

March 9, 2006

Dr. George Gray
Assistant Administrator
Office of Research and Development
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

VIA FACSIMILE - (202)565-2430

Dear Dr. Gray,

Thank you for meeting with us on February 17 to discuss the concerns of composites manufacturers and other small businesses regarding EPA's Integrated Risk Information System and other agency hazard assessment programs.

As we discussed during our meeting, small businesses are especially vulnerable to unwarranted and unintentional economic impacts that may result from EPA's chemical hazard and risk assessments and related communications. While IRIS is intended to serve as the first step in a thorough risk assessment process, in reality it is often the only and final step. Many workers, plant neighbors and product users, and even state and local regulators, use IRIS classifications as authoritative indications of actual risk. A classification for styrene with the label "suggestive evidence" would almost certainly cause many of the people potentially exposed to styrene in or near composites plants to believe that EPA is "suggesting" that they may get cancer. Such a confusing message from EPA would place a severe and in many cases unmanageable communications burden on thousands of small composites business owners across the country.

We believe that the scientific evidence on styrene – including negative data from extensive human studies, negative data from studies with rats exposed at high levels, and mode-of-action analysis of positive data from studies with mice – is consistent with a finding that there is no significant risk of workers, plant neighbors or product users getting cancer as a result of exposure to this substance. Our analysis suggests a classification of styrene as "not likely to be carcinogenic to humans."

However, if EPA finds it necessary to reflect a concern over the possible relevance of the mouse tumor findings, a characterization of styrene as having "limited animal evidence" would be much more accurate than "suggestive evidence," and would significantly lessen the risk of unwarranted economic impact to the composites industry, especially if EPA also provided a qualitative assessment of cancer risk in typical exposure scenarios. A similar approach was taken by an expert panel convened by the Harvard Center for Risk Analysis in a 2002 review of styrene hazard and exposure data.

In addition to IRIS, other communications from scientists in the Office of Research and Development and other EPA offices can present problems for small businesses. An example is the journal article authored by ORD scientists that we discussed on February 17, which incorrectly suggests that our companies are sending their workers home with impaired ability to operate motor vehicles.¹ This article is already being referenced by advocacy groups and may result in widespread concern among workers and plant neighbors, and may make it impossible for many of these small companies to afford liability insurance. No one outside of EPA and the journal knew that this article was going to be published. Scientists who are expert in the underlying body of literature have subsequently been severely critical of the article's

¹ Benignus, V.A., et al. 2005. Environmental Health Perspectives. 113: 532:538.

analysis and the over-reaching policy conclusions that the authors drew; yet the journal has so far refused to print their criticisms. Clearly, reliance on submission to a peer-reviewed journal and subsequent comments by other scientists is not a sufficient safeguard against this kind of unwarranted and irrevocable damage to an industry. Better supervision of this type of activity and more transparency for stakeholders before publication would likely have prevented this harm.

We were pleased to hear that your office will soon announce an IRIS transparency improvement program, and we look forward to participating in this effort. At all stages of IRIS chemical reviews and other agency hazard and risk assessments, we believe that ORD scientists and managers should engage industry scientists and other stakeholders in meaningful, open and full dialogue, on both science and science-policy matters.

Again, thank you for your attention to our concerns.

Sincerely,

A handwritten signature in blue ink, appearing to read 'John Schweitzer', is positioned above the typed name.

John Schweitzer
Senior Director of Government Affairs

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