



CAL DOOLEY
PRESIDENT AND CEO

June 22, 2011

Mr. Jacob J. Lew
Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Lew:

On March 9, 2009, President Obama pledged that “science and scientific process must inform and guide decisions of my Administration,” and signed a Presidential Memorandum directing each agency to use well-established scientific processes to inform public policy decisions. Unfortunately, recent actions by the federal agencies charged with evaluating chemical hazards and risks fail to meet the standards demanded by the President.

To rectify this, the Office of Management and Budget (OMB) must take greater responsibility in the coordination and review of chemical safety assessments. Stronger leadership from OMB will help ensure scientific integrity and eliminate duplicative, often conflicting, evaluations by agencies that cause confusion for consumers, chemical manufacturers and their customers.

The shortcomings of federal chemical safety assessments are exemplified by the recent National Academies of Science (NAS) review of the Environmental Protection Agency’s (EPA) Integrated Risk Information System (IRIS) draft assessment of formaldehyde. In its review, NAS stated that EPA failed to provide scientific evidence to support a number of its conclusions, including the linkage between formaldehyde and certain types of leukemia. The NAS committee went so far as to devote an entire chapter of its report to describing improvements needed by EPA to address the IRIS program’s long-standing systemic weaknesses.

The NAS committee clearly stated its concerns: “The committee is concerned about the persistence of problems encountered with IRIS assessments over the years, especially given the multiple groups that have highlighted them. If the methodologic issues are not addressed, future assessments may still have the same general and avoidable problems that are highlighted here.” As the NAS panel documents, the IRIS program continues to fall well-short of meeting the benchmarks of objectivity, scientific accuracy and transparency necessary to ensure high quality, reliable assessments.

In a letter to Administrator Jackson (enclosed), the American Chemistry Council (ACC) requested that EPA immediately amend the IRIS process to require NAS review of all IRIS assessments. We also asked that EPA make other fundamental changes to the program to improve its transparency and scientific credibility. Unfortunately, Acting Director of Research and Development Rebecca Clark's response on behalf of Administrator Jackson dismissed our suggestions, stating, "IRIS is a model for openness, transparency, scientific integrity and scientific quality," a statement at odds with the conclusions NAS reached about the program (May 4, 2011 letter from EPA to Dooley).

The concurrent evaluation of formaldehyde in EPA's IRIS program and the National Toxicology Program's 12th Report on Carcinogens (12th RoC) is another example of the disconnect between the President's stated commitment to scientific integrity and the actions taken by some federal agencies. Just a few weeks after NAS concluded that EPA's IRIS program had failed to scientifically justify its conclusion that formaldehyde causes specific types of leukemia, the 12th RoC concluded exactly the opposite, asserting that studies in humans have shown that formaldehyde causes myeloid leukemia (Report: <http://ntp.niehs.nih.gov/ntp/roc/twelfth/profiles/Formaldehyde.pdf>).

By failing to sufficiently reflect the conclusions of NAS and producing a contradictory report, the 12th RoC has created the potential for public confusion, alarm and economic harm to the 600,000 Americans employed in industries reliant on the production and use of formaldehyde, all without adequate scientific basis.

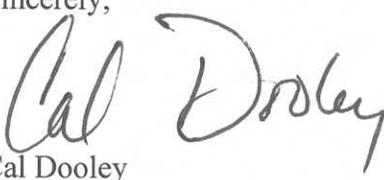
In addition to EPA's IRIS program and the NTP's RoC, the Agency for Toxic Substances Disease Registry (ATSDR), which is part of the Centers for Disease Control and Prevention, also manages a separate toxicological profiles program. IRIS, NTP and the ATSDR programs are all housed within different federal departments or agencies, employing different methods for assessing chemical risk. This overlapping and duplicative system often produces conflicting conclusions and guidance. Therefore, it is no wonder that the public, as well as private enterprises, remain confused and distrustful of the federal chemical regulatory system and its efficacy.

OMB is charged with ensuring the President's vision is implemented across the Executive Branch. Consistent with that mission, ACC requests the OMB address the duplication of efforts by these agencies to ensure the chemical assessment process reflects up-to-date scientific knowledge, meets the highest standards of scientific inquiry and employs best practices for stakeholder involvement and scientific peer review, including processes for acting on comments and peer review recommendations. Only such a review by OMB can guarantee the letter and spirit of President Obama's March 2009 Memorandum are consistently followed. As an immediate action, OMB should require EPA to submit all ongoing EPA IRIS assessments to the

NAS for independent review and report how the Agency will accommodate recommendations from NAS in the final assessments.

Protecting public health and safety must be our top priority, and sound chemical safety assessments are a critical part of meeting that goal. We would welcome the opportunity to work with your office to improve the efficiency, integrity and consistency of chemical safety assessments across the federal government so that America's consumers, workers, retailers and manufacturers can have confidence that the government's information is accurate and credible and so that American innovation and jobs are not jeopardized by decisions based on faulty science.

Sincerely,



Cal Dooley