

July 28, 2014

Fred Jenkins, Jr., Ph.D.
Designated Federal Official
FIFRA Scientific Advisory Panel Staff
USEPA/OSCP (7201M)
Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Dear Dr. Jenkins:

RE: FIFRA SAP Meeting: Review of New High-throughput Methods to Estimate Chemical Exposure; Docket ID EPA-HQ-OPP-2014-0331.

These comments are submitted on behalf of People for the Ethical Treatment of Animals and the Physicians Committee for Responsible Medicine, national animal protection and scientific advocacy organizations with a combined constituency of more than three million Americans who share the common goal of promoting reliable and relevant regulatory testing methods and strategies that protect human health and the environment while reducing, and ultimately eliminating, the use of animals.

We appreciate the opportunity to comment on the document that is the subject of this FIFRA Science Advisory Panel (SAP) meeting, i.e., the Exposure SAP White Paper: New High-throughput Methods to Estimate Chemical Exposure.

Our organizations would like to communicate our appreciation for the work EPA is doing to develop and implement computational tools under the ExpoCast initiative as outlined in the document prepared for this SAP meeting. Using such approaches to prioritize and screen the universe of chemicals in our environment will lead to a faster, more focused, and more humane, Endocrine Disruptor Screening Program (EDSP). We are pleased to see that EPA intends to use this approach with Toxic Substances Control Act (TSCA) chemicals as well. We would like to contribute the following general comments.

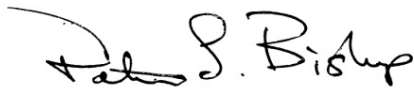
We support the use of a science-based approach to the prioritization of chemicals for testing by considering both hazard and exposure. The focus on those chemicals showing the greatest likelihood of both hazard and exposure will undoubtedly result in the use of far fewer animals in testing under the EDSP, and maximize protective activities for the least resource and time investment. The exposure modeling methods described in this white paper appear to offer a significant step forward in predicting exposure by assessing the many factors that contribute to exposure and their relative significance. EPA has mined and is drawing upon numerous and varied sources of information, both upstream (e.g., monitoring data) and downstream (e.g., biomarkers) of exposure. This is superior to some prior approaches used by EPA, such as

targeting a chemical for testing merely because it was produced in high volume, regardless of actual exposures.

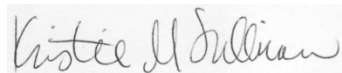
With regards to collection of additional data for HTTK under Section 4c. (pp. 124-125; Figure 44), we are unhappy to note that approximately 50 new *in vivo* toxicokinetics (TK) studies are being performed, but are appreciative that the bulk of the anticipated additional data will be mined from 500 legacy TK studies available in the National Toxicology Program database. We continue to urge the use of existing data whenever possible before considering any new animal testing.

We are truly excited by the enormous strides EPA is making in developing and implementing 21st century toxicology and risk assessment methods and the eventual effect this will have on both reducing the use of animals in regulatory testing and increasing regulatory efficiency. We look forward to seeing these methods successfully applied to prioritizing chemicals for evaluation under both EDSP and TSCA in the near future.

Sincerely,

A handwritten signature in black ink that reads "Patricia L. Bishop". The signature is written in a cursive style with a large, sweeping initial "P".

Patricia L. Bishop, MS
Research Scientist
Regulatory Testing Division
People for the Ethical Treatment of Animals

A handwritten signature in black ink that reads "Kristie M. Sullivan". The signature is written in a cursive style with a large, sweeping initial "K".

Kristie Sullivan, MPH
Director, Regulatory Testing Issues
Physicians Committee for Responsible Medicine