

May 24, 2011

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Via fax: 202-690-7203

Dear Secretary Sebelius,

First we would like to thank you again for the opportunity to meet with you and several members of your senior staff on December 13, 2010 to discuss concerns regarding the scientific and procedural inadequacies behind the recommendation by the National Toxicology Program (NTP) to list styrene as “reasonably anticipated to be a human carcinogen” in the impending 12th NTP *Report on Carcinogens (RoC)*.

Five months have now passed, and, as we have received no further updates from your office, it seems likely that your staff is close to finalizing this matter and that your decision regarding styrene and the *RoC* may be made public in the near future. Accordingly, we are making this appeal for you to again consider the validity of our concerns and to order a thorough re-review of the science on styrene before making your decision.

As you may recall, we expressed concern that the recommendation of the NTP was based on a selective reading of the available scientific information that ignored a large number of important studies that did not support the staff position. Not only was this information ignored, it was effectively excluded from the information presented to the NTP’s Board of Scientific Counselors. Moreover, the NTP staff recommendation is based on a novel manipulation of the data that was never peer reviewed. For all of these reasons, it is premature to include any conclusion regarding the carcinogenicity of styrene in the *RoC* until a review of NTP’s recommendation can be conducted using all available data, rather those few studies that arguably support the staff position.

The NTP staff has defended their proposal entirely on procedural grounds — that NTP followed its existing process appropriately and that the “reasonably anticipated” listing is the result — rather than on the proper scientific and public health matter of actual health risk. In fact, NTP agrees that they have not determined that styrene is actually a health risk to Americans in their daily lives.

The procedural defense is hollow. NTP staff appeared willing to set aside its procedure in the case of glass wool fibers: the Expert Panel voted not to list this material in the 12th *RoC*, but the staff proceeded anyway to submit a cancer listing recommendation to the Board of Scientific Counselors. NTP staff appears to consider the *RoC* process to be somewhat flexible when justifying a pre-determined classification recommendation, but not when that recommendation is challenged.

And more critically, proceeding with the proposed styrene listing based on procedural arguments when there are valid scientific grounds for doubting the accuracy of the listing can hardly be consistent with the President’s advocacy in favor of federal policy based on sound science and transparency, or consistent with the mission of HHS to provide useful and accurate information to the public. In fact, suggesting that a questionable scientific conclusion is justified because it is the result of NTP’s existing process is a criticism of the process, not a justification of the recommendation.

In greater detail, the facts as we see them are these:

- Styrene has been used safely for 60 years. It is used today by over 3,000 small and medium sized companies, employing over 750,000 Americans, to make products such as residential tub/showers, recreational boats, major components for wind and solar energy, leak-resistant gasoline storage tanks and pollution control equipment, tires, food packaging, and thousands of other products relied on by most Americans in their daily lives.
- A styrene listing in the RoC will trigger automatic OSHA warning labels, causing serious concerns among workers and plant neighbors, and threatening the viability of many companies.
- European Union scientists recently issued an EU Risk Assessment Report and determined that styrene is not a human carcinogen. The same conclusion was reached by an expert panel in a report in the November 2009 issue of the Journal of Occupational and Environmental Medicine.
- Dr. Elizabeth Delzell, the author of the study on workers in the styrene-butadiene rubber industry relied on by NTP for its assessment of human data, wrote to NTP officials on February 5, 2009, and argued that “The available scientific evidence is not sufficient to conclude that styrene causes lymphoma, leukemia or other cancers.” To support its claim for a likely link between styrene and cancer, NTP subjected Dr. Delzell’s data to a novel statistical analysis, which has never been formally described or submitted for peer review, in violation of NTP’s own peer review policy. According to an Oct. 22, 2010 letter from Congressmen Rick Boucher and John Shadegg, NTP officials claimed in a meeting with these Congressmen that this analysis could not be peer reviewed because “it was submitted over the phone”.
- Recent studies with genetically modified mice exposed to styrene, using Nobel Prize winning technology and partly funded by NTP, severely undercut NTP’s reliance on animal toxicity to support a cancer concern for humans. NTP has refused to consider these data on procedural grounds.
- The World Health Organization’s International Agency for Research on Cancer and the CDC’s Agency for Toxic Substances and Disease Registry both determined that styrene is a “possible” carcinogen, which indicates a much lower level of concern than NTP’s proposed “reasonably anticipated” carcinogen listing. Neither the IARC nor ATSDR “possible” classifications trigger OSHA warning labels. There are no cancer warnings required under the recently updated EU styrene regulations.
- The styrene industry submitted in October 2009 a carefully prepared Information Correction Request under the Data Quality Act, pointing out in detail the several scientific errors that contaminate NTP’s styrene listing proposal. NTP’s response to this Request relied entirely on references to NTP’s process, and completely failed to address the important scientific question of whether Americans are at risk of cancer from styrene exposure. SIRC’s February 2011 Appeal of NTP’s response is still pending, and we can only hope that the response will address the important scientific questions instead of again hiding behind NTP’s process.
- NTP makes no effort to respond to public comments until *after* an RoC listing is finalized and communicated to the public. This major procedural flaw means that NTP’s three peer review groups for styrene were not informed - in a meaningful and good faith manner - of the many scientific criticisms of NTP’s styrene position, and these panels conducted their reviews based only on the limited information provided by NTP staff. NTP claims that it “provided access” to public comments for its review groups, but this is not accepted practice and is woefully insufficient. The members of these panels have limited time for reviewing documents in preparation for a review meeting, and

depend entirely on the staff to summarize information and identify critical documents. NTP need not have taken extreme measures to fulfill its responsibility; for example, it would have been a simple matter for NTP to direct its contractor to include in the original Styrene Background Document an accurate summary of the public comments received when the Document was completed.

- The National Academy of Sciences recently conducted a review of EPA's draft cancer assessment for formaldehyde, and blasted EPA for its poor science review process. Both SIRC and the American Chemistry Council recently wrote to you and explained how the NTP's cancer reviews are even more procedurally deficient than EPA's. The NTP styrene assessment is scientifically inaccurate - and will misinform the public of health risks - precisely because the review process failed to meet the standards set by NAS.

NTP's blind reliance on its process and willful ignorance of the entire body of science is a direct threat to the employment of over 750,000 people who work in the thousands of small and medium sized companies that use styrene and styrene-based materials to make products that are used every day by virtually every American. Clearly the U.S. Congress intended the Report on Carcinogens to identify only the most putative potential carcinogens. Yet NTP appears willing to apply the most selective and opaque assessment process in order to list substances that others, following more sophisticated assessments, have deemed non-carcinogenic, or in any case not warranting any kind of public health warnings or labeling. This policy flies in the face of sound science — most certainly for a substance with as vast a scientific database as styrene's — and warrants serious scrutiny for its bias and complete lack of scientific rigor.

The deficiencies we describe above demonstrate that NTP's decision is fundamentally flawed because it was not based on reasonable extrapolations from reliable scientific evidence. Indeed, the very foundation of NTP's procedural defense is untenable because it assumes that the process trumps the science, when, ultimately, no amount of process can justify an unreasonable and scientifically unfounded decision.

We again call on you, in the cause of good science and accurate health risk information, to send the *RoC* styrene listing back to NTP, and to order a valid and thorough re-review of the data, consistent with the principles set forth by NAS as well as the several firm policy statements made by President Obama and his Administration in favor of Federal action based on sound science, transparency, and protection of small company viability.

Sincerely,



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