

Protecting Public Health from Phthalates Will Require Consideration of Cumulative Risks

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To the National Research Council
Committee on the Health Risks of Phthalates

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Thank you for the opportunity to present the views of the Environmental Working Group (EWG) on the need for a cumulative human health risk assessment for the industrial plasticizers and common consumer product chemicals called phthalates. EWG is a non-profit health and environmental research and advocacy organization based in Washington DC. Our views on this issue are informed by our own research on phthalates that spans biomonitoring and product research, and by our experience in conducting human health risk assessments to promote protective health standards.

We believe that a cumulative human health risk assessment for phthalates is needed to protect public health, is supported by the science, and is feasible using standard risk assessment techniques.

The impact of EPA's continued failure to conduct such an assessment is felt by states, companies, and consumers nationwide. States are proposing, and in the case of California passing, bills to ban phthalates in consumer products. Some companies are voluntarily reformulating cosmetics, toys and other products, replacing phthalates with alternate chemicals. These changes are driven by public pressure that stems from legitimate concerns over the health risks that EPA has failed to define. But the changes affect only a handful of states and only a fraction of phthalate-laden products, and they fail to uniformly protect public health.

Over the past seven years a series of scientific studies has demonstrated that the U.S. population faces chronic exposures to complex mixtures of phthalates. Over that same period scientists have published a number of epidemiology studies linking the chemicals to birth defects in baby boys and reproductive problems in men. This evidence joins many dozens of laboratory studies proving phthalates to be potent reproductive toxicants that target the male reproductive system, posing the greatest risks during development.

In 2003 EPA's Science Advisor noted the critical need for the agency to consider cumulative health risks (Gilman 2003): "For most of our history," he wrote, "EPA assessed risks based on individual contaminants and often focused on one source, pathway or adverse effect. But in reality, the public is exposed to multiple contaminants from a variety of sources, and tools are needed to understand the resulting combined risks. The Framework [for cumulative risk assessment] represents an important milestone for EPA in expanding our focus from an individual chemical-based approach to a community or population-based approach for multiple stressors."

EPA's review of the cumulative risks of phthalates is needed to ensure that the public is adequately protected from risks driven by demonstrated, ubiquitous exposures to multiple phthalates. Such an assessment is consistent with the current understanding of the additive risks of phthalates, and can be based on existing EPA methods. Key reasons for EPA to conduct a cumulative risk assessment for phthalates are detailed below.

EPA's safety standards for phthalates were set nearly 20 years ago and must be modernized to ensure public health protection. Phthalates are found in a remarkable range of consumer products spanning fragrance, nail polish, food packaging, and children's toys. Yet despite the ubiquity of exposures and the growing evidence linking phthalates to human health risks, 17 years have passed since the Environmental Protection Agency (EPA) last issued a significant revision to a public health standard (the reference dose, or RfD) for phthalates. EPA last revised the RfDs for di-2-ethylhexyl phthalate (DEHP) and diethyl phthalate (DEP) in 1988, for butylbenzyl phthalate (BBzP) in 1989, and for dibutyl phthalate (DBP) in 1990 (EPA 2007). These standards remain in place in spite of a substantial body of science published in the last 20 years on both the toxicity of phthalates and human exposures to these potent reproductive toxins.

The ubiquity of many forms of phthalates in consumer products supports the need for a cumulative risk assessment. Phthalates are high production volume chemicals used in products that range from cosmetics and medical IV tubing to food packaging and children's toys. EWG studies of phthalates in products include tests published in 2002 showing phthalates in nearly three-quarters of 72 name-brand, off-the-shelf cosmetics, including deodorant, hair gel, and hand and body lotions (EWG et al. 2002). Tests revealed detectable levels of five phthalates altogether (DEP, DBP, BBzP, DEP, DMP), including multiple phthalates in some individual products. Our online database of ingredients in more than 25,000 personal care products shows DBP in 138 nail care products widely available to consumers (EWG 2007a).

Demonstrated, ubiquitous exposure to multiple phthalates across the population supports the need for a cumulative risk assessment. Only a cumulative human health risk assessment can account for the well-documented exposures of the public to complex mixtures of phthalates.

Scientists at the Centers for Disease Control and Prevention detected phthalates in urine samples from all but 12 of 2,790 people tested (CDC 2005), with six or more phthalates found in 84% of people tested. This data demonstrates that EPA's past assessments of phthalate risks, with the implicit assumption that humans are exposed to just one phthalate at a time, may significantly underestimate risk and result in health standards (RfD's) that fail to adequately protect health. EWG's analysis of CDC data shows that DBP accounts for an average of only 29% of people's total exposures to phthalates, and DEHP accounts for just under one-third (32%). Considering exposure to just one phthalate at a time could result in significant underestimates of human health risks. Studies show that risks from these two phthalates in particular are additive (Gray et al. 2007), and in combination with CDC's findings on human exposures strongly support the need for EPA to update health standards based on an assessment of cumulative risks.

EWG's biomonitoring studies support CDC findings; we have found detectable levels of multiple phthalates in nearly all of 44 people tested (EWG 2007b).

A new body of data demonstrating reproductive toxicity of phthalates in baby boys and men supports need for an updated risk assessment. Phthalates have long been known to

be toxic to the male reproductive system of test animals, but a series of studies published over the last several years link the chemicals to reproductive damage in humans as well. Studies now show significant or suspected links between phthalate exposure and effects in the general population that include lower sperm concentrations, reduced sperm motility, sperm morphology changes, DNA breakage in sperm, changes in levels of reproductive hormones in men and male infants, and, in a preliminary study, feminization of newborn baby boys (e.g., Duty and Silva 2003, Duty and Singh 2003, Duty and Calafat 2004 and 2005, Swan and Main 2005, Hauser and Meeker 2006, Main and Mortensen 2006). This new body of data further supports the need for EPA to review and update its safety standards for phthalates.

A cumulative human health risk assessment is supported by science demonstrating the effects of additive doses of multiple phthalates. The fact that health risks are additive across chemicals with similar target organs and mechanisms of action is not new. Particularly relevant to phthalates are a number of studies demonstrating the additive risks of phthalates in particular and antiandrogenic chemicals more generally, including Gray et al. (2006), Hotchkiss et al. (2004), and Howdeshell et al. (2007). In the Howdeshell study researchers demonstrated additive effects of DBP and DEHP on reproductive malformations, with 3 of 16 cases showing effects significantly greater than what would be predicted by simple addition of the doses, what EPA refers to as a synergistic effect. Many phthalates demonstrate common forms of toxicity, and their impacts should be assessed as potentially additive.

Methods for conducting cumulative human health risks are technically feasible and widely available. Methods to calculate cumulative risks from exposures to multiple chemicals that pose similar health threats are not new. EPA pioneered methods for cumulative risk assessments beginning about 20 years ago with their assessments of dioxin. Congress mandated the assessment of cumulative risks for pesticides in food with the passage of the Food Quality Protection Act in 1996. EPA finalized formal methodologies for assessing cumulative risks in 2000 (EPA 2000).

EPA's Administrator Stephen Johnson has noted that cumulative risk assessments represent "a major step forward" in the Agency's ability to evaluate the safety of chemicals, and former EPA Administrator Carol Browner directed the Agency to use the approach in all significant assessments of risk (EPA 1997).

Administrator Browner directed EPA staff to "... take the steps needed to ensure that all major risks assessments undertaken in your area embrace [a] cumulative approach," adding that this is required to ensure that the agency could "better advise all citizens about the environmental and public health risks they face, and improve our ability to protect the environment and public health for the nation."

A May 2007 review of EPA's efforts in advancing cumulative risk assessments describe work in numerous programs and offices of the agency: "... the U.S. EPA National Center for Environmental Assessment has published ecologic risk assessment guidelines [EPA 1998] that incorporate cumulative risk considerations, and five watershed case studies have been prepared that demonstrate the methods. The Office of Air and Radiation has performed assessments of cumulative risks from hazardous air pollutants, and the Office of Pesticide Programs has developed guidance for conducting cumulative risk assessments of pesticides [EPA 2002]. The Superfund Program has included some evaluation of cumulative effects from chemicals in its guidance on risk assessments [EPA 1989], and several U.S. EPA regional offices have carried out cumulative risk projects [EPA 2003]" (Callahan and Sexton 2007).

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