

June 26, 2019

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U.S. Environmental Protection Agency  
EPA Docket Center,  
Docket ID No. EPA-HQ-OAR-2016- 0447 for the Boat Manufacturing NESHAP and  
Docket ID No. EPA-HQ-OAR-2016-0449 for the Reinforced Plastic Composites  
Production NESHAP  
Mail Code 28221T, 1200  
Pennsylvania Avenue NW  
Washington, DC 20460

**Re:** Comments of the Styrene Information and Research Center on the  
**National Emission Standards for Hazardous Air Pollutants: Boat  
Manufacturing and Reinforced Plastic Composites Production Residual Risk  
and Technology Review**

The Styrene Information and Research Center, Inc. (SIRC)<sup>1</sup> appreciates the opportunity to comment on EPA's proposed rule. 84 Fed. Reg. 22642 (May 17, 2019). SIRC supports the agency's conclusion that risks from the boat manufacturing and reinforced plastic composites production source categories are acceptable and meet the ample margin of safety criteria of Section 112 of the Clean Air Act. In particular, not treating styrene as a carcinogen in the context of this risk and technology review is appropriate.

#### **A. Potential Styrene Hazards**

EPA found that: "the EPA's IRIS database and other reputable peer-reviewed sources of cancer dose-response values are not available to assess cancer risks for this pollutant."<sup>2</sup>

SIRC has supported scientific research on styrene toxicology for decades, and the results of that work appear in public, peer-reviewed scientific journals. There are no strong or consistent indications that styrene causes any form of cancer in humans. Although some studies suggest that styrene-exposed workers may be at increased cancer risk, the human evidence for styrene carcinogenicity is inconclusive. Studies of general population

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<sup>1</sup> In North America, the Styrene Information and Research Center, Inc., (SIRC) serves as a resource for industry, federal and state governments, and international agencies on issues related to the potential impact of exposure to styrene on human health and the environment. SIRC was formed in 1987 as the principal focal point for the public information and research on styrene. SIRC is a non-profit organization comprising voting member companies involved in the manufacturing or processing of styrene, and associate member companies that fabricate styrene-based products. Collectively, SIRC's membership represents approximately 95% of the North American styrene industry.

<sup>2</sup> 84 Fed. Reg. at 22651.

environmental and consumer styrene exposure and cancer are less informative than the worker studies, but the available evidence does not suggest that these low exposures are a concern. Extensive studies on mouse lung tumors demonstrate that these are of low relevance to human cancer risk. No toxicity value estimates for cancer should be applied given the established lack of relevance of mouse lung tumors and inconsistent epidemiology evidence.

Thus, the scientific literature itself explains why “EPA’s IRIS database and other reputable peer-reviewed sources of cancer dose-response values are not available to assess cancer risks for this pollutant.”<sup>3</sup> Not treating styrene as a carcinogen for this risk and technology review is appropriate and not simply a matter of the absence of reputable cancer dose-response values.

In 2016, SIRC began a comprehensive risk assessment of styrene, with the goal of a systematic review of the scientific literature on styrene, developing hazard and exposure assessments, and assessing potential toxicological risk – with focus on workers in environments where styrene is made or used in manufacturing as well as the general population from environmental and consumer exposures. This project updates a risk assessment published in 2002 that SIRC sponsored through a grant to the Harvard Center for Risk Assessment.

The project was completed in early 2019 and submitted for publication. Following peer review, the manuscript was accepted for publication in mid-June by the Journal of Toxicology and Environmental Health, Part B: Critical Reviews (Manuscript ID UTEB-2019-0016.R1). We anticipate that the online version of this review and additional supporting materials will be available on the publisher’s website in several weeks. We will provide a copy or access for the agency’s review after publication. This new review supports the characterizations of styrene in this letter.

## **B. IARC Monograph Program**

EPA notes that “[i]n March 2018, the International Agency for Research on Cancer (IARC) revised the weight of evidence classification of styrene to Group 2A—“probably carcinogenic to humans.”<sup>4</sup> However, the change of styrene’s IARC classification from Group 2B to Group 2A is not attributable to new data but to changes by IARC to its classification rules, which are found in IARC’s Preamble to the Monograph series.<sup>5</sup> The finding of limited human cancer evidence for lymphatic and hematopoietic (LH) tumors only is the same conclusion made in 2002 when styrene was designated a Group 2B substance.

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<sup>3</sup> 84 Fed. Reg. at 22651.

<sup>4</sup> 84 Fed. Reg. at 22651.

<sup>5</sup> IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, “Preamble,” amended January 2006 and last updated January 2019. We note that the IARC Preamble was subsequently amended after styrene’s most recent review by IARC.

In the Preamble, IARC explicitly states that the Monographs identify cancer hazards even when risks are very low.

“The *Monographs* represent the first step in carcinogen risk assessment, which involves examination of all relevant information in order to assess the strength of the available evidence that an agent could alter the age-specific incidence of cancer in humans....

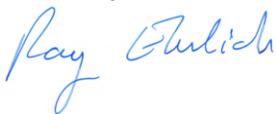
A cancer ‘hazard’ is an agent that is capable of causing cancer under some circumstances, while a cancer ‘risk’ is an estimate of the carcinogenic effects expected from exposure to a cancer hazard. The *Monographs* are an exercise in evaluating cancer hazards, despite the historical presence of the word ‘risks’ in the title. The distinction between hazard and risk is important, and the *Monographs* identify cancer hazards even when risks are very low at current exposure levels . . .<sup>6</sup>

Thus, EPA was correct that the IARC classification does not provide a basis for regulatory action or a conclusion that styrene presents a carcinogen risk.

Indeed, IARC notes that its evaluations “represent only one part of the body of information on which public health decisions may be based.” And, “[t]herefore, no recommendation is given with regard to regulation or legislation, which are the responsibility of individual governments or other international organizations.”<sup>7</sup>

Thank you for considering these comments.

Sincerely,



Ray Ehrlich  
Executive Director

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<sup>6</sup> Preamble, p. 2.

<sup>7</sup> Preamble at 3.

