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Office of Information and Regulatory Affairs
Office of Management and Budget
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RE: Comments on OMB's Proposed Risk Assessment Bulletin

The Styrene Information and Research Center, Inc. (SIRC)¹ appreciates the opportunity to submit comments on the *Proposed Risk Assessment Bulletin* (hereinafter *Bulletin*) developed by the Office of Management and Budget (OMB) in consultation with the Office of Science and Technology Policy (OSTP).² SIRC strongly supports OMB and OSTP's efforts to enhance the technical quality, objectivity and transparency of risk assessments prepared by Federal agencies, by establishing uniform, minimum standards for such assessments. As OMB notes:

*The increasing importance of risk assessment in the development of public policy, regulation, and decision-making requires that the technical quality and transparency of agency risk assessments meet high quality standards. Moreover, a risk assessment prepared by one federal agency may inform the policy decisions of another federal agency, or a risk assessment prepared by one or more federal agencies may inform decisions made by legislators or the judiciary.*³

Indeed, as the *Bulletin* recognizes, "[t]he dissemination of public risk information, even if it is not accompanied by a regulation, can induce changes in the behavior of consumers, patients, workers, and businesses" including affecting public perceptions of products and

¹ SIRC's mission is to evaluate existing data on potential health effects of styrene, and develop additional data where it is needed. SIRC has gained recognition as a source for information on styrene and helping ensure that regulatory legislation is based on sound science. For more information, visit www.styrene.org.

² See 71 Fed. Reg. 2600 (January 17, 2006), and the full text document at http://www.whitehouse.gov/omb/infoereg/proposed_risk_assessment_bulletin_010906.pdf/

³ *Bulletin* at pp. 2-3.

impacting supply chain relationships.⁴ Accordingly, SIRC fully supports OMB's proposal to establish minimum standards for risk assessments prepared by Federal agencies.

A. Overview and General Observations

To place these comments in perspective, it may be helpful to summarize the proposal.

- The *Bulletin* defines 'risk assessment' as "a scientific and/or technical document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment."⁵
- Risk assessments shall:
 - Provide a clear statement of their purpose and scope
 - Provide a characterization of the evaluated risk
 - Be scientifically objective
 - Discuss critical assumptions
 - Summarize key elements, findings, limitations and uncertainties
 - Place the risk in context with other risks familiar to the target audience
- For risk assessments used for regulatory analysis:
 - Evaluate alternative options
 - Compare baseline risk against alternative mitigation options
 - Provide estimates of population risk when estimates of individual risk are developed
 - Include a range of plausible risk estimates when possible
- For 'influential' risk assessments,' meaning those that are expected to have a "clear and substantial impact on important public policies or private sector decisions:"
 - Compare the agency's results with that of qualified scientific organizations on the same topic
 - Highlight central estimates as well as high-end and low-end estimates of risks when estimates are uncertain
 - Characterize uncertainty
 - Describe how the choice of risk endpoint influences the assessment relative to other risk endpoints
 - When human health effects are a concern, determinations of effects deemed adverse shall be specifically identified and justified
 - Discuss research needs to resolve scientific limitations or uncertainties
 - Consider and issue a response to all significant comments received on a draft risk assessment report.
- Agencies shall consider updating assessments in light of new data.
- Agencies shall prepare a certification that the agency has complied with the *Bulletin's* requirements.

⁴ *Bulletin* at p. 5.

⁵ Section I.3.

Although we are not experts in risk assessment, we have been long-term observers of the process. The elements contained in the proposed *Bulletin* are consistent with current risk assessment practices and administrative procedural norms. We recognize that there are certainly excellent risk assessments produced by Federal agencies today. However, the quality of risk assessment throughout the Executive Branch does not reflect uniform excellence, and considerable improvements can still be made. When an agency's risk assessment practices are consistent with current norms, the *Bulletin* will not be a burden. When improvement is necessary, the *Bulletin* will provide some concrete measures against which performance can be measured both internally and externally.

When finalized, the *Bulletin* will generate a number of benefits, including improved quality and consistency in treatment of the same risk by assessors scattered across the federal government. This consistency should enhance the fairness and equitable impact of decision making by decentralized decision makers. Indeed, the transparency features of the *Bulletin* will benefit not only the directly involved agency and public sectors, but also other agencies that will benefit from the efforts and experience of their peers in sister agencies. Even without OMB oversight, the *Bulletin* will help focus the dialogue between producers and consumers of risk assessments and should result in both higher quality assessments and better communications and understanding among all involved.

Because the *Bulletin* is intended to address the vast array of risk assessments prepared by the federal government, we do not read the *Bulletin* as being so inflexible as to impose a 'one size fits all' methodology on every risk assessment. We assume, and hope that OMB agrees, that the *Bulletin* needs to be implemented with a good dose of common sense and reasonableness. When particular provisions are not applicable to the risk assessment being conducted, those requirements should not be deemed necessary. OMB may wish to address this aspect in the preamble to the final *Bulletin* or other implementation guidance. Naturally, the risk assessments must also be consistent with the legislative and regulatory framework or requirements within which they are developed.

While SIRC believes that the goals articulated in the draft *Bulletin* would be greatly served by its prompt finalization in its current form, we have a few comments intended to refine, clarify or further illuminate sections of the draft. Our comments follow the structure of the draft *Bulletin*. We also note that our comments are presented primarily from the perspective of chemical toxicology and risk evaluation, as opposed to engineering and other types of risk assessments mentioned in the draft *Bulletin*.

In particular, the draft *Bulletin* should be revised so that:

- draft risk assessments shall be published for influential risk assessments
- certification statements of agency compliance shall not only report that the agency complied with the *Bulletin* but also report how the agency complied in a manner specific to the assessment
- the 'shall' wording in the *Bulletin* is reflected in the preamble.

B. Informing the public

The draft *Bulletin* observes a well-respected truth that the “dissemination of public risk information, even if it is not accompanied by a regulation, can induce changes in the behavior of consumers, patients, workers, and businesses.” SIRC urges OMB and agencies assessing risk to endeavor to put risk in perspective and provide context whenever possible. While risk assessors may make fine distinctions among methodologies and various measures of uncertainty, the general public, and occasionally the media, can easily misunderstand the technical presentation of risk information. For example, it has been our experience that there is a general lack of appreciation of the vast difference between hazard identification and actual risk.

On a positive note, we are encouraged by some of the U.S. Environmental Protection Agency's (EPA's) communication efforts. For example, in a recent question and answer document, EPA states:

Are there steps that consumers can take to reduce their exposure to PFOA?

At present, there are no steps that EPA recommends that consumers take to reduce exposures to PFOA because the sources of PFOA in the environment and the pathways by which people are exposed are not known. Given the scientific uncertainties, EPA has not yet made a determination as to whether PFOA poses an unreasonable risk to the public. At the present time, EPA does not believe there is any reason for consumers to stop using any consumer or industrial related products that contain PFOA.⁶

While such conclusions may be derived from formal risk assessments, a short agency statement in *plain language* is often the most effective way to inform the public and thereby guide their behavior.

C. Definitions

Influential risk assessment. SIRC supports the proposed definition. The scope of applicability of the definition would be improved by modifying the explanatory paragraph on page 9 as follows (underlining indicates addition):

Examples of “influential risk assessments” include, but are not limited to, assessments that determine the level of risk regarding health (such as reference doses, reference concentrations, and minimal risk levels), safety and environment. Documents that address some but not all aspects of risk assessment are covered by this *Bulletin*. Specific examples of such risk assessments include: margin of exposure estimates, hazard determinations, EPA Integrated Risk Information System (IRIS) values, risk assessments which support EPA National Ambient Air Quality Standards,

⁶ US EPA “Basic Information on PFOA,” available at <http://www.epa.gov/opptintr/pfoa/pfoainfo.htm#concerns>.

FDA tolerance values, ATSDR toxicological profiles, HHS/NTP substance profiles such as the NTP Report on Carcinogens, NIOSH current intelligence bulletins and criteria documents, and risk assessments performed as part of economically significant rulemakings. Documents falling within these categories are presumed to be influential for the purposes of this *Bulletin*.

SIRC agrees that the EPA's Integrated Risk Information System (IRIS) assessments, among others, should be classified as influential risk assessments. IRIS assessments are plainly risk assessments. As EPA states: "IRIS supports the first two steps of the risk assessment process; namely, the hazard identification and dose-response assessment steps. The primary qualitative and quantitative health hazard information in IRIS, the oral reference doses (RfDs), inhalation reference concentrations (RfCs), and carcinogenicity assessments, can serve as guides in evaluating potential health hazards and selecting a response to alleviate a potential risk to human health."⁷ Thus, these assessments describe risk to individuals and populations and are routinely used as a basis for regulations by program offices within EPA as well as state and local regulators. Moreover, depending on the conclusions of the IRIS review, advocacy groups and/or competitors have used IRIS values to disparage companies or products.

Risk Assessment. SIRC supports the inclusion of hazard determinations within the meaning of risk assessment. Some confusion exists based on occasional differentiation between hazard determination and risk assessment. For the purposes of the *Bulletin*, the risk assessment criteria should encompass hazard determinations.

D. Goals

While scientific objectivity and transparency are stressed throughout the draft *Bulletin*, we believe that these concepts merit inclusion in the list of Goals. Consistent with general risk assessment and reporting standards in the draft *Bulletin*, we recommend the addition of a sixth goal to section III of the draft *Bulletin*, similar to the following: "The agency shall strive to be scientifically objective and present its assessment with a high degree of transparency."

⁷ <http://www.epa.gov/iris/limits.htm>; visited June 13, 2006. The agency's description of the risk assessment elements of an IRIS assessment also state:

"The RfD and RfC can be used to estimate a level of environmental exposure at or below which no adverse effect is expected to occur. The RfD or RfC is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime. RfDs and RfCs are based on an assumption of lifetime exposure and may not be appropriately applied to less-than-lifetime exposure situations. RfDs and RfCs are also derived for the noncarcinogenic effects of chemicals that are carcinogenic.

The carcinogenicity assessments in IRIS begin with a qualitative weight-of-evidence judgment as to the likelihood that a chemical may be a carcinogen for humans. This judgment is made independent of consideration of the agent's potency. A quantitative assessment, which may include an oral slope factor and oral and/or inhalation unit risks, is then presented. The oral slope factor is an upper-bound estimate of the human cancer risk per mg of agent/kg body weight/day. The unit risk, which is calculated from the slope factor, is an estimate in terms of either risk per µg/L drinking water, or risk per µg/cu.m air concentration."

E. Risk Assessments Must be Objective and Based on the Weight of the Evidence

SIRC strongly supports the requirements of Section IV, paragraph 4, that risk assessments must be scientifically objective, "neither minimizing nor exaggerating the nature and magnitude of the risks." In our experience, EPA has resisted including central estimates of risk, opting instead to use "reasonable worst case" estimates (upper 95% confidence limits of central tendency). Although SIRC generally agrees that a rule of reason should prevail in applying the proposed risk assessment standards, we are concerned that OMB would exclude screening-level assessments from having to meet the standard of "neither minimizing nor exaggerating the nature and magnitude of risk."⁸

By their nature, results from screening level risk assessments are susceptible to misuse because of their focus on the upper bounds of unknown risks and easy dissemination. A case in point involves recent Associated Press (AP) articles concerning air pollutant health risk scores reported by EPA's Risk-Screening Environmental Indicators (RSEI) database.⁹ These articles were inflammatory and alarming precisely because they lacked a meaningful discussion on actual risks from air pollution. Accordingly, SIRC submits that a more cautious approach to the dissemination, if not the use, of screening-level assessments is warranted.

SIRC also agrees that risk assessments should be based on the best available data and on the weight of the available scientific evidence. OMB's Information Quality Guidelines and Information Quality *Bulletin* on Peer Review should help inform agency efforts in this regard.

Section IV.7.a might be clarified by editing it to read: "an evaluation of alternative regulatory options, clearly establishing the baseline risk as well as the risk reduction alternatives that will be evaluated"

F. Influential Risk Assessments Must Clearly Communicate Human Health Effects

SIRC fully supports the determination by OMB and OSTP that "[w]here human health effects are a concern, determination of which effects are adverse shall be specifically identified and justified based on the best available scientific information generally accepted in the relevant clinical and toxicological communities."¹⁰ As the *Bulletin* notes,

measuring the concentration of a chemical metabolite in a target tissue of the body is not a demonstration of an adverse effect, though it may be a valid indicator of chemical exposure. Even the measurement of a biological event in the human body resulting from exposure to a specific chemical may not be a demonstration of an adverse effect. Adversity typically implies some functional impairment or pathologic lesion that affects the performance of the whole

⁸ *Bulletin* at p. 9.

⁹ David Pace, *Unhealthy Air*, Assoc. Press (Dec 14, 2005).

¹⁰ *Bulletin* at p. 20; Section V, ¶7.

organism or reduces an organism's ability to withstand or respond to additional environmental challenges.¹¹

The draft *Bulletin* states: "In cases where qualified specialists disagree as to whether a measured effect is adverse or likely to be adverse, the extent of the differences in scientific opinion about adversity should be disclosed in the risk assessment report."¹² SIRC fully supports the notion that, where qualified experts disagree on whether a measured effect is adverse or likely to be adverse, the differences in scientific opinion should be disclosed by the risk assessment. Such clarifying information in Federal risk assessments could help forestall or dispel the increasingly uncontrollable rash of alarmist materials based on unclear risk assessments, and provide a better foundation for government, industry and other stakeholder communications. If an important goal of government is to support and advance informed health and environmental decision making by individuals and society as a whole, there is an obligation to present information in a manner that does not lend itself to false or misguided alarms, because bombardments with the health or environmental crisis of the day merely deafen the public and mask important information on which true public health advances can be based.

G. Standard for Characterizing Human Health Effects

Quite appropriately, OMB observes that the capacity of science to detect the presence of substances or their effects precedes our ability to understand the implications of such exposure or effect and whether it is an adverse effect. As part of its risk communication efforts, agencies need to be clear about these uncertainties and the distinctions between exposure, effects and adverse effects.

For example, at the federal and state level, there is an effort to expand biological monitoring. Properly conceived and conducted, the information from such efforts may provide better information regarding exposure. However, without careful communication by government and public health agencies, data describing exposure and effects can be easily mischaracterized as presenting risk in an increasingly risk-averse culture. Moreover, these mischaracterizations jump to the assumption that the exposure and risk must stem from industrial operations. In the case of styrene, as is the case with other substances, the supposition is often incorrect. First, while styrene might not sound natural to the general public, styrene is a naturally occurring component of pine trees, strawberries, cinnamon and roasted coffee. Second, styrene is found in both tobacco smoke and motor vehicle exhaust. Thus, the imputation of exposure and effect to industrial facilities can be unfounded. Risk communication that carries this type of information may aid the public, industry and government risk managers in making rational choices.

¹¹ *Id.*

¹² *Id.*

H. Peer Review, Agency Accountability and Oversight are Critical

SIRC strongly supports the *Bulletin's* directive that “[a]gencies should consider appropriate procedures for peer review and public participation in the process of preparing the risk assessment.” We concur with the *Bulletin* statement that “[p]ublic comments can play an important role in helping to inform agency deliberations.”

In particular, we believe that the public distribution for comment of a draft of all risk assessment documents would enhance the ultimate quality of the process, by taking into consideration as much information as possible prior to finalizing a risk assessment. The need for public circulation of a draft assessment is particularly important for influential risk assessments. We strongly encourage the inclusion of language in the *Bulletin* recommending the public distribution for comment of draft documents.

SIRC is gratified to learn that under the proposed risk assessment standards, agencies are “expected to consider all of the significant comments received on a draft influential risk assessment report” and that “[s]cientific comments shall be presumed to be significant.”¹³ We are concerned, however, that the *Bulletin* is not particularly directive, containing as many suggestions as it does imperative sentences (e.g., “An agency is expected to consider all of the significant comments received on a draft influential risk assessment report.”).

SIRC also has significant concerns that in the absence of judicial review, the *Bulletin* fails to provide more robust opportunity for additional review, particularly in those instances when an agency has failed to provide an explicit rationale for refusing to adopt an adverse position suggested by commenters. Accordingly, careful agency implementation of the risk assessment standards, and more importantly, close OMB oversight of agency compliance with the *Bulletin* will be critical to the development of risk assessments that are acceptable to *all* stakeholders.

I. Certification

Section VII requires agency certification of compliance. However, the draft *Bulletin* should be revised to make it clear that certification statements of agency compliance shall report both the fact of compliance and the manner of compliance, that is, how the agency complied in a manner specific to the assessment. For agencies that routinely conduct risk assessments, a readily adaptable format could be developed that would expedite compliance with such a requirement by indicating the chronological steps in compliance with the dates and agency or outside organizations involved and the assessment.

For each risk assessment subject to this *Bulletin*, the agency shall include a certification explaining that the agency has complied with the requirements of this *Bulletin* and the applicable Information Quality Guidelines, except as provided in

¹³ *Bulletin* at p. 20; Section V, ¶9.

Section VIII. The certification statement shall state how the agency complied in a manner specific to the assessment.

J. Conformance of Preamble and Bulletin

There is some potential for confusing the mandatory and discretionary intent of the *Bulletin* based on the use of the term 'should' in the preamble and 'shall' in the *Bulletin* itself. We urge that the term 'shall' be used uniformly in the preamble and the *Bulletin*. Suggested changes are reflected in the attached version of the draft *Bulletin*, which also reflects the other specific editorial changes recommended in these comments.

K. Conclusion

Thank you very much for the opportunity to provide comment on the *Proposed Risk Assessment Bulletin*. We hope that SIRC's comments will assist OMB and OSTP in their deliberations. Please contact me if you have questions or would like to discuss any aspect of these comments.

Very truly yours,

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

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Attachment: Proposed Revisions

Proposed Revisions

The three specific wording changes presented in SIRC's comments are reproduced below:

Page 9 as follows (Supplementary Information, Section I: Definitions) underlining indicates addition):

Examples of "influential risk assessments" include, but are not limited to, assessments that determine the level of risk regarding health (such as reference doses, reference concentrations, and minimal risk levels), safety and environment. Documents that address some but not all aspects of risk assessment are covered by this *Bulletin*. Specific examples of such risk assessments include: margin of exposure estimates, hazard determinations, EPA Integrated Risk Information System (IRIS) values, risk assessments which support EPA National Ambient Air Quality Standards, FDA tolerance values, ATSDR toxicological profiles, HHS/NTP substance profiles such as the NTP Report on Carcinogens, NIOSH current intelligence bulletins and criteria documents, and risk assessments performed as part of economically significant rulemakings. Documents falling within these categories are presumed to be influential for the purposes of this *Bulletin*.

Risk Assessment Bulletin Section IV. 7.a. (page 24):

an evaluation of alternative regulatory options, clearly establishing the baseline risk as well as the risk reduction alternatives that will be evaluated:

Risk Assessment Bulletin Section VII (page 25):

For each risk assessment subject to this *Bulletin*, the agency shall include a certification explaining that the agency has complied with the requirements of this *Bulletin* and the applicable Information Quality Guidelines, except as provided in Section VIII. The certification statement shall state how the agency complied in a manner specific to the assessment.