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Wendy Cleland-Hamnett
Acting Assistant Administrator
Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave. NW.
Washington, DC 20460-0001

Submitted electronically to docket EPA-HQ-OPPT-2016-0654-0001

Re: Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act

Dear Ms. Cleland-Hamnett:

The Styrene Information & Research Center (SIRC)¹ appreciates the opportunity to submit comments on the U.S. Environmental Protection Agency's (EPA's) proposed rule "Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act."² SIRC supported the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). We are committed to working with EPA to successfully implement the amendments to the Toxic Substances Control Act (TSCA).

SIRC's comments focus on areas we support and recommendations for improving the transparency, feasibility and credibility of the chemical risk evaluation process. We encourage EPA to consider SIRC's suggested changes and areas needed of further clarification in the final rule.

Our comments are organized around the topics of:

¹ In North America, the Styrene Information & 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. Headquartered in Washington, D.C., SIRC was formed in 1987 as the principal focal point for the public information and research on styrene. SIRC is a non-profit organization consisting of 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. SIRC's charter also addresses the interests of ethylbenzene producers.

² 82 Fed. Reg. 7562 (January 19, 2017).

- A. Improving transparency and public participation,
- B. Science, governance, and incorporating scientific criteria,
- C. Providing workable requirements for manufacturer-initiated risk evaluations, and
- D. The relationship between risk evaluation and risk management.

A. Improving Transparency and Public Participation

Transparency and public participation are continuing themes of the LCSA. The LCSA enhances existing transparency and public participation requirements of the Administrative Procedures Act (APA) and in case law. It is incumbent on EPA to be transparent not only about the process and procedures it employs and the data it relies upon, but also the basis and reasoning leading to the agency's risk evaluation, risk characterization, and risk management decisions.

Transparency for multiple audiences. There are four broad audiences for which risk evaluation and risk management documents must be designed: the scientific community, EPA management, regulated industries, and the public. EPA's decisions in the risk evaluation process and their explanations must be drafted with all four audiences in mind.

Reasonable Comment Periods. SIRC encourages EPA to communicate with stakeholders throughout the risk evaluation process and provide the public with adequate time to comment. This ongoing dialogue will be essential for ensuring that EPA meets its statutory deadlines, and that its decisions are not undone by ignored information or procedural errors. For nearly 25 years and varying Administrations, Executive Orders have consistently provided for 60-day comment periods.³ While TSCA requires the agency to provide no less than 30 days for the public to comment on the draft risk evaluations,⁴ EPA should follow recommended practices and allow 60 days for comments on manufacturer-initiated risk evaluations, and 90 days for comment on EPA draft risk evaluation documents.

B. Science, Governance, and Incorporating Scientific Criteria

We applaud EPA's efforts to include the scientific criteria as required by Section 26 of TSCA and references in the proposed regulatory text and descriptive material in the preamble. However, the failure of the agency to describe or define key terms suggests that the agency itself does not know what the terms mean, lacks internal agreement, or is attempting to cloak arbitrary

³ Executive Order 12866, Section 6(a)(1), 58 Fed. Reg. (Oct. 4, 1993). "In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days." While E.O. 12866 was revoked by Executive Order 13497 on January 30, 2009, it was replaced by Executive Order 13563 on January 18, 2011, which carried forward the 60-day comment period directive in section 2(b): "To the extent feasible and permitted by law, each agency shall afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally be at least 60 days." 76 Fed. Reg. at 3822 (Jan. 21, 2011).

⁴ 15 U.S.C. §2605(b)(4)(H).

decision making behind a veil of unscientific vagueness. None of these serve the agency or the public. If the agency's actions are based on science, this should be, like science, subject to a prior description, even if that is an unprovable theory or hypothesis remaining to be validated. It is just as helpful to describe what is unknown or uncertain as to describe what is known.

SIRC urges the agency to describe what it means by both science and best available science in governmental rulemakings. Our comments in Enclosure B present a short selection of expert views, including the limits on the use of science in government rulemakings. Science can describe what may happen, but the characterization of risk is a value-based determination based on societal determinations, which can vary.

For scientific criteria, we provide thoughts on terminology, such as weight of the evidence, unreasonable risk, conditions of use, and sentinel exposure. SIRC urges EPA to include definitions in the regulatory text and use language in the preamble to the final rule explaining how it interprets these significant terms and how they will be applied in the risk evaluation process.

SIRC agrees that EPA should develop a list of guidance documents on which each risk evaluation relies. But, a list of guidance documents and a list of scientific studies or information that the agency considered during the rulemaking is facially inadequate. Decisions must be supported by a description of how EPA applied its guidance to each step of the risk evaluation process and the Agency's rationale for its decisions. As for data quality, EPA must list and comply with the agency's data quality guidelines, issued under the Information Quality Act (IQA) and OMB's government-wide guidance. Failure to reference the IQA guidelines, which the agency is legally bound to follow, is a major oversight.

C. Providing Workable Requirements for Manufacturer-Initiated Risk Evaluations

SIRC encourages EPA to adopt a more flexible approach for manufacturer-initiated risk evaluations. The process should be similar for EPA and manufacturer-initiated risk evaluations.

EPA's unstated premise is that manufacturers know every downstream use and have detailed information concerning such uses. This is unrealistic. Throughout many segments of industry, downstream users treat various uses and processes as trade secret, proprietary or confidential information. Our legal and free enterprise system has respected these property rights. EPA itself administers systems under which companies that wish to use data held by EPA must fairly compensate the company who paid to have the information developed.

In the proposed rule, EPA is requiring manufacturers to provide significant information upfront to perform a risk evaluation given that the manufacturer must address all conditions of use, even uses the manufacturer does not engage in or have experience with. Requiring information

addressing *all* conditions of use might render impossible the statutory right of manufacturers to seek a risk evaluation through unachievable requirements.⁵ If a manufacturer seeks a risk evaluation, either the agency should issue notices seeking additional data for conditions of use that the manufacturer does not have information about (such as opening a docket) or it should permit a tailored evaluation based on the conditions of use of which the manufacturer is aware.

Finally, SIRC objects to the proposed requirement in Section 702.37(b)(4) that submitters must commit to providing EPA (upon request) with any risk assessment they possess or reasonably obtain or if they performed a risk assessment in the past. This requirement presents several legal concerns given that risk assessments are performed for many purposes and in a variety of approaches that may contravene EPA's approach or the LSCA. Risk assessments can also be done in anticipation of potential litigation or for confidential or proprietary risk management considerations. Thus, a company's risk assessment could be protected as attorney/client work product or other confidentiality protections.

D. The Relationship Between Risk Evaluation and Risk Management

Risk evaluation must support EPA's risk management functions. There is a process boundary between these two phases of TSCA implementation. Prioritization and risk evaluations under Section 6 (existing chemicals) must be conducted "without consideration of costs or other non-risk factors."⁶ But, "[i]t is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided under this chapter."⁷ The agency's "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."⁸

From this perspective, it is critical that agency decision makers not "hide behind science," but explain the why and what of their decisions in the risk evaluation and risk management process. Risk management determinations must articulate the often-difficult balancing of competing ideas, interests and facts. This is the fundamental point that Professor Wendy Wagner, a

⁵ SIRC does not agree that EPA must consider all possible conditions of use. We address that topic in our comments.

⁶ 15 U.S.C. 2605b(4)(A).

⁷ 15 U.S.C. §2601(c).

⁸ 15 U.S.C. §1601(b)(3).

former EPA staff member, made in her seminal 1995 article, “The Science Charade in Toxic Risk Regulation.”⁹

Despite growing pressure for an improved science-based regulatory system, however, surprisingly little effort has been dedicated to determining why past science-based regulatory strategies have failed. This Article squarely confronts this question by positing that these past failures are at least partly attributable to a pervasive “science charade,” where agencies exaggerate the contributions made by science in setting toxic standards in order to avoid accountability for the underlying policy decisions. Although camouflaging controversial policy decisions as science assists the agency in evading various political, legal, and institutional forces, doing so ultimately delays and distorts the standard-setting mission, leaving in its wake a dysfunctional regulatory program.

Although not a complete cure, a legal remedy that requires agencies to separate science from policy and entrusts the courts with reviewing the accuracy of these science-policy delineations may be an effective means of combating the charade.

Professor Wagner’s views on agency decision making were the basis for guidance developed by the Administrative Conference of the United States (ACUS) titled “Science in the Administrative Process.”¹⁰ Those recommendations align with Congressional direction in the amended TSCA. As explained in our comments, ACUS’s “Suggested Agency Practices Regarding the Use of Science in the Administrative Process” gives best practices benchmarks for EPA to follow. These recommendations include these concepts:¹¹

- Explaining agency scientific decision making
- Assuring transparent assessments
- Disclosing underlying studies and data
- Checkpoints and explanations
- Attribution for agency personnel (authorship credit)
- Encouraging debate

⁹ Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 Colum. L. Rev. 1613, 1614 and 1719 (footnotes omitted) (1995).

¹⁰ ACUS Administrative Conference Recommendation 2013-3, *Science in the Administrative Process* (June 14, 2013), available at https://www.acus.gov/sites/default/files/documents/Science%20Recommendation%20APPROVED-FINAL_1.pdf. The Recommendation notes that it “is based upon a report that deals with agency research and decisionmaking related to the natural sciences. WENDY WAGNER, *SCIENCE IN REGULATION: A STUDY OF AGENCY DECISIONMAKING APPROACHES* (Feb. 18, 2013).” ACUS “is an independent federal agency dedicated to improving the administrative process through consensus-driven applied research, providing nonpartisan expert advice and recommendations for improvement of federal agency procedures. Its membership is composed of innovative federal officials and experts with diverse views and backgrounds from both the private sector and academia.”

¹¹ Recommendation at pp. 4-7.

- Addressing legal obstacles to transparent decision making and
- Data disclosure

Most topics on the ACUS list are addressed in the preamble or proposed rule. However, among the recommendations not addressed are those involving encouraging debate, attribution for agency personnel, and addressing legal obstacles to transparent decision making. EPA should acknowledge the ACUS Recommendations and commit to implementing them. Enactment of the LCSA did not occur in a vacuum; the work of the ACUS, academics and others help set the stage for Congress' drafting and enactment of the amendments.

Thank you for the opportunity to provide comments on this proposed rule. SIRC looks forward to working with EPA to ensure the smooth and effective implementation of the risk evaluation regulation.

Sincerely,

A handwritten signature in black ink that reads "Jack Snyder". The signature is written in a cursive, flowing style.

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Enclosures

- A. Risk Evaluation Comments of the Styrene Information and Research Center
- B. Science and Governance Considerations

**Enclosure A – Comments of the Styrene Information and Research Center, Inc.
On EPA’s Proposed TSCA Chemical Risk Evaluation Rules**

A. Improving Transparency and Participation in the Rulemaking Process

As we stated in our comments of August 24, 2016, risk evaluations under TSCA should be transparent and provide the public with adequate opportunity to participate in the regulatory process. SIRC appreciates the early outreach and public meeting EPA held to prepare for drafting the scoping documents for each of the “First Ten” substances up for risk evaluation under this amended program. SIRC encourages EPA to continue that early outreach as it selects chemicals for future risk evaluations, and to allow stakeholders to share information about the chemicals on the public docket.

1. Transparency is Required

Transparency must be a priority for EPA as it performs risk evaluations not only to follow the express directions of Congress, but also to satisfy legal requirements under the Administrative Procedures Act (APA). Congress directed EPA to “show its work” and share with the public its process, data and reasoning used to make unreasonable risk decisions. EPA must provide its reasoning for a regulation: “If the notice fails to provide an accurate picture of the reasoning that has led the agency to the proposed rule, interested parties will not be able to comment meaningfully upon the agency’s proposal.”¹² Further, EPA must inform the public of the “nature and basis of the regulation or rule sufficiently to enable them to understand and identify the material issues relating to the justification for the regulation or rule so that they can comment thereon intelligently.”¹³ It is critical that EPA is transparent with the public about the process it uses and data it relies on, and criteria used to make risk evaluations so the public can comment effectively.¹⁴

Transparency and public participation are already required by the APA¹⁵ and case law, and enhanced by the LCSA. It is incumbent on EPA to be transparent not only about the process and procedures it employs and the data it relies upon, but also the basis and reasoning leading to the agency’s risk evaluation, risk characterization, and risk management decisions.

¹² *Connecticut Light & Power v. NRC*, 673 F.2d 525 (D.C. Cir. 1982).

¹³ *National Asphalt Pavement Association v. Train*, 539 F.2d 775 (D.C. Cir. 1976).

¹⁴ See also, *Ohio Valley Env'tl. Coalition v. United States Army Corps of Eng'rs*, 674 F. Supp 2d 783, 802-03 (S.D. W. Va. 2009).

¹⁵ 5 U.S.C. §553.

2. Transparency for multiple audiences

With governmental risk management as the goal, there are four broad audiences for which risk evaluation and risk management documents must be designed:

- (1) Scientific community. It is essential to have full understanding among scientists and to maintain EPA's credibility.
- (2) EPA management. Management is tasked with performing risk evaluations under the LSCA criteria and applying the risk management statutory criteria or governmental policies for taking potential regulatory action. The risk evaluation work product should make EPA management's job both easier and harder, that is, make it easier to understand the scientific opinions, but transparent enough that ranges or uncertainty and alternate explanations will prompt EPA to articulate the factors supporting its risk management decisions.
- (3) Public participation. This group includes the general public, interested citizens, and individuals with a good understanding of the scientific and regulatory issues and framework.
- (4) Regulated Industries. Industries that make or use chemicals undergoing a risk evaluations must be able to understand the research used and the science behind the conclusions EPA makes about the chemicals and why decisions are made.

3. Encouraging public participation

SIRC encourages EPA to communicate with stakeholders throughout the risk evaluation process and provide the public with adequate time to comment. For nearly 25 years and varying Administrations, Executive Orders have consistently provided for 60-day comment periods.¹⁶ While TSCA requires the agency to provide no less than 30-days for the public to comment on the draft risk evaluations,¹⁷ EPA should allow 60 days for comments on manufacturer-initiated risk evaluations, and 90 days for comment on EPA draft risk evaluation documents rather than leave the regulatory text ambiguous as proposed "no less than 30 days."

¹⁶ Executive Order 12866, Section 6(a)(1), 58 Fed. Reg. (Oct. 4, 1993). "In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days." While E.O. 12866 was revoked by Executive Order 13497 of January 30, 2009, it was replaced by Executive Order 13563 of January 18, 2011, which carried forward the 60-day comment period directive in section 2(b): "To the extent feasible and permitted by law, each agency shall afford the public a meaningful opportunity to comment through the Internet on any proposed regulation, with a comment period that should generally be at least 60 days." 76 Fed. Reg. at 3822 (Jan. 21, 2011)

¹⁷ 15 U.S.C. §2605(b)(4)(H).

Depending on how many conditions of use are evaluated for one given chemical and the complexity of the toxicological and exposure assessments, draft risk evaluations may well be lengthy and complicated, and lead to significant risk management decisions that impact the whole supply chain. Because risk evaluation documents are often complex, and because the release of the risk evaluation docket will likely be accompanied by new information or references being added to the rulemaking docket, a comment period of 90 days is needed. Further, for manufacturer-initiated risk evaluations, a defined comment period is needed to prevent potential delays. SIRC supports the American Chemistry Council (ACC) recommendation of 60 days with extensions permitted for particularly complex manufacturer requests because the information presented will be similar to EPA's draft scoping documents.

Section 702.45 (Risk Evaluation Timeframes and Actions) should be revised as follows:

(a) *Draft risk evaluation timeframe.* The EPA will publish a draft risk evaluation in the Federal Register and provide no less than a ~~90~~ **30-day** comment period, during which time the public may submit comment on EPA's draft risk evaluation

Section 702.37 (Submission of manufacturer requests for risk evaluations) should be revised as follows:

(2) *Public notice and comment.* Within 30 business days of receiving a request that EPA has determined to be valid under paragraph (e)(1) of this section, EPA will submit for publication the receipt of the request in the Federal Register, open a docket for that request and provide ~~no less than a 30~~ **a 60 calendar day** public comment period, during which time the public may submit comments and information relevant to whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. In particular, comments identifying any information gaps in the request (*e.g.*, any conditions of use not identified in the request).

B. Science, Governance, and Incorporating Scientific Criteria

The preamble to the proposed rule states:

EPA is not proposing to establish highly detailed provisions that will address every eventuality or possible consideration that might arise. Due to the rapid advancement of the science of risk evaluation and the science and technology that inform risk evaluation, this proposed rule seeks to balance the need for the risk evaluation procedures to be transparent, without unduly restricting the specific science that will be used to conduct the evaluations, allowing the Agency flexibility to adapt and keep current with changing science as it conducts TSCA evaluations into the future.¹⁸

¹⁸ 82 Fed. Reg. at 7567.

We agree that science and scientific test methods will continue to evolve. The preamble references high throughput and genomic response assays, among the information the agency will consider. Ten or twenty years ago, it is doubtful these scientific methodologies would be mentioned. But, science policy and the details of the agency's scientific thinking should be clear and express, even if the agency's policies and thinking change. To ignore this is to abdicate EPA's statutory and civic duties in implementing TSCA.

Section 26 requires that in carrying out the risk evaluation process, EPA comply with certain scientific standards "in a manner consistent with the best available science" and must decide based on the weight of the scientific evidence.¹⁹ SIRC supports:

- EPA's proposed incorporation of the "availability of information" requirements of Section 26 in the regulatory text under Section 702.47, "publically available information."²⁰
- EPA's proposed incorporation of the weight of the evidence requirement for risk determinations as required by Section 26 of TSCA.²¹
- EPA's proposed incorporation of the scientific standards and considerations under Section 26(h) of TSCA in section 702.41(b).²²

These requirements are critical to include in the regulatory text of the final risk evaluation rule to ensure that EPA carries out these required considerations when deciding based on science, including risk determinations. SIRC supports the ACC's proposed recommendation that EPA articulate in the rule the key decision points that will require compliance with the Section 26 scientific requirements. These should include, but are not limited to:

- The proposed scope and final scope for risk evaluation

¹⁹ 15 U.S.C. §2625 (h)-(i).

²⁰ Consistent with TSCA Section 26(j), EPA requires in this proposed rule that for each risk evaluation, EPA will maintain a public docket so the public can access the draft scope, final scope and draft risk evaluation, and the final risk evaluation; all notices, determinations, findings, consent agreements, and orders; any information required to be provided to the Agency under 15 U.S.C. §2603; a nontechnical summary of the risk evaluation; a list of studies; the final peer review report, including the response to peer review; and response documents to the public comments on the draft risk evaluation.

²¹ Consistent with TSCA Section 26(i), EPA requires in this proposed rule that EPA ensure "all supporting analyses and components of the risk evaluation are suitable for their intended purpose, and well-tailored to the problems and decision at hand, in order to inform the development of a technically sound determination as to whether a chemical substance presents an unreasonable risk of injury to health or the environment, based on the weight of the scientific evidence." 82 Fed. Reg. at 7578.

²² In this section, EPA requires that information about uncertainty and variability in each step of the risk evaluation process be integrated into an "overall characterization and/or analysis of the impact of the uncertainty and variability on estimated risks," and that EPA include a discussion of issues associated with data quality (including intended use of information, assumptions used) and the extent independent verification or peer review is used in the risk evaluation."82 Fed. Reg. at 7579.

- Hazard assessment
- Exposure assessment
- Selection and evaluation of technical procedures, measures, methods, protocols, methodologies, and models
- Basis for scientific assumptions
- Selection and evaluation of quality assurance procedures
- Decisions regarding variability and uncertainty
- Statistical methods
- The draft and final risk evaluation

While the scientific requirements of Section 26 of TSCA are largely incorporated into the regulatory text and need to be expanded as explained in the previous section, EPA fails to articulate a definition or concept for key scientific terms, including “weight of the evidence,” “best available science,” and “unreasonable risk.” EPA is clear about its intent and purpose for this rulemaking,²³ but these terms are not adequately defined by EPA and will be critical to clarify in a final rule.

1. Explaining Terminology – Weight of Evidence, Best Available Science, Conditions of Use, and Unreasonable Risk

Key scientific terms should be describable at least in terms of theory, hypotheses, practices, or experimentally validated learning. These are terms of governance, and EPA has an obligation to explain, in advance, how it will act when it uses these terms. Using undefined terms leaves the agency open to valid criticism and the prospect of arbitrary and capricious action based on an inconsistent application of these statutory terms to different substances, ultimately undermining the agency’s efforts and those of the public.²⁴ SIRC urges EPA to articulate in regulatory text—or the preamble language—how it interprets these significant terms and how they will be applied in the risk evaluation process.

a. Weight of the Evidence

SIRC appreciates the agency’s observation that the term weight of the evidence (WoE) has been used to describe approaches that vary in their details.²⁵ Six years ago, the National Academy of

²³ SIRC supports EPA’s stated purpose of the risk evaluation process in the regulatory text: “Purpose: This subpart establishes the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B).” 82 Fed. Reg. at 7575.

²⁴ *AFL-CIO v. OSHA*, 965 F.2d 962 (11th Cir. 1992)(OSHA’s unexplained use of varying safety factors in setting exposure limits for different substances deemed arbitrary and capricious).

²⁵ See, e.g., Lorenz R. Rhomberg, et al., A survey of frameworks for best practices in weight-of-evidence analyses, *Crit. Rev. Toxicol.*, 43(9): 753–784 (2013)(reviewed approximately 50 existing WoE frameworks).

Sciences (NAS) proposed a “roadmap” for reform and improvement of the Agency’s risk assessment process and called for development of a transparent and defensible methodology for weight-of-evidence (WoE) assessments.²⁶ This is the time and context for EPA to present a transparent and defensible methodology, which would be the basis for both good science and good governance.

Rhomberg, et al. (2013)²⁷ identified four phases of WoE:

- defining the causal question and developing criteria for study selection,
- developing and applying criteria for review of individual studies,
- evaluating and integrating evidence and
- drawing conclusions based on inferences.

We suggest that EPA adopt the ACC’s proposed definition of weight of the evidence in the regulatory text:

Weight of the evidence means a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

SIRC urges EPA to adopt this definition rather than neglecting to provide any definition based on a concern that science will evolve. Our proposed definition starts from that set out by the lead Senate Democratic negotiators of the LCSA.²⁸ The general considerations that the agency will take in risk characterization and risk determination should be established. Science will evolve and the agency’s experience with WoE reviews under TSCA will evolve. But, establishing regulatory criteria does not mean that the agency cannot change its policies and procedures. From an administrative law perspective, the path forward for change is simple: (1) the agency acknowledges its current policy or practice, (2) explains what new information or experience necessitates a change, and (3) presents the agency’s new policy or practice.

SIRC also encourages EPA to elaborate on its approach to risk characterization. The preamble to the final rule should discuss integrating and evaluating information during risk characterization. The WoE process includes:

²⁶ National Research Council (NRC), Review of the environmental protection agency’s draft IRIS assessment of formaldehyde (2011)(National Academies Press).

²⁷ Rhomberg, et al., n. 20, supra.

²⁸ The proposed definition uses that of the lead Senate Democratic negotiators on the LCSA. 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>.

- Assess all animal and human data relevant to mode of action (MoA), their human relevance and dose-response;
- Evaluate what types of data have been considered (i.e. human, animal, in vitro, MoA, or adverse effects or biological perturbations that may be markers of the apical effect);
- Trace the reasoning by which these data bear on evaluation of the assessment question;
- Consider alternative modes of action and develop a biological story for each plausible MoA/endpoint combination – articulate the reasoning behind how the endpoint illustrates an underlying causal process of potential concern;
- Consider relevance, response and predictive nature of the outcomes being treated as potential evidence, and use knowledge from other information (e.g. understanding of biological processes and pathways) and relationships on other chemicals to inform the relevance determinations, such as counterfactuals (observations that outcome changes when a hypothesized key causal element is removed);
- State professional judgments explicitly, noting the role of epistemic values and standards for declaration of sufficiency of evidence;
- Focus on exposures of concern for a chemical rather than solely on hazards that might be posed by that chemical at some sufficiently high, but unlikely exposure – consider the range of exposures relevant to the problem formulation in drawing conclusions about possible toxicity-generating processes;
- Use diagrams to help articulate and communicate causal hypotheses;
- Evaluate and integrate negative and null results in addition to positive results;
- Integrate data across all lines of evidence so interpretation of one will inform interpretation of the others. For example:
- Ask, if the proposed causative process and MoA were true, what other observable consequences should it have, and are these in fact seen;
- Note assumptions, especially when they are ad hoc because they are introduced to explain phenomenon already seen;
- Evaluate, compare and contrast alternative explanations of the same sets of results. Compelling hypotheses not only “are consistent” with particular pieces of data, but actually explain the array of results at hand much better than competing, contrary hypotheses;

- Present conclusions (in text, tables and figures) not just as the result of judgments, but in the context of how they were derived and chosen over competitors, including sensitivity analysis of dependence of conclusions on specific data or assumptions;
- Recognize that applying specific study results to address a more general causation question is an exercise in generalization.
- Based on results of the WoE evaluation, identify significant data gaps and needs and propose next steps;
- Clearly present and communicate the WoE results.

In the risk characterization phase, WoE determinations are characterized by clear articulation of the reasoning behind the conclusions and the basis for reaching them, and clear articulation and presentation of the relative support for each alternative, biologically plausible hypothesis. The WoE conclusions are communicated via narrative discussion, and accompanied by succinct diagrams, tables and figures to illustrate the logic and results of the WoE evaluation, including alternative explanations of the data.

b. Best available science

When considering the term “best available science,” SIRC encourages EPA to use the best—and all—available data for its TSCA evaluations. SIRC recommends that EPA adopt ACC’s proposed definition of the Best Available Science:

Best available science means information that has been evaluated based on its strengths, limitations and relevance and the Agency is relying on the highest quality information. In evaluating best available science the Agency will also consider the peer review of the science, whether the study was conducted in accordance with sound and objective practices, and if the data were collected by accepted methods or best available methods. To ensure transparency regarding best available science the Agency will describe and document any assumptions and methods used, and address variability, uncertainty, the degree of independent verification and peer review.

Regarding evaluation requirements, EPA should also amend proposed section 702.39(a)(2) to clarify that EPA will consider the “most recent version of EPA guidance” when relevant, rather than “existing EPA guidance” to ensure the most up to date scientific information is considered. As noted in our August 24, 2016, comments, EPA should not solely rely on existing hazard assessments from EPA program offices, or from other federal hazard assessment programs because those assessments represent only a point-in-time determination and may not reflect subsequent and substantive new data that could significantly inform or change the earlier

conclusions. All new, or previously unconsidered, data should be thoroughly and carefully integrated into EPA's final hazard evaluations.

SIRC also recommends that EPA consult its own Data Quality Guidelines as a resource for conducting risk evaluations. We encourage EPA to utilize resources already published by recognized scientific authorities to inform risk evaluations, such as data and conclusions already in place under the EU's Regulation for Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program and Health Canada. Similarly, the agency should take advantage of data and conclusions of other chemicals management programs when the chemical exposures are comparable. EPA should also have a formal plan for systematic review, including problem formulation and scoping, clear parameters for determining data quality, and application of a "weight of the evidence" approach to provide credible hazard assessments.

Regarding EPA's ability to rely on the best available science, SIRC also encourages EPA to use its existing resources, such as issuing a Notice of Data Availability (NODA), to inform stakeholders as the agency gathers more information, even after the initial scoping document has been published for a chemical substance. For the purposes of transparency and public participation, and relying on the most current information, this approach would allow the public to promptly access new information and avoid delays or objections if EPA's decision rests on data not previously disclosed.

c. Conditions of use

SIRC does not agree with EPA's interpretation of "conditions of use" in the proposed rule that conditions of use encompass all circumstances in which the chemical is used, manufactured, disposed of etc. rather than meaning "the circumstances, as determined by the Administrator, under which the chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." 15 U.S.C. §2602(4). For EPA to expeditiously complete risk evaluations and meet statutory deadlines, EPA must select particular circumstances ("the circumstances") in which to evaluate a chemical, as the statute requires, and determine which conditions of use are appropriate for risk evaluation. If EPA adopts a fit for purpose approach, it must allow for low risk uses to be reviewed more expeditiously and so more resources can be spent on comprehensive risk evaluations for uses with higher hazard and exposure.

EPA should also allow the scoping document detailing the conditions of use to be amended when appropriate. The scoping document should not be "locked down" as proposed; the public should not be prohibited from submitting to EPA new use information so certain conditions of use can be added or deleted as new information is discovered. As ACC's comments suggest, EPA should articulate in the final rule that EPA has the discretion upon showing of substantial need

or changed circumstances, or if the circumstances otherwise warrant an amendment, to remove or add a condition of use.

Also, EPA maintains that it will consider all conditions of use, but those conditions of use must be understood and defined within the context of the risk evaluation that EPA must perform. Within the context of “reasonably foreseeable uses,” the Agency should not consider speculative conditions of use because the lack of data, range of variables and degree of uncertainty will not permit a meaningful risk evaluation or risk determination. The LCSA repeatedly uses reasonably available science, data and information as the foundation of EPA TSCA regulation. The absence of adequate data regarding speculative conditions of use means that risk assessment and risk management are not appropriately triggered under TSCA. One of the outcomes of EPA’s risk management of existing chemicals under TSCA is to clarify what conditions of use are approved or restricted for substances on the TSCA Inventory. EPA has the authority to regulate novel and significant new uses not subject to a risk evaluation by promulgation of a significant new use rule (SNUR) under section 5(a)(2) of TSCA.

EPA should clarify, consistent with Congressional intent, that conditions of use does not include intentional misuse of a product.²⁹ If EPA is concerned about potential misuse of a substance under evaluation, it can promulgate a SNUR to address that. The SNUR approach would allow EPA to restrict potential misuses by negatively defining the regulated uses as, e.g., every use not considered in its section 6 risk evaluation for the substance. This would be significantly easier than positively defining all potential misuses in the context of a risk evaluation and equally effective. Conditions of use are limited to normal and readily foreseeable uses for which adequate information exists.

EPA should also clarify that the conditions of use should not include non-TSCA uses. The regulatory text should explicitly exclude substances not regulated under TSCA in the risk evaluation. Other statutes such as the Occupational Safety and Health Act (OSH Act), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Food, Drug and Cosmetic Act regulate uses that are outside TSCA such as pesticides, foods, drugs, cosmetics, tobacco products, and firearms. TSCA fills the gaps for the uses these statutes do not address.³⁰

²⁹ An array of other statutory programs address potential abuses, e.g., Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), 42 U.S.C. §§ 9601-9675; Solid Waste Disposal Act 42 U.S.C. §§ 6901-6992k)(which includes the Resource Conservation and Recovery Act), the Federal Hazardous Substances Act, 15 U.S.C. §§1261–1278 (see also 15 C.F.R. 1500.3), and the Occupational Safety and Health Act, 29 U.S.C. §651 et seq. (29 U.S.C. §654(a)(1) general duty clause).

³⁰ The amended TSCA in fact requires EPA to consult with OSHA when regulating worker exposures, further illustrating that TSCA is intended to fill the gaps in addressing exposures not already covered by other federal statutes: “To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.” 15 U.S.C. §2604(f)(5).

Finally, SIRC does not support EPA's proposal to explicitly consider alternative interpretations of results generated from the risk evaluation. The statute does not require this consideration of alternatives for risk evaluations, and a consideration of other interpretations of data could already be addressed if the Agency takes the weight of the evidence approach.

d. Unreasonable Risk

EPA does not define unreasonable risk. We agree that a rigid, prescriptive definition of unreasonable risk is not viable given potential advances in scientific understanding. Rather than focusing on a "definition," EPA should provide a framework discussion in the rule.

In the health and safety area, there are helpful examples, including those that did not consider non-risk costs. As one Supreme Court case noted, safety involves the assessment of whether the health gain justifies the health risk.³¹ This follows the observations of a scholar regarding the meaning of unreasonable risk under the original statute.³²

EPA must undertake regulatory action if it finds that use of a chemical "presents or will present an unreasonable risk of injury to [human] health or the environment." Congress deliberately chose not to define "unreasonable risk," but the legislative history makes it clear that it depends on a case-by-case consideration of the severity and likelihood of harm as against the benefits of the chemical, but does not include *de minimis* risks.

At outset, we can observe that the statute regulates risk without proof of actual harm. But the power to regulate mere risk could lead to the absent of value to society. The statutory unreasonable risk standard follows the judicial inference that safe does not mean absolute safety. In TSCA, Congress rejected the objective of a risk-free society.³³ The unreasonable risk standard incorporates cost-risk-benefit balancing to answer the question raised by relative safety.³⁴ EPA may not act without considering the degree of risk involved, the costs associated with regulation, and the benefits³⁵ that may be achieved by the proposed regulation. Finally, because the unreasonable risk standard is based on balancing several disparate factors, it

³¹ U.S. v. Rutherford, 442 U.S. 544 (1979). In evaluating the Food and Drug Administration's actions on a putative anti-cancer drug, the court stated that "a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." Id. at 556. The FDA evaluations was whether the "expected therapeutic gain justifies the risk entailed by its use." Ibid.

³² Applegate, John S., "The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control" 91 Columbia L. Rev. 261, 269 (1991)(footnotes omitted).

<http://www.repository.law.indiana.edu/facpub/719>.

³³ H.R. Rep. No. 1341, 94th Cong., 2d Sess. 13-15 (1976); see also Environmental Defense Fund, Inc. v. EPA, 636 F.2d 1267, 1278 n.30 (D.C. Cir. 1980).

³⁴ .See H.R. Rep. No. 1341 at 14, 35 (describing unreasonable risk in TSCA); S. Rep. No. 698, 94th Cong., 2d Sess. 12, reprinted in 1976 U.S. Code Cong. & Admin. News 4491, 4502 (same); S. Rep. No. 970, 92d Cong., 2d Sess. 10-11, reprinted in 1972 U.S. Code Cong. & Admin. News 4092, 4095 (describing unreasonable risk in FIFRA).

³⁵ By benefits, we do not mean costs or other non-risk factors, which are prohibited from consideration during the risk evaluation stage in the LCSA.

entails *ad hoc*, case-by-case decision making. Congress seems to approve of the case-by-case approach.

Therefore, SIRC supports adding ACC's suggested definition of unreasonable risk:

Unreasonable risk means that the Administrator has considered relevant factors including the effects of the chemical substance on health and the magnitude of human exposure to such substance under the conditions of use and the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance under the conditions of use. Factors considered to reach this risk-based determination may include: characterization of cancer and non-cancer risks (including margins of exposure for non-cancer risks), characterization of environmental risk, the population exposed (including any susceptible populations), the severity of hazard (the nature of the hazard), the irreversibility of hazard, and uncertainties associated with the analyses and data.

e. Sentinel Exposure

EPA proposes to define sentinel exposure to mean the "exposure(s) of greatest significance, which may be the plausible maximum exposure to an individual, population (or subpopulation), or the environment to the chemical substance of interest (or any combination thereof)."³⁶ SIRC encourages EPA to more clearly describe the term "sentinel exposure" to mean the exposures of greatest *toxicological or ecological* significance..." to more appropriately characterize the risk. SIRC also supports the ACC's assessment of EPA's proposed sentinel exposure definition that the use of the word "maximum" is problematic because it does not capture how the sentinel exposure approach is used by other international bodies. Relying on the highest exposure scenario does not mean that the maximal exposure is used. SIRC supports ACC's suggestion to use the term "plausible exposure" or "plausible upper bound exposure"

2. Information Quality Act

EPA has developed guidance on data quality, consistent with its obligations under the Information Quality Act.³⁷ The agency should reference its IQA guidelines in the rule, or, at minimum, the preamble to the final rule, when discussing the data relied upon in a risk evaluation. Obviously, the guidelines are part of the agency's established process to ensure data quality and must be observed.

³⁶ 82 Fed. Reg. 7576.

³⁷ Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated (October 2002) and available at <https://www.epa.gov/sites/production/files/2015-08/documents/epa-info-quality-guidelines.pdf>.

Transparency and public participation are continuing themes of the LCSA, which aligns with and reinforces Congress' direction under the IQA. Congress enacted the IQA to "ensur[e,] and maximiz[e,] the quality, objectivity, utility and integrity of information . . . disseminated by Federal agencies".³⁸ It required the Office of Management and Budget (OMB) to issue government-wide implementing guidance.³⁹ It also instructed each agency to issue its own guidelines, with two functions: (i) to apply the OMB Guidelines to the agency's particular circumstances, and (ii) to "establish administrative mechanisms allowing affected persons to seek *and obtain* correction of information . . . disseminated by the agency that does not comply with the [OMB] guidelines. . . ." ⁴⁰

OMB's Guidelines require all disseminations to meet "a basic standard of quality . . . appropriate to the nature and timeliness of the information . . ." ⁴¹ They define "quality" in terms of objectivity, utility and integrity.⁴² "Objectivity" is centrally relevant in cases of scientific health assessments. Objectivity has significant consequences both for the substance of such information and the way it is presented, as discussed below. "Utility" is also important as it refers to the usefulness of the information to its intended users, including the public.⁴³

Objectivity in Substance — From a substantive perspective, "objectivity" means that information must be *accurate, reliable and unbiased*.⁴⁴ Scientific information must be generated using sound statistical and research methods.⁴⁵ "Influential" scientific information must be sufficiently transparent to be reproduced, subject to several caveats.⁴⁶ This means, with respect to analytical results, that agencies must provide "sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public."⁴⁷

Influential information regarding risks to health, safety or the environment must be based on requirements, drawn from the Safe Drinking Water Act (SDWA), to use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and . . . data collected by accepted methods or best available

³⁸ Pub. L. No. 106-554, *supra* note 1, at § 515(a).

³⁹ See 67 Fed. Reg. 8452, *supra* note 2.

⁴⁰ Pub. L. No. 106-554, *supra* note 1, at § 515(b)(2)(B) (emphasis added).

⁴¹ 67 Fed. Reg. at 8458.

⁴² *Id.* at 8459; *cf.* 44 U.S.C. §3504(e)(1)(B) (2006).

⁴³ *Id.*

⁴⁴ 67 Fed. Reg. 8549 (emphasis added).

⁴⁵ *Id.*

⁴⁶ *Id.* at 8460.

⁴⁷ *Id.*

methods. . . .”⁴⁸ The same terminology of best available science was used by Congress again in the LCSA, further demonstrating the relevance of the IQA to risk evaluations under TSCA.

Objectivity in Presentation — Among other characteristics, “objectivity” means that information must be presented in an *accurate, clear, complete* and *unbiased* manner, which includes presentation in the proper context.⁴⁹ The sources of the information must be disclosed subject to confidentiality and privacy limits, and where appropriate, data should have full, accurate and transparent documentation, with sources of error identified.⁵⁰ Scientific, financial and statistical information must be accompanied by supporting data and models.⁵¹ Influential information regarding risks to health, safety or the environment must additionally meet requirement drawn from the SDWA; *i.e.*, it must be comprehensive, informative and understandable, and must specify: (i) each significant uncertainty and studies that would assist in resolving the same; and (ii) peer-reviewed studies that support, are directly relevant to or fail to support estimates and methodologies used to reconcile inconsistencies in data.⁵²

These core principles align with EPA’s proposals, and referencing the EPA IQA Guidelines is an important aspect of meeting the needs of the public and the mandates of both TSCA and the IQA.

3. Listing Guidance Documents

In the preamble to the proposal, EPA asks whether “a list of appropriate guidance documents be included on a case-by-case basis as part of the scoping document that undergoes public review and comment.”⁵³ SIRC agrees that EPA should publish a list of guidance documents. It should not be an administrative burden for EPA to compile a list of potentially relevant guidance documents. Such a list can be easily adapted to the review of any single chemical, and it is easy to envision that some guidance documents will have universal applicability, such as exposure guidelines, and IQA guidelines. Further, publication of a list will help the public know whether all appropriate guidelines have been properly considered by the agency.

We stress that, while listing guidance documents and information in the record is helpful, it does not relieve the agency of discussing the basis and rationale of its decisions so stakeholders can walk through the steps and details of EPA thinking and determinations. The LCSA, in a

⁴⁸ *Id.*; see also 42 U.S.C. §300g-1(b)(3)(A) (2006).

⁴⁹ 67 Fed. Reg. at 8459 (emphasis added).

⁵⁰ *Id.*

⁵¹ *Id.* at 8460.

⁵² *Id.*; see also 42 U.S.C. §300g-1(b)(3)(B).

⁵³ 82 Fed. Reg. at 7573.

variety of terms, repeatedly directs EPA to provide a transparent explanation of the how's and why's upon which its actions are based.

C. Providing Workable Requirements for Manufacturer-Initiated Risk Evaluations

Under section 702.37 of the proposed rule, EPA proposes to require that manufacturers who request a risk evaluation provide data upfront: “A request will meet EPA’s criteria if the request includes or references all information that is necessary for EPA to conduct a risk evaluation addressing all the circumstances that constitute conditions of use of the chemical substance within the meaning of TSCA Section 3...”⁵⁴ More so, if EPA determines that information is lacking, EPA will consider failure to submit additional information to be a withdrawal of the request to initiate a risk evaluation.

Most manufacturers, however, do not know or do not own or control much information regarding downstream uses. To produce that information to EPA in its consideration of the conditions of use of a chemical, the manufacturer must request that information from its customers. Because these are voluntary risk evaluations at the request of the manufacturer, the downstream user is not mandated to provide the manufacturer with the information for a risk evaluation. EPA is requiring manufacturers to provide significant information upfront to perform a risk evaluation given that in the proposed rule, the manufacturer must address all conditions of use, even uses the manufacturer does not engage in or have experience with.

In the final rule, SIRC encourages EPA to adopt a more flexible approach for manufacturers who do not have all the information EPA requires in the proposed rule to conduct a risk evaluation. Rather than requiring significant information addressing *all* conditions of use, manufacturers should just be required to provide information regarding conditions of use the manufacturer already has information on. For uses on which the manufacturer does not have information, rather than rejecting the manufacturer’s request, EPA can open the public docket — as the Agency already outlines in the proposed rule under Section 702.37(e)(2) — to gather more information from stakeholders about different conditions of use, and allow for other manufacturers and processors to voluntarily submit information on that chemical substance. If EPA wants to encourage manufacturers to use this regulatory option, EPA must acknowledge the real-world challenges manufacturers face of having limited use information and only require the submission of information the manufacturer already has or can reasonably ascertain in a time period.

Finally, SIRC objects to the proposed requirement in Section 702.37(b)(4) that submitters must commit to providing EPA (upon request) with any risk assessment they possess or reasonably obtain or if they performed a risk assessment in the past. This requirement presents several

⁵⁴ 82 Fed. Reg. 7576.

legal concerns given that risk assessments are performed for many purposes and in a variety of approaches that may contravene EPA's approach or the approach established in the LSCA. Risk assessments can also be done in anticipation of potential litigation or internal risk management considerations, and therefore, the company's risk assessment would be protected as attorney/client work product. The agency's risk evaluation process could be complicated and companies unfairly characterized if compelled to produce outdated or superseded risk assessments.

D. The Relationship Between Risk Evaluation and Risk Management

As EPA notes, risk evaluation should support EPA's risk management function. Stated in other terms, risk evaluation helps EPA frame its risk management functions. There is a process boundary between these two phases of TSCA implementation. Prioritization and risk evaluations under Section 6 (existing chemicals) must be conducted "without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment . . ." ⁵⁵ But, "[i]t is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided under this chapter." 15 U.S.C. §2601(c). The agency's "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment." 15 U.S.C. §1601(b)(3). Science is our best methodology for understanding what we can about the world and toxicology and environmental science provide the factual context for risk management decisions by the agency. But, as discussed, science provides no answer to the level of tolerable risk or the risk management actions. Those are, value and political determinations made within the context of EPA's statutory mandates.

From this perspective, it is critical that agency decision makers not hide behind science, but explain the why and what of their decision when making unreasonable risk determinations under section 702.43. Risk determinations, like risk management decisions, must articulate the often-difficult balancing of competing ideas, interests and facts. This is the fundamental point that Professor Wendy Wagner, a former EPA staff member, made in her seminal 1995 article, *The Science Charade in Toxic Risk Regulation*. ⁵⁶

⁵⁵ 15 U.S.C. 2605b(4)(A).

⁵⁶ Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 Colum. L. Rev. 1613, 1614 and 1719 (footnotes omitted) (1995).

Science has been the thorn in the side of environmental policy-makers since the dawn of environmental law. Sound environmental policy cannot be developed without some scientific basis; yet attempts to incorporate science into environmental regulations have met with failure. Reduced public participation, excessive regulatory delays, and the incomplete and inaccurate incorporation of science have plagued science-based environmental regulation for nearly three decades.

Toxic regulatory problems typically involve policy questions of great magnitude. That they also depend on science for their best resolution has been used by decision makers to divert attention away from the controversial policy choices and exaggerate the scientific justification for toxic standards in order to survive a number of legal, institutional, and political hurdles. Such behavior, however, presents serious consequences for democratic participation, leads to substantial delays in the regulation of toxics, and wastes judicial, administrative, and scientific resources. In order to offset the multiple, uniform incentives that cause this science charade, reforms that target the specific causes of the charade must be implemented.

While contemporary science can provide only partial answers to pressing environmental problems, this limitation is esoteric and often escapes the lay observer, leaving the capabilities of science susceptible to successful overstatement.

Overreliance on, and at times deliberate exaggeration of, the role of science in setting toxic standards are introduced to show that a science charade has pervaded toxics regulation for several decades.

Although not a complete cure, a legal remedy that requires agencies to separate science from policy and entrusts the courts with reviewing the accuracy of these science-policy delineations may be an effective means of combating the charade.

The statutory position of risk evaluation as a precursor to separate risk management determinations reflects Congress' direction to avoid the temptation to hide behind scientific risk evaluation and make risk management decisions transparent. This transparency is critical for many reasons, chief among them is enabling the public to understand why the agency took a particular approach and to provide a basis for demonstrating the agency is addressing similar risks equitably. The system can only be fair if the public and regulated community can compare and understand fair and equal treatment.

Professor Wagner's views on agency decision making were the basis for guidance provided by the Administrative Conference of the United States (ACUS) titled "Science in the Administrative

Process.”⁵⁷ Those recommendations align with Congressional direction in the amended TSCA. A summary list of pertinent “Suggested Agency Practices Regarding the Use of Science in the Administrative Process” follows using language from the ACUS Recommendation.⁵⁸

1. *Explaining Agency Scientific Decision making.* Agencies should explain in proposed and final decision documents how they ensured rigorous review of the scientific information underlying each science-intensive regulatory project. This includes a statement of how each agency evaluated the scientific information used in its analysis; how the agency provided that information to reviewers and the public; how the analysis was reviewed by experts and interested parties; and how the agency ensured that the final decision was supported by the scientific record.

2. *Assuring Transparent Assessments.* At an early stage in their decision making processes, agencies should identify the specific policy questions that may be informed by science; describe the design of the assessments needed to characterize risks and inform policy decisions; and describe the criteria to be used in reviewing and weighing existing studies. When completed, assessments should identify other appropriate analytical choices and explain why they were not chosen; provide a synthesis of the available evidence and relevant literature guided by the assessment design or criteria; identify significant assumptions and choices of analytical techniques; provide a statement of remaining uncertainties; and discuss how different plausible choices might change the results of the assessment. Where possible, agencies should also explain the relationship between their scientific findings and the final policy choice. Agencies should strive to communicate this information in a manner that is clear to the general public.

3. *Disclosing Underlying Studies and Data.* To the extent practicable and permitted by law and applicable policies, each agency should identify and make publicly available (on the agency website or some other widely available forum) references to the scientific literature, underlying data, models, and research results it considered. The agency should list all information upon which it relied in reaching its conclusions, and any information material to the scientific analysis it considered but upon which it ultimately

⁵⁷ ACUS Administrative Conference Recommendation 2013-3, Science in the Administrative Process (June 14, 2013), available at https://www.acus.gov/sites/default/files/documents/Science%20Recommendation%20APPROVED-FINAL_1.pdf The Recommendation notes that it “is based upon a report that deals with agency research and decision making related to the natural sciences. WENDY WAGNER, SCIENCE IN REGULATION: A STUDY OF AGENCY DECISIONMAKING APPROACHES (Feb. 18, 2013).” ACUS “is an independent federal agency dedicated to improving the administrative process through consensus-driven applied research, providing nonpartisan expert advice and recommendations for improvement of federal agency procedures. Its membership is composed of innovative federal officials and experts with diverse views and backgrounds from both the private sector and academia.”

⁵⁸ Recommendation at pp. 4-7.

did not rely. Consistent with the limitations in the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget and its own IQA guidelines, each agency should ensure that members of the public have access to the information necessary to reproduce or assess the agency's technical or scientific conclusions.

4. *Checkpoints and Explanations.* Agencies should establish explicit checkpoints for regulatory projects, defining both the conditions under which they intend to close their consideration of research or debate to reach a decision and when they might reopen that consideration, particularly when they are not bound by judicially enforceable deadlines. Agencies should explain their decisions to initiate, stop, or reopen consideration of research or debate. Such explanations should reference significant relevant ongoing research or other relevant factors.

5. *Attribution for Agency Personnel.* Agency personnel play an important role in producing their respective agencies' scientific analyses. Agencies should provide their personnel with some form of consensual attribution for reports or analyses to which they contribute in a significant way. If appropriate, such attributions should be made for personnel who contributed in a significant way to a technical or scientific report, including not only scientists but also economists, lawyers, and other contributors. Reviewers and other contributors could be identified by name and general contribution.

6. *Encouraging Debate.* Agencies should encourage vigorous debate among agency scientists and should explore ways of incorporating the diversity of that debate in any resulting work product. Agency employees should be encouraged to publish their scientific work in the peer reviewed literature, provided that they follow agency procedures and that confidential governmental deliberations are not compromised. Dissenting staff members should be protected from reprisals.

7. *Addressing Legal Obstacles to Transparent Decision making.* Agencies should identify legal obstacles that may impede otherwise appropriate public access to the scientific information underlying agency analyses or that may prevent the agencies' development of scientifically robust decision making processes. Agencies should recommend appropriate actions to eliminate such impediments, including revisions in existing law, to the Executive Office of the President.

8. *Data Disclosure.* To the extent practicable and in compliance with applicable legal restrictions, privileges, protections, and authorities, agencies should seek to provide disclosure of data underlying scientific research, including both privately and federally funded research being considered by the agencies.

Most topics in the ACUS list are addressed in the preamble or proposed rule. Among the Recommendations not addressed are those involving encouraging debate, attribution for agency personnel, and addressing legal obstacles to transparent decision making. EPA should acknowledge the ACUS Recommendations and commit to implementing them as best possible.

The ACUS recommendations apply to the entire risk evaluation process.

These principles should be evident in the regulatory language. We recommend revising §702.39 (Evaluation Requirements and Peer Review Procedures) in the proposed regulatory text as follows.

(b) Information and information sources

(4) Weight of scientific evidence. The Administrator shall make decisions based on the weight of the scientific evidence.

(5) Availability of Information. The Administrator shall make available to the public—

(i) a nontechnical summary of each risk evaluation;

(ii) a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those studies; and

(iii) an identification of the information, analysis, and basis used to make the designations each designation of a chemical substance.

(6) Reasonably available information. The Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

(e) Exposure assessment

(1) Where relevant, **take into account** the likely duration, intensity, frequency, and number of exposures under the conditions of use will be considered.

(2) Describe whether aggregate or sentinel exposures to a chemical substance were considered, and the basis for that consideration.

Section 702.41 (Risk Characterization and Peer Review Procedures) should be revised as follows:

(a) Risk Characterization Considerations. EPA will:

(1) integrate the hazard and exposure assessments into quantitative and/or qualitative estimates of risk for the identified populations (including any potentially exposed or susceptible subpopulation(s) identified in the final scope document published pursuant to 40 CFR 703.39(c)(6)(iv) and ecological characteristics for the conditions of use;

(2) the hazards and exposures for the conditions of use of the chemical substance will integrate and assess available information, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations,

(3) follow the data quality standards set forth in the Information Quality Act (“IQA”), Pub. L. No. 106-544 (2001), as well as the Office of Management and Budget’s guidelines, 67 Fed. Reg. 8452 (Feb. 22, 2002) and any EPA guidelines implementing the IQA; and

(4) describe whether aggregate or sentinel exposures under the conditions of use were considered and the basis for that consideration.

E. Conclusion

Thank you for the opportunity to provide these comments. SIRC looks forward to working with EPA to ensure smooth and effective implementation of the risk evaluation regulation.

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Enclosure B – Science and Governance

SIRC has included a comprehensive discussion of science and governance for EPA's consideration to reinforce the cornerstone values of the LCSA: public participation in the risk evaluation process and transparency in EPA decisions regarding chemical risk. The prudent administration of the scientific standards in TSCA, consistent with the academic concepts of science and governance, will benefit EPA as it establishes the risk evaluation process for existing chemicals.

While the term "science" is used pervasively, it means different things to different people. One might start by referencing scientific method, *careful, systematic and open reasoning about empirical evidence*. It is a powerful process for improving understanding and distinguishing between facts, inferences, and assumptions. It recognizes that our knowledge is incomplete or imperfect and, while recognizing that the bounds of knowledge can change, the range of likely answers from a regulatory perspective is reasonably bounded by the current state of scientific knowledge.

Another meaning of scientific method refers to the process of observation, development of a hypothesis and predictions based on that hypothesis, experimentation, and, ultimately develop a theory that consistently and accurately predicts the phenomena being observed. In this sense, a theory is a logical and consistent model or framework that describes some aspect of the universe. While the scientific method is widely taught, a body of literature criticizes this formulation as an inadequate or misleading description of the basis for scientific progress or discovery.⁵⁹

Science and Governance

Under the new statutory scheme, risk evaluation provides the basis for risk management, that is, appropriate action by the agency to address unreasonable risks. Both the statutory amendments and the proposed regulations use numerous scientific and technical terms. Science plays a critical role in this process, but what should be expected from science in the administrative process? What do we mean by 'science' and best available science? A common understanding of the meaning of these terms within the TSCA regulatory process is a prerequisite to meaningful communication within EPA, the scientific community and the public.

⁵⁹ Some examples include: Thomas S. Kuhn, "The Structure of Scientific Revolutions," N.R. Hanson, "Patterns of Discovery," and Paul Feyerabend, "Against Method." Suspicion followed by discovery is "the core of the empirical program of quantitative natural science." Fred L. Bookstein, "Geometry as Cognition in the Natural Sciences." The easiest, quick read on this are postings by Dr. Terry Halwes, who appears to be a professor in the Department of Psychiatry at Yale University School of Medicine. <http://www.dharma-haven.org/science/myth-of-scientific-method.htm>.

There is rich literature on the relationship between science and governance, sometimes referenced as science and the state (STS). Much of this focuses on participatory democracy, optimizing representative democracy and other very broad contract-with-the-state issues rarely addressed directly in agency rulemakings.

Sheila Jasanoff, the Pforzheimer Professor of Science and Technology Studies at Harvard University's John F. Kennedy School of Government is credited with helping establish STS as a distinct field of inquiry while also advancing research frontiers within the field. Her research centers on the role of science and technology in the authority structures of modern democracies, and focuses particularly on science in legal decision making.⁶⁰ While Professor Jasanoff refers to judges in this quote, within the context of her work, this guidance applies to both agency managers and political appointees.

It is not enough . . . to ask only the question that scientists have classically asked of each other's work: "Is it good science?" Judges, as society's delegates, should also ask the normative questions that must be raised in evaluations of public science: Is the science good for the purposes we need it for, and is it good enough for those purposes?⁶¹

A. Scientific Thinking

But agreement on the scientific method, which needs to be honored in agency science reviews, is an incomplete picture. We can characterize science as a method of discovering reliable knowledge about nature. Reliable knowledge is knowledge with a high probability of being true because its veracity has been justified by a reliable method.⁶²

The scientific method is practiced within a context of scientific thinking, and scientific (and critical) thinking is based on three things: using empirical evidence (empiricism), practicing logical reasoning (rationalism), and possessing a skeptical attitude (skepticism) about presumed knowledge that leads to self-questioning, holding tentative conclusions, and being undogmatic (willingness to change one's beliefs). These three ideas or principles are universal throughout science; without them, there would be no scientific or critical thinking.

⁶⁰ Her publications on these topics include *The Fifth Branch: Science Advisers as Policymakers* (Harvard University Press, 1990) and *Science at the Bar: Law, Science, and Technology in America* (Harvard University Press, 1995). Professor Jasanoff is a prominent member of expert groups in both the U.S. and the E.U. on these topics.

⁶¹ Sheila Jasanoff, *Technologies of Humility: Citizen Participation In Governing Science*, *Minerva* 41:223, at 234 (2003).

⁶² This discussion is based on and the following quote from Steven D. Schafersman, "An Introduction to Science: Scientific Thinking and the Scientific Method," (Jan. 1994) <http://www.freeinquiry.com/intro-to-sci.html>.

To quote Albert Einstein, “The whole of science is nothing more than a refinement of everyday thinking.”⁶³ As Nobel Prize recipient Gunnar Myrdal observed:

Facts do not organize themselves into concepts and theories just by being looked at; indeed, except within the framework of concepts and theories, there are no scientific facts but only chaos. There is an inescapable *a priori* element in all scientific work. Questions must be asked before answers can be given. The questions are an expression of our interest in the world, they are at bottom valuations.⁶⁴

B. Reference Manual on Scientific Evidence

The Reference Manual on Scientific Evidence is jointly authored by the Federal Judicial Center and the National Research Council.⁶⁵ The highly-regarded Chapter 3 of the Reference Manual is titled “How Science Works,” by David Goodstein. Given the focus of the risk evaluation proposal, this chapter by David Goodstein is relevant. Professor Goodstein begins by demonstrating that there is no coherent theory of science and that proposed theories are all seriously flawed.

The first is that science is, above all, an adversarial process. It is an arena in which ideas do battle, with observations and data the tools of combat. The scientific debate is very different from what happens in a court of law, but just as in the law, it is crucial that every idea receive the most vigorous possible advocacy, just in case it might be right. Thus, the Popperian ideal of holding one’s hypothesis in a skeptical and tentative way is not merely inconsistent with reality; it would be harmful to science if it were pursued. . . . not only ideas, but the scientists themselves, engage in endless competition according to rules that, although they are not written down, are nevertheless complex and binding.”

Professor Goodstein’s list of “Some Myths and Facts About Science” tells their own tale.

Myth: Scientists must have open minds, being ready to discard old ideas in favor of new ones.

Myth: The institution of peer review assures that all published papers are sound and dependable.

Myth: Science must be an open book. For example, every new experiment must be described so completely that any other scientist can reproduce it.

⁶³ “Ideas and Opinions,” p. 270, *Physics and Reality* (1936); *The Columbia World of Quotations* (1996) Columbia University Press.

⁶⁴ Gunnar Myrdal, *The Political Element in the Development of Economic Theory*, at vii (1955).

⁶⁵ “Reference Manual on Scientific Evidence,” Third Edition, Authoring Organizations: Committee on the Development of the Third Edition of the Reference Manual on Scientific Evidence; Federal Judicial Center; National Research Council (2011), available as a free pdf download at http://www.nap.edu/catalog.php?record_id=13163.

Myth: When a new theory comes along, the scientist's duty is to falsify it.

Myth: University-based research is pure and free of conflicts of interest.

Myth: Real science is easily distinguished from pseudoscience.

Myth: Scientists are people of uncompromising honesty and integrity.

Professor Goodstein's comparison of science and law echoes that of Sarewitz.

The objective of the law is justice; that of science is truth. These are among the highest goals to which humans can aspire, but they are not the same thing. Justice, of course, also seeks truth, but it requires that clear decisions be made in a reasonable and limited period of time. In the scientific search for truth there are no time limits and no point at which a final decision must be made. And yet, despite all these differences, science and the law share, at the deepest possible level, the same aspirations and many of the same methods. Both disciplines seek, in structured debate and using empirical evidence, to arrive at rational conclusions that transcend the prejudices and self-interest of individuals.

Professor Goodstein has a strong message about the limits and purpose of peer review. In his view, peer review: (1) works well in identifying nonsense, (2) does not work well in choosing between competing, potentially valid ideas (which is where we often land), and (3) is not designed to identify cheating or fraud. Personally, I view good peer review as a part of the solution, but not the whole solution and hope this reference might be helpful in getting peer review.

"In the competition among ideas, the institution of peer review plays a central role. Scientific articles submitted for publication and proposals for funding often are sent to anonymous experts in the field, in other words, to peers of the author, for review. Peer review works superbly to separate valid science from nonsense, or, in Kuhnian terms, to ensure that the current paradigm has been respected. It works less well as a means of choosing between competing valid ideas, in part because the peer doing the reviewing is often a competitor for the same resources (space in prestigious journals, funds from government agencies or private foundations) being sought by the authors. It works very poorly in catching cheating or fraud, because all scientists are socialized to believe that even their toughest competitor is rigorously honest in the reporting of scientific results, which makes it easy for a purposefully dishonest scientist to fool a referee. Despite all of this, peer review is one of the venerated pillars of the scientific edifice."⁶⁶

⁶⁶ "Kuhnian" refers to Thomas Kuhn, a physicist who retrained himself as an historian, and popularized the word "paradigm." Kuhn described science in terms of paradigm shifts.

C. Science may not provide a single answer

The academic experts' assessment of modern science departed from tradition or popular image two decades ago. A short and highly readable summary of these developments is presented in "How Science Makes Environmental Controversies Worse," by Professor Daniel Sarewitz.⁶⁷ A central premise of the article is that science does not lead to a single answer, but provides many tools that may suggest different answers from different perspectives. One example is rabid disagreement between ecologists and geneticists whether genetically modified organisms were found in Mexico. Professor Sarewitz contends that the view of both disciplines must be considered and respected. Science, in this example, does not answer the question. The author characterizes scientific uncertainty as including a lack of coherence among competing scientific understandings as opposed to simply a lack of scientific understanding or experimental uncertainty. More to the point, Sarewitz maintains that science does not provide values or ethical constraints. Those need to be provided by the legislature in statutory language and applied by the administrative agency. Here, that would be the risk management phase of EPA's risk evaluation process.

There are many competing views represented within science, views which can support various policy decisions.⁶⁸ Rather than waiting for science to point the direction toward one optimal policy, policy makers should consider scientific research, with other political and social objectives, and make policy decisions based on these factors. Others maintain that policymakers should not expect scientists to produce "proof" to support a policy decision.⁶⁹ Ultimately, most important decisions in the real world are made with high uncertainty, but are justified by a high level of commitment to a set of goals and values. . . Implementing a broad

⁶⁷ Sarewitz, D. *How Science Makes Environmental Controversies Worse*. *Environmental Science and Policy*, 7, 384-403 (2004). See also, Lövbrand, E. and Öberg, G. (2005). Discussion: Comment on "How Science Makes Environmental Controversies Worse" by Daniel Sarewitz, *Environmental Science and Policy*, 7, 385-403; "When Scientists Politicise Science: Making Sense of the Controversy Over The Skeptical Environmentalist" by Roger A. Pielke Jr., *Environmental Science and Policy*, 7, 405-417; and Sarewitz, D. and Pielke Jr., R. (2005). Discussion: Response to Lövbrand and Öberg. *Environmental Science and Policy*, 8, 199-200.

⁶⁸ Sarewitz explains: "First, science supplies contesting parties with their own bodies of relevant, legitimated facts about nature, chosen in part because they help make sense of, and are made sensible by, particular interests and normative frameworks. Second, competing disciplinary approaches to understanding the scientific bases of an environmental controversy may be causally tied to competing value-based political or ethical positions. The necessity of looking at nature through a variety of disciplinary lenses brings with it a variety of normative lenses, as well. Third, it follows from the foregoing that scientific uncertainty, which so often occupies a central place in environmental controversies, can be understood not as a lack of scientific understanding but as the lack of coherence among competing scientific understandings, amplified by the various political, cultural, and institutional contexts within which science is carried out."

⁶⁹ Oreskes, N. (2004). Science and Public Policy: What's Proof Got to do With It? *Environmental Science and Policy*, 7, 369-383. 'The appropriate standard for judging science is neither proof, nor certainty, nor unanimity, but a broad and firm consensus of the relevant experts in the field. . . . To demand that scientists satisfy some abstract notion of "proof" is to fly in the face of the historical evidence about how science has ever proceeded'

legal framework for environmental protection in the U.S. was a response to a social and political consensus, not authoritative knowledge.⁷⁰

D. Scientific Skepticism

A key feature of scientific and critical thinking is skepticism, the constant questioning of assumptions and conclusions. Good scientists and critical thinkers constantly examine the evidence, arguments, and reasons for their beliefs. The scientific method and scientific thinking provide one method to test beliefs and assumptions against objective reality by predicting the consequences or logical outcomes. If the logical consequences match objective reality--as measured by empirical evidence-- these beliefs are reliable knowledge, your beliefs have a high probability of being true.

Many people view skeptics as closed-minded and, once possessing reliable knowledge, resist changing their minds--but just the opposite is true. A skeptic holds beliefs tentatively, and is open to new evidence and rational arguments about those beliefs. Skeptics are undogmatic, i.e., they will change their minds, but only in the face of new reliable evidence or sound reasons that compel one to do so. Skeptics have open minds, but not so open that their brains fall out: they resist believing something in the first place without adequate evidence or reason, and this attribute is worthy of emulation. Science treats new ideas with the same skepticism: extraordinary claims require extraordinary evidence to justify one's credulity. We must have some method of deciding what to believe or not, and that method is the scientific method which uses critical thinking.⁷¹

⁷⁰ See, e.g., *Environmental policy in the 1990s: reform or reaction?* edited by Norman J. Vig, Michael E. Kraft, CQ Press (1997) and Sarewitz at 398 (2004).

⁷¹ This discussion is based on Steven D. Schafersman, "An Introduction to Science: Scientific Thinking and the Scientific Method" (Jan. 1994)