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CPR CENTER FOR PROGRESSIVE REFORM

April 28, 2008

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

Re: IRIS Assessment Development Procedures (2008)

Dear Administrator Johnson:

We are writing to express our concerns about the recently-released "IRIS Assessment Development Procedures (2008)." The Center for Progressive Reform ("CPR") is a nonprofit research and educational organization whose network of scholars across the nation is dedicated to protecting health, safety, and the environment through analysis and commentary. Recognizing the fundamental importance of strong scientific evidence to the difficult decisions you must make, we want to call your attention to some aspects of the revised IRIS assessment process that we fear will hinder EPA's work in protecting human health and the environment.

Our overarching concern is that the IRIS database lacks data points that are essential to EPA's mission, yet the revisions to the IRIS Assessment Development Procedures will actually slow the development of new assessments, rather than streamline the process.

The most troubling gaps in the IRIS database include the absence of toxicological profiles for many chemicals EPA is responsible for regulating under the Clean Air, Safe Drinking Water, and Emergency Planning and Community Right to Know Acts. In 2005, CPR reviewed the database and found that more than one-fifth of the Hazardous Air Pollutants listed in the Clean Air Act were missing from IRIS.[1] Moreover, we found that the IRIS assessments that were available often had not been updated in many years.

In order to ensure that IRIS remains a useful source of up-to-date toxicological information for EPA staff and the many other public health officials who regularly access the database, reforms to the IRIS Assessment Development

[1] Steinzor, Baer, and Shudtz, *Overcoming 'Environmental Data Gaps': Why What EPA Doesn't Know about Toxic Chemicals Can Hurt* (July 2005), *available at* http://www.progressivereform.org/articles/Data_Gaps_510.pdf.

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Procedures should focus on transparency and streamlining the development of new toxicological profiles. But the most recent changes to the process will achieve the opposite result.

Bringing the Assessment Process to a Standstill

One new aspect of the new Assessment Development Procedures stands out from all others as a threat to smooth development of new IRIS toxicological profiles – the opportunity for other federal agencies to claim that a chemical being assessed by EPA is "mission critical." The mission critical designation halts the development of a new IRIS profile while the outside "sponsoring" agency develops a research plan, arranges cost-benefit analysis of the new research, consults with other agencies on the research plan, develops reports on the research, and organizes external peer review of the final reports. Though the guidance document outlining the new IRIS Assessment Development Procedures assumes all of this work can be completed in less than two years, it lacks any strict rule that would jump-start the assessment process if the development of new research drags on too long.

Secret Interagency Review

After the Office of Research and Development ("ORD") has developed a Draft Qualitative Assessment, taken comments on the document from the public and other agencies, potentially halted the process for development of new science on mission critical chemicals, and considered all comments and new information, a Draft Toxicological Review is developed. Once that document has been cleared through ORD and EPA's Intra-agency IRIS Review Committee, it is sent to the White House Office of Management and Budget ("OMB"), which is tasked with organizing interagency review. After OMB has compiled all of the comments from other agencies and provided them to ORD, ORD must address those comments in a "disposition of comments" document and revise the Draft Toxicological Review.

The entire interagency review process will be conducted in secret because the new IRIS Assessment Development Procedures states that other agencies' comments are deliberative. This is an untenable situation – it presents a major opportunity for political interference. A recent report from the Union of Concerned Scientists highlights the problem of OMB interference with the work of EPA scientists.[2] We can only expect more of this problem when OMB is in charge of the IRIS interagency review process and all of the work is shielded from public oversight through the deliberative process privilege.

Moreover, putting OMB in charge of the IRIS interagency review process denigrates the role of EPA scientists. Each agency has an IRIS "point of contact" with whom ORD communicates in the early stages of the IRIS assessment process. There is no need to insinuate OMB as an intermediary between ORD and the agencies' points of contact once the assessment process reaches the stage of reviewing Draft Toxicological Reviews.

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[2] UNION OF CONCERNED SCIENTISTS, *Interference at the EPA: Science and Politics at the U.S. Environmental Protection Agency* 28-30 (Apr. 2008), *available at* http://ucsusa.org/assets/documents/scientific_integrity/Interference-at-the-EPA.pdf.

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Secret Meetings

Another threat to transparency in the IRIS review process we found in the new guidance document is the repeated opportunity for "third party consultants" to be called in for secret meetings with agency staff. First, if another agency is sponsoring new short-term research on a mission critical chemical, "ORD or the sponsoring agency can call meetings and teleconferences to discuss critical issues articulated in correspondence among the agencies." They can invite "third party consultants" to those meetings. Second, the sponsoring agency is supposed to get independent, external peer review of this short-term research on mission critical chemicals. "If ORD or the sponsoring agency deems that consultation is warranted, ORD or the sponsoring agency may call a meeting to discuss critical issues and significant disagreements about the peer reviews. Third-party consultants may be invited by ORD or the sponsoring agency to participate in this meeting."

There is no requirement that these meetings, the participants, or what is said, be memorialized in any way. We urge you to bring some level of transparency to these meetings.

Inadequate Review of the New Guidance

With all of these concerns in mind, we are troubled that EPA chose to release these revisions to the IRIS Assessment Development Procedures without any meaningful opportunity for public analysis or comment. President Bush's Executive Order 13,422 and the OMB's Bulletin on Good Guidance Practices require agencies to post a draft of any economically significant guidance document and publish a notice in the Federal Register that alerts the public of an opportunity to comment on the draft document. Even if the IRIS Assessment Development Procedures are not "economically significant," they are surely significant from a policy perspective and should be open for public comment under the OMB Bulletin.

IRIS toxicological assessments play an integral role in EPA's work in almost every program area, and we urge you to consider whether the recent changes to the IRIS Assessment Development Procedures will help or hinder the fast and transparent creation of new toxicological profiles. Thank you for the opportunity to comment.

Sincerely,

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