COMMITTEE ON SCIENCE AND TECHNOLOGY
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
U.S. HOUSE OF REPRESENTATIVES

HEARING CHARTER

"EPA's Restructured IRIS System: Have Polluters and Politics Overwhelmed Science?"

Wednesday, May 21, 2008
11:00 a.m. – 1:00 p.m.
2318 Rayburn House Office Building

The Subcommittee on Investigations and Oversight will hold the first of two hearings on the Integrated Risk Information System (IRIS) at the Environmental Protection Agency (EPA).

We have three excellent witnesses who can place the role of IRIS in perspective as well as address questions regarding the Bush Administration's evolving system to draft and review IRIS entries:

Mr. John Stephenson, *Director, Natural Resources and Environment, Government Accountability Office.*

Dr. George Gray, *Assistant Administrator for Research and Development, United States Environmental Protection Agency.*

Ms. Susan Dudley, *Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget.*

What Is IRIS and Why Does It Matter?

IRIS was established in the 1980s to provide a single source of information on the risks associated with exposure to chemicals. The IRIS database provides a hazard identification and dose-response analysis, scientific information that when combined with estimates of exposure allow regulatory agencies to produce a risk assessment. Historically, entries to the database were the result of extensive in-house development by the science staff at EPA, peer review processes with experts from outside the agency, and opportunities for public input and comment. To the degree interagency communications occurred, they were managed by EPA (See Figure 1).

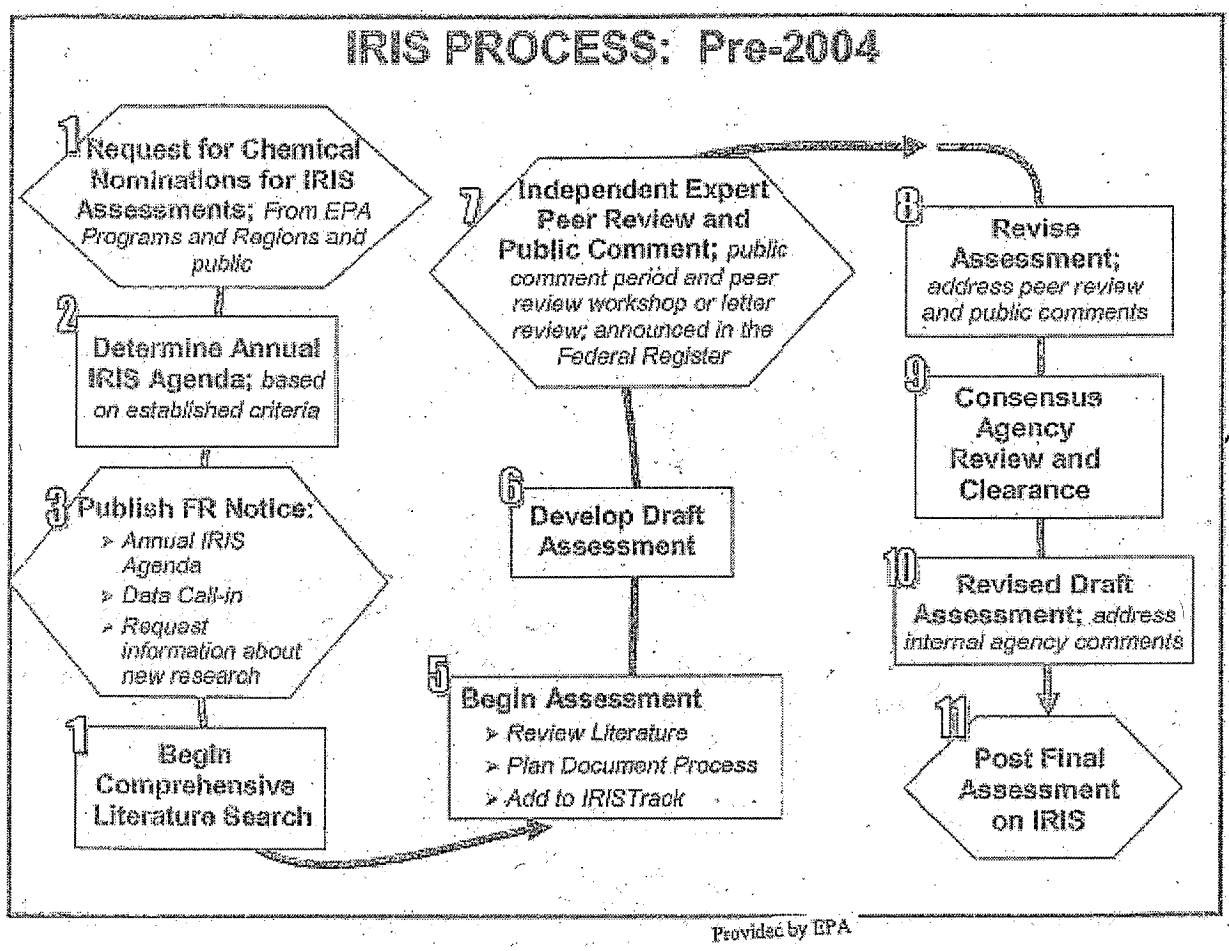
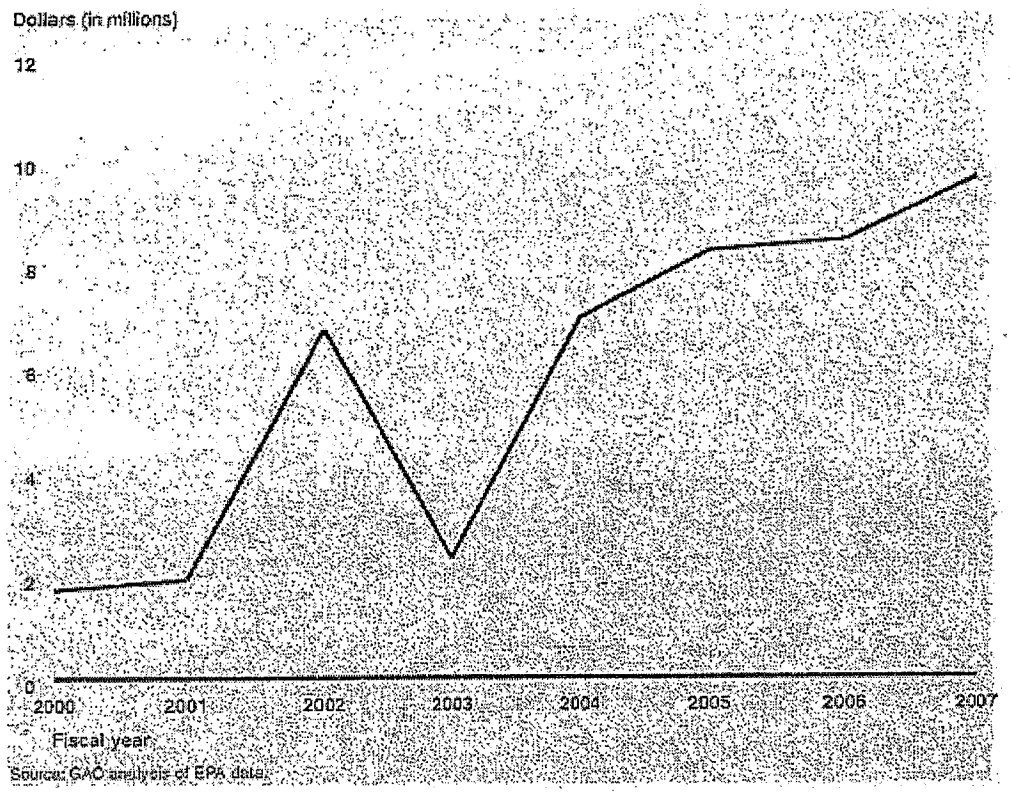


Figure 1. Pre-2004 IRIS Process (EPA).

While not a regulatory product itself, IRIS is designed to help regulators set priorities about what to regulate and inform regulators about what level of exposure workers or communities can absorb safely. A long-recognized principle in the U.S. approach to regulation has been the distinction between risk assessment—the characterization of what science tells us regarding a particular hazard—and risk management, or what you want to do about the hazard (including choosing to do nothing). Science can point to where regulation may be needed, but science may not be the sole consideration in setting a regulatory standard or approach. IRIS is designed to be a risk assessment tool. Government officials in Federal agencies, in State and county governments and even in foreign countries, have come to rely upon IRIS for the most reliable, most comprehensive statements on what science tells us about the risk associated with a particular chemical.

A long-standing challenge for the IRIS database is meeting the requests for information on the many chemicals that are manufactured and utilized in global commerce, and updating information on chemicals that have been previously evaluated. IRIS is loosing ground to the torrent of new chemicals introduced to the marketplace. Approximately 700 new chemicals enter commerce each year. Those new chemicals are added to the over 80,000 currently reported under the Toxic Substances Control Act (TSCA) as being in the market. In addition, about one half of the assessments on approximately 480 chemicals currently in the database need to be updated according to EPA staff estimates. To keep IRIS relevant would require aggressive moves to speed the production and approval of entries. Congress has actually increased funding for IRIS staff in recent years in an effort to address this severe backlog (this Committee supported increased funding in Chairman Boehlert's FY2007 Views and Estimates Report to the Committee on the Budget—see Figure 2 for a representation of the IRIS budget).



Note: In fiscal year 2002, a congressional appropriations conference committee designated $5 million to accelerate the development of new IRIS values and to update current IRIS values. According to EPA officials, this funding was provided to various EPA program offices to support the IRIS assessments that program offices were leading at that time. In addition, EPA has reprogrammed funds from some of its other programs to expand the IRIS program to support the development of IRIS assessments, especially high-priority chemicals.

Figure 2. Funding for the IRIS Program, Fiscal Years 2000-2007 (GAO).

IRIS Slows to a Crawl

Instead of seeing IRIS entries spike with funding and personnel increases, additions and updates to IRIS have slowed to a crawl (Figure 3). Only four IRIS listings have been finalized in the past two years. In comparison, the state of Minnesota requested new or updated assessments of 52 chemicals of concern in the 2006 solicitation for the 2007 Program. [1]

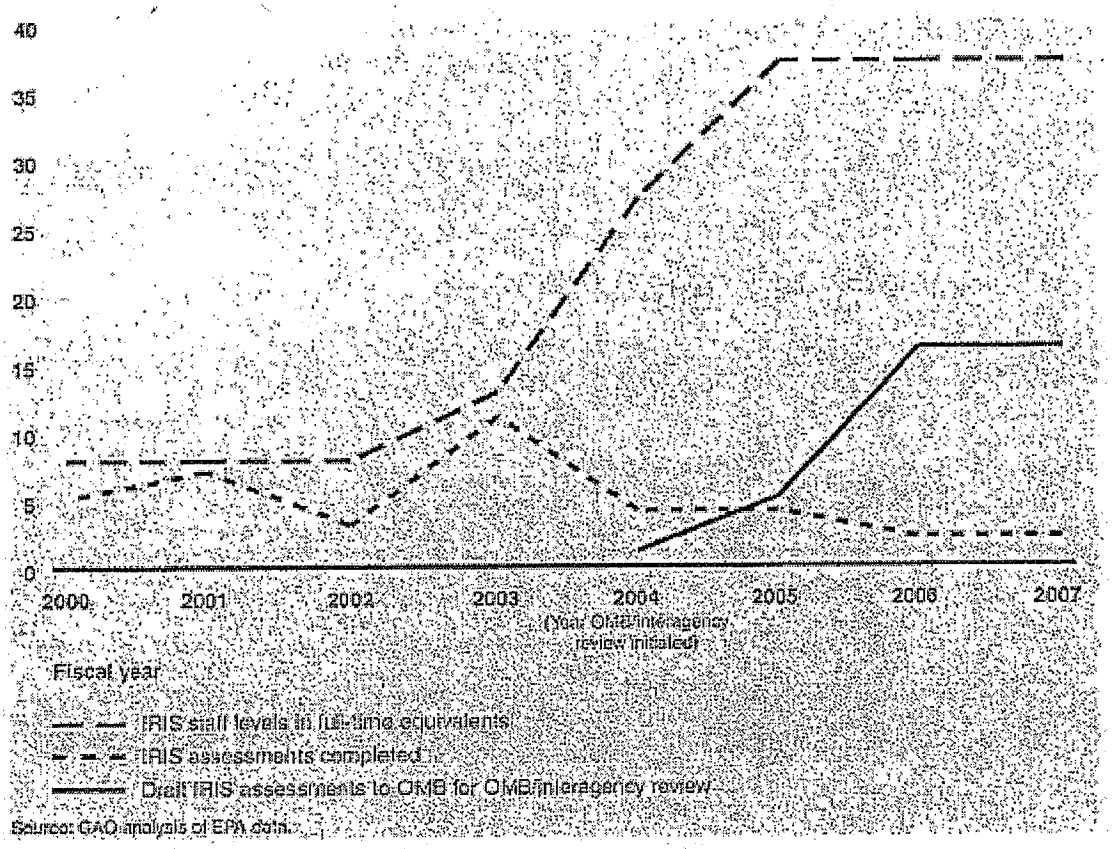
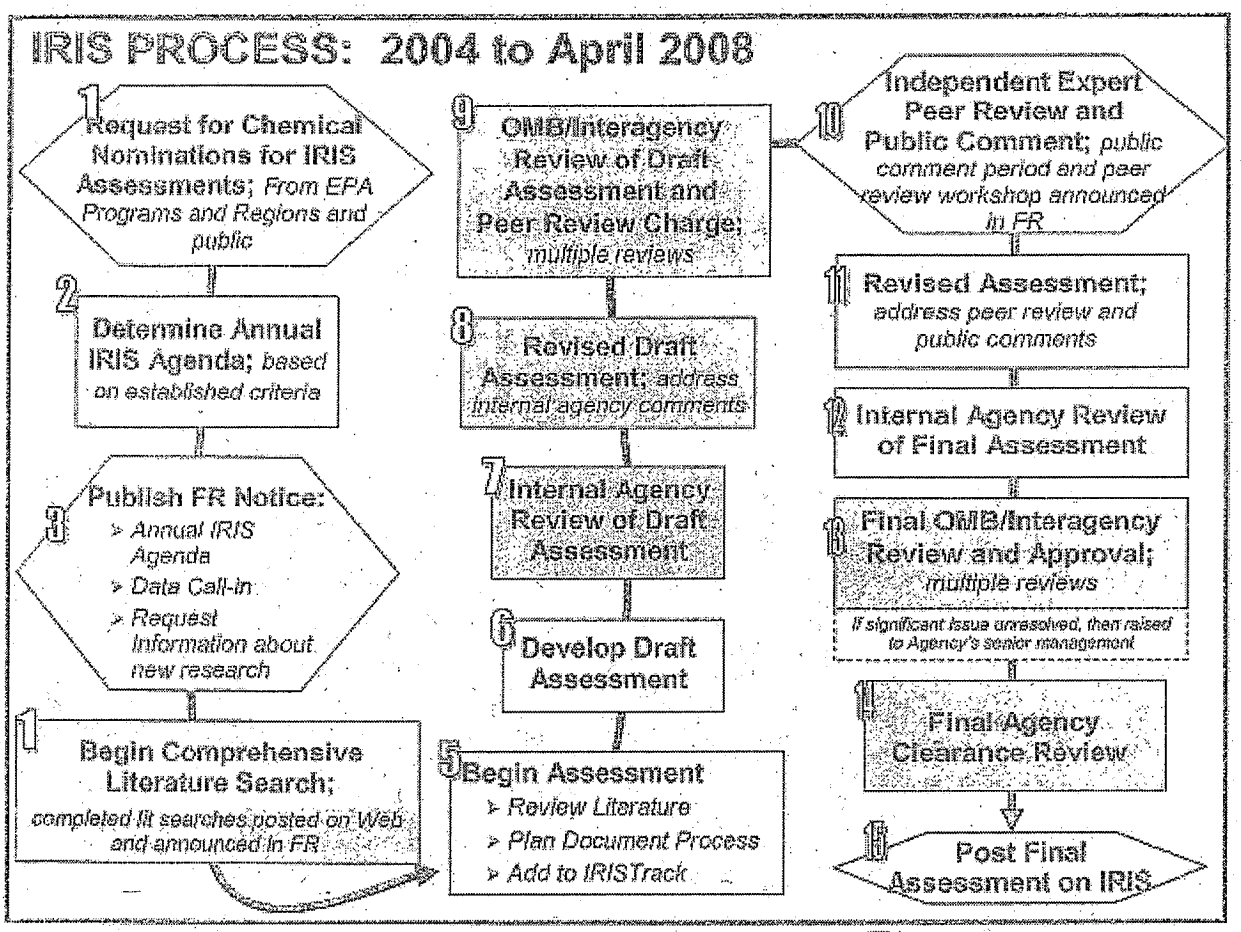


Figure 3. Number of Completed IRIS Assessments, Draft Assessments sent to OMB, and IRIS Staff in Full-Time Equivalents, Fiscal Years 2000-2007 (GAO).

This outcome appears to be tied to the intervention of OMB in the IRIS review and approval process. Beginning in 2004, OMB established a formal system of interagency review (Figure 5). This system, ostensibly designed to improve the quality of IRIS entries, appears to have all but stopped IRIS entries. On April 10 of this year, EPA announced a new IRIS review and approval system that is even more elaborate than its predecessors (Figure 4).

[1] Submission by the Minnesota Department of Health to the Integrated Risk Information System (IRIS); Request for Chemical Substance Nominations for the 2007 Program. Docket ID No. EPA-HQ-ORD-2006-0950.



Provided by EPA

Figure 4. 2004-April 2008 IRIS Process (EPA).

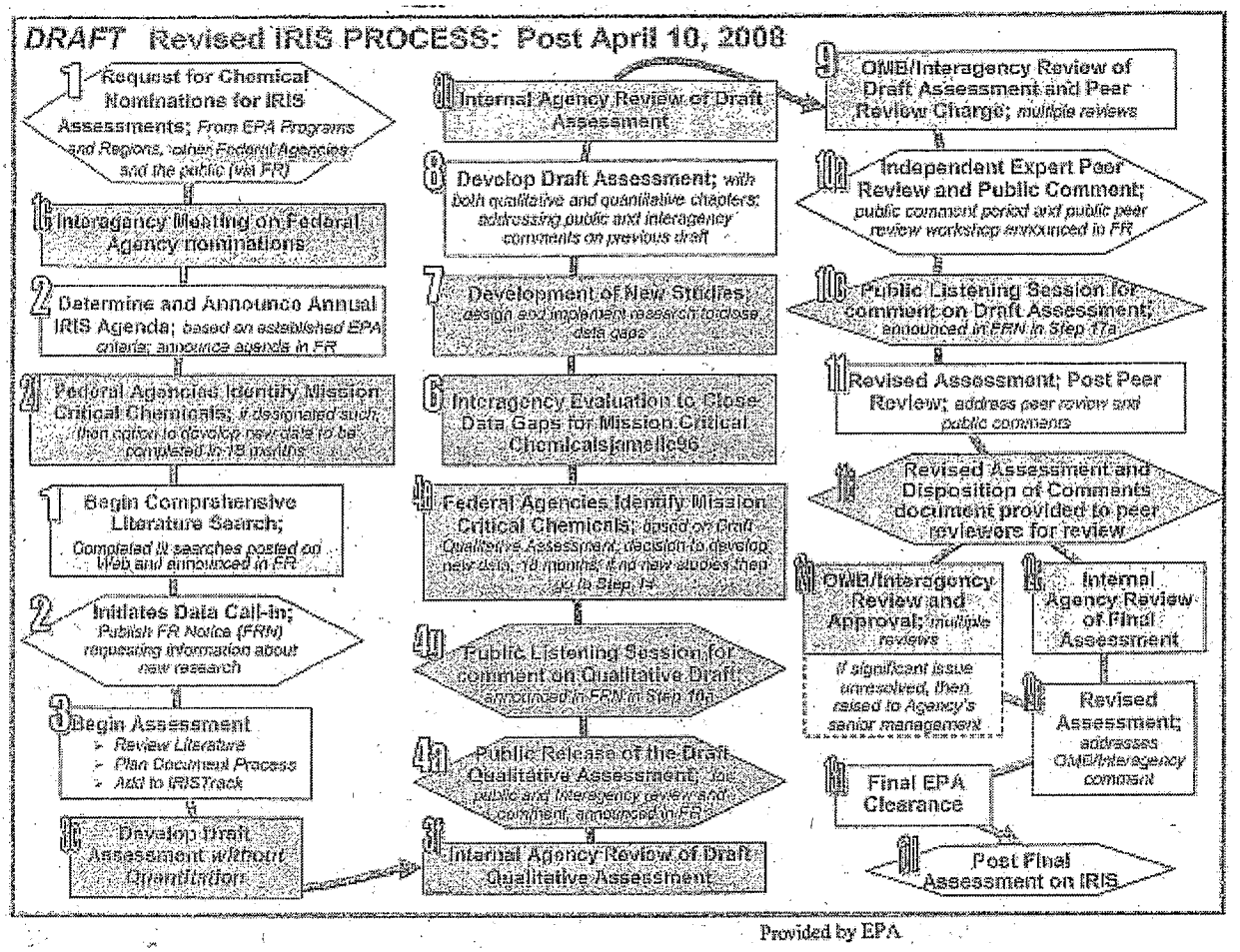


Figure 5. Post April 10, 2008 Revised IRIS Process (EPA).

It appears that any IRIS listing that is the least bit controversial will take six years or more to be completed. The interagency process allows agencies with a direct conflict of interest multiple opportunities to influence the development and content of IRIS assessments all within a process that lacks any transparency for Congress or the public. The Department of Defense, the Department of Energy and NASA all are responsible for pollution on the federal lands they manage and for the health and safety of the personnel that manage their facilities and operations. Rocket fuel, jet fuel, solvents, munitions, nuclear waste all contain hazardous materials that can become pollutants contaminating aquifers and air, and exposing workers and families to real harm.

IRIS Entries Become a Political Science

EPA leadership has agreed to OMB establishing a review that gives polluting agencies lengthy, unmonitored opportunities to try to convince OMB that the risks of a particular substance should not be set at a particular level. It is hard to understand what special science expertise these other agencies bring to the table such that OMB needs to set up an interagency review to discuss science.

Remember that the development of IRIS assessments and, the risk assessment process generally, is supposed to be separate from the risk management process. There you would expect interested parties, including other Federal agencies, to discuss how to manage risks by weighing costs and benefits in a search for the best option given a particular configuration of risk and need. IRIS is supposed to be solely about what science says regarding health and environmental risk associated with the listed chemicals. With 7000 scientists, and mandated by law and appropriation to be the nation's lead agency on environmental science, EPA really has no peers when it comes to understanding the science at stake in IRIS listings.

The process established on April 10 allowing agencies to discuss a particular IRIS listing is closed to the public. Because that work represents pre-deliberative discussions, any materials from that process are not subject to the Freedom of Information Act. Because these processes are managed by OMB, it will be very difficult for Congress to learn of what is happening due to OMB's consistent assertions that all of their work should be shielded from Congress and the public. Whether the proposals that come out of this lengthy, secretive process are based solely on science, or whether other considerations held sway, would be very hard for anyone to ever prove.

IRIS is withering. It is loosing its relevance due to the sweep of time, new science and new substances as well as its own inability to refresh its data. The process put in place on April 10 appears guaranteed not to improve this situation, but to make it worse. But even if the process was somehow producing more entries, more quickly, the integrity of the process is itself in question and that alone will undermine the utility of the IRIS database. If policy makers and the public believe the science has been cooked to meet a polluter's agenda, then they will not have confidence in the science. It is a simple problem and one that the April 10 revision puts at center stage.

The Subcommittee hopes to explore these issues with witnesses on Wednesday morning.

The Minnesota Department of Health Submission to the Integrated Risk Information System (IRIS); Request for Chemical Substance Nominations for 2007 Program (Docket ID No. EPA-HQ-ORD-2006-0950)

The Health Risk Assessment staff at the Minnesota Department of Health wish to nominate a list of chemicals to be included in the Integrated Risk Information System (IRIS); Request for Chemical Substance Nomination for 2007 Program. These chemicals are of concern to the Minnesota Department of Health because they are among contaminants found in Minnesota groundwater. In Minnesota, health based values are derived for such contaminants. When conducting risk assessments, the Minnesota Department of Health has relied upon the IRIS summaries as a resource for the development of these health protective values. Therefore, it is our hope that you take our nominated chemicals in consideration. By obtaining IRIS summaries of these chemicals it will result in a more thorough and accurate risk assessment process.

1,2,3 – Trichloropropane
1-Methylnaphtalene
1-Methylphenol
2,2 – Dichloropropane
2,3,4,5 – Tetrachlorophenol
2,3,5,6-Tetrachloroterephthalic acid
2,6-dinitrotoluene
2,6-diethylaniline (Alchlor degradate)
2-Nitrophenol
3,5-Dichlorophenol
4-Isopropyltoluene
Acetochlor ESA
Acetochlor OA
Alachlor ESA (degradate of Alachlor)
Alachlor OA (degradate of Alachlor)
Aluminum
Deaminated diketomethribuzin (degradate of Metribuzin)
Deaminated metribuzin (degradate of Metribuzin)
Deethylatrazine (degradate of Atrazine and Propazine)
Deisopropylatrazine (degradate of Atrazine, Cyanazine and Simazine)
Diallate
Diazion
Dichlorofluoromethane
Diketometribuzin (degradate of metribuzin)
Dimethenamid
Dimethenamid ESA (degradate of Demethenamid)
Dimethenamid OXA (degradate of Dimethenamid)
Ethafluralin
Hydroxyatrazine
Iron
Isopropyl ether
Isoxaflutole
Lithium
Metolachlor ESA
Metolachlor ESA

The Minnesota Department of Health Submission to the Integrated Risk Information System (IRIS); Request for Chemical Substance Nominations for 2007 Program (Docket ID No. EPA-HQ-ORD-2006-0950)

Metsulfuron-methyl (Ally)
Monomethyl tetrachloroterephthalic acid
n-Butylbenzene
Nicosulfuron
n-Propylbenzene
Primisulfuron-methyl (Beacon)
Radionuclides (all)
Sec-Butylbenzene
Sodium
Thifensulfuron methyl
Tin
Total petroleum hydrocarbons
Tribenuron-methyl
Triclopyr
Trinitro-phenylmethylnitramine
Triphenyltin hydroxide
Vanadium

In addition, the Minnesota Department of Health currently needs and uses reference concentrations and reference doses for less than chronic periods of exposure to assess risks from a variety of exposure scenarios. These scenarios include less than chronic exposures that commonly occur at contaminated sites resulting in the need for less than chronic toxicity values to assess current risks. The EPA 2002 "A review of the reference dose and reference concentration processes" has guided much of the practice of the department in this area.

The department has found that health effects that result from less than chronic periods of exposure, when combined with high drinking water exposures associated with specific life stages (e.g., childhood), result in drinking water values that are lower and therefore more appropriate as drinking water standards for the general population than the value calculated using a chronic reference dose and lifetime average dose. As a result, the department is very interested in recent efforts by IRIS to develop less than lifetime reference values, and urges the EPA to continue to develop and publish these analyses. The department also urges the EPA to consider the potential that effects observed in chronic studies result from early exposures rather than continuous exposure. To the extent that studies are available, the department urges the EPA to present acute, short-term, longer term, and chronic evaluations (recommendations for critical studies for each and resulting reference doses) for each chemical that undergoes review in the future.

For questions or to request additional information, please contact:

Paul Moyer, MS
Environmental Research Scientist
651-201-4912
paul.moyer@health.state.mn.us