

CAL DOOLEY  
PRESIDENT AND CEO



July 8, 2011

The Honorable Cass R. Sunstein  
Administrator  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
725 17th Street, NW  
Washington, DC 20503

Dear Administrator Sunstein:

The American Chemistry Council (ACC) and its member companies have noted with increasing concern that important decisions by federal agencies are not based on scientifically rigorous processes. That failure undermines public and private sector confidence in the regulatory process and specific agency decisions, and can seriously harm American innovation and jobs. The Office of Information and Regulatory Affairs (OIRA) now has an important opportunity to make a lasting improvement in federal regulatory processes and the scientific basis for decision-making – changes that can help grow the economy by providing predictability and a level playing field. I would appreciate the chance to meet with you to discuss our mutual interests in this area and ACC's suggestions for improvements.

Our most recent concerns arise from several decisions by federal agencies that demonstrate a pattern for selective application of science, non-uniform processes, and poor peer review practices. In ACC's view, this pattern creates a significant risk that federal agency decisions are little more than what you have described as "uniformed stabs in the dark." At a minimum, the pattern undermines the ability to meet President Obama's goal of ensuring that science guide the decision-making process. It can also undermine the struggling economic recovery in the United States. Recent examples include:

- The Department of Health and Human Services' 12<sup>th</sup> Report on Carcinogens, which inappropriately linked formaldehyde exposures to increased risks of certain types of leukemia despite a recent National Academy of Sciences assessment that raised concerns about the underlying science that was the basis for HHS's conclusion. The same report caused needless confusion by failing to clarify the type or level of exposure to styrene which may present concerns.
- The Environmental Protection Agency's (EPA) lack of transparent, science-based criteria by which the Agency would identify and prioritize chemicals for further action under the Office of Pollution Prevention and Toxics' Enhanced Chemical Management Plan. Compounding this problem is an EPA proposal currently under OIRA review which



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would list substances as a “chemical of concern” under the Toxic Substances Control Act. Because states, manufacturers and retailers often rely on such lists to ban or restrict products, these decisions have the potential for immediate (and often irreversible) adverse market impacts.

- EPA’s decision to accelerate the Integrated Risk Information System (IRIS) assessment of hexavalent chromium, despite its awareness of a \$4 million mode-of-action study with important implications for the assessment that will be published this year.
- IRIS’s continuing failure to address comments raised in peer-review of several assessments (including dioxins and formaldehyde) highlighting systemic weaknesses in the IRIS assessment process. This has included critical feedback from EPA’s own Science Advisory Board and the National Academy of Sciences (NAS). In the case of dioxin, peer reviews raised concerns in 1995, 2001 and again in 2006 that remain unaddressed by IRIS. The NAS’s recent review of the formaldehyde assessment reinforced similar concerns with the IRIS process.

Collectively, these examples speak to the need for a strong oversight presence on science and science-based decision-making in the federal agencies. OIRA is best positioned to exercise that oversight, both in reviewing regulatory proposals of the agencies and developing guidance to be applied by the agencies in their processes. Increased OIRA oversight of the scientific basis for agency actions will improve public confidence in the federal regulatory system, minimize the potential for unwarranted commercial and economic impacts, eliminate duplicative and conflicting agency actions, and assure that science properly guides federal decisions.

I would appreciate the opportunity to meet personally with you and your staff to discuss our suggestions for both short- and long-term improvements in the use of science in federal decision-making. My staff will follow up with your office to schedule a meeting in the near future.

Sincerely,

A handwritten signature in black ink that reads "Cal Dooley". The signature is written in a cursive, slightly slanted style.

Cal Dooley  
President and CEO