TESTIMONY

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Hearing on

Status of Reforms to EPA's Integrated Risk Information System

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Chairmen Broun and Schweikert, Ranking Members Maffei and Bonamici, thank you for the opportunity to testify this afternoon about the great importance of the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) to the protection of public health in the country and around the world.

I am a law professor at the University of Maryland Carey School of Law and the President of the Center for Progressive Reform (CPR) (http://www.progressivereform.org/). Founded in 2002, CPR is a network of sixty scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. We have a small professional staff funded by foundations. I joined academia mid-career, after working for the Federal Trade Commission for seven years and the House Energy and Commerce Committee for five years. For seven years, I served as the lawyer for small, publicly-owned electric systems. My work on environmental regulation includes four books, and over thirty articles (as author or co-author). My most recent book, published by the University of Chicago Press, is *The People's Agents and the Battle to Protect the American Public: Special Interests, Government, and Threats to Health, Safety, and the Environment*, co-authored with Professor Sidney Shapiro of Wake Forest University's School of Law, which comprehensively analyzes the state of the regulatory system that protects public health, worker and consumer safety, and natural resources, and concludes that these agencies are under-funded, lack adequate legal authority, and consistently are undermined by political pressure motivated by special interests in the private sector. Cambridge University Press will publish a book I have written entitled *Why Not Jail*: *Industrial Catastrophes, Corporate Malfeasance, and Government Inaction* this coming January. I have served as consultant to the EPA and testified before Congress many times.

IRIS is a critical element of EPA's efforts to protect people and the environment from the dangers of toxic chemicals. Started as an internal EPA database used to develop toxicological profiles for common chemicals, the program has grown into a much more valuable tool and is renowned throughout the world as a crucial element of governments' efforts to protect their people. IRIS profiles set the reference dose, or RfD, for a given chemical on the basis of existing scientific literature. An RfD is the amount below which human exposure is deemed unlikely to cause adverse health effects. IRIS receives some 2,000 internet visits a day, testament to its importance as among the best, most comprehensive databases for this kind of baseline information. And, although IRIS itself most definitely is not a regulatory program, it provides a strong scientific foundation for much of the rest of the agency's work. Without the scientific determinations IRIS contains, EPA would be hard-pressed to develop standards for the control of emissions of toxic chemicals that cause brain damage, cardiovascular illness, reproductive dysfunction, cancer, and a range of other diseases. Conversely, delaying the production of IRIS profiles costs lives and endangers public health, an intolerable outcome that this Committee must not allow to happen.

My testimony today makes three points:

1. IRIS assessments have once again slowed to a crawl, once again reaching the nadir of performance under the Bush Administration. The Obama Administration needs to stop jawboning with industry stakeholders and support the revitalization of this critical initiative.
2. The highest, best use of the National Academies' expertise would be to help the IRIS program identify ways to develop a significantly larger number of robust assessments *quickly*.
3. To achieve that goal of quickly developed, robust assessments, Congress, the EPA Administrator, and the National Academies must confront the very serious problem of regulated industries commandeering the IRIS assessment process by barraging the agency with endless, minor, repetitive, and irrelevant objections to individual risk assessments.

IRIS and the Public Health

On Thursday, January 9, 2014, a leaking tank of "crude MCHM" (technically, 4-methylcyclohexanemethanol) fouled the Elk River in West Virginia, leaving 300,000 people without access to clean drinking water. The spill prompted a "do not use" order from local officials that was slowly lifted over the course of a week while the water system was flushed to the point where samples dropped below a 1 part-per-million "screening level" proposed by the U.S. Centers for Disease Control (CDC). In an astonishing display of all that is wrong with our country's approach to regulating toxic chemicals, Governor Earl Ray Tomblin told residents of the state capital, "it's your decision" whether to drink water distributed by the local public water system after the "do not use" orders were lifted.

What the Governor was saying – without actually saying it – was, "I have no clue whether the water is safe to drink." He didn't have a clue because crude MCHM is one of the tens of thousands of chemicals that pervade our lives but have not been subject to a robust hazard or risk assessment. The IRIS database has over 500 chemical profiles, but crude MCHM is not one of them.

Crude MCHM's absence from the IRIS database is likely due to the fact that it does not fall squarely within the ambit of EPA's three key statutes for regulating toxic chemicals: the Clean Air Act (CAA), the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), more commonly known as the Superfund law, and the Safe Drinking Water Act (SDWA).[1] The IRIS program operates on a shoestring budget, so its agenda for developing assessments is largely driven by the needs of regulatory offices at EPA. The Office of Air and Radiation, for instance, needs IRIS assessments to fulfill its statutory mandate to write rules for CAA § 112 Hazardous Air Pollutants (HAPs). Congress explicitly listed over 180 chemicals in the 1990 Clean Air Act Amendments for which EPA must set emission standards and then later determine whether those standards adequately control residual risks. IRIS assessments are critical to EPA's work in this area.

This incident, which gives us a frightening glimpse of what life without government could be like, suggests that we need to dramatically expand IRIS, rather than allowing self-interested stakeholders to hound it to death.

Without the scientific determinations IRIS contains, EPA would be hard-pressed to develop standards for the control of emissions of toxic chemicals that cause brain damage, cardiovascular illness, reproductive dysfunction, cancer, and a range of other diseases. IRIS assessments are also invaluable to the decisionmakers involved in cleaning up Superfund sites and brownfields across the United States. As our industrial past makes way for a growing service-sector and knowledge-based economy, and as urban renewal projects sprout up in old cities like Baltimore, Pittsburgh, and Chicago, state regulatory agencies have to make decisions about how to clean up complex contamination. Again, IRIS assessments provide the starting point for making strong, science-based decisions.

The thing that makes IRIS assessments so valuable is that they are robust and well-documented, but then summarized clearly and concisely and available to anyone who has access to the Internet. Individuals, community groups, public interest organizations, local officials – in short, everyone – has the information to make well-informed decisions about the hazards of a toxic chemical if an IRIS profile is available. To go back to Governor Tomblin's infamous statement, "it's your decision" would be a more reasonable response to the end of a "do not use" order in a world where every chemical in commerce has an IRIS assessment. But that is not the world we live in. Delaying the production of IRIS profiles costs lives and endangers public health, an intolerable outcome.

Unfortunately, IRIS is already riddled with disturbing gaps in the data in its chemical profiles, and it is missing profiles for many dangerous chemicals altogether. EPA's efforts to fill IRIS's data gaps were largely stymied during the Bush Administration, and not by accident. The Administration imposed "reforms" designed to subject EPA's scientists – the ones who should be making final decisions on the safety of chemicals – to a host of political pressures from government agencies with neither scientific expertise nor an interest in protecting the environment. The Obama Administration recognized the problem, but its revisions to the IRIS

[1] I consider the Toxic Substances Control Act largely irrelevant to this conversation because of EPA's dismal track record in issuing regulations under § 6 of that statute.

process have left key issues unaddressed and of late it has displayed a disturbing tendency to retreat in the face of a blistering and self-serving industry campaign to stifle this vital program.

EPA is many years behind in completing profiles of hundreds of chemicals. In 2011, we found that 109 HAPs were either included in IRIS but missing critical elements, or entirely absent from the database. So severe are the delays in the IRIS process that they are the principle reason that GAO has determined that EPA's toxic chemical regulatory program is at risk of becoming obsolete. (See GAO's 2013 "High Risk Programs" report at http://www.gao.gov/assets/660/652133.pdf.)

For the first year or two, the Obama Administration managed to increase the number of completed profiles to nine annually. At that rate, EPA would not catch up with its existing backlog for another 55 years. But in the last two years, industry attacks on IRIS have been so intense that the pace has once again slowed to Bush levels, giving IRIS the appearance of the walking dead of regulatory program, an outcome that threatens to undermine EPA's effectiveness. One reason for this latest round of malaise is that the Obama Administration's new IRIS process left in place many of the roadblocks GAO had previously identified, including interagency review of individual assessments, multiple reviews by outside science panels, and prioritization of a few high-profile assessments at the expense of faster assessments.

Make no mistake about it: the chemicals we are talking about here are the worst of the worst, produced in amounts of millions of pounds annually. As just one example, chromium compounds, which are categorized in the worst ten percent of all toxic chemicals and are among the hazardous air pollutants missing from IRIS, are emitted in amounts exceeding 58 million pounds annually. Unsafe exposure to chromium compounds causes cancer, suppresses immune systems, and harms kidney and respiratory functions. Over the last several years, industry has sponsored several studies of chromium. When a study documents adverse effects at common levels of exposure, the sponsors commission a second study designed to rip apart the first. Unfortunately, the victims of this endless treadmill are neither the sponsors, nor the scientists engaged in chasing each other's tails, but rather the public's health.

This brings me to my second point.

What the National Academies Can Do for IRIS

From my perspective outside the National Academies, the two committees responsible for the 2011 formaldehyde review and this most recent review of the IRIS process have missed golden opportunities to provide constructive advice on the biggest concern about the IRIS program: how to develop new assessments quickly, on a limited budget. Rather than flyspecking the faults of specific IRIS assessments, and subjecting the program as a whole to highly critical examination, two issues must be addressed to solve this problem: the IRIS program's agenda, and so-called "stopping rules."

Agenda

With my colleagues at the Center for Progressive Reform, I came up with a list a few years ago of all of the Clean Air Act HAPs, Superfund "high priority" substances, and Safe

Drinking Water Act contaminants that did not have IRIS profiles. We found more than 200 individual chemicals, which we consider mission-critical for EPA. To whittle that list down to something more manageable, we proposed an approach that takes environmental justice into account. In our view, the burden on already disadvantaged communities must be a top priority for the nation.

Environmental justice, as defined by EPA, means "fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies."[2] In practice, EPA's policy for ensuring environmental justice places an obligation on EPA staff to consider first, whether their actions disproportionately impact any group(s) of people, and second, whether all affected groups have a meaningful opportunity for involvement in the regulatory process.

IRIS staff could take into account the potential for disproportionate impacts by analyzing emissions and exposure data for the unassessed HAPs, Superfund priority chemicals, and drinking water contaminants to determine where clusters of those unassessed chemicals can be found. We made a rudimentary attempt at doing so and were able to identify a handful of communities where polluters release a large diversity of toxic air pollutants and where the emissions include a large number of HAPs without IRIS profiles. We identified 47 chemicals that deserve to be at the top of the IRIS program's agenda. Our methodology was but one way that IRIS staff might take environmental justice into account when prioritizing new assessments.

Stopping Rules

Once EPA starts an IRIS assessment, there must be an end in sight. An assessment must be declared finished and its results posted on the web. When significant new science is produced suggesting that the numbers must be lowered or raised, EPA can reexamine the profile. Too often, though, regulated industries manage to push EPA on a treadmill where it never escapes the wait for one study or another to be completed before moving forward with a draft assessment. The trouble is, science is always evolving. EPA cannot wait on all the science to resolve itself an the "truth" to be announced—that simply is not the nature of the scientific enterprise. Instead, EPA must adopt clear rules that explain why agency experts have moved to the next stage in the assessment process. The National Academies endorsed stopping rules in the most recent report, but did so without providing sufficient, detailed guidance to EPA. Theoretically, the timelines laid out in the IRIS process flow charts produced at the beginning of the Obama Administration under Administrator Lisa Jackson's leadership would suffice. But those timelines have ever been enforced. I am not aware of a single assessment that has been completed in the 26 months (for "standard" assessments) or 39 months (for "complex" assessments) contemplated by these commitments.

Given that the science of risk is always evolving, any stopping rule has a degree of arbitrariness to it, but that is not a reason to shy away from setting the rules. The assessment

[2] ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF POLICY, ECONOMICS AND INNOVATION, EPA'S ACTION DEVELOPMENT PROCESS: INTERIM GUIDANCE ON CONSIDERING ENVIRONMENTAL JUSTICE DURING THE DEVELOPMENT OF AN ACTION (2010) available at http://epa.gov/compliance/ej/resources/policy/considering-ej-in-rulemaking-guide-07-2010.pdf (accessed Nov. 2, 2010).

process includes a point at which IRIS staff publish their literature search strategy and results for public comment. One approach to stopping rules would be to use the end of the comment period as the stopping point: if ongoing or recently completed research is not in a form that meets the selection criteria, then it will not be considered. That approach takes into account the critical – but often ignored – fact that IRIS profiles *are not regulations*. The rulemaking process under the CAA and SDWA, as well as decisions about cleanup of contaminated sites, provide numerous opportunities to re-assess the state of the science on a chemical. IRIS assessments are just a starting point.

Industry Influence at IRIS

Stopping rules are an important way to speed up the IRIS process, but they are insufficient to address the larger problem of too much industry influence over the IRIS program.

In recent years, the IRIS program has hosted numerous stakeholder engagement events, some tied to specific assessments, others related to broader science issues or even general concerns about the IRIS program as a whole. However, this openness has obscured the agency's commitment to the protection of public health because EPA senior management's naïve idea that process will placate its critics has left it vulnerable to cynical exploitation by regulated industries.

Take, for example, last month's meeting on the inorganic arsenic and hexavalent chromium assessments. A group of public interest-oriented scientists, led by Dr. Kathleen Burns of the group Sciencecorps, reviewed the agenda for the meeting and found that industry-sponsored speakers filled 37 of the 46 speaking slots during the arsenic meeting and 40 of the 41 slots during the chromium meeting.[3] Regular participants in IRIS public forums and related events will confirm a similar imbalance in the public input at those events – with heavy reliance on industry and comparatively less input from environmentalists, community groups, and others without a financial interest in IRIS.

The National Academies made a helpful suggestion on this point that deserves repeating. The committee reviewing the IRIS process noted that:

> [non-industry] stakeholders have fewer resources and are not generally organized and staffed to provide comments or detailed scientific input. Thus, their important perspectives and voices might be less well represented to EPA. Therefore, the committee encourages EPA to continue the additional efforts to ensure that the full breadth of perspectives on the IRIS process and specific IRIS assessments are made available to the agency.
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> One way to ensure broad stakeholder input would be to provide technical assistance to enable under-resourced stakeholders to develop and provide input to the IRIS program; this could be modeled after other EPA technical-assistance programs. For example, EPA's Superfund program has a long history of providing technical assistance in the

[3] http://www.sciencecorps.org/Boycott_Statement_to_EPA_re_IAs_&_CrIV_mtg_6-24pm.pdf

form of grants and more recently direct consultation to neighbors of sites on the National Priorities List.[4]

Recognizing the resource constraints under which the IRIS program operates, the proposed technical assistance grants and direct consultation idea deserve thorough consideration. Another idea would be to simply limit the round robins of preliminary meetings, stakeholder listening sessions, and repetitive peer review, instead running the process for crafting an IRIS profile in a far more efficient manner.

Conclusion

Discussions about how the IRIS program can best accomplish its goals often devolve into debates about the minutiae of chemical risk studies. Let us not lose sight of what is really at stake: the priceless notion that the water we drink and the air we breath ought to be clean and healthy.

[4] NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES, *Review of EPA's Integrated Risk Information System (IRIS) Process*, 23 (2014).

Setting Priorities for IRIS:

47 Chemicals that Should Move to the Head of the Risk-Assessment Line

by CPR Member Scholar Rena Steinzor and
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Setting Priorities for IRIS: 47 Chemicals that Should Move to the Head of the Risk-Assessment Line

Executive Summary

EPA's Integrated Risk Information System (IRIS) is the starting point for new regulations under the Clean Air Act (CAA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and the Safe Drinking Water Act (SDWA). Scientists in the IRIS office produce risk assessments of individual chemicals, which regulatory staff then combine with exposure data and statute-based policy choices to write new emissions limits and cleanup standards. In previous reports, the Center for Progressive Reform (CPR) has described massive gaps in the IRIS database, including more than 250 chemicals for which EPA's air, drinking water, and Superfund offices need robust risk assessments.[1] In this white paper, we describe how EPA should prioritize the work it will take to close those data gaps. We have developed a list of 47 chemicals that IRIS staff should move to the top of its list of priorities, based on the air toxics, drinking water, and Superfund program offices' most pressing needs.

Toxicology is predicated on the axiom that the dose makes the poison. IRIS profiles provide EPA, state and local public health officials, and the public with information about the relevant doses for hundreds of toxic substances. We recommend EPA improve its priority-setting process for IRIS by taking a two-step approach to deciding which data gaps to fill first. As a first step, EPA must foster better cooperation and communication between IRIS staff and their colleagues in the air, drinking water and Superfund program offices, to ensure that the priorities of risk assessors in the IRIS office parallel the priorities of risk managers in the program offices. Second, EPA should take environmental justice into consideration and determine whether there are patterns of unknown chemicals being emitted in large quantities in disadvantaged communities.

[1] CENTER FOR PROGRESSIVE REFORM, *Corrective Lenses for IRIS: Additional Reforms to Improve EPA's Integrated Risk Information System* (Oct. 2010), *available at* http://www.progressivereform.org/articles/IRIS_1009.pdf [hereinafter CPR, *Corrective Lenses for IRIS*].

Table 1: Priority Chemicals List				
Air toxins	***Superfund pollutants***	***Drinking water contaminants***	***Multi-media threats***	***Environmental justice concerns***
Cadmium compounds	Polycyclic aromatic hydrocarbons	1,2-Diphenyl-hydrazine	Acetamide[1,3]	1,1,2-Trichloro-ethane[1,2,4,5]
Carbonyl sulfide	Arochlor 1260	1,3-Dinitro-benzene	4-Amino-biphenyl[1,2]	1,2-Dichloro-ethane[1,2,3,4]
Formaldehyde	Arochlor 1242	Acetochlor ethanesulfonic acid	Arochlors[1,2]	Chlorobenzene[4,5]
Hydrogen fluoride	Arochlor 1221	Acetochlor oxanilic acid	Chromium[2,3]	Diaminotoluene[4]
Lead compounds	Cobalt	Alachlor ethanesulfonic acid	Cobalt[2,3]	Hexachloro-benzene[4,5]
Mercury compounds	DDT, O,P'	Alachlor oxanilic acid	Ethylene oxide[1,3]	Hexachloro-ethane[1,3,4,5]
Methanol	Nickel	Diazinon	2,3,7,8-Tetra-chlorodibenzo-p-dioxin[1,2]	Methyl iodide[5]
Methylene chloride	Endrin ketone	N-Nitroso-dimethylamine (NDMA)	Vanadium[2,3]	Phthalic anhydride[2,3]
Nickel compounds	Chromium(VI) oxide	N-Nitroso-diethylamine (NDEA)		Quinone[2]
Phenol	Methane	N-nitroso-di-n-propylamine (NDPA)		Urethane[3]
		Terbufos		
			[1]Air, [2]Superfund, [3]Drinking water	Chemicals above are released in the following ZIP codes: [1]70734, [2]70805,[3]71730, [4]77541, [5]77571

In CPR's last paper on IRIS's information gaps, we identified 253 unique substances that need new or updated IRIS assessments.[2] In this paper, we selected the 47 substances from that list that EPA should move to the front of the line. The IRIS program staff are currently working on new assessments for just 17 of these 47 substances,[3] underscoring our concern that statutory priorities are not sufficiently factored into the IRIS agenda. The 47 unique substances listed in

[2] CPR, *Corrective Lenses for IRIS*, *supra* note 1, *at* 2-3.

[3] ENVIRONMENTAL PROTECTION AGENCY, *Integrated Risk Information System (IRIS); Request for Chemical Substance Nominations for 2011 Program*, 75 Fed. Reg. 63,827 (Oct. 18, 2010).

Table 1 include: ten hazardous air pollutants (HAPs) in the greatest number of upcoming air toxics standards; the ten highest-scoring Superfund priority substances; 11 substances listed on the drinking water Contaminant Candidate List; eight substances that appear on more than one list; and the ten highest-emitting HAPs in areas with environmental justice concerns.

Introduction

EPA's three key statutes for regulating toxic chemicals in commerce are the Clean Air Act (CAA), the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), and the Safe Drinking Water Act (SDWA). These statutes share two characteristics that make environmental regulation complex: they are media-specific, which balkanizes the regulatory landscape; and they require EPA to quantify the risks of individual chemicals before setting regulations.

At present, EPA takes nominations for new chemical risk assessments from Deputy Assistant Administrators, Deputy Regional Administrators, federal agencies that participate in reviews of draft IRIS assessments, and the public, then uses six criteria to select chemicals for IRIS assessments from among the nominations. But this process has not been sufficient to push the IRIS office to complete assessments in time for EPA program offices to regulate toxic substances.

The priority setting process functions like a black box: We know the criteria EPA applies and we know which IRIS profiles are completed, but we do not know how EPA applies these criteria to the un-assessed and under-assessed substances to set IRIS priorities. Based on the large number of chemicals identified by program offices that have not been assessed, we can infer that EPA's current process is not prioritizing assessments to meet the program offices' needs.

In this paper, we propose a two-step process for prioritizing new chemical reviews in the IRIS program: first, risk assessors from the IRIS office and risk managers from the regulatory offices need to work together to develop a complete list of chemicals in need of IRIS assessments; second, the chemicals should be prioritized in terms of the existing regulatory agenda and environmental justice concerns.

EPA program offices provide public information about chemicals considered for regulation, which we have parsed to develop a list of 253 substances that could be the starting point for discussions between IRIS risk assessors and regulatory risk managers. The CAA HAPs have been public since the Clean Air Act Amendments of 1990 were made law; the Agency for Toxic Substances and Disease Registry (ATSDR), a program under CERCLA, periodically publishes a list of priority chemicals; and, under the SDWA, the Office of Water must publish a Contaminant Candidate List (CCL) every five years. This information gives the IRIS staff guidance about chemicals of concern to EPA, but does not help them to prioritize their work.

Since IRIS staff cannot tackle all 253 substances at once, a more robust effort at coordination is necessary, including regular meetings between the staff and managers of all offices to set short- and long-term priorities. Those priorities should be informed by environmental justice concerns. Specifically, EPA should prioritize the assessment of chemicals that lack IRIS profiles and are emitted in large quantities in communities with significant populations of poor and minority residents and in localities where a large number of un-assessed chemicals are emitted together. In this white paper, we profile five communities that bear the burden of numerous un-assessed HAPs and multiple Superfund sites.

Improving priority-setting policies will put the IRIS staff on the right path, but the database will remain outdated without reforms to the assessment process. Potentially regulated parties, particularly industry and other federal agencies like the Department of Defense and National Aeronautics and Space Administration, have isolated IRIS as a choke point for regulation. Their opposition has resulted in an IRIS program that can neither keep up with the demands that have already been made, nor incorporate information about new substances. IRIS staff must consider new ways to avoid the problem of "information capture," whereby potentially regulated parties dump so much new data on the agency – and do so with such frequency – that new assessments become mired in continuous controversy.

Setting Priorities, Step One: Improving Communication between Regulatory Office and IRIS Staff

EPA program offices have specific deadlines and plans to complete regulatory actions on toxic chemicals. The IRIS staff should be well-attuned to the deadlines and priorities of the program offices, and strive to provide program offices with the best available risk assessment information in a timely manner to support regulatory decisions. There should be regular communication and interaction between the program office staff and IRIS staff to facilitate priority-setting and ensure that priorities are consistent with the needs of the program offices.

The next three sections provide some additional details about the three programs and some thoughts on prioritizing chemicals that are important to each program.

Hazardous Air Pollutants

The CAA Amendments of 1990 specify 188 toxic air pollutants that EPA must regulate through a two-step process. First, EPA must issue "technology-based" standards for all major sources of HAPs. At this stage, EPA staff simply determine emissions limitations based on the average emission limitation of the best performing 12 percent of existing sources. EPA has issued 96

technology standards covering 174 "major" and "area" sources.[4] In the second step of the HAPs regulations, EPA must evaluate "residual risks" associated with air pollutants eight years after the technology-based standards are promulgated, in an effort to determine whether the technology-based standards protect public health with "an ample margin of safety."[5]

IRIS profiles are integral to the residual risk determinations. EPA considers an ample margin of safety to be exposures below the reference concentration (RfC or inhalation value) listed in IRIS for non-carcinogens, and the level at which added cancer risk does not exceed one in one million.[6] But the IRIS database is missing assessments or inhalation values for 107 of 188 HAPs, slowing progress toward completion of residual risk standards. In fact, EPA's Science Advisory Board (SAB) reviewed the Office of Air and Radiation's (OAR) methodology for completing two residual risk evaluations and implored EPA to complete IRIS profiles for all HAPs in a timelier manner.[7] They said that EPA's alternate method of determining risk was too simplistic, and recommended that EPA elaborate on the proposed method. But they stressed that the best course of action was to complete IRIS profiles for all the HAPs.

Data gaps in IRIS's HAPs coverage stymie public health efforts led by state and local agencies, too. In 2005, the Mayor of Houston, Bill White, ordered a task force on air pollution in the area. Houston's Ship Channel is home to large number of petrochemical refineries and other chemical plants, and has high concentrations of a broad range of HAPs. The Task Force focused on 176 HAPs listed in EPA's 1999 National Air Toxics Assessment that were present in the 10 counties that comprise the greater Houston area. The researchers expressed difficulty in developing risk characterizations for Houston-area HAPs: "The intrinsic challenges of comparing HAPs-related health risks are illustrated by the fact that 118 (67%) of the 176 HAPs examined by the Task Force were assigned to the uncertain risk category. This decision was based on their collective judgment that there is insufficient evidence on hand to ascertain whether these substances currently pose a significant threat to the health and well being of Houston residents." Of the 118 HAPs placed in the uncertain risk category, 63 are missing IRIS profiles or lack inhalation values.

EPA completed the last of the technology-based standards in 2006, so it must issue all residual risk standards by 2014. With that deadline in mind, and with input from OAR, IRIS staff should set an agenda for completing risk assessments on all HAPs in an order that will pave the way for

[4] ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF INSPECTOR GENERAL, EVALUATION REPORT: KEY ACTIVITIES IN EPA'S INTEGRATED URBAN AIR TOXICS STRATEGY REMAIN UNIMPLEMENTED, Report No. 10-P-0154, (2010).
[5] 42 U.S.C. § 7412(f).
[6] *See, e.g.*, ENVIRONMENTAL PROTECTION AGENCY, *National Emission Standards for Coke Oven Batteries*, 70 Fed. Reg. 19,993 (Apr. 15, 2005).
[7] ENVIRONMENTAL PROTECTION AGENCY, SCIENCE ADVISORY BOARD. *Review of EPA's draft entitled, "Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing,"* SAB-10-007, *at* 5 (May 7, 2010) [hereinafter EPA, *RTR Methodology*].

OAR's regulatory agenda. EPA has already finalized 16 residual risk standards and proposed or requested comment on 17 others. IRIS and OAR staff should work together to determine how the 13 HAPs covered by proposed standards but lacking key IRIS data could be assessed in time to meet OAR's regulatory timeline. A recent consent decree prompted by a Sierra Club lawsuit sets deadlines for 16 more residual risk standards that cover 114 HAPs—43 of which lack inhalation values in the IRIS database and should also be prioritized for review by IRIS staff.

CPR reviewed EPA's proposed rules and the 16 other standards which EPA must propose under the consent decree, and identified 123 HAPs in these upcoming standards.[8] Table 2 highlights the top 10 of those 123 HAPs, based on the number of upcoming rules in which they appear. The Appendix (Table A2) provides a longer list—all 46 HAPs that appear in upcoming standards but lack inhalation values or do not have IRIS values. Input from OAR would be valuable in improving the usefulness of this priority list. OAR needs IRIS profiles for HAPs to complete the residual risk standards, and OAR should share its needs with ORD, so IRIS profiles can be completed in a timely manner.

Table 2: Hazardous Air Pollutants with Insufficient IRIS Information in Upcoming Residual Risk Rules

Chemical
Cadmium compounds*
Carbonyl sulfide
Formaldehyde
Hydrogen fluoride*
Lead compounds
Mercury compounds
Methanol
Methylene chloride
Nickel compounds
Phenol

** No IRIS profile information.*

Human Health Effects: Cadmium compounds

Cadmium compounds have been linked to kidney disease, lung damage, cancer, and fragile bones.

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, TOXFAQ FOR CADMIUM, (Sept. 2008), *available at* http://www.atsdr.cdc.gov/tfacts5.pdf (accessed Oct. 21, 2010).

[8] ENVIRONMENTAL PROTECTION AGENCY, *Risk and Technology Review, Phase II, Group 2*, 72 Fed. Reg. 14,741-14,744 (Mar. 29, 2007); ENVIRONMENTAL PROTECTION AGENCY, *National Emission Standards for Hazardous Air Pollutant Emissions: Group I Polymers and Resins*, 73 Fed. Reg. 60,437-60,440 (Oct. 8, 2008).

Superfund Pollutants

Superfund is a critical part of EPA's overall mission. The Superfund program has a budget of $1.3 billion; it makes up 12 percent of EPA's total budget.[9] Cleanup standards for Superfund inform other waste management programs, including the Resource Conservation and Recovery Act and private-sector cleanup efforts. IRIS profiles are the first step in setting Superfund standards and initiating work that radiates beyond Superfund.

Superfund sites are places of significant soil and groundwater pollution, often by multiple contaminants. EPA prioritizes cleanup efforts based on whether contaminants pose an immediate hazard or a longer-term cleanup effort. Sites that are not marked for emergency response are added to the National Priorities List (NPL). After a site has been added to the NPL, it undergoes a seven-step process through which EPA oversees the remediation of a site, a process that begins with risk assessment.

The CERCLA requires ATSDR to periodically compile a list of "high priority" substances.[10] ATSDR generates this list from substances that are found in sites on the NPL. The list is placed in a weighted priority order that takes into account the frequency with which substances are found at sites on the NPL, the toxicity of the substance, and the likelihood of human exposure to the substance at a site. ATSDR provides the IRIS staff with quite a bit of useful information to make determinations about how to prioritize substances for IRIS assessment. ATSDR updates the list periodically, with new substances being added and others removed as the sites on the NPL change.[11] Nonetheless, many substances remain on the list for years, because they are common industrial chemicals, or are persistent environmental toxics. Even the longstanding high priority chemicals lack sufficient coverage in IRIS – 17 substances that have been on ATSDR's list since 1997 do not have IRIS profiles (*See* Appendix, Table A4).

Why ATSDR?

Dividing responsibilities across multiple agencies is one strategy to avoid agency capture. Congress created the ATSDR in 1986, after the integrity of EPA's Superfund program had been called into question by the actions of Reagan administration officials in charge of the program.

ATSDR's list, like the CAA's list of HAPs, provides an obvious indication of an EPA regulatory office's needs. But similar to its treatment of HAPs data gaps, EPA's IRIS agenda does not explain how it will address data gaps for substances on the ATSDR high priority list. There is no formal relationship between the ATSDR list and the IRIS agenda process. Research conducted

[9] ENVIRONMENTAL PROTECTION AGENCY, FY 2010 EPA BUDGET IN BRIEF, 2, 6 (Apr. 2009) *available at* http://www.epa.gov/budget/2010/2010bib.pdf (accessed Dec. 15, 2010).
[10] 42 U.S.C. § 9604(i).
[11] AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, CERCLA PRIORITY LIST OF HAZARDOUS SUBSTANCES, lists are available for 1997, 1999, 2001, 2003, 2005 and 2007, *available at* http://www.atsdr.cdc.gov/cercla/07list.html (accessed Sept. 16, 2010) [hereinafter ATSDR, CERCLA PRIORITY LIST].

by ATSDR should flow freely between ATSDR and the IRIS program – indeed IRIS was created when EPA combined several disparate databases of human health information maintained by various program offices at EPA. The Superfund program should support IRIS to the extent that ATSDR is able to assist the IRIS program in completing assessments, identifying key studies, and making judgments about weight-of-the-evidence evaluations of toxic chemicals.

Table 3: Top Ten ATSDR Priority Chemicals not Listed in IRIS[12]

Chemical	*ATSDR points*[13]
Polycyclic aromatic hydrocarbons	1316.98
Aroclor 1260	1177.77
Aroclor 1242	1093.14
Aroclor 1221	1018.41
Cobalt	1015.57
DDT, O,P'	1014.71
Nickel	1005.4
Endrin ketone	978.99
Chromium(VI)oxide	969.58
Methane	959.78

Human Health Effects: Nickel

Exposure to nickel dust has been linked to respiratory problems including bronchitis and reduced lung function. Occupational exposures have been linked to lung and nasal cancer.

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, TOXFAQ FOR NICKEL, (Aug. 2005), *available at* http://www.atsdr.cdc.gov/tfacts15.pdf (accessed Oct. 21, 2010).

Drinking Water Contaminants

The Safe Drinking Water Act (SDWA) requires EPA to set standards for limits on drinking water contaminants. Unlike HAPs, which were specified by Congress, EPA is responsible for identifying water contaminants. EPA identifies additional water contaminants that might be candidates for regulation every five years by generating a new Contaminant Candidate List (CCL).[14] The lists contain recommendations both for chemicals and microbiological contaminants. Since 1996, EPA has published three CCLs that contain 156 distinct chemical substances.[15] IRIS profiles are missing for 64 (41 percent) of these substances. Absence of an IRIS profile hinders regulation of drinking water contaminants because the Water Office uses health risk information to prioritize unregulated substances to monitor, as well as determine what order to regulate water contaminants.

[12] ATSDR, CERCLA PRIORITY LIST, *supra* note 11.
[13] Points are assigned by ATSDR is based on an algorithm that utilizes the following three components: frequency of occurrence at NPL sites, toxicity, and potential for human exposure to the substances found at NPL sites. *See* AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, CERCLA PRIORITY LIST OF HAZARDOUS SUBSTANCES, WHAT IS THE CERCLA LIST, *available at* http://www.atsdr.cdc.gov/cercla/index.asp (accessed Sept. 19, 2010) [hereinafter ATSDR, WHAT IS THE CERCLA LIST].
[14] 42 U.S.C. § 300g-1(b)(1)(B)(i).
[15] ENVIRONMENTAL PROTECTION AGENCY, *Announcement of the Drinking Water Contaminant Candidate List; Notice*, 63 Fed. Reg. 10,273 (Mar. 2, 1998); ENVIRONMENTAL PROTECTION AGENCY, *Drinking Water Contaminant Candidate List 2; Final Notice*, 70 Fed. Reg. 9,071 (Feb. 24, 2005); ENVIRONMENTAL PROTECTION AGENCY, *Drinking Water Contaminant Candidate List 3 – Final*, 74 Fed. Reg. 51,850 (Oct. 8, 2009).

The SDWA requires the EPA Administrator to make a public health finding about a contaminant before EPA moves to regulate the substance. The public health finding requires three determinations: first, EPA must establish that the contaminant may have an adverse effect on human health; second, the agency must determine that the contaminant is known or likely to occur in public water systems; and third, EPA must determine that regulation through SDWA presents a meaningful opportunity for reducing public health risks.[16] Reference doses contained in IRIS profiles are exactly relevant to the first determination. The IRIS program has not kept up with demand to provide information about CCL substances, which makes it more difficult for EPA to make the health risk related determinations required under SDWA.

Table 4 lists 11 of the 64 substances that appear in the CCLs that do not have IRIS profiles, culled from the larger list because they are also tracked under the Unregulated Contaminant Monitoring program. In the Appendix (Table A5), we identify nine additional substances EPA tracks under the Unregulated Contaminant Monitoring program that do not appear on the Contaminant Candidate Lists, but are missing IRIS profiles.

Table 4: UCMR Listed Substances also on CCL without IRIS profiles
Chemical
1,2-diphenylhydrazine
1,3-Dinitrobenzene
Acetochlor ethanesulfonic acid
Acetochlor oxanilic acid
Alachlor ethanesulfonic acid
Alachlor oxanilic acid
Diazinon
N-nitrosodiethylamine (NDEA)
N-nitrosodimethylamine (NDMA)
N-nitroso-di-n-propylamine (NDPA)
Terbufos

Human Health Effects: Ethylene Oxide

Ethylene oxide has been linked to miscarriage, respiratory and nervous system effects. Ethylene oxide is listed of programmatic importance both for safe drinking water and as a HAP.

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, TOXFAQ FOR ETHYLENE OXIDE, (Jul. 1999), *available at* http://www.atsdr.cdc.gov/tfacts137.pdf (accessed Oct. 21, 2010).

[16] 42 U.S.C. §300g-1(b)(1)(A).

Setting Priorities, Step Two: Considering Environmental Justice

IRIS staff can use the regulatory offices' legal obligations and administrative priorities to start the process of choosing which chemicals need new or updated assessments, but those two factors will still leave them with a substantial list. IRIS staff should further prioritize new assessments by taking into consideration environmental justice concerns.

Environmental justice, as defined by EPA, means "fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies."[17] In practice, EPA's policy for ensuring environmental justice places an obligation on EPA staff to consider first, whether their actions disproportionately impact any group(s) of people, and second, whether all affected groups have a meaningful opportunity for involvement in the regulatory process.

In the IRIS assessment priority-setting context, IRIS staff could take into account the potential for disproportionate impacts by analyzing emissions and exposure data for the unassessed HAPs, CERCLA priority chemicals, and drinking water contaminants to determine where clusters of those unassessed chemicals can be found. Over the next few pages, we profile five communities where HAPs that have insufficient profiles are released in significant quantities. These five communities were chosen because they are sites with a large diversity of toxic air pollutants and have the largest number of HAPs without IRIS profiles. In addition to considering HAPs, we also looked at the presence of Superfund sites, and toxic chemical releases listed in EPA's Toxic Release Inventory (TRI). After we selected the communities, we probed basic demographic information from the 2000 Census, which is listed in the community profiles.

Our methodology is but one way that IRIS staff might take environmental justice into account when prioritizing new assessments. These communities are subject to diverse exposure to toxic chemicals through multiple pathways. We selected them based on the presence of the largest number of exposures to substances that are missing IRIS profiles, but these communities are also exposed to an even larger diversity of toxins.

One of EPA's long-term goals is to better understand the cumulative impacts of multiple toxins.[18] Chemical-by-chemical information contained in IRIS – oral exposure limits, inhalation values – is exactly the kind of toxicology information needed to complete cumulative risk

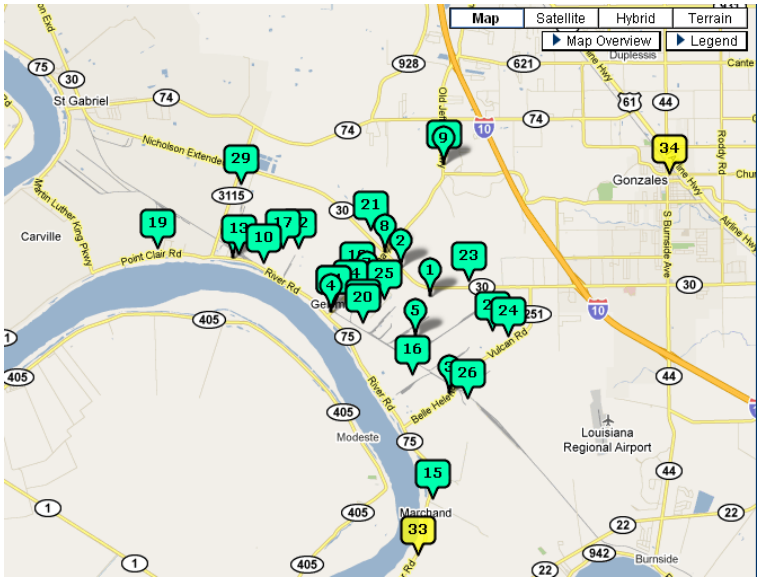
[17] ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF POLICY, ECONOMICS AND INNOVATION, EPA'S ACTION DEVELOPMENT PROCESS: INTERIM GUIDANCE ON CONSIDERING ENVIRONMENTAL JUSTICE DURING THE DEVELOPMENT OF AN ACTION (2010) *available at* http://epa.gov/compliance/ej/resources/policy/considering-ej-in-rulemaking-guide-07-2010.pdf (accessed Nov. 2, 2010).

[18] *See, e.g.*, Thomas Burke, *Overview of Cumulative Risk, presentation before Environmental Protection Agency, Mid-Atlantic Cumulative Risk Workshop* (2003), *available at* http://www.epa.gov/region3/environmental_justice/cumriskwkshop.htm (accessed Dec. 1, 2010).

analysis. Cumulative risk assessments are highly dependent on toxicology information about each of the various toxic substances and exposure pathways. If toxicology information is not present, then the evaluation cannot be credibly completed. Cumulative risk assessments become less credible as the number of data gaps increase. EPA must identify both where there is a large diversity of exposure to toxic substances, and which toxic substances that appear in these areas are missing critical toxicology information. The IRIS office should then strive to prioritize substances that hinder cumulative risk assessment.

EPA's environmental justice policies also require that staff consider whether all affected groups are able to meaningfully participate in program decisions. IRIS staff can help more groups participate more meaningfully in the regulatory process by finalizing new chemical profiles for toxins that appear in communities like those profiled below. These communities often have limited resources to devote to participation in the highly technical standard-setting and permitting decisions that affect the quality of their air, water, and soil. The existence of IRIS profiles for all relevant chemicals helps these communities advocate for themselves. The IRIS office should strive to support environmental justice by identifying unassessed chemicals from our list that appear in communities that are not adequately included in the decision making process.

Geismer, LA 70734
Ascension Parish



Geismer, Louisiana is located about 30 miles south of Baton Rouge. It is home to a large number of petrochemical facilities, including the largest manufacturing facility for the chemical company BASF. According to EPA's Toxic Release Inventory, residents of Geismer are exposed to 94 toxic chemicals.

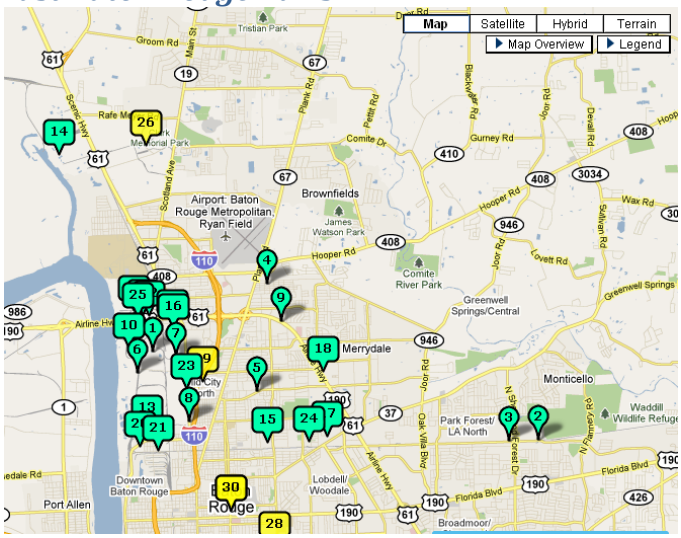
Blue markers represent sources of air pollution. Yellow markers are Superfund sites.

Toxics Release Inventory Information for 70734				
Total Releases (lbs)	*Air Releases (lbs)*	*Water Releases (lbs)*	*Land Releases (lbs)*	*Transfers to Off-Site Treatment Works (lbs)*
9,522,750	2,530,641	6,738,084	27,569	226,457

Sources of Toxic Substance Exposures for 70734 and Ascension Parish		
Air toxics not in IRIS	*Superfund sites (70734)*	*Superfund sites (Ascension, LA)*
14	2	5

Demographics Information for Geismer and Ascension Parish		
	70734	*Ascension Parish*
Race		
White	58.7%	77.6%
Black	36.9%	19.8%
Native American	0.0%	0.4%
Asian	1.6%	0.4%
Pacific Islander	0.0%	0.0%
Hispanic/Other	0.4%	0.9%
Median household income	$39,336	$44,288
% below poverty line	12.9%	12.8%

Baton Rouge, LA 70734
East Baton Rouge Parish



Baton Rouge is the capital of Louisiana. It lies on the Mississippi River, about eighty miles west of New Orleans. Baton Rouge is home to a deepwater port connecting the Mississippi River to the Gulf of Mexico. Major industries in Baton Rouge include petrochemical production, plastic, rubber, and timber and paper products, which contribute to air and water pollution in the area. According to EPA's Toxics Release Inventory, residents of Baton Rouge are exposed to 116 different toxic chemicals.

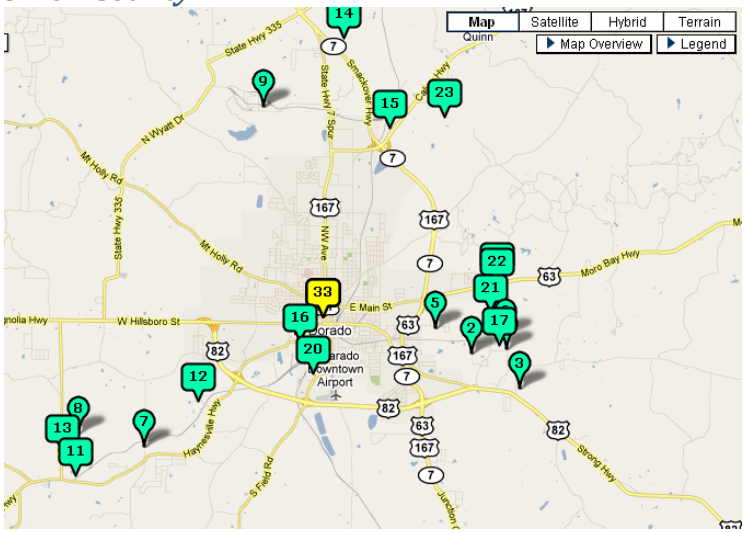
Blue markers represent sources of air pollution. Yellow markers are Superfund sites.

Toxics Release Inventory Information for 70805				
Total Releases (lbs)	*Air Releases (lbs)*	*Water Releases (lbs)*	*Land Releases (lbs)*	*Transfers to Off-Site Treatment Works (lbs)*
9,961,982	4,725,250	5,089,631	250	146,851

Sources of Toxic Substance Exposures for 70805 and East Baton Rouge Parish		
Air toxics not in IRIS	*Superfund sites (70805)*	*Superfund sites (East Baton Rouge Parish)*
12	1	18

Demographics Information for Baton Rouge and East Baton Rouge Parish		
	70805	*East Baton Rouge Parish*
Race		
White	10.7%	51.8%
Black	86.8%	44.5%
Native American	0.2%	0.3%
Asian	0.8%	2.5%
Pacific Islander	0.0%	0.0%
Hispanic/Other	0.5%	2.8%
Median household income	$21,203	$42,173
% below poverty line	34.2%	17.6%

El Dorado, AR 71730
Union County



El Dorado, Arkansas is located in the southern part of the state, near the Louisiana border. It was once a site for oil extraction. More recently it is the home to a diversity of chemicals manufacturing, including agricultural chemicals, automotive chemicals, pesticides, bleaching agents and synthetic dyes. The town of El Dorado contains six Superfund sites. EPA estimates residents of El Dorado are exposed to 177 toxic chemicals.

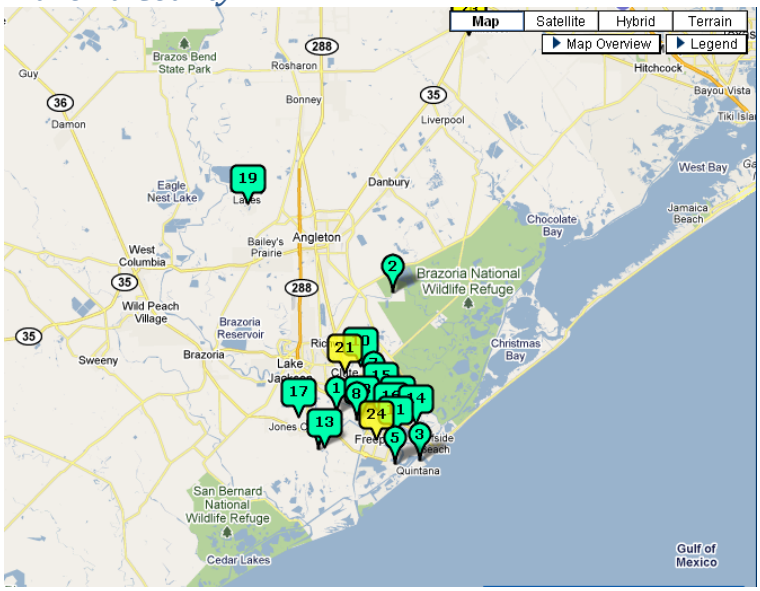
Blue markers represent sources of air pollution. Yellow markers are Superfund sites.

Toxics Release Inventory Information for 71730				
Total Releases (lbs)	*Air Releases (lbs)*	*Water Releases (lbs)*	*Land Releases (lbs)*	*Transfers to Off-Site Treatment Works (lbs)*
7,749,243	1,209,550	4,369,657	1,464,241	705,794

Sources of Toxic Substance Exposures for 71730 and Union County		
Air toxics not in IRIS	*Superfund sites (71730)*	*Superfund sites (Union County)*
14	6	7

Demographics Information for El Dorado, AR and Union County		
	71730	*Union County*
Race		
White	66.2%	64.8%
Black	31.6%	33.1%
Native American	0.3%	0.3%
Asian	0.4%	2.5%
Pacific Islander	0.0%	0.0%
Hispanic/Other	0.5%	2.8%
Median household income	$30,565	$37,120
% below poverty line	18.8%	18.6%

Freeport, TX 77541
Brazoria County



Freeport, Texas is located on the Gulf of Mexico coast south of Houston. It is home to a deepwater port and large-scale petrochemical manufacturing. Freeport also maintains a liquefied natural gas terminal. These sites are major sources of air pollution in Freeport. EPA reports that residents of Freeport are exposed to 136 toxic chemicals.

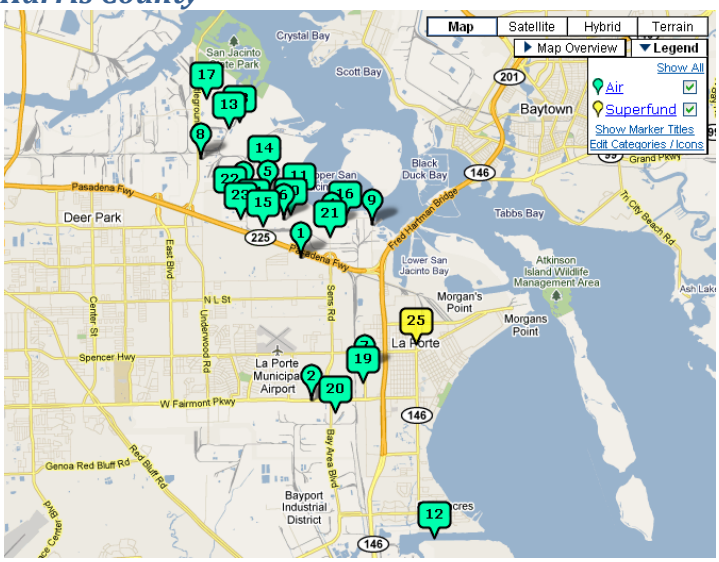
Blue markers represent sources of air pollution. Yellow markers are Superfund sites.

Toxics Release Inventory Information for 77541				
Total Releases (lbs)	*Air Releases (lbs)*	*Water Releases (lbs)*	*Land Releases (lbs)*	*Transfers to Off-Site Treatment Works (lbs)*
5,377,060	2,452,712	2,535,381	69,489	319,470

Sources of Toxic Substance Exposures for 77541 and Brazoria County		
Air toxics not in IRIS	*Superfund sites (77541)*	*Superfund sites (Brazoria County)*
9	2	10

Demographics Information for Freeport, TX and Brazoria County		
	77541	*Brazoria County*
Race		
White	83.5%	82.2%
Black	12.1%	11.2%
Native American	0.6%	0.6%
Asian	0.4%	4.6%
Pacific Islander	0.0%	0.0%
Hispanic/Other	19.8%	2.1%
Median household income	$33,933	$60,784
% below poverty line	23.5%	9.2%

La Porte, TX 77571
Harris County



LaPorte, Texas is on Galveston Bay and is located in Houston's Ship Channel, which is home to a large number of petrochemical facilities. In 2005, the Mayor of Houston ordered a task force to investigate the effects of air pollution in the Houston area, including Harris County. Data gaps in IRIS hindered the task force's ability to assess health effects. In addition to air pollution, Harris County also contains 81 Superfund sites. According to EPA, residents of LaPorte are exposed to 279 toxic chemicals.

Blue markers represent sources of air pollution. Yellow markers are Superfund sites.

Toxics Release Inventory Information for 77571				
Total Releases (lbs)	*Air Releases (lbs)*	*Water Releases (lbs)*	*Land Releases (lbs)*	*Transfers to Off-Site Treatment Works (lbs)*
4,379,416	2,195,039	1,680,546	169,558	334,272

Sources of Toxic Substance Exposures for 77571 and Harris County		
Air toxics not in IRIS	*Superfund sites (77571)*	*Superfund sites (Harris County)*
16	1	81

Demographics Information for LaPorte, TX and Harris County		
	77571	*Harris County*
Race		
White	81.5%	73.5%
Black	6.7%	18.7%
Native American	0.6%	0.7%
Asian	0.7%	5.1%
Pacific Islander	0.0%	0.2%
Hispanic/Other	7.9%	1.3%
Median household income	$56,552	$42,598
% below poverty line	7.2%	15.9%

Streamlining the Process

Improving the priority-setting process for completing IRIS assessments is key to bringing the IRIS database up to date. But considering that EPA has such a large number of assessments to complete, it must also address how it manages its workload, and devise a process that allows the IRIS program to complete more assessments each year. EPA should streamline the process by setting goals for how many assessments to complete each year, drawing from substances of programmatic importance; eliminating the interagency review process; relying on outside science review only in the most complex cases; and preventing a few high-profile assessments from impeding progress on others by completing those assessments on a separate track with a separate budget.

In addition to structural problems with the IRIS process, regulatory agencies including EPA are plagued by information overload.[19] The regulatory process does not discourage—and actually encourages—interested parties to submit large volumes of unfiltered information to agencies. As a result, attention, not information, is in short supply in making regulatory decisions. The consequences of this overload of information include an increased cost of participation in the regulatory process – both to produce competing analyses and information and to review and understand information submitted by other interests. Industry interests, having more resources to participate in this process, dominate the process in terms of the amount of information submitted to agencies and critical evaluation of information submitted by other interests. This creates an echo chamber effect where agencies hear one perspective—industry's—much more often than others, creating a perception that the dominant perspective is the correct one.

This drop-off in pluralistic participation is described as "information capture."[20] By volume and frequency of participation, better-funded industry interests influence agencies in favor of the industry position. The IRIS program is subject to substantial information capture due to the complexity of the assessment process and the highly technical nature of its work. The IRIS office faces a prodigious backlog of assessments, and a stream of critique of its work. Industry has a strong incentive to flood the agency with more information than it can effectively process. Since there are no mechanisms in the regulatory process to limit interested parties from dumping raw data into the record, there is too much information for agency staff to read through. The agencies, battered by searching judicial review of their prior decisions, take it upon themselves to respond to the content of all the submissions made to the agency in the course of the regulatory process, in an attempt to insulate themselves against future litigation.

Although the IRIS process is not a regulatory process, it is subject to many of the same challenges in terms of information overload. ORD staff is inundated from the start with

[19] Wendy Wagner, *Administrative Law, Filter Failure, and Information Capture,* DUKE L. J. Vol. 59, (2010) [hereinafter Wagner, *Filter Failure*].
[20] *Id.*

information. Before a draft assessment is published, ORD staff comb through the literature and produce a "screening-level literature review," which is then published in the *Federal Register* and opened for public comment. Industry and other interests, including other federal agencies, then submit additional studies and data that ORD staff must read and synthesize. Part of this process is motivated by industry's efforts to generate the appearance of controversy, a deregulatory tactic that dates from the tobacco industry's 1960s efforts to suppress and obfuscate the relationship between smoking and cancer.[21]

Information capture is not unique to the IRIS process. But with such a large backlog of assessments to complete, the IRIS process could be a good test case for strategies to reduce the influence of excessive information. Placing some manner of filtering requirement on interest groups, akin to limits placed by appellate courts on litigants, could provide some relief to agencies in addressing information overload.[22] Limits would encourage interested parties to point to specific studies or findings relevant to issues with IRIS assessments. EPA staff could then focus on a few problems and more quickly finish the weight-of-the-evidence determinations required for IRIS.

Conclusion

CPR's research has identified 253 substances awaiting IRIS assessments, an unacceptably high number. EPA's program offices need IRIS information to complete statutorily mandated tasks. EPA should set a goal for working through these assessments, and then submit a budget proposal that reflects the resources it would take to finish the work in that amount of time. Congress should then provide the IRIS program with adequate funding to complete the work. Although the current budget situation is such that many programs are being cut, our own back-of-the-envelope calculations estimate that the IRIS backlog could be cleared in five years for approximately $100 million. In the context of the federal budget, this is not an unbearable request. Indeed, it would amount to 0.003 *percent* of the $3.5 trillion in federal outlays from FY2009. The IRIS process should be reformed to remove roadblocks and reduce the amount of time it takes to complete assessments.

Moving forward, EPA should set priorities based on program office need, taking into consideration environmental justice factors. Some mechanism for setting the IRIS agenda based on expected needs of the program offices should be developed. The IRIS staff should determine how many assessments must be completed based on the need from the program offices, not based on the available budget. To the greatest extent feasible, program offices should give ORD advance notice of chemicals of interest, so the IRIS staff can integrate these substances into the

[21] DAVID MICHAELS, DOUBT IS THEIR PRODUCT: HOW INDUSTRY'S ASSAULT ON SCIENCE THREATENS YOUR HEALTH (OXFORD UNIVERSITY PRESS) (2008).
[22] Wagner, *Filter Failure*, *supra* note 19, *at* 1419.

agenda-setting process. EPA should analyze whether certain communities are disproportionately affected by chemicals for which there is no IRIS information and strive to prioritize these assessments as well.

IRIS should push the regulatory agencies forward. It should also screen the epidemiology literature for candidate substances and provide information that prods the program offices to act under statutory authority. The relationship between the program offices and IRIS should be symbiotic and reinforcing.

Appendix: Additional Tables of Chemicals Indicated by Program Offices Not Listed in IRIS

Table A1: Substances identified by CPR as CAA, SDWA, or Superfund data gaps that are being assessed by IRIS staff
Chemical
Arochlors (polychlorinated biphenyls)[1,2]
Cadmium[1]
Carbonyl sulfide[1]
Chloroform[1]
Cobalt[2,3]
1,2-Dichloroethane[1]
1,4-Dioxane[1]
Ethylene oxide[1,3]
Formaldehyde[1]
Methanol[1]
Methyl *tert*-butyl ether[3]
Methylene chloride[1]
Nickel[2]
Polycyclic aromatic hydrocarbons[2]
2,3,7,8-Tetrachlorodibenzo-p-dioxin[1,2]
Tetrachloroethylene[1]
Trichloroethylene[1]
[1]Air pollutants; [2]Superfund pollutants; [3]Drinking water contaminants

Table A2: Hazardous Air Pollutants with Insufficient IRIS Information in Proposed or Mandated Residual Risk Rules	
Chemical	
Benzyl chloride	Hexachlorobenzene
Bis(chloromethyl) ether	Hexachloroethane
Bromoform	Hydrogen fluoride
Cadmium compounds	Isophorone
Carbonyl sulfide	Lead compounds
Chlorine	Lindane
Chlorobenzene	Mercury compounds
Chloroform	Methanol
Chloromethyl methyl ether	Methyl iodide
Cyanide compounds	Methyl isothiocyanate
2,4-D	N,N-Dimethylaniline
Dibenzofuran	Nickel compounds
1,2-Dichloroethane	o-Toluidine
Dichloromethane	Pentachloronitrobenzene
Diethyl sulfate	Phenol
Dimethyl carbamoyl chloride	Selenium
2,4-Dinitrophenol	Styrene oxide
2,4-Dinitrotoluene	1,1,2,2-Tetrachloroethane
1,4-Dioxane	Tetrachloroethylene
Dioxin and dioxin-like compounds	1,2,4-Trichlorobenzene
Ethyl acrylate	Trichloroethylene
Ethylene oxide	2,4,5-Trichlorophenol
Formaldehyde	2,4,6-Trichlorophenol

Table A3: Hazardous Air Pollutants with Insufficient IRIS Information in the Hazardous Organic NESHAP
Chemical
Anthraquinone
Bromonaphthalene
Chloronaphthalene
Chrystene
Fluoranthene
Alpha-Naphthalene sulfonic acid
Beta-Naphthalene sulfonic acid
Alpha-Naphthol
Beta-Naphthol
Naphthol sulfonic acid
1-Naphthylamine
2-Naphthylamine
1,4-Naphthylamine sulfonic acid
1,2-Naphthylamine sulfonic acid
1-Nitronaphthalene
Tetrahydronaphthalene

These chemicals are not listed in the Clean Air Act Amendments of 1990 with the other HAPs profiled in this paper, but they were regulated by EPA under the Hazardous Organic NESHAP. We have included them because there is also insufficient IRIS information on these chemicals.

Table A4: ATSDR Priority Chemicals Listed for more than 10 years not in IRIS[23]	
Chemical	*ATSDR points[24]*
Aroclor 1240	888.11
Radon-220	804.54
Tributyltin	802.61
Neptunium-237	802.13
Iodine-129	801.64
Gamma-chlordene	702.59
Americium	701.62
Carbon Monoxide	684.49
Chromium trioxide	610.85
Benzopyrene	603.00
Actinium-227	602.57
Ethoprop	602.13
Alpha-chlordene	601.94
Calcium arsenate	601.48
Hydrogen fluoride	588.03
Pentaerythritol tetranitrate	545.59
Carbazole	534.52

[23] ATSDR, CERCLA PRIORITY LIST, *supra* note 11.

[24] Points are assigned by ATSDR is based on an algorithm that utilizes the following three components: frequency of occurrence at NPL sites, toxicity, and potential for human exposure to the substances found at NPL sites. *See* ATSDR, WHAT IS THE CERCLA LIST, *supra* note 13.

Table A5: Water Contaminants Tracked under Unregulated Contaminant Monitoring, not in the CCL lists, not in IRIS
Chemical
2,2’,4,4’,5,5’-Hexabromobiphenyl
2,2,4,4’,6-Pentabromodiphenyl ether
Dacthal di-acid degradate
Dacthal mono-acid degradate
Lead-210
Metolachlor ethane sulfonic acid
Metolachlor oxanilic acid
Polonium-210
Terbufos sulfone

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 The John Merck Fund and the Bauman Foundation for funding this white paper. CPR also thanks the Public Welfare Foundation and the Deer Creek Foundation for their generous support of CPR's work on regulatory issues in general.

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