They also assume that liquid formula has 2.5 parts per billion (ppb) BPA, even though their own testing of just 14 liquid formulas found up to 5 times more than this (13 ppb). These errors contradict the accepted risk assessment practice of focusing on risks to the most highly exposed population. FDA claims that its analysis was highly conservative, but in reality it underestimates risks to the most vulnerable infants by a wide margin.

When FDA evaluates new drugs for approval they are required to consider all available evidence of toxicity, not just the findings of studies that conform to standard designs of past decades. In this case they disregard studies showing that BPA exposure harms the developing brain and reproductive system, and encourage parents to continue exposing their children to BPA when safer alternatives exist.

Given FDA's reckless disregard for children's health, State and Federal actions are needed to protect children from avoidable contaminants in baby bottles and infant formula.