MICHAEL P. WALLS
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

March 31, 2009

Mr. Kevin Neyland
Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W. Washington, D.C. 20503
Via Email to: *oira_submission@omb.eop.gov*

Dear Mr. Neyland:

The American Chemistry Council (ACC) appreciates this opportunity to provide additional comments to the Office of Information and Regulatory Affairs regarding chemical evaluation, risk assessment and regulation in regards to a new Executive Order on Federal Regulatory Review. These comments and suggestions supplement those provided to OMB by ACC on March 16, 2009.

As we have stated, President Clinton's Executive Order 12866 has provided an important and effective framework for oversight of the federal regulatory process. While elements of that framework could be enhanced, we believe the essential structure of Executive Order 12866 should be retained. ACC has long maintained that the practice of federal agency risk assessment can and should reflect the best science and practices in risk assessment, and we support OMB's actions of outlining the goals and general principles for risk assessment. Such actions by OMB are intended to enhance scientific objectivity, and promote efficiency and consistency government-wide. These actions have advanced the technical quality and objectivity of federal risk assessments, particularly by promoting more transparency in what science was being considered and leveraged in federal decision-making.

Even more can be done to ensure that advanced risk assessment approaches are employed by the agencies, particularly by assuring that potential risks are objectively portrayed. In the following comments, ACC makes several recommendations in the context of the Environmental Protection Agency's Integrated Risk Information System (IRIS), where we believe that IRIS – and those who use that system – would benefit from assurances that the most up-to-date, reliable, and high quality science has informed the program.

Recent changes in chemicals policy in other countries and regions of the world, and at the state level, have raised questions about the adequacy of the U.S. chemical management system. ACC acknowledges the public's concern about the U.S. chemical management system, and the Council and our members are committed to supporting a regulatory program that is both scientifically sound and publicly credible. In our view, decision-making in the federal chemical regulatory program should be timely, scientifically-justified, efficient, effective and transparent.

In the case of risk-based regulatory decision-making, all stakeholders agree it is essential for agencies to use:

- The best available science. Science evolves continuously, as newer research improves on prior understandings and knowledge advances. It is a basic tenet of the scientific process and federal administrative law that decision-making should rely on the best science available at the time the decision is made. Better science can mean less uncertainty, and less need to rely on default assumptions.

- Weight of evidence analysis. While this phrase has several meanings in different contexts, scientists generally agree that science-based decision-making ought to take into account all available and relevant information. No research or analysis should be excluded *a priori*; rather, questions about the quality of the work ought to affect the weight that is given it, so that the best science is weighted most heavily.

- Peer review. Historically, the scientific community has relied upon probing analysis by other knowledgeable scientists as the best means of assessing the merits of a scientific work in the short term (i.e., before enough time has passed to see if the work can be replicated). Peer review has been well-established at EPA for many years, and since 2005 has been required at all federal agencies.

ACC agrees that there are areas where the current IRIS process can be improved. ACC supports efforts to improve EPA's risk assessment processes to develop scientifically comprehensive and accurate risk assessments, and we support transparency in the IRIS system. The Agency's recent improvements in the IRIS process (April 2008) represent an effort to foster continuous improvement practices in these important EPA activities.

ACC has been concerned for some time now that the IRIS process moves more slowly than desired. For example, many of the existing IRIS assessments are dated. We agree IRIS needs to be more effective in keeping up with new scientific information and reducing its backlog. This has been ACC's long-standing perspective. We have supported efforts to provide more resources for the IRIS program to make it more effective. However, even with the addition of 10 positions in EPA's IRIS program (approved in FY 2006 budget), the production rate for IRIS assessments has not increased substantially and a significant number of IRIS assessments remain outdated. Currently, about 80% of the assessments have not been updated for more than 15 years, and approximately 90% of the IRIS assessments are now 10 years or older.

The IRIS program has not made use of readily available opportunities to more rapidly develop new assessments, or revise out-dated assessments. For example, the program has not systematically used recent scientifically robust chemical risk assessments developed by or for other EPA and Federal Agency programs and not-for-profit risk assessment organizations as starting points for new or updated IRIS assessments. The risk assessments prepared for the EPA's Voluntary Children's Chemical Evaluation Program (VCCEP) are examples of up-to-date, scientifically rigorous risk assessments that the IRIS program could use.

The use of such assessments (or similar high-quality assessments developed by other federal agencies or comprehensive risk assessments authored outside government that have undergone independent scientific review for transparency, completeness and quality) should result in more rapid IRIS assessments without compromising scientific quality. Of course, EPA would need to develop a process for evaluating the scientific quality of such assessments to assure they comply with its own standards, as well as develop a means for appropriate revision. The program's use of such comprehensive and scientifically rigorous assessments as the initial step in an IRIS assessment or an IRIS update would provide considerable savings in resources, time and effort by EPA and would increase throughput in the program.

Over the last 10-15 years, the IRIS assessments have required greater scientific effort and time to prepare because the science of risk assessment has advanced and the techniques and approaches applied 20 years ago are now outdated. New scientific methods must now be used in IRIS assessments. These methods include the development and application of modeling for dose extrapolation across species and routes of exposures, incorporation of biologically based modes of action, explicit evaluation of possible differential sensitivity at different life stages and use of chemical specific adjustment factors. It must be emphasized that there is a need to have IRIS fully evaluate the best available scientific data. Currently, many assessments require several time consuming iterations to achieve the necessary degree of comprehensiveness and objectivity. While under the April 2008 IRIS process some additional time and effort may be necessary at the initial stages to enable a comprehensive collection and review of all relevant data, this will be time and effort well invested. The upfront investment should lead to a more complete, high quality initial draft assessment, and this should be expected to reduce the time and effort that is needed for re-analysis and re-drafting when a poor, less than comprehensive draft assessment is hastily developed.

Many of the improvements made in the IRIS processes by EPA in April 2008 address the findings and recommendations of the 2006 Government Accountability Office (GAO) report entitled "Human Health Risk Assessment -- EPA Has Taken Steps to Strengthen Its Process, but Improvements Needed in Planning, Data Development, and Training" (available at http://www.gao.gov/new.items/d06595.pdf). In that report the GAO recommended that 1) EPA enhance early planning of each risk assessment; 2) EPA identify and communicate data needs to the public and private research community; and 3) that the Agency support development and implementation of in-depth training for risk assessors and managers.

We believe that certain specific improvements in the IRIS process announced in April 2008 (specifically the steps of a) developing a literature search and requesting any additional information; and b) seeking comment on the qualitative assessment) will go a long way toward assuring that all the available relevant and valid scientific data can be identified early in the process so that the Agency will have this information and can incorporate it into the risk assessment in lieu of assumptions or defaults. Early and frequent public participation can help ensure that risk assessments are based on the best available information and are appropriately scaled and oriented to the relevant questions. These process improvements allow the Agency to collect scientific information on possible modes of action at the right time in the process (the qualitative assessment stage), so that these can be explored, evaluated, and if appropriate, used in the quantitative stage of the risk assessment. These improvements should contribute to more transparent and scientifically

comprehensive and robust IRIS assessments that reflect the most up-to-date scientific research and knowledge.

The risk assessments contained in the IRIS database provide important support for federal regulatory action across a number of programs. Although IRIS assessments address only hazard identification and dose-response, and thus are not complete risk assessments, IRIS values (RfDs, RfCs, Cancer Potency Slope values) are widely used locally, at the state level, nationally and internationally as the toxicity characterization portion of site-, situation-, and media-specific risk assessments. IRIS values are routinely used in Superfund, air toxics and drinking water risk assessments. Another important example is the National Toxicology Program's technical reports on toxicity and Reports on Carcinogens, which, like IRIS values, are not complete risk assessments but comprise a critical component of a risk assessment.

The Council believes that the OMB review of Agency risk assessments is an important and necessary action. Risk assessments are an integral part of benefit-cost analysis (BCA), as they are necessary to evaluate the benefits of various courses of action (i.e., what risks will be reduced and by how much?). BCA, in turn, is crucial to full and effective implementation of Executive Order 12866. Agency risk assessments, including IRIS dossiers, are used to establish regulatory actions such as site cleanups and facility permits, and therefore play a central role in the regulatory process. Agency risk assessments made available to the public are "information" "disseminated" by those agencies, and hence fall within the scope of the Information Quality Act (IQA).[1] OMB review focused on improving the quality of assessments, principally by increasing their objectivity and utility, advances the objectives outlined in the IQA and OMB's Guidelines under it. OMB regulatory analysis should include any analysis used to support rulemaking.

Unfortunately, agency risk assessment practices continue to suffer from a range of features that have been identified – in many cases, years ago — as problematic. These features systematically exaggerate actual risks and thereby seriously compromise the value of risk assessments as inputs to regulations and regulatory impact analyses. ACC documented the problems associated with these practices in a 2003 submission to OMB. In brief, however, ACC is most concerned about the following practices:

- *Intermingling of policy judgments with scientific assessments*. EPA freely acknowledges that it mixes risk management policy choices into the risk assessment process.[2]
- *Reliance on conservative worst-case assumptions, such as extreme and implausible estimates of exposure* (e.g., "maximally-exposed individual"). EPA frankly admits that it does this.[3]
- *Selective use of relevant test results*. A pattern of policy-biased selections is typically practiced, in which attention is focused narrowly on those results from toxicological or epidemiological studies that lead to the highest estimates of risk (or lowest estimates of an

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[1] 44 U.S.C. § 3516 note.

[2] *See* EPA Office of the Science Advisor Staff Paper, *An Examination of EPA Risk Assessment Principles and Practices* (EPA/100/B-04/001) (Feb. 2004), § 2.1.3 ("These policy positions not only shape the risk assessment process, but are also a factor in the decision-making process outside of risk assessment.").

[3] *Id.* § 2.2.7 ("[EPA's Office of Air and Radiation] has not modified the assumption of 70-year, 24-hour per day, outdoor exposure, even though] OAR recognizes that the majority of people do not reside outdoors and in one location for their entire lives.").

"acceptably safe dose"). Data sets are selected that display the effect(s) at the lowest dose level, for the most sensitive effect, in the most sensitive organ or tissue, all in the most vulnerable species, strain and gender. Conflicting evidence (specifically, evidence that tends to support a conclusion of lower or no risk) is customarily discounted or ignored.

- *Basing cancer risk estimates primarily on statistical upper-bounds* (of risk, at a specified dose) *or statistical lower-bounds* (of dose, for a specified level of risk).
- *Basing risk assessments on non-adverse effects* (i.e., adaptive changes, absent evidence for adverse consequences).
- *Failing to acknowledge the considerable uncertainty inherent in risk assessments and the degree to which that uncertainty is accounted for or masked by use of assumptions.*
- *Requiring full-fledged risk assessments where screening assessments could generate sufficient information for the question at hand.*

Many of the problems discussed above could be reduced or eliminated by upgrading the quality, objectivity, utility, transparency and integrity of risk assessment practices across federal agencies and particularly within EPA's IRIS program. For example, many current risk assessment practices are insufficiently focused, and do not follow processes to assure that the nature and magnitude of the risk is neither minimized nor overstated. Time-consuming and resource-intensive disputes could be avoided, and defensible health-based reference doses and standards could be issued more quickly and at lower cost by improving the policies and practices within EPA's risk assessment programs. Such improvements should include requiring: 1) application of a systematic framework for evaluating weight of evidence that entails quantitative assessment of biologically plausible modes of action in lieu of, or at the very least in addition to, default assumptions; 2) central estimates of risk; 3) application of conventionally-accepted criteria for specifying adverse effects; 4) the conduct of formal uncertainty analysis; and 5) transparency in all aspects of the assessment, including documenting full consideration and the rationale for action or inaction with respect to comments received on key substantive scientific issues.

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If you have any questions regarding ACC's comments or recommendations please do not hesitate to contact me.

Sincerely,

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Vice-President
Regulatory & Technical Affairs