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October 21, 2004

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

Subject: Additional comments on the HPV Test Plan for Hindered Phenols category

Dear Administrator Leavitt:

We are writing to communicate to you our frustration with the EPA's failure to post revised HPV test plans in a timely manner so as to allow for public review. We are specifically concerned here with the test plans for Styrenated phenols and 1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione, formerly part of the Hindered Phenols category.

We did not submit comments on the original test plan as no animal testing was proposed. However, it took EPA **more than one year** to post ACC's revised test plan, which was submitted to the agency on July 17, 2003 but not posted until Sept. 1, 2004. The revised test plan splits the original hindered phenols category into four separate test plans which consist of two categories (Styrenated phenols and Bridged alkyl phenols) and two stand-alone chemicals: 1,3,5-tris(3,5-di-ter-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione and 4-methylphenol, reaction products with dicyclopentadiene and isobutylene. With four separate test plans, toxicity data cannot be used in a weight-of-evidence approach to fill SIDS data gaps and thereby reduce animal testing. Had EPA posted ACC's revised test plans in a timely manner, we could have made a number of suggestions that would have allowed the ACC to significantly reduce, or completely eliminate, the use of animals in toxicity tests.

First, the reproductive/developmental toxicity endpoints for styrenated phenols could have been filled by a read-across approach to data on these endpoints for the bridged alkyl phenols, instead of conducting additional animal tests such as the OECD 421. Unfortunately, 675 animals were killed in an unnecessary test as a result of the ACC's revisions and the EPA's delay in posting the ACC's revised test plans.

Second, the OECD 414 test for 1,3,5-tris(3,5-di-ter-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione (CAS No. 27676-62-6) was wasteful and unnecessary. The ACC's RAPA panel does not appear to have considered the supplemental developmental data from the 2-year carcinogenicity study on this chemical. Although this data was not from a traditional study design, it nonetheless provides useful

information for these endpoints, i.e. both developmental and reproductive toxicity. Moreover, we could have suggested that the ACC review the toxicity data of a similar chemical produced by Cytec Industries, Tris (4-t-butyl-3-hydroxy-2,6-dimethylbenzyl)-s-triazine-2,4,6-(1H,3H,5H)-trione (CAS No. 40601-76-1). Both chemicals are used as antioxidants in polymer systems and both are approved by the FDA for use in food packaging materials. Furthermore, both chemicals have similar structure and physicochemical properties, as well as toxicity profiles. Cytec indicated that they are conducting a combined reproductive/developmental screen (OECD 421) for their chemical, trade name CYANOX 1790. ACC's RAPA panel overlooked this information, conducted their own developmental study, and killed 1,300 animals in a duplicative test. Had we been able to access the revised test plan in a timely manner, we would have been able to suggest that the ACC's RAPA panel review of all of these data, thereby avoiding separate and duplicative testing.

We are dismayed by the EPA's disregard for the concerns of a large section of the American public represented by the animal protection organizations (more than 10 million members) in this "right-to-know" program. We are also troubled by the ACC's lack of concern for animal welfare. For example, a thorough review of the data could have eliminated testing for developmental toxicity from the test plan for 1,3,5-tris(3,5-di-ter-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione, or, if those data were not adequate, the ACC should have agreed to conduct the screening test following OECD protocol 421 instead of OECD 414 (thus reducing the number of animals killed by half). Either route would have represented an EPA-accepted method for assessing developmental toxicity and would have ensured a significant reduction in animal suffering.

The EPA's failure to allow for public review of proposed testing directly contradicts its claim that this is a "public right-to-know" program. The EPA is continuing to fail to take its HPV oversight responsibilities seriously; the ACC's RAPA panel failed to consider existing data and conducted unnecessary tests that killed approximately 2,000 animals. Combined, these failures clearly demonstrate that the responsible parties are not giving even "token" attention, or making serious attempts, to follow 'animal welfare' principles put in place at the beginning of the HPV program.

We look forward to a prompt response to this letter. Please contact Dr. Sandusky at 202-686-2210, ext. 302 or csandusky@pcrm.org, or Megha Even at ext. 327 or meven@pcrm.org. Thank you in advance for your reply.

Sincerely,

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