



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

DEC 7 2000

THE ADMINISTRATOR

J. Routt Reigart, M.D.  
Chair  
Children's Health Protection Advisory Committee  
Medical University of South Carolina  
165 Cannon Street, Suite 503  
P.O. Box 250853  
Charleston, SC 29425

Dear Dr. Reigart:

Thank you for your letter recommending improvements to the Environmental Protection Agency's (EPA's) rulemaking process for children's health protection. Your recommendations regarding integration of the *EPA's Rule Writer's Guide to Executive Order 13045* (the Guidance) into the Agency, its organization and usability, and improvements in technical support for risk assessors are well taken and will be considered as we make our final revisions to the Guidance. As you know from your ongoing work with EPA's Office of Children's Health Protection (OCHP), we have continued to work over the past several months internally and with our external stakeholders to improve the Guidance. I would like to formally respond to your recommendations and let you and the Children's Health Protection Advisory Committee (CHPAC) know of activities occurring in the Agency since December, 1999.

The report from the CHPAC and the results of a phone survey of rule writers to determine accessibility and usefulness of the Guidance are being circulated within the Agency. Further input from EPA managers and staff who are responsible for the regulatory development process is also being sought in order to develop a complete picture of what is working with the Guidance and what is not. I anticipate revised Guidance later this year.

Once the Guidance is revised, I have asked Ramona Trovato to work with Paul Lapsley, the Director of the Regulatory Management Division at EPA, to better integrate the goals of children's environmental health protection into applicable standard operating procedures and training for Agency rule writers. They will also consider development of an evaluative instrument for upper level managers to assure continuing improvement in the rulemaking process relative to considering risks to children.

The Office of Children's Health Protection has also transmitted to the Agency Awards Board your recommendation that a new annual EPA award for "Excellence in Children's Environmental Health Protection" be established. This award would recognize outstanding efforts by EPA employees in enforcement, standard setting, research, or technology transfer and acknowledge them in front of their peers.

Finally, we fully support your recommendation regarding a feedback loop to research planning when data gaps are identified during rulemaking. In February, EPA's Science Policy Council, chaired by Deputy Administrator Michael McCabe, approved a pilot project on children's health to evaluate the principles of the Agency's *Strategic Framework for Science*. This pilot also addressed part of our accountability system's Goal 8 for "Sound Science and Improved Understanding of Environmental Risk." The pilot effort involved conducting an agency-wide survey of recent rules, regulations, standards and major risk assessments to understand what progress the Agency is making in evaluating children's health. The survey indicated that although attempts have been made to evaluate children's health effects, as called for in Executive Order 13045 and in the Administrator's 1995 Policy on Risk Assessment, EPA generally does not have the data needed to evaluate current toxicity values and ensure that they are protective of children. Guidance for certain endpoints such as developmental immunotoxicity is currently lacking. Despite a limited survey response rate, a teleconference subsequent to the survey concluded that there may be a benefit for the Agency to periodically check on how well children's environmental health is being integrated into the regulatory, risk-assessment, and standard-setting process.

Improvement in our ability to protect children's health is a top Agency priority, and I thank CHPAC for its recommendations and continued efforts in this regard.

Sincerely,



Carol M. Browne

cc: Ramona Trovato  
Paul Lapsley