September 28, 2012

Office of Research and Development (ORD) Docket
Mail Code: 28221T
1200 Pennsylvania Avenue NW.
Washington, DC 20460
Submitted to the Docket at http://www.regulations.gov

Re: Request for Public Comment on the EPA's External Review Draft of "A Framework for Human Health Risk Assessment to Inform Decision Making" Docket # EPA-HQ-ORD-2012-0579; FRL-9706-3

Dear Sir or Madam:

In a July 30, 2012 Federal Register notice (FRN), the U.S. Environmental Protection Agency (EPA) announced a 60-day public comment period for the external review draft of "A Framework for Human Health Risk Assessment to Inform Decision Making (Framework)." The Center for Advancing Risk Assessment Science and Policy (ARASP),[1] which fosters activities to promote the adoption of policies and practices that assure the best available science and methodologies are the foundation for chemical assessments, is pleased to provide the following comments in response to EPA's announcement. In the FRN,[2] EPA noted that the Framework is intended to foster increased implementation of existing Agency guidance for conducting human health risk assessments and improve the utility of risk assessment in its decision-making. Unfortunately, processes used by EPA for assessing risks to the environment and human health have often lacked a consistent, coherent, science-based framework. It is clear that EPA's risk assessment activities have not been adequately or consistently coordinated within the Agency and this lack of coordination creates the potential for incomplete assessments, duplication of effort and inconsistent findings.

ARASP supports science-based decision-making and our members have worked with other stakeholders on the Alliance for Risk Assessment project: "Beyond Science and Decisions: From

[1] ARASP is a coalition of independent groups and associations that promotes the development and application of up-to-date, scientifically sound methods for conducting chemical assessments and is comprised of the following member organizations: Acrylonitrile Group, ACC Chlorine Chemistry Division, ACC Ethylene Oxide Panel, ACC Formaldehyde Panel, ACC Hexavalent Chromium Panel, ACC High Phthalates Panel, ACC Hydrocarbon Solvents Panel, ACC Oxo Process Panel, ACC Propylene Oxide/Propylene Glycol Panel, ACC Public Health and Science Policy Team, ACC Olefins Panel, ACC Vinyl Chloride Health Committee, American Cleaning Institute, American Petroleum Institute, CropLife America, Halogenated Solvents Industry Alliance, Silicones Environmental, Health and Safety Council of North America, and the Styrene Information and Research Center.
[2] Federal Register Volume 77, Number 146 (Monday, July 30, 2012), Pages 44613-44614

Problem Formulation to Dose-Response"[3] which has resulted in the development, by an expert science panel, of a "fit for purpose" interactive risk assessment methods framework, and a compendium of more than 30 case studies which can help guide risk assessors to a variety of assessment methods relevant to a range of decision contexts, each illustrated by case studies. ARASP commends EPA for developing a Framework that seeks to address recommendations by the National Research Council's (NRC) report, "Science and Decisions: Advancing Risk Assessment,"[4] regarding planning, scoping and problem formulation in the risk assessment process. Creating this Framework and devoting increased attention to the design and utility of an assessment is particularly important to ensure that risk assessments provide meaningful information for regulatory decision-making. While ARASP's comments will focus on four areas of the Framework: Planning, Risk Assessment, Public, Stakeholder and Community Involvement, and Informed Decisions, we also strongly encourage EPA to develop a plan for the timely and effective implementation of the Framework into its risk assessment process.

Planning

Early Engagement

Many risk assessments are performed in order to inform specific decisions regarding regulatory actions, and the Framework notes throughout that the risk assessments should ensure that they are "fit for purpose," meaning that they provide the level and complexity needed to offer meaningful information for the decision-making process. The Framework discusses the formation of a risk assessment team and identifies several key questions that should be addressed in the Planning and Scoping step such as "What are the overall purposes and general scope of the risk assessment?" As noted by the NRC report: "*Good design involves bringing risk managers, risk assessors, and various stakeholders together early in the process to determine the major factors to be considered, the decision-making context, and the timeline and depth needed to ensure that the right questions are being asked in the context of the assessment.*" ARASP agrees that early engagement and an enhanced dialogue between risk assessors and risk managers will help ensure that the purpose and scope of the assessment are appropriate for the risk manager's needs. This dialogue will also help ensure that the risk assessors do not spend excessive resources on conducting the assessment when such resources are not necessary and similarly that sufficient resources are allotted when justified. Input from the public, internal and external stakeholders, and the affected community(ies) will also provide valuable information at the planning stage.

Design of the Assessment

The specific purpose of an assessment and how the information will be utilized can have significant implications for how the assessment is conducted. Consequently, focusing greater attention on design in the early stages of risk assessment, specifically on planning, scoping and problem formulation will result in a more useful scientific product. In

[3] http://www.allianceforrisk.org/ARA_Dose-Response.htm
[4] National Research Council, Sciences and Decisions: Advancing Risk Assessment (2009) (Washington, DC: National Academies Press).

designing the risk assessment EPA should ensure that the plan clearly identifies the major factors to be considered in the assessment (e.g., what regulatory decision will be informed by the assessment and what problem the assessment is seeking to address?). The upfront design of the assessments needs to be transparent and specify the key issues that are to be assessed and the specific methods, assumptions, and evaluation procedures that will be utilized. Input from the research community and stakeholders should be part of this activity, so that the most up-to-date data can be obtained and the most relevant methods can be considered and used. This information should be clearly documented for each assessment and provided to stakeholders for review, external scientific analysis and comment prior to undertaking the assessment. For particularly challenging assessments, EPA should consider having the risk assessment protocol or plan subjected to both public review and independent peer review. Additionally, the plan should be continuously reviewed and revised as needed, throughout the risk assessment to ensure that the assessment remains "fit for purpose."

Risk Assessment

EPA currently has guidance on many of the steps associated with conducting various components of a risk assessment (e.g., hazard identification, dose-response characterization and exposure assessment). However, the Agency has not consistently and effectively implemented those guidance documents. In particular, EPA's Integrated Risk Information System (IRIS) Program presents point estimates upon which to assess risk, yet EPA's Risk Characterization Guidance[5] recommends ranges, rather than single point estimates.

The processes for considering scientific information and data, and the standards and criteria used in risk assessment need to be applied throughout the Agency in a uniform manner. The Framework broadly describes EPA's risk assessment process and aspects that the risk assessor may consider during the review (e.g., exposure, mode of action, relevancy for human health risk) including integrating the available information into a final risk characterization. The Agency should further expand its Framework to ensure that there is adequate transparency in the risk assessment process. This should include: (1) documentation that consistent, scientifically objective data evaluation protocols are used to evaluate studies – so that the same procedures are used irrespective of who conducted the study, where it was conducted, or who funded it; (2) a description of the key decision points and assumptions employed; (3) clear documentation of the underlying criteria and methods used in assessing weight of evidence and characterizing uncertainty; and (4) clear documentation of the rationale that lead to the final risk characterization. For assessments beyond screening level determinations, the characterization must provide a full picture -- not just a worst case or upper bound estimate, or an estimate based on one set of default or conservative assumptions. The

[5] EPA's Guidance for Risk Characterization. (1995). http://www.epa.gov/spc/pdfs/rcguide.pdf and EPA's Risk Characterization Handbook (2000). http://www.epa.gov/spc/pdfs/rchandbk.pdf

framework should specify that assessments need to explicitly document the impact of assumptions and defaults and also present results using scientifically plausible alternatives.

Public, Stakeholder and Community Involvement

Peer engagement and review are two important factors to ensure that high quality, reliable science supports decision-making. As noted in the Framework *"Public participation is an essential aspect of the EPA's process for making decisions to achieve the agency's mission of protecting human health and the environment. This provides the EPA with the opportunity to obtain and consider a range of views on the issue being assessed as well as on management options. Effective public involvement (including key stakeholders and/or communities) can enhance the deliberative process and improve the content of the agency's decisions (U.S. EPA 2003c), which is consistent with sustainability principles. A critical feature of the Framework is the involvement of the public, stakeholders and communities at key points in the process."*

Unfortunately, while peer review plays a crucial role in development of the best scientific evaluations and is integral to identifying information that would reduce uncertainty in significant areas of the assessment EPA has often fallen short of effectively engaging the public, external scientific experts and other stakeholders in the risk assessment process. ARASP is generally encouraged by EPA's commitment to stakeholder engagement as described in the Framework and recommends that EPA also include a plan to engage the public earlier in the risk assessment process and ensure that peer review recommendations are adequately addressed before a risk assessment is finalized. Specifically, in cases where peer review findings and recommendations indicate the need for significant re-analyses and extensive revision, the revised assessment should go back to the peer reviewers to verify that findings and recommendations have been fully and adequately addressed.

Informed Decisions

One of the concluding chapters of the Framework focuses on making informed regulatory decisions based on transparent and useful risk assessment information. This includes providing information on the strength of the scientific evidence, the range of possible risk to the exposed population, and the uncertainties in the underlying data. EPA notes that its programs "*…routinely apply components of this Framework for Human Health Risk Assessment to Inform Decision Making"* and the Agency also notes that *"Further, 'institutionalization' of this Framework for Human Health Risk Assessment to Inform Decision Making will contribute transparency to the agency's risk assessment process and a level of consistency across assessments, across media and programs as well as between human health and ecological outcomes."* ARASP strongly encourages EPA to implement and utilize all components of this Framework consistently across its program offices.

The development and adoption of a Framework for informed decision-making is a critical step in improving the Agency's conduct and application of chemical risk assessments in the regulatory process. ARASP looks forward to the opportunity to engage more fully in the review of the Framework during the upcoming expert peer review meeting and learning about the Agency's plans to implement the Framework. If you have any questions feel free to contact Dr. Richard Becker at Rick_Becker@americanchemistry.com or Dr. Kimberly Wise at Kimberly_Wise@americanchemistry.com.

Sincerely,

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