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December 22, 2004

Michael O. Leavitt, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building, 1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

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Subject: Comments on the HPV Test Plan for Phthalic acid tetrabromo ester

Dear Administrator Leavitt:

The following comments on ACC's test plan for the chemical phthalic acid tetrabromo ester are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

The ACC's Brominated Phthalate Ester Panel (BR PEP) submitted their test plan on July 23, 2004, for the chemical phthalic acid tetrabromo ester (CAS No. 26040-51-7). This chemical is used as an antioxidant that protects against thermo-oxidative degradation. ACC has utilized structure activity relationship programs and models, specifically ECOSAR, to estimate toxicity to fish and other aquatic organisms. We commend this approach for estimating ecotoxicity. In addition, the estimated octanol/water partition coefficient for phthalic acid tetrabromo ester is 11.95 and the material is not readily soluble in water. The EPA has stated that acute fish tests are inappropriate for compounds with log Ko/w values above 4.2. When the above studies are considered together, these data should be sufficient for a screening level program and we concur that no further testing should be carried out.

With regard to human health effects, ACC has submitted detailed information on acute, chronic, and genotoxic effects of this chemical. The SIDS endpoint for reproductive toxicity was filled using histopathology data from reproductive organs from the repeated dose study. This is a scientifically valid analysis when considering the toxicity of a chemical and this approach demonstrates a thoughtful analysis by ACC. Although data were not located for developmental toxicity of phthalic acid tetrabromo ester, the sponsor appropriately concludes that additional animal testing will not add to our understanding of this chemical's toxicity. A thorough examination of existing toxicity data shows no adverse effects, even at very high doses. As indicated in both the October 1999 letter as well as the December 2000 *Federal Register* notice, HPV participants "*may conclude that there is sufficient data, given the totality of what is known about a chemical,*

including human experience, that certain endpoints need not be tested. As with all chemicals, before generating new information, participants should further consider whether any additional information obtained would be useful or relevant.” We support this type of “weight-of-evidence” analysis and agree that additional animal studies are not warranted.

For this test plan, ACC’s BR PEP adhered to animal welfare principles set forth by the EPA, including EPA’s stated goal that HPV participants “maximize the use of existing and scientifically adequate data to minimize further testing”. We concur that no additional testing is needed for the purposes of the HPV program. Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 327, or via e-mail at meven@pcrm.org.

Sincerely,

Megha Even, M.S.
Research Analyst

Chad B. Sandusky, Ph.D.
Director of Toxicology and Research