

OPEN LETTER TO EPA FROM SCIENTISTS AND HEALTH ADVOCATES OPPOSING NEW PROCESS FOR IRIS DATABASE

September 17, 2008

Stephen Johnson, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Administrator Johnson:

We, the undersigned scientists and public health professionals with toxicological experience and expertise, are writing to voice our strong opposition to the new process for the Environmental Protection Agency's chemical assessment program, the Integrated Risk Information System (IRIS).¹ We urge you to abandon these policy changes that will hinder the ability of the EPA and scientists throughout the world to protect the public from exposure to unsafe chemicals.

The IRIS program's public searchable database contains EPA's scientific analysis of the potential human health effects of exposure to more than 540 chemicals, including highly hazardous chemicals such as vinyl chloride, butadiene, benzene, lead, mercury, and asbestos.² Although not regulatory in nature, IRIS assessments are relied upon by states, EPA program offices and governments throughout the world for setting standards for drinking water, air emissions, and toxic waste cleanups.

In April 2008, the EPA announced a new review process granting greater control over IRIS to other federal agencies, even those with clear conflicts of interest. Under the new rules, major polluters such as the Department of Energy (DOE) and the Department of Defense (DOD) will have multiple opportunities to dilute and delay the judgments of EPA's scientists and prolong by months or years the review of certain chemicals. Even worse, the new policy would categorize all inter-agency comments on draft IRIS assessments as "deliberative," which, if unchallenged or upheld by the courts, will shield the comments from scrutiny by the scientific community and the public.

A review of the new procedures by the U.S. Government Accountability Office (GAO) was released this spring, titled: *Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*.³ A summary of the report is also available online.⁴

¹ IRIS Process (2008 update) <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190045>

² Integrated Risk Information System (IRIS) <http://cfpub.epa.gov/ncea/iris/index.cfm>

³ United States Government Accountability Office. *Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*. Report to the Chairman, Committee on

The GAO report provides several examples of interference by EPA's political appointees, DOD, and the White House Office of Management and Budget (OMB), to delay or weaken IRIS assessments.⁵ These include:

- *Naphthalene*, a possible cancer-causing agent of jet fuel.⁶ Six years after initiating the IRIS review, the EPA has sent it back to the drafting stage after repeated objections from OMB and DOD;
- *Royal Demolition Explosives (RDX)*, used in munitions.⁷ RDX is a possible carcinogen known to leach from soil to groundwater. EPA delayed its review by seven years at the request of the DOD to wait for DOD-sponsored research. Some of that research is still outstanding.
- *Formaldehyde*, is a cancer-causing gas used to manufacture building materials such as pressed wood.⁸ The EPA began an IRIS assessment of formaldehyde in 1997. In 2004 members of Congress requested that the assessment be delayed until the completion of a large epidemiological study from the National Cancer Institute. In the absence of a completed IRIS assessment, the EPA's Office of Air and Radiation relied on a cancer risk assessment provided by an industry-funded organization in drafting its 2004 rule regulating formaldehyde emissions. The industry study found formaldehyde to be 2,400 times less potent than the proposed IRIS value, which was based on robust, peer-reviewed science. This weaker value was used to justify exempting certain plywood and composite wood manufacturing facilities from regulation under the Clean Air Act.⁹ The rule was later struck down by a federal court, but the IRIS assessment remains unfinished 11 years after it was begun.
- *Trichloroethylene, TCE*, a solvent used as a degreasing agent. TCE is one of the most common contaminants of superfund sites across the nation, and has been linked to cancer, including childhood cancer, and birth defects.¹⁰ The IRIS draft was initiated in 1998, and in 2001 said TCE was 'highly likely' to cause cancer, and specifically noted the added health risks when exposures took place during childhood. Now, ten years after beginning the assessment, it is back at the draft stage.

Environment and Public Works, U.S. Senate. Report No. GAO-08-440; March 2008. Available at <http://www.gao.gov/new.items/d08440.pdf>

⁴ Toxic Chemicals: *EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals* GAO-08-743T April 29, 2008. Summary at <http://www.gao.gov/docsearch/abstract.php?rptno=GAO-08-743T>

⁵ GAO report. *Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*. Pages 37-42

⁶ ATSDR ToxFAQs for naphthalene. <http://www.atsdr.cdc.gov/tfacts67.html>

⁷ ATSDR ToxFAQs for RDX. <http://www.atsdr.cdc.gov/tfacts78.html>

⁸ ATSDR ToxFAQs for formaldehyde. <http://www.atsdr.cdc.gov/tfacts111.html>

⁹ GAO report pages 37-39.

¹⁰ ATSDR ToxFAQs for trichloroethylene. <http://www.atsdr.cdc.gov/tfacts19.html>

- *Tetrachloroethylene, or perchloroethylene (perc)*, a dry cleaning and degreasing chemical which is a widespread groundwater contaminant. The IRIS assessment of perc was initiated in 1998. In 2006 *Risk Policy Report* revealed that the assessment was held up when EPA scientists rejected a directive from George Gray, a political appointee who directs the EPA’s Office of Research and Development, to reanalyze cancer risks using a “nonlinear” model which assumes a safe level of exposure.¹¹ The scientific staff insisted scientific evidence would not support using that model. This assessment is still being delayed.¹²

The GAO’s scathing critique concluded that the new procedures would sacrifice public trust in open government, compromise scientific credibility, and delay or derail the public release of robust scientific assessments needed by governments to set health-protective limits for hazardous chemicals.¹³ Moreover, GAO concluded that, “given the importance of the IRIS program to EPA’s ability to protect public health and the environment, Congress should consider requiring EPA to suspend its new process...”

These changes would compound what has already become an intolerable delay in completing new and updated assessments. The GAO report summary notes that, “The IRIS database is at serious risk of becoming obsolete because EPA has not been able to routinely complete timely, credible assessments or decrease its backlog of 70 ongoing assessments--a total of 4 were completed in fiscal years 2006 and 2007.”¹⁴ The GAO concludes that, “recent assessment process changes, as well as other changes EPA was considering at the time of GAO’s review, further reduce the timeliness and credibility of IRIS assessments.”¹⁵

The EPA IRIS program serves a critical scientific service to the public, and must be preserved and protected to conduct its work without political interference. The EPA’s authority to determine the risks posed by hazardous chemicals should not be compromised by interference from other federal agencies or industry stakeholders with conflicted interests. EPA’s recent changes undermine the scientific integrity of the IRIS process, and weaken protections for public health and the environment. We implore you to defend your staff and the agency by withdrawing the new IRIS procedures and ensuring that health assessments are established in an open process, free from inappropriate political interference or inappropriate policy considerations.

¹¹ Clean Air Report via InsideEPA.com. Staff rebuff ORD Chief’s bid for new risk study for key solvent. Inside Washington Publishers. Vol. 17, No. 20. October 5, 2006. Originally reported in Risk Policy Report, September 26, 2006, p1.

¹² On January 25, 2007 the California Air Resources Board ordered the phase out the use of perchloroethylene, from dry cleaning, with a complete ban by 2023, See details in news release at: <http://www.arb.ca.gov/newsrel/nr012607b.htm>

¹³ Toxic Chemicals: *EPA’s New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals* GAO-08-743T April 29, 2008. Summary at <http://www.gao.gov/docsearch/abstract.php?rptno=GAO-08-743T>

¹⁴ Ibid.

¹⁵ Ibid.

Respectfully,

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