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Jim Jones
Acting Assistant Administrator
Environmental Protection Agency
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Ariel Rios Building
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Dear Sirs,

As representatives of People for the Ethical Treatment of Animals International Science Consortium (PISC) and the Physicians Committee for Responsible Medicine (PCRM), we are writing regarding duplicative animal toxicity testing requirements for 34 chemical substances which are included in a proposed Test Rule and Significant New Use Rule (SNUR) under the U.S. Toxic Substances Control Act (TSCA)¹ and registered (or preregistered) in the E.U. Registration, Evaluation, Authorisation and Restriction of Chemical Substances Regulation (REACH) program. When completed, REACH dossiers for these substances will likely include most or all of the testing called for under the proposed Test Rule and SNUR. **Approximately 10,000 animals could be poisoned and killed in these completely duplicative tests.**

Attached, please find a Microsoft Excel spreadsheet containing publicly available information for 16 chemical substances for which duplicative animal test data will be required under the proposed Test Rule and REACH (SNUR substances are not included). In particular, please note that CAS 118-48-9 (EC 204-255-0) and CAS 69834-17-9 (EC 274-140-8) are no longer HPV according to 2012 Chemical Data Reporting submissions. The U.S. Environmental Protection Agency (EPA) should remove testing requirements for these substances from the proposed Test Rule. In addition, total production volume is not publicly available for CAS 25377-73-5 (EC 246-917-1) and CAS 68442-77-3 (EC 270-489-5). EPA should

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determine if these substances are still HPV when finalizing the proposed Test Rule.

As noted by the American Chemistry Council (ACC) in its comments on the proposed Test Rule and SNUR,² U.S. companies may be unable to obtain full study data submitted to the European Chemicals Agency (ECHA) under REACH from the Substance Information Exchange Forums (SIEFs) or consortia which own the studies, even by paying compensation; SIEFs may limit use of the data to REACH compliance. In such cases, those subject to TSCA Test Rules may have no recourse other than to conduct duplicate tests.

EPA and ECHA must work together to prevent this suffering and waste of lives. A Statement of Intent to enhance cooperation was signed by ECHA Executive Director Geert Dancet and EPA Office of Pollution Prevention and Toxics (OPPT) Director Wendy Cleland-Hamnet on November 15, 2010. Its scope specifically includes “scientific collaboration and information exchange, in particular with regard to the registration (i.e., inventory) as well as hazard and risk assessment of chemical substances...”³ Speaking recently at the 2013 GlobalChem Conference, OPPT Assistant Administrator Jim Jones alluded to both legal barriers that impede cooperation as well as legal mechanisms that could compel companies to make study data available and suggested that EPA is negotiating with SIEFs in specific cases.

The attached spreadsheet lists REACH lead registrants for two substances; however, the identities of the remaining 14 lead registrants are not publicly available. We urge EPA and ECHA to identify and negotiate with all lead registrants to make study data available to EPA. In addition, we urge EPA to:

- 1) delay finalizing testing requirements pending completion of studies conducted under REACH,
- 2) accept Organisation for Economic Cooperation and Development (OECD) guideline study data in place of American Society for Testing and Materials (ASTM) International guideline study data, and
- 3) be flexible in its specific data requirements.

Under REACH, robust summaries of study data similar to those required under OECD’s Screening Information Data Set (SIDS) and EPA’s HPV Challenge Program are made publicly available. As noted by the ACC in its comments on the proposed Test Rule and SNUR, robust summaries are often not significantly different in detail than published reports, and EPA has explained that they are “intended to provide sufficient information to allow a technically qualified person to make an independent assessment of a given study report without having to go back to the full study report... A robust study summary therefore reflects the objectives, methods, results, and conclusions of the full study report”⁴ Under its HPV Challenge 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. Penalizing manufacturers by requiring full study data no longer serves its intended purpose. Finally, in its October 14, 1999 letter articulating animal welfare principles, EPA directed participants to

maximize the use of existing data and conduct a thoughtful, qualitative analysis rather than use a rote checklist approach while stating its intention that future test rules should proceed consistently with these principles.⁵ EPA should therefore accept robust summaries if full study reports are unavailable or specify which additional study details are required, as it did in its HPV Challenge Program.

We look forward to learning of your agencies' efforts to ensure that duplicative testing is avoided for the sake of these 10,000 animals and potentially many more in future chemical testing requirements.

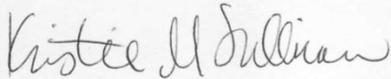
Yours sincerely,



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encl: Public data: HPV4, REACH

cc: Wendy Cleland-Hamnett, Office of Pollution Prevention and Toxics, EPA
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Antonio Tajani, Industry and Entrepreneurship, EC
Janez Potočnik, Environment, EC

¹ Federal Register, Vol. 76, No. 204, pp. 65580 – 65608

² Available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2010-0520-0056>.

³ Available at <http://www.epa.gov/oppt/echa.epa soi.pdf> and
http://echa.europa.eu/documents/10162/13606/soi_echa_us_epa_20101220_en.pdf.

⁴ EPA, Draft Guidance on Developing Robust Summaries (1999). Available at
<http://www.epa.gov/chemrtk/pubs/general/robsumgd.htm>.

⁵ Available at <http://www.epa.gov/hpv/pubs/general/ceoltr2.htm>