

Testimony

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US EPA

Public Meeting on the IRIS Assessment Plan for Naphthalene

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- Time Allotted: Assuming 5 minutes

Good afternoon. I am Jessica Ryman-Rasmussen, Senior Policy Advisor at the American Petroleum Institute (API). API represents all segments of America's oil and natural gas industry. API previously submitted comments to this docket in the Fall of 2018 on the Draft IRIS Assessment Plan. These comments remain relevant to the current Assessment plan and will be briefly recapitulated today. Additionally, I will describe more recent research sponsored by API using new approach methods (NAMs) that can inform the updated IRIS Assessment Plan. Finally, API is aware of a recent publication in Environmental Health Perspectives by EPA staff that seems relevant to hazard identification and dose-response assessment for naphthalene. We have some concerns about this publication that we will also share today.

API's written comments to this docket in 2018¹ described the API-managed the Naphthalene Research Committee (NRC), which was formed in 2007 to answer scientific questions about naphthalene's mode of action and carcinogenic potential. This research was grounded in recommendations made at the 2006 EPA-sponsored Naphthalene-State-of-the Science-Symposium. This multi-year, multi-million-

¹ EPA-HQ-ORD-2014-0527-0008

dollar research program for naphthalene resulted in a number of high quality *in vitro* and *in vivo* studies that have been published in the peer-reviewed scientific literature. These studies address the mode of action (MOA) and human relevance of respiratory tract tumors in rodents.

As EPA moves forward with its Directive to phase out animal testing and reliance by 2035, the use of MOAs and other New Approach Methods (NAMs) will not be optional, but essential. API was encouraged to see differences in metabolism and health effects related to the MOA for nasal tumors identified as Key Science issues in the Assessment Plan.

As EPA transitions to the use of NAMs that are fit-for-purpose for risk assessment, including hazard identification and dose-response assessment, API would like to remind the IRIS Program of the 2020 publication by Bailey and Rhomberg in *Toxicology In Vitro* entitled Incorporating ToxCast™ Data Into Naphthalene Human Health Risk Assessment. This manuscript was sponsored by API. Importantly, it is API's understanding that the authors corresponded with EPA staff regarding data quality during the development of the analysis. The results of the analysis were extrapolated to human equivalent concentrations using the PBPK model of Campbell et al. (2014). The results were consistent with a previously published weight-of-the-evidence analysis performed by Bailey and Romberg in 2015. The consistency of the ToxCast™ data and analysis with the weight-of-the-evidence analysis is an

important one, since, to API's knowledge, ToxCast™ data are not yet regarded as having stand-alone status for hazard identification and dose-response assessment.

Finally, API is aware of a July 2021 publication in *Environmental Health Perspectives* entitled *Health Effects of Naphthalene Exposure: A Systematic Evidence Map and Analysis of Potential Considerations for Dose-Response Evaluation* by EPA staff who co-authored the Assessment Plan. We could find no reference to this publication in the Assessment Plan. API is aware that the hold on the naphthalene assessment was released in June 2021 and of the disclaimer that the views of the authors do not necessarily represent the views and policies of EPA. Given the amount of time it would take to conduct such an analysis and publish the work in a peer-reviewed journal, we are curious as to if this work was done while the assessment was technically on hold. According to the November 2020 Draft IRIS Handbook, the initial stages of assessment development are Scoping and Problem formulation with the output as the Assessment Plan, which we are here to discuss today. Of concern to API is a lack of clarity regarding the influence of the EHP publication in the IRIS process for naphthalene and the degree to which it reflects the work of the IRIS Program on the naphthalene assessment, particularly if it encompasses any of the next stages of assessment development (e.g. Systematic Review and subsequent steps that will ultimately lead to the Draft Assessment).

API looks forward to subsequent opportunities for public comment as the assessment develops. We will be watchfully curious as to whether and how the results from subsequent steps in the IRIS Process for naphthalene and the draft assessment are consistent with the EHP publication. We appreciate the opportunity to comment.