

June 6, 2012

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Dear Mike,

It is my understanding that the Chronic Hazard Advisory Panel (CHAP) on Phthalates is completing its work reviewing phthalates and phthalate alternatives. Just last month, my colleagues and I published a review article, titled "A Critique of the European Commission Document 'State of the Art Assessment of Endocrine Disrupters," in *Critical Reviews in Toxicology*, which is available online at: http://informahealthcare.com/doi/full/10.3109/10408444.2012.690367. I have enclosed a copy for your review.

As you know, I am a Principal at Gradient, an environmental consulting firm headquartered in Cambridge, MA. My longstanding interest in weight-of-evidence methods and in the evaluation of potential endocrine disruption by chemical exposure prompted a request from the American Chemistry Council for me to organize a panel to review and comment on a recent review document that the European DG Environment had commissioned and posted on the internet regarding the "state of the art" of evaluation of endocrine disrupters. The panel I convened comprised me, Gradient scientist Dr. Julie Goodman, Dr. Christopher Borgert of Applied Pharmacology and Toxicology, Inc., and two academics, Drs. Warren Foster and Glen Van der Kraak. The paper I have attached is the product of that panel and its deliberations.

Although the January 2012 "State of the Art Assessment" (SOA) was presented as building on the 2002 WHO/IPCS survey and evaluation, titled "Global Assessment of the State-of-the-Science of Endocrine Disruptors," as our critique outlines, the SOA assessment falls well short of what is required. The earlier WHO/ICPS document was generated over several years, with guidance and contributions from dozens of international scientific experts. As we argue in the paper, any document that would build on the WHO/IPCS state-of-the-science assessment would need to:

- distinguish between apparent associations of outcomes with exposure and the inference of an ED basis for those outcomes;
- constitute a complete and unbiased survey of new literature since 2002;
- consider strengths and weaknesses and issues in interpretation of the cited literature;
- follow a weight-of-evidence (WOE) methodology, such as that set out in the 2002 WHO/IPCS document, for evaluation of evidence of ED;
- document the evidence for its conclusions or the reasoning behind them; and

• present the evidence for or reasoning behind why conclusions that differ from those drawn in the 2002 WHO/IPCS document need to be changed.

As we document in our critique, we conclude that the 2012 SOA document fails to meet these criteria.

Perhaps our greatest concern is that a number of notable and highly visible scientific debates that are current in the field -- about specific chemicals and also about general issues bearing on the potential for low environmental doses to actively disrupt endocrine control of physiology -- are not characterized and in most cases not even noted. As I am sure you are aware, characterizing the spectrum of informed opinion, the evidence supporting different views, and the nature of issues that are under current scientific debate would seem essential to any review that aimed at characterizing the current state of the science.

Two of the authors of our review article, Warren Foster and Glen Van Der Kraak, were members of the Steering Group that provided oversight, expertise, and guidance for the WHO/IPCS project. As we state in our review article, the failure to address the evidence and reasons behind changes in conclusions vis-à-vis the 2002 WHO/IPCS review is especially concerning.

In short, the 2102 SOA assessment has neither the rigor nor the carefully wrought and widely based consensus among knowledgeable scientists that characterized the earlier 2002 WHO/IPCS state of the science review. I hope you will be able to read our critique and bear its points in mind as the CHAP undertakes its evaluations.

Sincerely,

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