Testimony of
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Making EPA Great Again

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Summary

The American Chemistry Council (ACC)[1] appreciates this opportunity to provide testimony on the U.S. Environmental Protection Agency's (EPA) process for evaluating and using science to support regulatory decision making.

The business of chemistry is a critical component for manufacturing safe, high quality products and ACC member companies rely on science to conduct the research necessary to discover new chemistries and identify new applications of existing chemistries. They also rely on science to develop new tools for assessing the potential hazards, exposures and risks of chemical substances. Similarly, they expect high quality, up to date science and relevant reliable assessment processes to underpin regulatory decisions by the Federal government. Reliance on the highest quality, best available science is critical to ensuring public trust. Without it, consumers are at a severe disservice and lose confidence in regulatory decision making, leading to product de-selection that is not supported by science, unwarranted public alarm and unnecessary costs. ACC supports actions to enhance the integration of the best available scientific knowledge and methods as the foundation for regulatory decision making across EPA. We also support advancing the technical quality and objectivity of EPA evaluations, particularly through enhancing transparency in both what science is being considered and how it is being interpreted and integrated.

Over the last 30 years, advances in scientific techniques and knowledge have improved our understanding of how chemicals interact with the human body and the environment. Research programs within industry, academia and government have expanded to investigate the underlying biological processes for chemical interactions and to improve the scientific basis of chemical policies and product stewardship efforts. It is simply not enough to have the science available for use. There must also be a transparent process and a willingness to enable integration of the science into EPA policies and practices. Current processes for evaluating scientific information and conducting chemical assessments at EPA are not always based on transparent, objective or consistent use of the best available science. In recent years, there has been a focus on EPA's Integrated Risk Information System (IRIS) program and addressing deficiencies identified by the National Academy of Sciences (NAS)[2]. These deficiencies are also evident in other EPA chemical assessment programs.

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for fourteen percent of all U.S. exports. Chemistry companies are among the largest investors in research and development.

[2] National Academy of Sciences (NAS). NRC (National Research Council). Review of EPA's Integrated Risk Information System (IRIS) Process. Board on Environmental Studies and Toxicology. Division on Earth and Life Studies. Washington, DC: The National Academies Press, 2014. Available at http://www.nap.edu/catalog.php?record_id=18764.

ACC has consistently called upon EPA to improve the design and conduct of its chemical assessments. Recommended improvements have included adoption of consistent and transparent study evaluation methods to determine the quality and reliability of critical studies. We have also encouraged EPA to utilize an improved framework for integrating study results based on a weight of the scientific evidence approach that incorporates modern knowledge of mode of action to establish cause and effect. Furthermore, we have recommended that EPA improve its peer review and accountability practices for addressing both public comments and peer review recommendations. Although EPA has made efforts to identify practices for systematically reviewing the available science and to strengthen its peer review processes, the actual implementation of these practices has been slow and often lacking. This has been fundamentally due to the lack of a consistent science-based framework for conducting chemical evaluations within EPA.

Over the past several years Congress has worked to update and reform the Toxic Substances Control Act (TSCA) and in 2016 passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). The LCSA establishes new requirements for the review of new and existing chemicals manufactured and used to make U.S. products; including requiring use of the best available science and a weight of evidence process to evaluate scientific information. EPA now has a mandate to apply high quality, reliable scientific information while evaluating new chemicals and prioritizing and evaluating the risks of existing chemicals. Implementing these new provisions will require significant changes to EPA's scientific evaluation procedures, particularly for existing chemicals. However, as we have recently seen in EPA's proposed framework rule for risk evaluation, EPA believes that existing practices meet the standards of the LCSA. ACC does not support this belief and we plan to continue to be a constructive partner to both Congress and EPA in identifying approaches that enhance the chemical assessment process. ACC's testimony today outlines four areas that can improve the evaluation of scientific information at EPA:

- Clear framework for conducting the chemical assessment;
- Application of consistent criteria for selecting and evaluating scientific data;
- Transparent and objective integration of scientific evidence; and
- Independent and robust peer review.

I. Clear Framework for Conducting Chemical Assessment

EPA and other federal government agencies conduct chemical assessments to inform risk management decisions. As such, EPA should ensure that the assessments it conducts will address the information needs of decision makers. EPA is tasked with evaluating new chemicals to be manufactured and used to make U.S. products and existing chemicals in the marketplace. As such, any assessment that EPA undertakes should be fit for purpose in order to effectively and efficiently utilize its limited resources. This can help ensure that chemical assessments are based on the best available information and are appropriately scaled and oriented to address relevant questions regarding risk. EPA should also make use of all available science evaluations, including primary scientific literature, grey literatures and reviews, conducted to inform the chemical assessment process and determine information needs. In this initial phase of chemical assessment, EPA can determine if a screening level

assessment will identify and assess risk sufficiently or if a more refined risk evaluation is needed.

EPA is currently interpreting the LCSA as requiring the Agency to evaluate *all* conditions of use of a chemical, regardless of how small, in the risk evaluation. This interpretation is unreasonable and inconsistent with other provisions in the LCSA which, clearly indicate that EPA has discretion to select the conditions of use that it will consider in the scope of a risk evaluation. There are significant questions about EPA's ability to meet the stringent evaluation deadlines of the LCSA if the Agency takes the position that all uses of a substance must be evaluated. A tiered approach, where EPA uses the scoping step to conduct a quantitative screening level analysis, will allow EPA to focus its limited resources on more robust refined risk evaluations for only those conditions of use where unreasonable risks cannot be ruled out.

In order to adequately and effectively evaluate the available science to make timely and science based decisions regarding potential risk from exposures, methods for conducting a chemical assessment must be clearly defined up front. The protocol, developed before the chemical evaluation begins, defines the methodologies that will be used in the assessment. It is made publicly available before the assessment begins and becomes a living document that can be commented upon and modified as needed. The protocol includes: a clear testable question/hypothesis, the planned search strategy (including criteria for inclusion and exclusion of studies), the criteria that will be used for study quality and risk of bias evaluations (including, for example, consideration of study design and confounders), the plan for integrating/synthesizing scientific evidence using a weight of evidence approach, the plan for quantifying and presenting findings, and the plan for peer review of the assessment. Section 6(b)(4)(B) of the LCSA requires EPA to establish, by rule, "a process to conduct risk evaluations." Incorporation of a protocol which includes these important risk evaluation elements is missing from EPA's proposed rule for risk evaluation. Without these elements it is not clear how EPA can meet the LCSA requirements that, for the first time in federal law, provide a statutory requirement mandating best available science and weight of the scientific evidence requirements to inform agency decision making.

In EPA's IRIS program there are similar concerns regarding scientific evaluation procedures. These concerns have been well articulated by the NAS. Assessment approaches also appear to be hampered by a lack of coordination among programs regarding the chemical assessments being undertaken and how those assessments can be utilized by other EPA programs. For instance, past assessments by EPA's IRIS program (e.g., n-butanol, trimethylbenzenes) did not seem to consider data developed by other EPA program offices in previous chemical assessments. It also has not been clear why the TSCA Work Plan chemicals program, within the Office of Pollution Prevention and Toxics (OPPT), at times evaluated the same chemicals that the IRIS program evaluated.

ACC recommends that EPA identify a consistent framework for conducting chemical assessments, including the methods to be utilized in the assessment and the utility of the assessment for regulatory decision making, prior to initiating the assessment These practices should be consistent with requirements outlined in section 26 of the LCSA which, requires

EPA to improve the quality, transparency and relevance of the scientific information, approaches, methods, protocols, and models that are used to evaluate chemical risks. EPA must additionally ensure that the information used is reasonable for and consistent with the intended use of the information.[3] When assessments are being conducted to inform significant rulemakings, EPA must make certain that these important standards are being met.

II. Application of Consistent Criteria for Selecting and Evaluating Scientific Data

Scientific evaluations must utilize transparent and consistent criteria for selecting the most relevant scientific information and evaluating the evidence to draw scientifically defensible conclusions to support decision making. In particular, a systematic approach can ensure that EPA is using clear procedures and protocols to develop reproducible and scientifically sound assessments. It is critical that EPA rely on the studies of the highest quality not simply those studies that produce the lowest points of departure or the highest exposure estimates. A lack of sufficient review of study information may lead to establishing unrealistic risk characterizations and exposure concentrations that are not relevant to actual human exposures. For example, in the Work Plan chemical draft risk assessment of 1-bromopropane, EPA did not provide information regarding the quality of the individual studies. Appendix M of the assessment identifies some quality considerations, but EPA did not provide any information regarding its own findings from its quality review of the individual studies. Additionally, no information was provided to describe how considerations were applied and what constitutes a study of "high quality" or "good quality."[4] Simply choosing the lowest value is not consistent with the best available science approach envisioned under the LCSA. As noted before, this new language will require that EPA make significant changes to its risk evaluation practices.

Given the lack of consistency in evaluating scientific information, EPA should develop, through an open and transparent process, (1) protocols that define the process for the acquisition of the scientific literature including study inclusion/exclusion criteria; and (2) a framework for evaluating studies for quality, reliability and relevance. Notably, the LCSA calls on the EPA risk evaluation process to comply with the best available science provision in Section 26(h), the weight of the scientific evidence provision in 26(i) and the transparency provision in 26(j).

III. Transparent and Objective Integration of Scientific Evidence

Considerable progress has been made over the years to improve understanding of the potential for risk from chemical exposures. In order for the Agency to reach scientifically robust conclusions, it must employ a transparent weight of evidence framework that

[3] Section 26(h)(1) states that the Administrator shall consider "the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information."

[4] See Comments of the American Chemistry Council on the TSCA Work Plan Chemical Draft Risk Assessment of 1-Bromopropane , Docket No. EPA-HQ-OPPT-2015-0084, May 9, 2016

integrates evidence from human epidemiological studies, laboratory animal research and mechanistic research. This includes evaluating the strengths and limitations of the human and animal data, understanding the biological significance of responses in animal models and of mechanistic research, and applying current scientific knowledge to extrapolate those findings to humans.

EPA's 2005 Guidelines for Carcinogen Risk Assessment[5] emphasize the importance of weighing all of the evidence—including both studies that provide evidence of an effect as well as those that provide no evidence of an effect—in reaching conclusions about the potential for a chemical to be carcinogenic to humans. The weighing of the evidence includes addressing not only the likelihood of human carcinogenicity, but also the conditions under which such effects might occur. Weighing the scientific evidence entails clearly explaining the kinds of evidence available (e.g., epidemiology, toxicology, mechanistic) and how that evidence fits together in drawing conclusions regarding human relevance and dose-response. Section 6(b)(4)(F)(i) of the LCSA requires risk evaluations to integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance. Additionally, Section 26(i) of the LCSA requires EPA to make decisions using a weight of scientific evidence approach. The Congressional Record clearly describes how a weight of the scientific evidence approach requires the consideration of the strengths, limitations and relevance of each study.[6]

Unfortunately, it has been unclear how the EPA programs apply weight of evidence approaches or how the programs incorporate mode of action information when evaluating the science to reach decisions. There also appears a lack of acknowledgement in some EPA programs regarding science that supports a threshold for safe exposures to a chemical. In 2011, the NAS[7] reviewed the draft formaldehyde IRIS assessment and concluded that EPA had not sufficiently documented methods to identify or evaluate relevant scientific studies; and had not adequately integrated the lines of evidence from the available animal, human, and mechanistic data. The NAS report also called the draft formaldehyde assessment subjective and potentially problematic given the inconsistencies in the available scientific data. The NAS also noted areas where EPA's approaches may not be scientifically justified. For example, the NAS review noted that with regard to the biologically based dose-response (BBDR) model manipulations made by the EPA "…some of the manipulations are extreme, may not be scientifically justified, and should not have been used as the basis of rejection of the use of the BBDR model in its assessment. Model manipulations that yield results that are implausible or inconsistent with available data should be rejected as a basis for judging the utility of the model."

[5] EPA 2005. Guidelines for Carcinogen Risk Assessment. Available at http://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

[6] See Senate Congressional Record, June 7, 2016 at page S3518, available at: https://www.congress.gov/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf.

[7] National Academy of Sciences (NAS). National Research Council (NRC). Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Washington, DC: The National Academies Press, 2011.

In addition to identifying scientific concerns with the formaldehyde IRIS assessment the NAS also identified recurrent problems with EPA's process for evaluating chemicals more broadly. While the EPA is working to address these NAS recommendations, after more than 5 years, the IRIS program is still falling short and has not yet released a final assessment that is fully consistent with these important NAS recommendations. In addition to the IRIS program, and more recently, in a 2016 Work Plan chemical review of 1-bromopropane, EPA had multiple studies for identified hazards, such as reproductive and developmental toxicity, and carcinogenicity. EPA also had multiple exposure studies to consider. However, the Agency failed to apply a weight of evidence approach.

When there are multiple studies available, the only scientifically defensible approach is to weigh the studies by considering study characteristics and determining which studies are of higher quality and should be given greater weight in the assessment. Failure to employ a weight of evidence approach is a critical deficiency that seriously limits any conclusions that can be drawn. To ensure clarity and consistency in the scientific evaluation process, EPA should (1) develop a clear weight of evidence framework to identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study; and (2) integrate evidence based upon strengths, limitations, and relevance. This approach should be implemented in all programs and codified in EPA's risk evaluation framework regulations under the LCSA.

IV. Independent and Robust Peer Review

Peer review is essential in the evaluation of scientific information to ensure the development of scientifically defensible assessments. It also allows for the review of the underlying assumptions, methodology, criteria, and conclusions reached in the evaluation. EPA currently has several mechanisms to conduct peer review of scientific information including the Science Advisory Board, Science Advisory Panel, NAS contracted review and ad hoc peer review. As outlined in EPA's 2015 Peer Review Handbook,[8] "the success and usefulness of any peer review depends on the quality of the draft work product submitted for peer review, the care given to the statement of the issues or "charge," the match between the peer review draft product and the form of peer review, the match between the peer review draft product and the scientific/technical expertise of the reviewers, and Agency use of peer review comments in the final product."

Unfortunately, peer review processes and approaches are inconsistently applied throughout the Agency, including the selection of peer review panel members and the consideration given to public and peer review comments. During some EPA peer review meetings, the peer reviewers have appeared to be overly deferential to EPA and reluctant to be seen as criticizing EPA staff. We have also seen situations where peer reviewers have suggested discounting a study solely based on the funding source, without any considerations being given to the quality of the study. Also, EPA staff often comment throughout peer review meetings, essentially participating as peers, while industry experts are typically excluded

[8] EPA Peer Review Handbook 4th Edition, 2015. Available at https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf

from the dialogue. This practice undermines the integrity of the reviewers' role as independent and external to the assessment itself.

A critical element of peer review is also the consideration of public comments. The public plays an important role in the review process by helping identify key scientific information and potential concerns with the assessment being evaluated. Currently, there is no robust consideration of public comments in the peer review process. Reviewers on the EPA Science Advisory Board (SAB) are not given clear advice regarding what it means to "consider" public comments. In fact we have seen SAB chairs ignore public input because they are not required to address it. When this has occurred, SAB staff have not clarified to the peer reviewers that they can and should respond to public input.

In 2013, EPA's IRIS program announced a revised process that included an explicit response to comments step. However, 2016 IRIS assessments of trimethylbenzenes and ammonia and the 2017 ethylene oxide assessment contained no response to public comments in the final documents and only addressed peer review comments. This is a clear departure from EPA's commitment in step 5 of its IRIS process which states that the Agency "Develops a disposition of peer review and public comments and provides these as an appendix to the IRIS assessment."[9] Compounding concerns, the SAB committee reviewing the trimethylbezene assessment also did not respond to public comments, essentially creating a black hole where public comments are provided to the Agency but no clear responses are provided. Peer review should be independent and objective allowing for robust engagement with stakeholders to provide a thorough review. It should also include a quality assurance process that explicitly evaluates whether the peer review recommendations and public comments were completely and adequately addressed.

Conclusion

The incorporation of up to date scientific information, approaches and methods to ensure that EPA decision making is firmly based on high quality science is critical to protecting human health and the environment. This can be achieved by transparent, objective and consistent application of evaluation processes throughout EPA to evaluate and integrate scientific information utilizing a weight of scientific evidence process as required under the LCSA. Further, a robust and independent peer review process must be employed. ACC looks forward to working with members of the Committee to enhance the approaches to ensure that high quality science is the foundation to regulatory decision making regarding potential chemical hazards and risks.

[9] EPA IRIS Process Flow Chart. Available at https://www.epa.gov/sites/production/files/2014-03/documents/iris_process_flow_chart.pdf.

Kimberly W. White is a Senior Director in the American Chemistry Council's Chemical Products and Technology Division where she works in support of scientific research and chemical assessments that are firmly based on up-to-date scientific knowledge, meet the highest standards of scientific inquiry and are evaluated in accordance with the most relevant scientific approaches. For the past 5 years, Dr. White has served as a scientific advisor to industry partners for the development and execution of scientific research to inform chemical hazard assessments. She has also worked to identify emerging issues and trends in science policy and risk evaluation. Dr. White has presented at scientific symposia; collaborated to organize multi-stakeholder workshops to improve the conduct of chemical assessments; and managed scientific research programs. Additionally, Dr. White has coauthored publications on weight of evidence frameworks, problem formulation in chemical assessment and understanding potency information associated with human exposures. She has also been the lead representative in discussions with regulatory and chemical assessment agencies. In her most recent past position, Dr. White served as a Scientific Advisor with the American Petroleum Institute where she managed toxicology research, regulatory response, and product stewardship efforts for the oil and natural gas industry. She has also held positions as an Environmental Manager for Boar's Head Provisions Co., Inc. and as an Environmental Scientist for Resource Management Concepts, where she managed environmental compliance and sustainability efforts. Dr. White possesses B.S. and M.S. degrees in biology and a Ph. D in Environmental Toxicology.