

Public Testimony before the U.S. House of Representatives'
Committee on Science, Space & Technology, Subcommittee on Investigations & Oversight
and
Committee on Small Business, Subcommittee on Health Care & Technology

Joint Hearing: "How the *Report on Carcinogens* Uses Science to Meet its
Statutory Obligations, and its Impact on Small Business Jobs"

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Good morning. My name is Dr. James Bus. Over my career as a toxicologist, I have served as President of the Society of Toxicology and served on science advisory bodies of the National Academy of Sciences (NAS), EPA, FDA and NTP. I am here today as a concerned scientist and represent the Styrene Information and Research Center, of which my employer, Dow Chemical, is a founding member.

I, Dow, and the styrene industry are keenly interested in protecting the health and safety of workers, customers and the public. Objective, evidence-based reviews of scientific research are essential elements of our decision making about our products and facilities.

The NTP is globally recognized as an "authoritative body;" chemical classifications in its *Report on Carcinogens (RoC)* carry significant consequences for businesses large and small, including regulatory actions and commercial impacts. Thus, it is essential that *RoC* classifications represent the highest quality scientific evaluations.

My comments today focus on three key shortcomings in NTP's *RoC* process, and are based in part on issues revealed in recent *RoC* evaluations, including styrene.

First, the *RoC* process is almost entirely *ad hoc* and lacks explicit criteria needed to assure consistency and transparency.

Importantly NTP's *RoC* process is completely silent about criteria needed to guide scientific evaluations at several key process stages. For example, draft "Monographs" provide the primary rationale for *RoC* classifications. Yet the recently updated *RoC* process states Monograph reviews only include "external scientific input, **as needed** (e.g., consultants, *ad hoc* presentations, expert panels)" (**emphasis added**).

A 2011 NAS assessment of the EPA review of formaldehyde details a number of scientific best practices for assessments of chemicals in general and points out that *ad hoc* review processes cannot be relied on to produce scientifically valid assessments; indeed, evidence based approaches are now being used by other institutions such as the Institute of Medicine.

Second, the RoC process lacks adequate checks and balances, including peer review and addressing outside/conflicting data

NTP's new process limits review by its Board of Scientific Counselors (BSC) to NTP's initial draft "concept document," which is akin to an outline of what NTP's review intends to examine. Peer review of the critical draft Monographs by external Expert Panels is left entirely to the discretion of the NTP, including the key steps of expert panel member selection and identification of review charge questions.

In addition, interagency peer review of draft Monographs is reduced to providing "inputs" that will only be considered at the discretion of NTP and are not further shared with the Expert Panels or the public. Finally, draft Monographs are presented to the NTP BSC for information only, denying this senior advisory body any meaningful peer review.

This is not transparent or credible peer review.

Finally, the RoC fails to employ scientific best practices, relies on outdated approaches and has not adopted recent NAS recommendations.

The NAS has specifically outlined several fundamental best practices necessary to assure that processes for toxicology-related assessments of chemicals are evidence based, objective and scientifically credible.

The process used to prepare the RoC falls considerably short of these objectives. For example:

- NTP has previously stated that RoC reviews are based on "strength of the evidence"¹ as compared to more comprehensive weight of evidence analyses used by groups such as the Institute of Medicine. The RoC heavily favors findings supporting NTP's proposed listing position, while contrary findings are seldom given much weight.
- Although external public comment is solicited, NTP has stated, **as a matter of policy**, it will no longer offer any written response,² thereby masking the existence of differing scientific views.

Summary

In summary, the current RoC process falls well short of producing evidence-based listing decisions.

I urge Congress to oversee a thorough assessment of the RoC – ideally through an NAS review – to ensure that any future RoC listings are evidence-based, provide accurate public health information and reflect the highest scientific standards in its processes, and to begin to determine the RoC's fundamental relevancy going forward.

This will increase the public's and industry's confidence in the RoC's listings and their application to science-informed decision-making.

Thank you.

¹ "Peer Review of Draft Substance Profiles for the 12th Report on Carcinogens," slide 6 of presentation by Mary S. Wolfe of NTP to the NTP Board of Scientific Counselors Meeting, 24 Feb 2009, <http://ntp.niehs.nih.gov/files/Wolfe20090224.pdf>.

² NTP Board of Scientific Counselors Meeting, 15 Dec 2011, statement of Dr. John Bucher. The statement referred to can be found at 6:00 minutes of the recording that is available at <https://www.box.com/shared/static/ea274f5a6547994936ac.wma>.