



Styrene Information and Research Center (SIRC)
910 17th Street NW #500-B, Washington, DC 20006
Phone: 202-787-5996 www.styrene.org

December 6, 2012

Dr. Lori White
Designated Federal Officer for the BSC
Office of Liaison
Policy and Review Division of NTP, NIEHS
P.O. Box 12233, K2-03
Research Triangle Park, NY 27709

Dear Dr. White:

We commend the National Toxicology Program (NTP) for pursuing an evidence-based framework for literature-based scientific health assessments and believe **this approach holds promise** for significant improvements in the NTP's assessment process.

However, we believe that NTP's current draft of the document "NTP Approach for Systematic Review and Evidence Integration for Literature-Based Health Assessments" ("Systematic Review Document") **has not received sufficient input from the outside scientific community and is not detailed enough at this time to warrant a final decision by the Board of Scientific Counselors (BSC)**. The BSC should have the benefit of hearing the issues that the scientific community believes need to be addressed by the NTP before it reaches any final conclusions about this new approach.

Therefore, we request that after hearing of the progress made on the NTP document at the December 11 BSC meeting, the BSC and NTP take the following steps:

(1) **Initiate a 90-day public comment period** inviting full review of NTP's ideas for systematic review by the larger scientific community. Once these comments are received, NTP should make a point-by-point response to the comments and make revisions to its documents accordingly and then submit them for peer review either by the BSC or by a specially-constituted group of experts.

(2) Once the above step is completed, NTP should **implement this new approach to systematic review on a pilot basis** with full transparency and participation by interested scientists. **The current document is so general in nature that it would be possible to use it to support totally opposite conclusions regarding a specific substance.** While we would hope that additional specificity could be added as a result of the public comment process, we believe that a full understanding of how the systematic review framework would work in practice within NTP will require that NTP implement the system initially in a pilot, case-by-case form with active participation by interested outside scientists. In our view, it will be only after NTP has adjusted the process to reflect lessons learned in these pilot cases that NTP and the BSC would be in a position to approve the implementation of the process on a broader scale with any confidence in the soundness of the approach.

The potential significance of this new approach being proposed by the NTP should not be minimized. If we understand NTP's commendable intent, this Systematic Review Document will guide many future decisions by the NTP, and these decisions could have profound significance for public health and for the use of, and exposure to, substances in our society. However, **it would be improper for NTP to develop these new approaches and put them into practice without both a robust public comment period and the resulting revisions** as well as a period of pilot projects in which the details of this important framework are worked out with full participation at each of the steps by all interested parties. **Pursuing a robust public involvement process in the development of this new process is consistent with this Administration's commitment to transparency and active solicitation of participation by stakeholders as well as the general public.**¹

Should there be any doubt about the lack of adequate solicitation of comments and participation by the larger scientific community, we have outlined in an attachment the steps that we understand that NTP has taken with regard to public comments. These steps in our view are clearly inadequate. NTP staff may argue in response that they have substituted the efforts of a handpicked working group for a meaningful public comment period. But, this working group met in private in August to examine documents that have not been made public and provided its comments to the NTP. As you are aware, this working group was made up of seven people from the academic world, one from a state agency, and one from industry. However talented these workgroup members may be, they certainly do not represent the wide spectrum of talented stakeholders of NTP assessment programs, and are not substitute for an open and meaningfully timed public comment period by knowledgeable and experienced scientists in the scientific community outside the NTP.

Because we have not had access to the full contents of this new approach and have not been permitted adequate time to review the relevant documents and prepare constructive comments, at this time we are unable to provide you substantive constructive comments on NTP's proposed new approach to systematic review.

Thank you for the opportunity to present our views on this important document.

Very truly yours,
[Redacted]

Jack Snyder, Executive Director
Styrene Information & Research Center
91 17th Street, NW – Suite 500B
Washington, DC 20006
Jack_Snyder@styrene.org
(202) 787-5997

This document submitted electronically.

¹ See, for example, Executive Order 13563

Attachment: Chronology showing that NTP has not actively solicited public comment

Date	NTP Action	What said	Comment
April 25, 2012	<i>Federal Register</i> notice announcing June 21 st BSC meeting.	Directed readers to an agenda o NTP website. Agenda shows planned discussion of Systematic Review.	No mention of specific topics in the <i>FR</i> notice, including Systematic Review. Public had to be sufficiently interested in NTP generally to look at the website.
June 21, 2012	BSC meeting.	Presentations made; public comments allowed.	Presentations were more detailed than documents made available on website for preparation of comments
August 28, 2012	Workgroup of BSC meets to review Systematic Review papers.	Closed Meeting; no public allowed.	Papers reviewed were more extensive than provided to the public.
October 4, 2012	<i>Federal Register</i> notice announcing December 11 th BSC meeting.	Directed readers to an agenda on NTP website.	No mention of specific topics in the <i>FR</i> notice, including Systematic Review.
November 29, 2012	Listserve notice.	Comment period extended to December 6 th .	No mention of availability of newer draft of the Systematic Review process.
December 11, 2012	BSC meeting.	Presentations to be made and comments allowed.	For at least one of the relevant presentations (Implementation of Systematic Review), no documents made available for review in advance; this makes public comment almost impossible.