



February 28, 2012

**SUBMITTED VIA E-MAIL**

Dr. Ruth Lunn  
Director, Office of the Report on Carcinogens  
Division of the National Toxicology Program  
National Institute of Environmental Health Sciences  
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Re: Report on Carcinogens (Federal Register Volume 77, Number 12, January 19, 2012, Page 2728-2729).

Dear Dr. Lunn:

The American Chemistry Council (ACC) appreciates the opportunity to comment on the National Toxicology Program's (NTP) Report on Carcinogens (RoC).<sup>1</sup> We strongly recommend that NTP not push ahead with initiating the 13<sup>th</sup> RoC until the Congressionally-mandated review by the National Academy of Sciences (NAS) of the 12<sup>th</sup> RoC's evaluation of formaldehyde and styrene is completed.

In 2011, ACC commented extensively on NTP's RoC process, documenting that the methods NTP employs in evaluating substances for the RoC lack clear and consistent data evaluation procedures and fall well short of using a sound scientific methodology for integrating the totality of the scientific evidence for establishing causation and for determining significance at environmentally relevant levels of exposure. Additionally, numerous shortcomings in scientific criteria and administrative practices of the 12<sup>th</sup> RoC have been noted by ACC and others, demonstrating a clear need for NTP to improve the scientific rigor and transparency of future RoCs.

These deficiencies in the RoC processes also garnered the attention of Congress, which by bipartisan action in December 2011 passed the Consolidated Appropriations Act (HR 2055). Among other things, this law directs the Department of Health and Human Services (HHS) to commission the NAS to conduct a scientific peer review of the 12<sup>th</sup> RoC determinations related to formaldehyde and styrene. This NAS review of styrene and formaldehyde will necessitate examination of the underlying RoC practices for data evaluation and causation determination and the RoC peer review processes. Therefore, the review's findings and recommendations will not

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<sup>1</sup> Department Of Health and Human Services, Request for Public Comment on Nominations and Call for Additional Nominations to the Report on Carcinogens. Federal Register Volume 77, Number 12, January 19, 2012, Page 2728-2729).



only be informative for styrene and formaldehyde, but importantly, should also apply to the scientific evaluation procedures of future RoC substances.

HHS and NTP should await completion of the NAS review before moving forward with the 13<sup>th</sup> RoC. HHS and NTP can then take the appropriate steps to implement the forthcoming NAS recommendations to improve the RoC methodologies and, after that, commence development of the 13<sup>th</sup> RoC. In this manner, policymakers and the public will have confidence that the 13<sup>th</sup> RoC, and future RoCs, are firmly based on up-to-date scientific knowledge, meet the highest of standards of scientific inquiry, and are evaluated using peer-review procedures that meet the administration's policies of scientific integrity and transparency. Moving forward with developing the 13<sup>th</sup> RoC before the NAS completes its review is counterproductive because it will perpetuate long standing deficiencies in the scientific rigor of the RoC process and lead to unwarranted economic and regulatory impacts on affected chemicals.

ACC appreciates your consideration of these comments. If you have any questions related to these comments or would like additional information please contact me [Redacted]

Sincerely,  
[Redacted]

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