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

HEARING CHARTER

"Toxic Communities: How EPA's IRIS Program Fails the Public"

Thursday, June 12, 2008
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

The Subcommittee on Investigations and Oversight will hold the second hearing on the Integrated Risk Information System (IRIS) at the Environmental Protection Agency (EPA).

On May 21, 2008, the Subcommittee heard the Government Accountability Office's (GAO) evaluation of the Administration's new process for reviewing and approving chemical assessments for inclusion in the IRIS database. In their March 2008 review of EPA's IRIS program GAO found that the IRIS database was at serious risk of becoming obsolete because the Agency has not been able to complete credible assessments in a timely manner or to reduce the backlog of 70 assessments that were in the development, review or approval process. [1] In their subsequent examination of the process implemented by the Administration on April 10, 2008, GAO testified that the recent assessment process changes and the other process changes being implemented by EPA were likely to increase the time needed to finalize IRIS assessments and to further reduce the credibility of IRIS assessments.[2]

The witnesses will address the role of IRIS assessments in the regulatory process for implementing environmental statutes administered by EPA and by state, territorial, and tribal governments and the consequences of extended delay in the IRIS assessment process for public health. They will also address questions regarding the Bush Administration's evolving system to draft and review IRIS entries. Witnesses include:

- **Mr. Jerome Ensminger,** *Master Sergeant U.S. Marine Corps (ret.)*
- **Mr. Lenny Seigel,** *Center for Public Environmental Oversight*
- **Dr. Linda Greer,** *Senior Scientist, Natural Resources Defense Council*
- **Dr. David G. Hoel,** *Professor, Medical University of South Carolina*

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[1] U.S. Government Accountability Office (GAO). 2008. *Chemical Assessments Low Productivity and New Interagency Process Limit the Usefulness of EPA's Integrated Risk Information System.* GAO-08-440.
[2] U.S. Government Accountability Office (GAO). 2008. *Chemical Assessments EPA's New Assessment Process Will Further Limit the Productivity and Credibility of Its Integrated Risk Information System.* Testimony before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, House of Representatives.

What is the Role of an IRIS Assessment in the Regulatory Process?

Federal and state governments adopt environmental and public health laws to protect natural resources and the public. EPA, state, territorial, and tribal governments implement environmental statutes through the issuance of regulations that set standards for air and water quality and for cleanup of contaminated areas. Regulations also set deadlines for achieving the standards. At the federal level, EPA administers environmental statutes to protect public health and the environment, to establish criteria for the handling and disposal of hazardous materials, and that govern the cleanup of contaminated land and water. The preparation of a regulation requires assembling a wide variety of information to define risk and justify the risk management approach mandated by the regulation. In addition to the information and procedural requirements imposed by individual statutes, there are general statutes governing the issuance of regulations by federal agencies that also impose procedural and information requirements (e.g. Administrative Procedures Act, Paperwork Reduction Act, Unfunded Mandates Reform Act) and there are Executive Orders and guidance from the Office of Management and Budget (OMB) that also require procedures and analyses to be done in support of a regulation.

Two of the most commonly required analyses are risk assessments and cost-benefit analyses. While not a regulatory product itself, IRIS is designed to help regulators set priorities about what to regulate and inform regulators on a safe exposure level for workers or communities. An IRIS assessment 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. Delay in the production of the IRIS assessment translates into delay in implementation of environmental statutes and in establishment of standards to protect public health.

While some state governments have environmental programs that independently establish standards (e.g. California), many state governments and virtually all territorial and tribal governments rely upon the federal government to develop and evaluate the scientific information that will determine safe levels of exposure and allow regulatory agencies to set standards for air and water quality to protect public health and the environment. For example, in response to EPA's solicitation to set priorities for developing IRIS assessments, the state of Minnesota submitted a list of 52 chemicals of concern.[3]

[3] 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.

The Case of Trichloroethylene: How Long Does a Controversial IRIS Assessment Take to Complete?

In its March 2008 report on EPA's IRIS program GAO examined six specific IRIS assessments that are in process.[4] One of the six assessments was of trichloroethylene or TCE. GAO's report provided the following timeline for the development of a cancer assessment of TCE for inclusion in the IRIS data base: EPA developed a cancer assessment of TCE for inclusion in the IRIS data base, but withdrew it in response to peer reviewers' comments in 1989. EPA initiated a new TCE cancer assessment in 1998 and issued a new draft assessment in 2001. This draft and its findings were controversial. It was reviewed by EPA's Science Advisory Board and released for public comment. The National Academy of Sciences (NAS) was asked to review the draft and to resolve issues raised in the SAB review and through the public comment process about methods EPA used to assess the risk of TCE. In 2006, the NAS panel released their report. The panel stated:

> The committee found that the evidence on carcinogenic risk and other health hazards from exposure to trichloroethylene has strengthened since 2001. Hundreds of waste sites in the United States are contaminated with trichloroethylene, and it is well documented that individuals in many communities are exposed to the chemical, with associated health risks. Thus, the committee recommends that federal agencies finalize their risk assessment with currently available data so that risk management decisions can be made expeditiously.[5]

Despite this direction from the NAS to move forward, EPA has not yet released its assessment of TCE. According to GAO, the assessment is back at the draft development stage and will not be finalized until 2010.

What are the Consequences for public health when IRIS Assessments are delayed?

TCE is a solvent that has been in commerce since the 1920s. TCE is a degreasing agent and has been widely used in manufacturing and industrial settings. It is one of the most commonly identified contaminants at sites included on EPA's National Priority List (NPL) under the Superfund program. It is a found in air, water, and soils. A number of different cancers, reproductive and developmental problems, neurotoxic effects, and autoimmune disease have all been associated with exposures to TCE.

Since TCE is a contaminant of air, water, and soils its cleanup is determined through various statutes administered by EPA including: the Safe Drinking Water Act, the Clean Air Act, and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) or Superfund. Under each of these statutes, EPA has the authority to set maximum contaminant levels that define safe drinking water, set air

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[4] U.S. Government Accountability Office (GAO). 2008. *Chemical Assessments Low Productivity and New Interagency Process Limit the Usefulness of EPA's Integrated Risk Information System.* GAO-08-440.
[5] National Research Council. 2006. *Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues.* The National Academy Press. Washington, DC. p. 2.

quality standards that define clean air, and that set standards for clean up of contaminated soil and water at superfund sites. These standards cannot be strengthened until EPA has completed the IRIS assessment, a risk assessment, and other supporting studies and information requirements (e.g. cost-benefit analysis, regulatory impact analyses, etc.) needed to support a regulation. Many people believe the TCE standards currently in place are inadequate to protect human health especially that of children and other sensitive subpopulations.

The Subcommittee will hear from two witnesses whose family or communities have experienced serious health impacts that are associated with exposure to TCE. One of the sites listed on the Superfund NPL is Camp Lejeune, the Marine Corps base in North Carolina. The drinking water source for the base is contaminated with TCE and tetrachloroethylene (PCE or perc). The Marine Corps closed contaminated drinking water wells in 1985, and the site was listed in 1989. The Agency for Toxic Substances and Disease Registry estimated that up to 1 million people were exposed to these toxic contaminants before the contaminated wells were closed in 1985.

The community of Mountain View, California has several TCE cleanup sites. Several of the contaminated sites are located on federal lands including the Orion Park Military Housing Area (U.S. Army). These areas are still undergoing clean up and remediation and residents of the area are still exposed to TCE through a process known as vapor intrusion.

Mr. Ensminger and Mr. Seigel will discuss the experiences of their family and community, respectively and why they believe EPA's IRIS program needs reform.

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

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:

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