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June 4, 2008

Mr. Charles Auer  
Director, Office of Pollution Prevention and Toxics  
Environmental Protection Agency - East  
Room 3166  
1201 Constitution Ave., NW  
Washington, D.C. 20460

Docket Number: EPA-HQ-OPPT-2008-0319

RE: Comments on ChAMP: submitted electronically to [auer.charles@epaemail.epa.gov](mailto:auer.charles@epaemail.epa.gov)  
and [oppt.ncic@epa.gov](mailto:oppt.ncic@epa.gov).

Dear Mr. Auer,

I am writing on behalf of several animal protection organizations, including the Physicians Committee for Responsible Medicine, the Humane Society of the United States, Doris Day Animal League, and People for the Ethical Treatment of Animals, whose combined memberships include more than 12 million Americans.

As you know, our organizations were active stakeholders in the original HPV program, and have reviewed and commented on the vast majority of HPV test plans. Our comments were directed primarily at ways to reduce the animal testing proposed in this program. During the HPV program, EPA developed animal welfare guidance with input from our scientists and posted this guidance on the HPV website. This guidance may still be found at the following links (<http://www.epa.gov/hpv/pubs/general/ceoltr2.htm> and <http://www.epa.gov/hpv/pubs/general/anfacs2.pdf>), although it is clearly stated that this guidance has not been updated nor do there appear to be plans to do so for the newly announced Chemical Assessment and Management Program (ChAMP).

It is for this reason that I am providing to you in an attachment to this letter a brief summary of the original guidance under HPV as well as expanded guidance that we developed based on extensive review of test plans in HPV. The process of reviewing HPV test plans provided valuable experience in identifying the many ways in which proposed testing would have been either superfluous (e.g., insoluble materials and fish testing) or the resultant data difficult to interpret in terms of human and environmental health. These principles have been through a vetting process during the course of the original program, and are considered scientifically acceptable by many major stakeholders.

We therefore ask EPA to update the animal welfare guidance for participants in ChAMP and request that EPA notify the manufacturers of this updated guidance, both in a letter to participants and by posting the guidance on the ChAMP website. I would be more than willing to work with your scientific staff to further develop these principles.

The impetus to reduce and replace the use of animals in regulatory testing is growing stronger every year. As shown by the original HPV Program, throughout the course of just a few years new ideas are put into practice that could reduce the number of animals killed. There are a number of initiatives underway in the US and the European Union designed to explore ways to minimize traditional *in vivo* testing, by developing alternative *in vitro* or *in silico* test methods and by integrating weight-of-evidence and alternative approaches into testing strategies. As ChAMP begins, it would be prudent to include provisions that allow for continuous and consistent update of testing guidelines, in order to recommend the most updated assays, test guidelines, protocols, and/or approaches. Information along this line of thought is also included in the attached suggested animal welfare guidance.

Thank you for your attention. I look forward to your favorable response, and to working with EPA to further develop the animal welfare principles that are essential to the success of ChAMP.

Regards,



Chad B, Sandusky, PhD  
Director of Research and Toxicology

Cc: Martin Stephens, Humane Society of the United States  
Sara Amundson, Doris Day Animal League  
Jessica Sandler, People for the Ethical Treatment of Animals  
Kristie Stoick, Physicians Committee for Responsible Medicine