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ENHANCING SCIENCE AND POLICY FOR CHEMICAL RISK ASSESSMENTS

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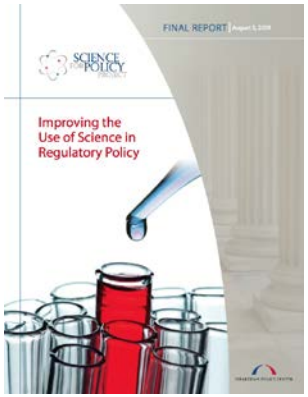
Statement of the Problem

Executive Summary

The use of science in the formulation of regulatory policy – by both the Executive Branch and the Congress – has been a political flashpoint in recent decades.[1] Policy makers often claim that particular regulatory decisions have been driven by, or even required by science; their critics, in turn, have attacked the quality or the interpretation of that science. Such conflict has left the U.S. with a system that is plagued by charges that science is being "politicized" and that regulation lacks a solid scientific basis. As a result, needed regulation may be stymied, dubious regulations may be adopted, issues can drag on without conclusion and policy debate is degraded. Moreover, the morale of scientists is weakened, and public faith in both government and science is undermined.



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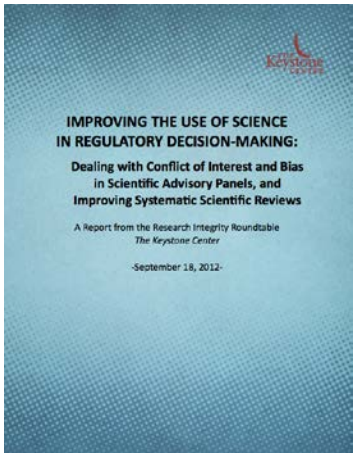
Statement of the Problem

EXECUTIVE SUMMARY

Critics of the manner in which science is used in regulatory decision-making processes tend to raise two kinds of concerns. They question the composition of committees that are empaneled to recommend or review the science behind a regulatory decision and they question the way an agency or committee has reviewed the relevant scientific literature, charging that the reviewers used or omitted the wrong studies, and/or that the studies were not appraised appropriately.



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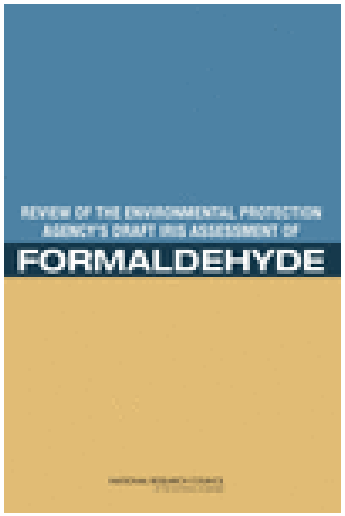
Moving Forward

THE FORMALDEHYDE IRIS ASSESSMENT: THE PATH FORWARD

The committee recognizes that the completion of the formaldehyde IRIS assessment is awaited by diverse stakeholders, and it has tried to be judicious in its recommendations of specific changes noted in its report. However, the committee concludes that the following general recommendations are critical to address in the revision of the draft assessment. First, rigorous editing is needed to reduce the volume of the text substantially and address the redundancies and inconsistencies; reducing the text could greatly enhance the clarity of the document. Second, Chapter 1 of the draft assessment needs to discuss more fully the methods of the assessment. The committee is recommending not the addition of long descriptions of EPA guidelines but rather clear concise statements of criteria used to exclude, include, and advance studies for derivation of the RfCs and unit risk estimates. Third, standardized evidence tables that provide the methods and results of each study are needed for all health outcomes; if appropriate tables were used, long descriptions of the studies could be moved to an appendix or deleted. Fourth, all critical studies need to be thoroughly evaluated for strengths and weaknesses by using uniform approaches; the findings of these evaluations could be summarized in tables to ensure transparency. Fifth, the rationales for selection of studies that are used to calculate RfCs and unit risks need to be articulated clearly. Sixth, the weight-of-evidence descriptions need to indicate the various determinants of "weight." The reader needs to be able to understand what elements (such as consistency) were emphasized in synthesizing the evidence.



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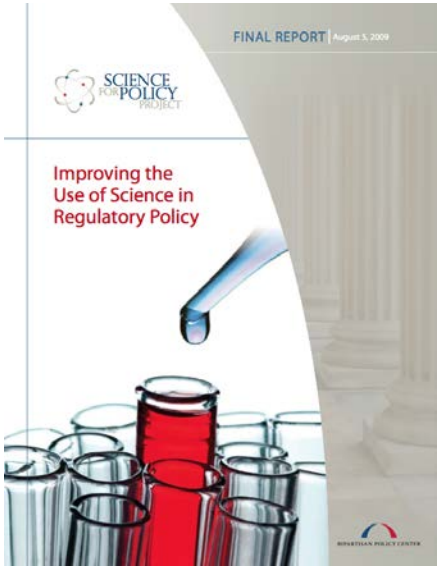
RECOMMENDATION FOUR: The federal government, universities, scientific journals and scientists themselves can help improve the use of science in the regulatory process by strengthening peer review, expanding the information available about scientific studies, and setting and enforcing clear standards governing

conflict of interest.



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Our Focus Today

- Data Evaluation and Integration
- Peer Review