

Opening Statement
The Honorable Paul Broun, M.D. (R-GA)
Ranking Member, Subcommittee on Investigations and Oversight
Fixing EPA's Broken Integrated Risk Information System

June 11, 2009

The Integrated Risk Information System (IRIS) process was originally developed in the mid-1980's for a specific task. Different offices throughout the Environmental Protection Agency (EPA) were relying on different assessments of the health effects of exposure to chemicals. IRIS was intended to establish a uniform database within EPA that represented consensus determinations.

Over time, however, IRIS became an authoritative resource on chemical toxicity. As a credit to the agency's diligence, other agencies, states, the international community, and industries increasingly began to rely on IRIS, and the assessments took on increased importance. These outside groups have sought to impact a process that was not initially designed to handle external pressures. The result has been an IRIS process that has effectively broken down.

As we learned from GAO last year, EPA had a backlog of 70 ongoing assessments and managed to complete only 2 assessments in each of the last 2 years. Even when EPA managed to produce assessments, the National Academy of Sciences has roundly criticized their work. The competing priorities of issuing assessments in a timely manner and producing assessments that are scientifically credible are central to the problems we face today.

The completely unsatisfactory timeframes for these assessments are the result of several factors. Reviews are becoming more complex as attention increases for high profile chemicals, EPA management and program decisions are delaying completion, outside stakeholder reviews are becoming more detailed, and Congressional action is becoming more prevalent. All of these delays have compounding effects and create a "domino effect" on schedules as Mr. Stephenson pointed out in previous testimony.

Until recently, the IRIS process was an opaque process that had no schedule deadlines and limited outside review. While the previous Administration's proposed process wasn't perfect, it was the first time that the process was formalized, thoroughly explained, and given strict timelines. If nothing else, the previous Administration recognized the untenable nature of the existing IRIS process and presented a proposal to fix the problem.

While the previous process wasn't perfect, neither is this the new process. Previous processes required EPA to develop a consensus assessment – the original purpose of the IRIS process. The newly proposed process does not require each EPA office to concur on assessments, but rather to simply consult. Furthermore, these internal agency consultations are not required to be available to the public, which ultimately limits

transparency. EPA's failure to develop consensus assessments raises the question of how authoritative and useful IRIS will be in the future.

One of the common themes the new proposal is being sold by is its new streamlined process. As I mentioned earlier, the natural tension between thoroughness and timeliness of assessments begs the question of whether a streamlined process will ultimately sacrifice scientific credibility, especially considering recent negative reviews from the National Academy of Sciences. In order to streamline the process, the new Administration has cut out quality control measures such as visibility into the adjudication of peer review comments; the requirement for a qualitative assessment review; the public review of that qualitative assessment; the evaluation of agency interests in closing data gaps for mission critical chemicals, the design and implementation of new studies for mission critical chemicals, and the development of short-term research projects that may aid in filling data gaps. More importantly, this new streamlined process uses a bit of slight-of-hand to take the scientific literature review and data call-in periods off the schedule entirely. This work will still be done, but EPA doesn't account for this time in its schedule, allowing them to create the appearance of a speedier process.

One of the largest criticisms of the previous proposal was the role played by the White House, and more importantly the Office of Management and Budget (OMB) and the Office of Regulatory Information and Affairs (OIRA). Despite these previous criticisms, the new process states that White House offices will continue to be involved in the interagency consultation process. Apparently this was only a concern when it was politically fashionable. If anyone had a problem with the previous Administration's "meddling," you can probably expect more of the same since OIRA is staffed almost exclusively by career civil servants.

Some may try to dismiss this concern by noting that EPA is now ultimately responsible for the process, but they always had final authority, even under the previous process. It could be claimed that even with that previous authority, EPA was still subordinate to the influence of OMB. Similarly, one could argue that EPA will truly have final authority under the new process, but the last time I checked the EPA Administrator still worked for the President. The only difference is that now maybe the Administrator also works for the new Environment Czar Carol Browner. We aren't really sure about this since she is removed from any type of Congressional oversight, transparency, or accountability. I hope that science's "rightful place" doesn't turn out to be behind the cloak of deliberative process and executive communication.

Despite concerns about White House meddling, OMB has provided useful input into EPA assessments according to GAO's 2008 report. While OMB should certainly not use this review process to obstruct or prevent assessments, EPA also shouldn't be afraid to address valid scientific inquiries. Additionally, OMB plays an important role in shepherding the interagency process. Without OMB taking the lead in this process, it remains to be seen if EPA will have enough clout to force or compel other agencies to comply with its timelines and directions.

This also raises another question relating to who will ultimately be the adjudicator of conflicts and arbiter of scientific disputes. In an ideal world, neither the White House nor EPA would be involved in this, as it truly is a discussion meant for the scientific community. Unfortunately in the real world there needs to be a bureaucratic referee. Is EPA truly an unbiased partner when they are the agency that drafts the assessments? What incentive does EPA have to incorporate peer reviewer's comments that may contradict their opinions? Are we setting up a system where EPA will be responsible for monitoring its own work? Even if EPA is unbiased, are the Office of Research and Development (ORD) staff tasked to conduct these assessments experts on every chemical and aware of all the science? If the answer is no, then aren't we essentially making pure, but poorly informed assessments? If none of these questions matter because assessments go through peer review, why would it matter if other agencies, industry, or the White House were involved since the final product will be peer reviewed?

As you can tell, I remain very skeptical of the new process but I do see some commendable aspects. New transparency measures for the interagency review process are promising even though they don't extend to internal communications between EPA line offices which could prove to be just as informative and important. Despite this bright-spot, several other questions remain.

On that final note, Mr. Chairman, I am attaching a letter from Toxicology Excellence for Risk Assessment (TERA) to my statement that I will enter into the record. I appreciate your indulgence and look forward to the witnesses' testimony.