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October 30, 2012

Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

Re: Docket ID USTR-2012-0028; U.S.-EU Regulatory Compatability

Submitted via Regulations.gov

To Whom It May Concern:

These comments regarding duplicative chemical toxicity testing requirements are submitted on behalf of PETA's International Science Consortium (PISC) and the Physicians Committee for Responsible Medicine. Representing the regulatory policy positions of People for the Ethical Treatment of Animals and its international affiliates, PISC promotes reliable, relevant approaches to reduce, and ultimately eliminate, the use of animals in regulatory testing. PCRM is a national non-profit coalition of physicians, scientists, and laypersons dedicated to ethical medicine and research, including regulatory testing.

On October 21, 2011, the US Environmental Protection Agency (EPA) proposed a test rule under the Toxic Substances Control Act (TSCA) section 4(a) for a group of high production volume (HPV) chemicals (Federal Register, Vol. 76, No. 204, pp. 65580 – 65608) that would require animal toxicity testing for 16 chemicals that are also subject to registration under the European Commission's Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) regulation, EC 1907/2006. When completed, REACH registration dossiers for these chemicals will likely include most or all of the testing called for by EPA.

EPA encourages the submission of existing data relevant to the testing specified in its proposed rule and notes that, to the extent that these data are judged sufficient, such testing will not be required in the final test rule. Data developed for REACH could, therefore, obviate EPA's proposed testing requirements. However, EPA states that these submitted data "must be in the form of full copies of unpublished studies or full citations of published studies..." As noted by the American Chemistry Council in its comments on the proposed rule (ACC; Docket ID: EPA-HQ-OPPT-2010-0520-0056), "it is often not feasible for persons subject to EPA test rules to obtain data from the Substance Information Exchange Forums (SIEFs) or consortia which own the studies submitted or to be submitted to ECHA [European Chemicals Agency] under REACH, even by offering to pay data compensation." In such cases, those subject to TSCA test rules may have no recourse other than to sponsor duplicative testing.

This duplicative testing could be avoided if EPA were to obtain the relevant full study reports from ECHA. A Statement of Intent related to chemical management activities was signed by representatives of ECHA and EPA on November 15, 2010 (http://echa.europa.eu/documents/10162/13606/soi_echa_us_epa_20101220_en.pdf) which affirms that any exchange of such information between the agencies will require an international agreement to be established between the European Union and the United States. Such an agreement is critical and we urge the Office of Information and Regulatory Affairs (OIRA) and the Directorates General for Trade, Enterprise and Industry (Directorates General) to implement such an agreement with all due speed as this would clearly support the goals of "reducing excessive regulatory costs, unjustified regulatory differences, and unnecessary red tape."

In some cases, full study reports may not be submitted to ECHA. However, the REACH regulation states that "the result of each toxicological and ecotoxicological study" "shall be made publicly available…" These results are posted on ECHA's web site in the form of robust summaries of data similar to those which were the basis of the Organisation for Economic Cooperation and Development's (OECD) Screening Information Data Set (SIDS) and EPA's HPV Challenge Program. EPA's proposed test rule is, in fact, the fourth such rule regulating chemicals that were not sponsored in this program. EPA accepted robust summaries as an incentive to encourage, or "challenge," manufacturers to make basic hazard information available to the public voluntarily, without being subject to rulemaking. In the years since the HPV Challenge Program, manufacturers have necessarily shifted their focus to the REACH regulation. EPA is now requiring companies subject to this test rule to submit full studies, instead of robust summaries, to penalize companies for not voluntarily participating in the program. However, penalizing manufacturers in this way no longer serves its intended purpose. Moreover, in its October 14, 1999 HPV Challenge Program guidance articulating animal welfare principles (http://www.epa.gov/hpv/pubs/general/ceoltr2.htm), EPA directed participants to maximize the use of existing data and conduct a thoughtful, qualitative analysis rather than use a rote checklist approach and EPA affirmed its intention that HPV test rules should proceed consistently with these principles. In the interest of reducing animal testing and increasing efficiency, EPA should accept robust summaries as sufficient if full study reports are unavailable.

Approximately 10,000 animals' lives will be saved by avoiding duplicative tests for these 16 chemicals. In addition, savings in dollars can be calculated from the economic analysis prepared for the proposed test rule (Docket ID: EPA-HQ-OPPT-2010-0520-0032) which estimates the social cost per chemical to be $336,000; for 16 chemicals, therefore, the total savings is approximately $5,376,000. It is impossible to know how many chemicals will be subject to similar test rules in the future; however, according to EPA's Existing Chemicals Program Strategy (http://www.epa.gov/oppt/existingchemicals/pubs/Existing_Chemicals_Strategy_Web.2-23-12.pdf), the TSCA inventory of chemicals in commerce now exceeds 84,000 chemicals, with approximately 7,000 chemicals currently produced at

volumes of 25,000 pounds or greater. According to a statistical update recently released by ECHA, 4,632 unique substances have so far been registered under REACH. The potential for duplicative testing requirements in the near future is huge and can be expected to grow with the continued expansion of the chemicals industry.

For the reasons given above we ask OIRA and the Directorates General to intervene in this test rule to prevent wasteful spending, inefficiencies, and animal deaths.

Thank you for you're the opportunity to provide these comments and for your consideration. I can be reached at 757-793-8941 or via email at JosephM@peta.org should you have any questions.

Yours sincerely,

Joseph Manupello
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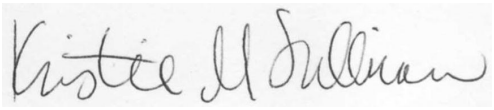

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