



CAL DOOLEY
PRESIDENT AND CEO

April 25, 2012

The Honorable Paul Broun
Chairman, Subcommittee on Investigations &
Oversight
Committee on Science, Space, & Technology
United States House of Representatives
Washington, D.C. 20515

The Honorable Paul D. Tonko
Ranking Member, Subcommittee on
Investigations & Oversight
Committee on Science, Space, & Technology
United States House of Representatives
Washington, D.C. 20515

The Honorable Renee Ellmers
Chairwoman, Subcommittee on Healthcare &
Technology
House Committee on Small Business
United States House of Representatives
Washington, D.C. 20515

The Honorable Cedric Richmond
Ranking Member, Subcommittee on Healthcare
& Technology
House Committee on Small Business
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Broun, Ranking Member Tonko, Chairwoman Ellmers, and Ranking Member Richmond:

The House Committee on Science, Space, & Technology, Subcommittee on Investigations & Oversight, and the House Committee on Small Business, Subcommittee on Healthcare & Technology are scheduled to hear testimony today from several witnesses concerning the National Toxicology Program's (NTP) Report on Carcinogens (RoC) and its impact on jobs, and the economy. The American Chemistry Council (ACC), a national trade association representing approximately 160 member companies and the business of chemistry which employs nearly 800,000 workers, requests that ACC's perspectives on this important issue be entered into the hearing record.

America's consumers, workers, retailers and manufacturers must have confidence that the government's chemical evaluations are accurate and credible. Indeed, the protection of public health, American innovation and jobs depend on the decisions made in chemical evaluations. We must ensure that those decisions are made on the basis of the highest quality and most reliable science.



Unfortunately, the NTP's Report on Carcinogens (RoC) continues to fall well short of meeting the benchmarks of objectivity, scientific accuracy, and transparency necessary to ensuring high quality, reliable assessments.

Inconsistent Science and Duplicative Programs

ACC has significant concerns with the quality of the RoC evaluation process, as well as the duplicative, inconsistent scientific review processes that exist across multiple agencies and departments. NTP's RoC, EPA's Integrated Risk Information System (IRIS), and the Centers for Disease Controls (CDC) Agency for Toxic Substances and Disease Registry (ATSDR) programs are all housed within different federal departments or agencies. There is considerable overlap in the substances they evaluate, but each program employs different methods for assessing chemical hazards and risks. These overlapping and duplicative programs often produce conflicting conclusions and guidance.

The concurrent evaluation of formaldehyde in EPA's IRIS program and the NTP 12th RoC is a prime example. Just a few weeks after a National Academy of Sciences (NAS) panel concluded that EPA's IRIS program had failed to scientifically justify its conclusion that formaldehyde causes specific types of leukemia, the 12th RoC made the same mistake as EPA, asserting that studies in humans have shown that formaldehyde causes myeloid leukemia.¹ By failing to sufficiently reflect the conclusions of NAS, and by producing a contradictory report, the 12th RoC has created the potential for public confusion and alarm as well as economic harm to the 600,000 Americans employed in industries that depend on the production and use of formaldehyde, all without adequate scientific basis. Although the listing of a substance in the RoC does not constitute a regulation or rulemaking per se, listing determinations often trigger regulatory actions by Federal and State agencies, product deselection, and product liability suits.

It is abundantly clear that federal risk assessment activities are not being coordinated, despite direction and guidance provided by the Administration.²

ACC strongly recommends that the Committees carefully consider the relevance and necessity of the RoC. The RoC was a novel approach when Congress authorized it over 30 years ago, but it has been eclipsed by other government programs and the vast array of information available over the Internet. A similar overlap appears to be highly likely for assessments slated to be conducted on the non-cancerous effects of chemicals within the NTP's newly established Office of Health Assessment and Translation. To the extent possible, duplicative and unnecessary chemical evaluation programs should be eliminated, and even those that are specifically mandated by Congress should receive greater scrutiny to confirm their continued value and relevance.

¹ See <http://ntp.niehs.nih.gov/ntp/roc/twelfth/profiles/Formaldehyde.pdf>.

² See OMB "Final Information Quality Bulletin for Peer Review" and OMB's "Updated Principles for Risk Analysis" (<http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>; http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/m07-24.pdf).

Flawed Process and Procedures

ACC is also concerned about the implications of the largely pro forma manner in which the NTP went about revising portions of the RoC process late last year. On October 31, 2011, NTP published a Federal Register notice seeking stakeholder input on the RoC processes, but allowed only 30 days for submission of written comments. Immediately after the comment period, NTP scheduled discussion of its final revisions by its Board of Scientific Counselors (BOSC) on December 15, 2011, and the agenda specified only half an hour for presentation by NTP, comments by stakeholders, and discussion by the BOSC. ACC objected to the Director of NIEHS regarding this truncated process, and she replied, "While we appreciate the suggestions, we believe that the announced public comment process and timeline provide a reasonable opportunity for interested parties to provide external input, while enabling the NTP to move forward consistent with the RoC's statutory reporting time frame." ACC strongly disagrees that the process was adequate to obtain meaningful input or to obtain the necessary independent review by outside scientists.

With bipartisan support, Congress passed the Consolidated Appropriations Act of 2012, which directed the Department of Health and Human Services to contract with NAS to "conduct a scientific peer review of the 12th Report on Carcinogens determinations related to formaldehyde and styrene. Included in the review should be all relevant, peer-reviewed research related to both formaldehyde and styrene." Despite this explicit Congressional mandate, NTP has yet to contract with the NAS and instead, is immediately moving forward with development of the 13th RoC.

These actions demonstrate the NTP's lack of commitment to improve the data evaluation and weight of evidence procedures of the RoC to meet current standards, including those identified by the NAS in Chapter 7 of the April 2011 NAS formaldehyde scientific peer review report. ACC recommends that the Committees direct the NTP to immediately contract with the NAS to review the 12th RoC styrene and formaldehyde evaluations which led to the listing decisions, and await the report from this NAS review before moving ahead with the 13th RoC. ACC is concerned that unless fundamental and permanent improvements are made, the 13th RoC will suffer from the very same shortcomings that plagued the 12th RoC.

The NTP RoC has reached an important crossroad – unless its policies and practices are revised and significantly improved to meet the highest standards of scientific integrity, transparency, and peer review, flawed assessments will continue to be produced. Continued public confusion, unwarranted alarm, unnecessary product de-selection, and litigation will continue to be the result. Improving the quality of chemical assessments will lead to significant benefits for everyone through better public health decisions based on accurate information and better use of public and private sector resources that can be refocused on promoting American jobs and innovation.

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ACC and its members look forward to working with you and the both Committees as discussion around the RoC continues. If we can provide any additional information on ACC's perspectives on this or related topics, please contact me.

Sincerely,

A handwritten signature in black ink that reads "Cal Dooley". The signature is written in a cursive, slightly slanted style.

Cal Dooley
President and CEO