The IRIS Information Roadblock:

How Gaps in EPA's Main Toxicological Database Weaken Environmental Protection

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Executive Summary

The Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) is considered by many to be the gold standard database for toxicological information and human health effects data, used by risk assessors around the world. Information for chemicals that are included in the database is authoritative and accessible to anyone with an Internet connection, and the IRIS website receives as many as 20,000 hits daily.

IRIS profiles serve as a "cornerstone" for a host of decisions in the public and private sector. In regulating hazardous air pollutants under the Clean Air Act, determining what type of remediation is proper for a particular brownfield development, or any number of other important decisions to protect public health, worker safety, and the environment, the ultimate choices are based on what is in essence a two-step process – (1) scientists conduct a risk assessment and (2) policymakers use that risk assessment to inform their decisions about risk management.[1]

Data in the IRIS database can be used to answer some of the fundamental questions in the risk assessment step, which is what makes the database so important. Individual chemical profiles found in the database present the acceptable numerical dose of each chemical that, if ingested (eaten), inhaled, or absorbed through the skin could cause cancer, brain damage, respiratory illness, and a raft of other adverse health effects. To come up with these crucial cornerstones for pollution control, EPA scientists compile the best available scientific research, study and debate disparate and sometimes contradictory research findings, and consider the "weight of the evidence" to derive the numbers. All of this is done according to a step-by-step process, and informed by detailed guidelines. EPA's scientists are well-respected internationally and the agency is the final arbiter of environmental protections at home, so the imprimatur placed on toxicological values at the end of the IRIS process gives them great weight.

Unfortunately, EPA's efforts to update and supplement IRIS have slowed to crawl in recent years as special interests—especially the Office of Management and Budget (OMB), the

The authors thank Leila Ashkeboussi for her assistance in developing the tables in this report and analyzing the current coverage of hazardous air pollutants in the IRIS database.

[1] *See* NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, *Science and Decisions: Advancing Risk Assessment* (2009), and NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, *Risk Assessment in the Federal Government: Managing the Process* (the "Red Book") (1983).

Department of Defense (DOD), the Department of Energy (DOE), and the National Aeronautic and Space Agency (NASA) have thrown unwarranted barriers in its path. The result is that IRIS, which should provide a crucial foundation for protection, is outdated, incomplete, and ultimately ineffective. As just one central example of the implications of IRIS sabotage, this report examines how many "hazardous air pollutants" (HAPs) identified by Congress in 1990 for rapid regulatory controls are either omitted from IRIS or characterized inadequately in the database:

- 17 percent of the hazardous air pollutants—32 HAPs in all--are missing completely, including highly toxic and pervasive chemicals like hydrogen fluoride and chloroprene; and

- 67 percent (the 32 without profiles, plus 94 others that have only partial profiles), including formaldehyde and methanol, lack information about the most relevant data point needed to devise controls for toxic air pollution – the inhalation reference concentration.

Unfortunately, the widespread use of IRIS has motivated potential targets of these decisions – including regulated industries, defendants in toxic tort lawsuits, and government agencies that use and dispose of toxic chemicals--to demand a prominent role in changing the numbers developed by EPA scientists. These special interests recognize that IRIS profiles can result in decisions that will increase their operating expenses, and have become adept at influencing the process by which chemical profiles are included in IRIS. During the Bush Administration, they had important allies at the Office of Management and Budget (OMB) who successfully imposed so many opportunities for review and second-guessing that EPA found it very difficult to update IRIS.

The process for crafting a new IRIS profile underwent two rounds of revision during the Bush Administration. Both increased the opportunity for special interests and OMB economists to challenge EPA scientific findings. Recognizing the implications of these biased and unwarranted procedures for scientific integrity within the government, on May 20, 2009, EPA Administrator Lisa Jackson revised these procedures for a third time, making strides toward streamlining the process but failing to go far enough to liberate the process from inappropriate interference.

The Jackson reforms leave two major issues unresolved. First, the process still offers too much opportunity for other government agencies to wield excessive influence over decisions that should be left to EPA scientists and IRIS program staff. The revised process maintains an interagency review process that grants agencies with a vested interest in the final content of an IRIS profile special opportunities for input and influence. As a result, DOD, which, as the nation's largest source of toxic waste has a decidedly parochial interest in the outcome of IRIS decisions, will continue to have privileged access to the development of the profile. This privileged treatment is unwarranted because, for the purposes of IRIS profiles, DOD has no more

expertise to offer, and exactly the same underlying motivation, as the private sector actors who are provided an ample, but single, opportunity to comment on the profile. Just as it would be wrong for EPA to give any other special interest privileged access beyond what is available during the public comment period, so too should special interests within the government be denied this second opportunity to distort the agency's scientific deliberations. **The entire interagency review process undermines the scientific integrity of the IRIS process and should be abandoned.**

The second issue left unresolved by Administrator Jackson's revisions is how EPA will determine which new chemicals should be added to the database and which existing IRIS profiles need to be updated. **EPA should revise its agenda for expanding the IRIS database so as to ensure that the agency has the tools necessary to achieve its statutory mandates. For instance, EPA should commit to completing individual profiles for Clean Air Act HAPs within specific, reasonable periods of time.**

Introduction

Originally created in 1985 as a centralized source of health effects information that was previously scattered throughout the agency's program and regional offices, EPA's IRIS database is an important source of information about the potential human health effects of chemicals for individuals, groups, and institutions that need accessible and accurate information about toxic chemical risks. The database is accessed thousands of times daily, by users around the world. The health effects information contained in the database is used by EPA staff making risk management decisions about air and water quality standards, hazardous waste site remediation and more, as well as by litigants in toxic tort cases, state-level environmental regulators, and academic researchers.

In its final form, an IRIS profile will contain both quantitative and qualitative information about a toxic chemical. The qualitative aspects of a profile provide information about the potential adverse health effects posed by exposure to the chemical. The quantitative information estimates the level of daily exposure to a chemical that will result in adverse health effects, and is expressed as an oral reference dose (RfD), inhalation reference concentration (RfC), oral slope factor, or oral and inhalation unit risks for carcinogenic effects. The profile will also contain qualitative discussion of the studies that EPA staff considered in developing the RfD, RfC, or other data point. IRIS profiles also describe the uncertainties encountered in the assessment process and EPA's confidence in its conclusions.

The scientific validity of the end result is important because the information in an IRIS profile can be used to answer vital questions in the risk assessment/risk management process, the fundamental decisionmaking paradigm that drives most environmental and public health decisions. Under the Clean Air Act, Safe Drinking Water Act, and various other statutes, the

basic structure of EPA's regulatory program is a two-step process: (1) risk assessment, and (2) risk management. In its influential "Red Book" (the most widely cited resource on basic risk assessment policy), the National Academy of Sciences provides a concise explanation of the risk assessment/risk management process:

> Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision.[2]

IRIS profiles are most pertinent to the risk assessment stage of environmental and public health decisions. Risk assessment involves four distinct steps: (1) hazard identification; (2) dose-response assessment; (3) exposure assessment; and (4) risk characterization.[3] IRIS profiles can be used to complete the first two steps, making the database a powerful utility for anyone involved in risk assessment/risk management decisionmaking.

In short, the data in IRIS reflect, or at least ought to reflect, the best information available to the government about the risks associated with a broad range of chemicals in commerce. That information ought to be accurate, current, and comprehensive.

But as IRIS has become an important central repository for health effects information, it has also become a focal point of advocates' efforts to promote or staunch new decisions to protect public health. The final conclusions posted in a chemical's IRIS profile can have a significant impact on how a party might be regulated under the Clean Air Act or Safe Drinking Water Act, what controls or cleanup might be required for a hazardous waste site containing the chemical, or whether a company will incur liability for exposing workers or the public to the chemical. Obviously, these decisions can have important implications for public health and private firms' bottom lines, so the skilled advocates who are employed to promote those interests will do what they can to shape the information posted in IRIS profiles.

With this increased interest in the IRIS program by special interests, there has been increased interest in the process the EPA staff use to update profiles, particularly the amount and forms of "peer review" undertaken for each profile as it goes from initial staff draft to final posting in the database. In fact, the process for crafting a new IRIS profile has undergone major revisions three times in the last five years and the focus of each revision has been to change which institutions will have the power to review the IRIS program staff's work, when they will be able to exercise those powers, and what effect the outside reviewers' comments will have on the further development of the IRIS profile.

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[2] The "Red Book," at 3.
[3] *Id.*

In the end, we believe that recurrent review of IRIS profiles by other federal agencies needs to be curtailed. The underlying scientific research supporting IRIS profiles has already been peer reviewed, IRIS program staff have the experience, education, and training to adequately review the existing literature and make scientifically valid decisions, and each additional layer of review threatens the integrity of the process and delays the development of new profiles and updates to existing profiles. Some review – such as review by other EPA program staff and independent experts – is useful and necessary, but some – particularly interagency review – is, in effect, nothing but stakeholder interference masked as "peer review."

After discussing the most recent changes to the IRIS process, we will present evidence of a major gap in the IRIS database – the lack of information about hazardous air pollutants that EPA is responsible for regulating under the Clean Air Act Amendments of 1990.

The IRIS Process: New Revisions and Old Problems

Before 2004, the process for adding a chemical profile to the IRIS database was far less complex, and it produced the quality of information that gave the database its reputation as a useful source of information for a variety of risk assessment/risk management decisions. Yet, in the intervening years there have been three attempts to redesign the assessment process, all of which have made it more complex, mainly through additional opportunities for government agencies outside of EPA to review the IRIS program staff's work.

On May 20, 2009, EPA Administrator Lisa Jackson wrote a memorandum asking the Office of Research and Development (ORD) "to immediately implement a new IRIS process that will be more responsive to the needs of the Agency and its government partners in protecting the health of Americans."[4] In a thinly veiled rebuke of the Bush-era changes to the IRIS process and the problems caused by those revisions, Administrator Jackson explained that the IRIS process

> …will be more transparent and timely, and it will ensure the highest level of scientific integrity. The process will be entirely managed by EPA, which will have final responsibility for the content of all IRIS assessments after considering the scientific input of experts at other agencies and White House offices. To guarantee the scientific quality of the IRIS assessments, the process will include the opportunity for public comment and rely on a rigorous, open, and independent external peer review. Changes in EPA's scientific judgments during this public process will be clearly documented and explained, maximizing the transparency of the final product. While still robust, the assessment development process will be shortened to 23 months, speeding the availability of IRIS

[4] Memorandum from Lisa P. Jackson, Administrator, Environmental Protection Agency, to Assistant Administrators et al., Re: New Process for Development of Integrated Risk Information System Health Assessments (May 21, 2009), *available at* http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=489350 (accessed June 5, 2009).

assessments to the risk assessor community and the public and providing for more timely action to protect public health.[5]

Administrator Jackson outlined the new process in seven steps:

1. EPA develops and completes a draft IRIS toxicological review
2. EPA conducts an internal agency review of the draft
3. EPA initiates interagency science consultation on the draft IRIS toxicological review
4. EPA initiates independent external peer review of the draft IRIS toxicological review, public review and comment on the draft IRIS toxicological review, and holds a public listening session
5. EPA revises IRIS toxicological review and develops an IRIS summary
6. (a) EPA conducts an internal review of the final IRIS toxicological review and IRIS summary
   (b) EPA-led interagency science discussion
7. EPA completion of IRIS toxicological review and IRIS summary

EPA deserves credit for several of these changes. It was a wise decision to abandon the practice of allowing outside parties to name certain chemicals as "mission critical," a designation that enabled other government agencies to essentially hijack the IRIS process. Similarly, Administrator Jackson has done well to remove the unnecessary step of designing and implementing new studies to fill data gaps. Certainty in this area of science is extremely rare, and IRIS profiles are only meant to describe the current state of the science on a given chemical. It was also important for EPA to improve transparency with respect to interagency review of IRIS profile development, insofar as interagency review is necessary. (It is important to note, as the Government Accountability Office (GAO) has,[6] that White House involvement in IRIS profile development is generally through oral communications, which are not explicitly covered in the new policy.) Finally, it was good for EPA to establish its primacy in developing IRIS profiles by eliminating the OMB-led review procedures.

However, the new process leaves two major issues unresolved: it still has potential for allowing institutions other than EPA to wield excessive influence over decisions that should be left to IRIS program staff, and it fails to adequately address the problem of establishing priorities to guide which as-yet un-profiled chemicals will be added to the database first.

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[5] *Id.*

[6] U.S. GOV'T ACCOUNTABILITY OFFICE, CHEMICAL ASSESSMENTS: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System, GAO-08-440, *at* 23 (March 2008).

The Problem of Interagency Review

One problematic change to the IRIS process implemented during the Bush Administration and retained in Administrator Jackson's new policy is the privileged access to the process for federal agencies outside of EPA. GAO has concluded that several layers of interagency review can actually limit the credibility of an IRIS assessment.[7] The problem is that these agencies are often more concerned about potential future regulation than the efficient development of a high-quality IRIS profile. In other words, their interests align more with special interest groups than with IRIS program staff, creating a situation where they can be tempted to abuse their ability to influence the development of a particular IRIS profile. Moreover, GAO has warned that interagency review is a key factor in "EPA's inability to achieve a level of productivity that is needed to sustain the IRIS program and database."[8] GAO's concerns have been echoed by EPA's congressional overseers: The U.S. House of Representatives' Committee on Science and Technology, Subcommittee on Investigations and Oversight, released a report detailing how the White House Office of Management and Budget (OMB) exploited the interagency review process to engage in debates that are better suited to other modes of review, like independent external review by scientific experts.

Rocket Fuel in Drinking Water Forces IRIS into Slow Motion

EPA's effort to update the IRIS profile for perchlorate illustrates the delay and obfuscation linked to interagency review. Perchlorate is used as a main ingredient in rocket fuel and in very small doses may disrupt thyroid hormone production by the thyroid gland. Thyroid hormone imbalances can, in turn, negatively impact fetal and neurological development. In recent years, scientists have discovered that substantial portions of waters in the Western United States are contaminated with perchlorate. Some 20 million residents of Western states may be exposed to elevated levels of perchlorate in their drinking water.

Perchlorate's ubiquity is due mainly to the Cold War arms race. During that time, solid fuel rockets and missiles were developed as an alternative to liquid-fueled propellants. But as the hundreds of thousands of missiles manufactured during the Cold War reach the end of their useful lives or become obsolete, the military must find some way to dispose of them. For many years, the Army, Navy, and Air Force have disposed of unused munitions using the Open Burning/Open Detonation (OB/OD) method. OB/OD simply entails digging a hole, placing unused missiles in it, filling it, and detonating the missiles. This method is preferred by the military because it is quick and, in the short term, cheap.

Unfortunately, one of the primary constituents of solid rocket fuel is ammonium perchlorate, and when perchlorate-containing munitions are disposed of using the OB/OD method, significant

[7] *Id. at* 43-55.
[8] *Id. at* 22.

amounts of perchlorate are released into the soil. In some military ranges used for OB/OD, perchlorate has been measured in concentrations of tens of thousands of parts per million. As water leaches through the soil, perchlorate anions attach to chemicals in the water and seep into the groundwater.

Several Western states, particularly California, have begun pushing the Department of Defense (DOD) to clean up perchlorate on its bases before any additional groundwater contamination occurs. Recognizing the monumental costs that it could incur as a result of being forced to clean up all of the perchlorate-contaminated soils on its lands, DOD has refused to start cleanup until a national perchlorate drinking water standard is established.

Recognizing that EPA's development of a national drinking water standard (a risk management decision) is predicated on the development of a robust risk assessment for perchlorate, DOD has made a concerted effort to inject its own policy preferences into the risk assessment process, a campaign that not only slowed the process significantly, but also limited the credibility of the final IRIS profile for perchlorate. EPA began work on a new IRIS profile for perchlorate in 1998. By 2002, EPA staff had come up with a draft assessment and had ushered it through both internal and external peer reviews. But as the agency neared completion of the final IRIS profile, DOD, with the White House and OMB at its side, insisted that EPA ask the National Academy of Sciences to review the draft IRIS assessment. This second, more time-consuming round of external peer review gave DOD another opportunity to try to poke holes in the work of the EPA scientists who had been laboring on the perchlorate assessment for the previous four years. But DOD's critique of the IRIS program staff's work strayed far beyond the scientific questions confronting the panel. DOD sent Colonel Daniel Rodgers to deliver this message to the panel:

> We support this review because we very much want to get the science right, because only credible science can lead to credible decisions.… Thousands of men and women in the uniformed services of the United States of America eagerly await the results of your careful and considered and objective deliberations, for what you decide will have a greater impact on their lives than on any others.… [T]here is no room for reliance on science policy precaution for its own sake.… Every layer of policy precaution inhibits our ability to train … [putting] our combat forces and, ultimately, our nation at risk.[9]

The fact that DOD and OMB pressured EPA to hold another round of external peer review just so that they could inject these risk management issues into the risk assessment process is disturbing. So too is the fact that it took until 2005 before the final IRIS profile for perchlorate was posted, some seven years after EPA began the process of adding it to the database. The delay was due, in large part, to DOD's obstructionism.

[9] Colonel Daniel Rodgers, U.S. Air Force, presentation to the National Academy of Sciences Committee to Assess the Health Implications of Perchlorate Ingestion, October 27, 2003, 2-3, *quoted in* Rena I. Steinzor, MOTHER EARTH AND UNCLE SAM: HOW POLLUTION AND HOLLOW GOVERNMENT HURT OUR KIDS (Univ. of Texas Press, 2008).

Most disturbing about the incident is the fact that the Bush-era creation of a strong interagency review process was designed specifically to give DOD and other potentially affected agencies the opportunity to engage in similar chicanery for any future IRIS profile update. The history of the development of the interagency review process is outlined in the U.S. House Science Committee, Subcommittee on Investigations and Oversight report, "Nipping IRIS in the Bud." The report shows that OMB – not EPA – drove the development of the 2004 and 2008 revisions to the IRIS process and served as a conduit for other agencies suggest how EPA should gather and respond to their concerns on future IRIS profile updates. The report also documents how the evolution of a new interagency review process caused confusion and delay in the ongoing work of IRIS program staff.

GAO has cited interagency review as a primary culprit in decreased credibility and delayed development of at least two other IRIS profiles – naphthalene and trichloroethylene (TCE). These chemicals implicated the interests of the Department of Energy and National Aeronautics and Space Administration (NASA), resulting in multi-year delays that GAO linked to EPA's sister agencies.

A Partial Fix: The Jackson Revisions to IRIS Process

To her credit, Administrator Jackson has made it clear that she intends for EPA to have complete power in managing the interagency review process. However, the powers granted to other agencies under the old process were hard-won and are unlikely to be simply returned to EPA. We are confident that EPA's commitment to holding the reins during the development of new or revised IRIS profiles will be tested by both OMB and other federal agencies.

In fact, we have already observed OMB scientists injecting themselves into other aspects of EPA's work during the Obama Administration. Most notably, the docket for EPA's proposed "endangerment finding" with respect to carbon dioxide under the Clean Air Act is riddled with documentation of OMB scientists critiquing the minute details of EPA scientists' work. In doing so, OMB staff stray beyond both their expertise and mandate. Neither EPA's endangerment finding, nor a particular IRIS profile is a regulatory action with which OMB should be involved. OMB has an Executive Order mandate[10] (albeit one that is subject to some criticism) to review and coordinate federal agencies' rulemaking. It does not have a mandate to review "pre-regulatory" work like IRIS assessments. Yet, we expect OMB will continue to avail itself of its considerable powers and we are concerned that OMB could inappropriately impact the development of new or revised IRIS profiles.

Ideally, Administrator Jackson should abandon the interagency review stage, but encourage other federal agencies to critique draft IRIS profiles during public comment period – at the same time, and under the same procedures, as all of the other potentially affected interest groups.

[10] Executive Order 12,866, 58 Fed. Reg. 51735 (Oct. 4, 1993).

If that solution is not adopted, EPA must at minimum improve the mechanisms it uses to ensure that EPA staff and other agencies will be held accountable for problems and delays caused by interagency review. For instance, in order to avoid unnecessary delay, EPA should establish strict timelines for other agencies' comments. In addition, all communications between EPA and other government officials, whether oral or written, should be placed immediately in a publicly accessible docket. As GAO affirms, "transparency in the IRIS assessment process can provide assurance that these scientific assessments are appropriately based on the best available science and that they are not impacted by policy issues and considerations."[11] Unfortunately, such accountability mechanisms are missing from Administrator Jackson's May 20 memorandum.

A Case Study of IRIS's Gaps: Clean Air Act Hazardous Air Pollutants

Also missing from the most recent revisions to the IRIS process is any discussion of how EPA will prioritize the chemicals that need to be added to the database and the chemicals whose IRIS profiles need to be updated. Some 548 substances are currently listed in the IRIS database. While that is a significant number given the work required to get information posted in the database, EPA is responsible for protecting Americans from literally thousands of chemicals. Roughly 700 new chemicals enter commerce each year. Obviously, EPA cannot complete an IRIS profile for every new chemical – not only would such an effort demand prodigious resources, but there simply is not enough information available to accomplish the task for many chemicals.[12]

The simple fact that a chemical exists in commerce is not sufficient reason to put it on the IRIS agenda. IRIS program staff make decisions about which chemicals to add to the database and which existing profiles need to be updated based on the availability of new scientific information, personnel and resource constraints, program office need, and public interest. Congressional objectives play a smaller role, often through the proxies of EPA program staff. Below, we present research showing that those proxies are not enough to ensure that Congress's major public health objectives are fully integrated into the IRIS agenda, particularly in the realm of air toxics.

In the 1990 amendments to the Clean Air Act, Congress listed 188 hazardous air pollutants (HAPs) and mandated that EPA establish regulations to protect Americans from the dangers posed by those HAPs. EPA's regulations were to occur in two stages. First, EPA was to establish "technology-based" emissions standards. Congress instructed EPA to devise regulations that would promote the implementation of the maximum achievable control

[11] GAO Report on IRIS, *supra* note 6, *at* 54.
[12] *See, e.g.*, ENVIRONMENTAL PROTECTION AGENCY, *HPV Chemical Hazard Data Availability Study*, *available at* http://www.epa.gov/HPV/pubs/general/hazchem.htm (accessed June 5, 2009) (noting that 93 percent of chemicals produced or imported at rates over 1 million pounds per year are missing one or more of the basic toxicity screening tests that are necessary for even a minimum understanding of the chemical's toxicity).

technologies, in particular, "the average emission limitation achieved by the best performing 12 percent of the existing sources" of each HAP.[13] Recognizing that "technology-based" regulation is an expedient but imperfect solution, Congress added another provision to the Clean Air Act to ensure that public health would not remain threatened even after implementation of the maximum achievable control technologies. That provision calls on EPA to assess the residual risks posed by each HAP and promulgate further regulation of any HAP "to provide ample margin of safety to protect public health."[14] In other words, Congress instructed EPA to double-check its work, directing EPA to come up with technology-based regulation, do a risk assessment to see how well that technology-based regulation works in terms of delivering public health benefits, and then, if necessary, promulgate regulations to reduce any excess residual risk.

The creation of an IRIS profile for each HAP should be an integral part of EPA's efforts to control residual risks under the Clean Air Act. For each HAP, if IRIS program staff were to develop a profile that listed an inhalation Reference Concentration (RfC), the uncertainty factors applied, and a description of the reasoning behind their assessment, staff from other EPA offices could then use that information in conjunction with exposure monitoring data, information on environmental fate and transport, and other relevant data to complete a full risk assessment for each HAP. From there, risk management decisions could be formulated and regulations could be designed.

This idealized process, however, will not be realized because the IRIS agenda does not give sufficient weight to congressional mandates and program office needs, as evidenced by the poor coverage of HAPs in the IRIS database. Today, nearly 20 years after Congress gave EPA a list of priority chemicals, some 17 percent are not listed in IRIS at all. Worse, two-thirds of the Clean Air Act HAPs do not have inhalation RfCs listed in the database. Specific chemical identities are listed in Appendix A to this report, but the numbers alone provide a clear picture of the problem:

- Of the 187 HAPs,[15] only 155 (83 percent) have IRIS profiles
- Of the 187 HAPs, 126 (67 percent) are missing inhalation RfC values.

The potential consequence of not taking the necessary steps toward regulating these HAPs is profound. In Tables 1 and 2, below, we provide basic data on environmental releases of some HAPs not adequately profiled in the IRIS database. The data come from EPA's Toxic Release Inventory (TRI), which provides access to chemical release information submitted by the firms that produce and use the chemicals. We ranked all 32 HAPs not listed in the database and all 94 HAPs whose IRIS profiles are missing inhalation RfCs, based on total air releases reported in

[13] 42 U.S.C. § 7412 (d).
[14] 42 U.S.C. § 7412 (f)(2).
[15] One of the 188 originally listed HAPs was dropped under procedures provided for in the statute.

TRI.[16] The top ten chemicals in each category are presented in Table 1, which show that the unlisted chemicals are released at a rate of hundreds of thousands of pounds per year. In Table 2, we present information about the health effects of some of these chemicals, compiled from information available through the Center for Disease Control and Prevention's Agency for Toxic Substances Disease Registry (ATSDR), and the chemicals' materials safety data sheets (MSDS).

Table 1: TRI Data for HAPs with Inadequate IRIS Profiles

	CAA § 112 HAP	Fugitive Air Releases (lbs)	Point-source Air Releases (lbs)	Total TRI-listed Air Releases (lbs)
Chemicals Missing IRIS Profiles	Hydrogen fluoride	2,452,724	65,156,022	67,608,746
	Chloroprene	64,747	656,681	721,428
	Ethylene oxide	132,988	152,247	285,235
	Diethanolamine	161,693	22,411	184,103
	Ethyl acrylate	29,944	40,548	70,492
	Cobalt compounds	7,209	48,181	55,390
	Titanium tetrachloride	39,825	8,029	47,854
	o-Toluidine	6,146	9,291	15,437
	Cadmium compounds	1,929	7,537	9,467
	4,4'-Methylenedianiline	7,135	1,083	8,218
Chemicals with IRIS Profiles, But No Inhalation RfC	Methanol	32,762,661	96,585,081	129,347,741
	Carbonyl sulfide	138,196	19,761,297	19,899,493
	Formaldehyde	1,008,494	8,238,753	9,247,247
	Dicholormethane	2,088,462	3,159,631	5,248,093
	Chlorine	376,275	4,721,400	5,097,675
	Trichloroethylene	1,964,316	2,393,993	4,358,309
	Phenol	608,149	3,306,085	3,914,234
	Ethylene glycol	1,208,014	1,215,586	2,423,600
	Tetrachloroethylene	779,616	990,373	1,769,989
	Lead compounds	285,344	517,365	802,709

[16] For information about the air releases reported to TRI under the Emergency Planning and Community Right-to-Know Act, see http://www.epa.gov/tri/triprogram/whatis.htm (accessed June 9, 2009).

Table 2: Health Effects Information for Certain HAPs Listed in Table 1

Hydrogen fluoride	Hydrogen fluoride and other fluoride compounds released into the environment from industry are subsequently carried by the wind and rain to surrounding water, soil, and food sources. Hydrogen fluoride accumulates in plants and animals, and will not degrade in the natural environment. Humans come into contact with hydrogen fluoride through exposure to contaminated soil, water, and food. The health effects associated with hydrogen fluoride vary depending on the magnitude of exposure. Low to moderate level exposure results in irritation to the skin, eyes, and respiratory tract. High level exposure results in increased bone density in adults and dental fluorosis (causing fragility of the teeth) in children. Extremely high level exposure results in brittle bones and damage to the heart.
Chloroprene	Acute exposure to chloroprene via inhalation may result in coughing, dizziness, drowsiness, headache, sore throat, unconsciousness, and chest pain. Exposure through inhalation can occur very rapidly because harmful contamination of the air is reached quickly upon evaporation of Chloroprene at 20°C. At short-term exposure, chloroprene is a respiratory irritant and may cause adverse effects on the kidneys, liver, and central nervous system. Exposures that far exceed the safe occupational exposure limit may result in death. Chloroprene is a possible human carcinogen.
Formaldehyde	Formaldehyde is used in many industries and laboratories. Although most of the general population is exposed to low levels on a daily basis, Formaldehyde can cause irritation of the skin, eyes, nose, and throat. High levels of exposure may cause some types of cancers. Formaldehyde is given off as a gas from the manufactured wood products used in new mobile homes. Ingestion of large quantities of formaldehyde can cause vomiting, coma, and death.
Methanol	At low level inhalation exposure, methanol is an irritant to the mucous membranes and has toxic effects on the nervous system, specifically the optic nerve. Once absorbed into the body it is slowly eliminated, but symptoms of poisoning may include headache, nausea, vomiting, drowsiness, blurred vision, blindness, and possibly coma or death. Chronic exposure to methanol may lead to significantly impaired vision. People with pre-existing skin or eye disorders, or impaired liver or kidney function, may be more susceptible to toxicity.

As any risk assessor knows, "the dose makes the poison," and the old adage explains why it is important for EPA to develop IRIS profiles for these chemicals. To develop residual risk regulations under the Clean Air Act, EPA first needs to conduct a full risk assessment for each chemical. EPA program staff could use information like what we have presented in Tables 1 and 2 to complete the hazard identification and exposure assessment steps of the risk assessment process, but without a full IRIS profile, the all-important dose-response assessment step is missing.

In short, EPA needs to do a better job of prioritizing its IRIS agenda based on statutory and program need. The Clean Air Act HAPs list is an obvious place to start, but there are other programs that are also in need of high quality health effects information (e.g., the Safe Drinking Water Act Contaminant Candidate List).

Conclusion

EPA's IRIS database is an important tool for both the agency itself and for risk assessors around the world. Development of new and revised profiles is too important to be mired in interagency squabbles masked as "peer review." To improve the utility and maintain the credibility of the database, EPA should prioritize new assessments based on statutory and program need and should eliminate the interagency review process, which gives privileged status to agencies that have a financial or operational interest in a chemical.

About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization comprising a network of scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation, and improved public access to information. The Center for Progressive Reform is grateful to the Public Welfare Foundation and the Deer Creek Foundation for their generous support of CPR's work on regulatory issues.

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