

# Overcoming ‘Environmental Data Gaps’: Why What EPA Doesn’t Know about Toxic Chemicals Can Hurt

by *Rena I. Steinzor, Katherine Baer, and Matt Shudtz*

A Center for Progressive Reform White Paper

July 2005

## Introduction/Overview

In an infamous report covering 2,863 organic chemicals produced or imported in amounts above one million pounds annually, the U.S. Environmental Protection Agency (EPA) concluded that there is no toxicity information available for 43% of such chemicals and that a full set of basic toxicity information is available for only 7%.<sup>1</sup> During the decade that followed release of this troubling set of statistics, we have made less progress in closing this yawning data gap than we have in discovering new threats to public health.

Air toxics are a telling case in point. As a class of pollutants, they pose a grave health threat. Health problems linked to air toxics include cancer as well as non-cancer effects such as damage to the immune, neurological, reproductive, developmental, and respiratory functions.<sup>2</sup> Air toxics exacerbate asthma,<sup>3</sup> and recent research has revealed that exposure to such chemicals can cause chromosomal abnormalities in unborn children.<sup>4</sup> These health problems combine with high release and exposure rates, leaving millions of Americans living in areas where there are “potentially significant health concerns.”<sup>5</sup> In its first National Air Toxics Assessment (NATA), EPA found that the cumulative cancer risk from 32 air toxics placed more than 200 million people (approximately 2/3 of the U.S. population) at a lifetime cancer risk exceeding one in 100,000.<sup>6</sup> Congress recognized the magnitude of the threat when it enacted the 1990 Amendments to the Clean Air Act (CAA), which required EPA to regulate some 188 air toxics according to a rigorous timetable. These provisions were among the most controversial, and most popular, in that landmark legislation.<sup>7</sup>

Given such high exposure rates and severe cancer risk profiles, understanding the full effects of all air toxics should be a national health priority. Unfortunately, like the rest of toxics research, our understanding of air toxic health effects is plagued by data gaps.<sup>8</sup> These data gaps are reflected in EPA’s Integrated Risk Information System (IRIS), arguably the world’s most prominent toxicological database since opening for public use in 1988 as manifest by its incredibly high usage rate. In February 2005 alone, for instance, the IRIS website received 626,591 successful requests.<sup>9</sup> Moreover, although IRIS was created as the central repository for toxics information for EPA, it is now used worldwide as revealed by the domains requesting IRIS information which range from Nepal to Guatemala to the United Kingdom.<sup>10</sup>

Despite the prominence of this central database for local, national, and international use, IRIS is riddled with data gaps that limit its utility and hamper regulatory action. While IRIS currently contains toxicological profiles for 544 chemicals, this number is woefully short compared to almost any other list of environmentally significant chemicals. For instance, IRIS assessments are unavailable for many chemicals EPA is responsible for regulating under the Clean Air, Safe Drinking Water, and

*Rena I. Steinzor is a Professor of Law at the University of Maryland School of Law, which recently named her the Jacob A. France Research Professor. She is a Board Member and Founding Member of the Center for Progressive Reform (CPR). Katherine Baer is a Policy Analyst with CPR. Matt Shudtz is a third year law student at the University of Maryland School of Law. Additional information about the authors appears on page 22 of this white paper.*

Emergency Planning and Community Right to Know Acts. Remarkably, over one-fifth of the Hazardous Air Pollutants (HAPs) regulated under the CAA are missing from IRIS, and data for those HAPs included in IRIS is on average almost 12 years old.<sup>11</sup>

Despite obvious need to bridge such regulatory data gaps, federal agencies, including EPA, the National Institute of Environmental Health Studies (NIEHS), and the Centers for Disease Control (CDC) have not been given sufficient funding to close such gaps. Public funding for toxicological research has remained relatively flat over the last 30 years, and IRIS research will undoubtedly suffer further as discretionary domestic spending declines. Further, although IRIS is housed in EPA's National Center for Environmental Assessment (NCEA), and staffed with highly competent and technically skilled scientists, there is apparently little coordination or integration between NCEA and other research programs within EPA or outside agencies, such as the NIEHS National Toxicology Program (NTP).

As if these impediments were not enough and despite its obvious worldwide usefulness, IRIS is being further crippled by political efforts to undermine it. The Office of Management and Budget (OMB), the primary deregulatory power in this Administration, is making plans to subject IRIS to increased White House scrutiny, largely as a result of Defense Department complaints about state use of draft IRIS values.<sup>12</sup>

Data gaps are created and perpetuated in many ways, including the structure of environmental laws that fail to require information production, the tort liability system that penalizes knowledge of product information, and corporate confidentiality provisions that allow shielding of such information.<sup>13</sup> This paper, however, focuses on the data gaps problem from the ground level of federal research, based on the belief that to ensure the production of the best and most unbiased science, research must be conducted, funded, or supervised by the government.<sup>14</sup>

With these assumptions in mind, CPR has undertaken research on both EPA's IRIS and the federal research budget (size, scope and priorities) and planning process in the area of toxics, along with efforts to weaken IRIS from outside EPA. Focusing generally on the problem of data gaps as reflected in the lack of IRIS assessments,

and specifically on existing data gaps in the air toxics arena as a case study, CPR evaluated the gaps in IRIS alongside the federal government's stated spending priorities and actual allocation of research dollars within EPA's Office of Research and Development (ORD). First, we present information on how IRIS works, detail its gaps, and explain how EPA is addressing some of these issues. Second, we evaluate the budget and planning process at ORD and analyze how data gaps are created in this context. Third, we provide examples of how IRIS is being further undermined via outside interference. Finally, we offer initial suggestions for IRIS reform to move toward closing toxics data gaps. These suggestions include:

- Increase funding for IRIS assessments;
- De-ossify the IRIS peer review process;
- Revise the IRIS prioritization scheme to reflect statutory and regulatory needs;
- Elevate and integrate IRIS in the ORD planning process;
- Establish a systematic method by which research projects are cut;
- Insulate EPA's scientific research from political pressure;
- Improve the transparency of EPA's budget.

### ***Defining the Problem: Data Gaps in EPA's Integrated Risk Information System***

Since creating IRIS in 1985, EPA has continually added new chemicals to the database and updated the information for chemicals already present on the list. As a result of these efforts, IRIS currently contains entries for 544 chemicals, which comprise a significant portion of the most widely used and produced chemicals in the U.S. Nonetheless, there are substantial data gaps in IRIS. Even where information does exist, a recent review of the database suggests much of that information could be updated. Enormous demand for IRIS data (the database received an average of over 22,000 hits per day in February 2005) underscores both the value of the information and the importance of maintaining the database.<sup>15</sup>

## What is IRIS?

IRIS was created in 1985 as a centralized database of health effects information for use by EPA employees. Prior to its creation, EPA employees only had access to balkanized information pertinent to risk assessment and risk management. IRIS was meant to ameliorate this situation by providing an easily accessible, centralized source of consistent information. Successful implementation of the IRIS program led regulated parties to become increasingly interested in the information available in the database. As a result, EPA opened IRIS to the public in 1988.

Since its inception, the database has been continuously updated. EPA, through its IRIS program office, undergoes an annual planning process to determine which chemicals should be added to the database. EPA selects chemicals for inclusion in the IRIS database based on four criteria:

- 1) Agency statutory, regulatory, or program implementation need;
- 2) the availability of new scientific information or methodology that might significantly change current IRIS information;
- 3) interest to other levels of government or the public; [or]
- 4) most of the scientific assessment work has been completed while meeting other Agency requirements, and only a modest additional effort will be needed to complete the review and documentation for IRIS.<sup>16</sup>

Once a chemical has been selected for inclusion in IRIS, EPA gathers all available information related to the toxicology of that chemical and then conducts an extensive evaluation and peer review process. A team of researchers reviews the compiled studies, and if they provide adequate information, the team will use the studies to develop two draft reports. After completing the second draft, EPA conducts three rounds of peer review for each assessment, re-writing the draft after each round to incorporate necessary changes. External peer review is part of the third round, when EPA also publishes the draft assessment in the Federal Register. Once the external peer review process is complete, EPA assembles a final draft of the assessment and posts it on

the IRIS website. For each chemical in the database, EPA provides at least one of the following: an oral reference dose, an inhalation reference concentration, hazard identification, oral slope factors, or oral and inhalation unit risks for carcinogenic effects.

## How Is IRIS Used?

IRIS information is used by EPA and many other federal agencies, with data from IRIS assessments key to federal regulatory programs. Further, IRIS data are relied upon by numerous and varied other entities, including state agencies, lawmakers, corporations, private citizens, the judiciary, and international consumers. Together, this wide audience makes IRIS perhaps the most valuable source of toxicological information in the world.

In the federal regulatory arena, for example, IRIS is used in risk management activities and in setting standards in areas like water quality. The IRIS database is a primary source of toxicological information for EPA program offices. EPA officials use the oral and inhalation reference doses, cancer weights of evidence, and dose-response curves to set necessary regulatory standards. For instance, the extent to which EPA requires Superfund site decontamination is often determined through use of IRIS data. In fact, need for toxicological data for Superfund site contaminants has been the primary impetus behind development of new assessments in recent years.<sup>17</sup> The recently-posted assessment of perchlorate will likely be the basis for water quality standards that will determine how the Department of Defense (DOD) addresses perchlorate contamination on military ranges (see perchlorate case study below).

IRIS is also used extensively at the state level. For instance, lawmakers in three states – Delaware, Illinois and New Jersey – specifically utilized IRIS in crafting state laws,<sup>18</sup> while many other states use IRIS values for environmental regulation.<sup>19</sup> For instance, in 1993 South Carolina “change[d] water quality standards for human health protection based on reference dose factors or cancer potency factors obtained from [IRIS].”<sup>20</sup> Significantly, California uses IRIS in composing the Proposition 65 (Prop 65) list of chemicals known to the State to be toxic to humans.<sup>21</sup> The District of Columbia has also used IRIS oral reference doses and carcinogenic potency factors in setting water quality standards.<sup>22</sup>

## Case Study: IRIS and Perchlorate

The story of perchlorate cleanup provides a good example of both the importance of IRIS assessments and the shortcomings of EPA's IRIS program. Perchlorate, used as a main ingredient in rocket fuel, is a particularly dangerous chemical as very small doses may disrupt thyroid hormone production by the thyroid. In recent years, scientists have discovered that substantial portions of waters in the Western U.S. have been contaminated with perchlorate. In fact, 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 munitions. Solid fuels had the advantages of being relatively stable and needing less time to load in the event of potential attack. Anecdotal evidence even suggests that the shorter time needed to arm solid fueled rockets helped steel President Kennedy's nerves during the Bay of Pigs standoff.

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 the hole, filling the hole, and detonating the missiles. This method is preferred because it is quick and, in the short term, cheap.

Unfortunately, this method is problematic as one of the primary constituents of solid rocket fuel is ammonium perchlorate. When perchlorate-containing munitions are disposed of using the OB/OD method, significant 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 patently refused to start cleanup until a national perchlorate drinking water standard is established.

This is where IRIS comes in. In 1995, EPA suggested an oral reference dose (RfD) for perchlorate in the range of 0.0001 to 0.0005 mg/kg-day. EPA began work on a new IRIS assessment for perchlorate in 1998. After putting the draft assessment through both internal and external peer review, in 2002 the Office of Research and Development (ORD) released a new draft report proposing an RfD of 0.00003 mg/kg-day (translating into a decrease from 4-18 ppb to 1 ppb). Because the final determination of the IRIS RfD value will have significant impact on human health, the environment, and DOD's cleanup costs, under heavy lobbying from DOD and the White House, EPA asked the National Academy of Science's National Research Council (NRC) to review the draft IRIS assessment.

In January 2005, NRC published a report suggesting that an RfD of 0.0007 mg/kg-day was proper, based on the evidence available from various studies. In mid-February EPA posted a new IRIS assessment for perchlorate with an RfD of 0.0007 mg/kg-day, leading to less stringent cleanup standards and liability compared to EPA's previous RfD estimate. Although the NRC is generally viewed as an objective body, a Natural Resources Defense Council investigation revealed that the White House and the Pentagon exerted pressure on panel members to downplay perchlorate's risk, making the panel's recommendation questionable.

What can we learn from the development of the perchlorate IRIS assessment? First, we see how important an assessment can be. Depending on what water quality standards are eventually derived from the RfD, cleaning up perchlorate could cost billions of dollars. Second, we see how the process of developing an IRIS assessment is greatly slowed by an ossified peer review process. In the seven years since the process began, millions of gallons of perchlorate have leached into drinking water supplies. Millions more will likely seep through before drinking water standards are set and DOD finally begins cleaning up some of the contaminated soil. Third, given the political pressure placed on the NRC panel, it is clear that IRIS is not immune, as it should be, from outside forces who would gladly manipulate the science to avoid cleanup and liability costs. Shockingly, in light of an RfD it maintains is still over-protective, DOD has even proposed additional review of draft IRIS assessments by the White House and the Office of Management and Budget prior to publication. IRIS' viability as a tool for successful risk management will greatly depend on how EPA reforms peer review of draft assessments in the near future.

IRIS information is useful to non-governmental entities as well. Members of the American Law Institute/American Bar Association Continuing Education Program suggest that the public availability of the information and its presentation in simplified, non-technical form is beneficial to developers interested in purchasing contaminated properties.<sup>23</sup> The accessibility of IRIS information enables these developers to have more interactive discussions with regulators in setting remediation goals. This use is evidenced by the District of Columbia's administration of its Brownfield Revitalization Amendment Act of 2000. Participants in the Voluntary Cleanup Program are permitted to use IRIS information to create site-specific standards for cleanup.<sup>24</sup>

IRIS has also been used to resolve litigation. In *United States v Akzo Chemicals, Inc.*,<sup>25</sup> the government sued a chemical manufacturer under Sections 106 and 107 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) to recover certain cleanup costs and compel further cleanup action.<sup>26</sup> IRIS data were used in a consent decree to determine that the defendant's failure to clean the contaminated site posed a cancer risk and to set remediation goals for site cleanup.<sup>27</sup>

Lastly, IRIS assessments are useful to international users as reflected in the IRIS web tracking statistics. In March, 2005, for instance, domains representing 96 countries outside the U.S. requested IRIS information.<sup>28</sup>

Given the diverse uses of IRIS in so many processes from the local to international level, IRIS is a prominent and respected source of toxicological data. The vital nature of IRIS underscores the need to ensure that it is current, complete, and based on clean science.

## *The Status of IRIS*

### *Chemicals Listed on IRIS*

At this time, there are 544 chemicals listed on the IRIS database.<sup>29</sup> Assessed chemicals include some of the most economically and environmentally significant chemicals, from benzene to PCBs to vinyl chloride. While IRIS provides a significant source of information to the public, it is riddled with data gaps. Detailed criticism of the extent of information available on IRIS is discussed below.

### *Assessments in Progress*

Because IRIS is such an important source of toxicological information, EPA constantly works to update it. Recently, EPA launched the IRIS Chemical Assessment Tracking System, which enables the public to monitor the status of assessments in progress.<sup>30</sup> According to this system, there are currently 81 assessments being conducted by various EPA offices.<sup>31</sup> The updating process has been hampered by slow progress in recent years. According to the Fiscal Year 2003 Agenda, only four chemicals were added to IRIS between January, 2002 and February, 2003.<sup>32</sup> By February 2004, only twelve more chemical assessments had been added to IRIS.<sup>33</sup> From February 2004 until March 2005, EPA was only able to update four existing IRIS assessments and add a single new assessment.<sup>34</sup>

The Fiscal Year 2004 (FY 2004) Agenda noted that several reviews were delayed because of "a higher level of complexity" involved in their updates.<sup>35</sup> EPA stated that "[h]ighly complex assessments often lead [the Agency] to identify new research needs, apply new methodologies, or conduct multiple, in-depth, high level external scientific peer reviews to ensure the application of sound science."<sup>36</sup> While it is understandable that certain chemical analyses or peer reviews might take longer than others, the combination of this particular list of ten chemicals (including some that have recently been the subject of heated regulatory debate<sup>37</sup>) and the lack of any timetable for completion is alarming. EPA also announced in the FY 2004 Agenda that the assessments of another twelve chemicals would be halted indefinitely.<sup>38</sup>

Some of the chemicals that are currently being assessed are part of a pilot program whereby EPA is testing the feasibility of adding acute or less-than-lifetime exposure information to IRIS assessments. The proposal to add shorter-term exposure data was announced in the FY 2003 Agenda.<sup>39</sup> In their current form, IRIS assessments contain oral reference doses, inhalation reference concentrations, cancer weights of evidence, and other data only for lifetime exposures to toxins. The goal of the pilot program is to develop assessments that are more reflective of the shorter duration exposures to chemicals that many citizens face.

The FY 2004 Agenda also announced that a number of chemicals slated for a new assessment will not be assessed for IRIS because they are pesticides that are being investigated by EPA's Office of Pesticide Programs (OPP) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).<sup>40</sup> According to EPA, this step was "taken to more efficiently utilize Agency resources."<sup>41</sup> While on its face this would seem to be a laudable goal, further inquiry revealed a significant problem. EPA notes that the assessment program run by the OPP relies on pesticide registrants for the scientific data used to develop their health assessments.<sup>42</sup> Obvious conflict of interest issues will arise due to this systemic reliance on industry for health assessment information and lack of any external peer review.<sup>43</sup>

### *Stakeholders Workshop*

In March 2003, EPA invited IRIS stakeholders to attend a workshop to critique "the criteria EPA uses to determine the annual IRIS agenda."<sup>44</sup> EPA announced the results of this workshop in August, 2003.<sup>45</sup> According to EPA, "[w]hile workshop panelists generally supported the current priority-setting criteria, they suggested that EPA evaluate whether public health concerns are sufficiently addressed by the current criterion for statutory, regulatory, and programmatic need."<sup>46</sup> In response to this criticism, "EPA reviewed previous nominations to determine if public health concerns were implicitly covered by the statutory, regulatory, or programmatic needs driving the nominations" and found "that public health concerns appear to be adequately subsumed in the current IRIS nomination process and no additional public health criterion is needed at this time."<sup>47</sup>

EPA failed to recognize that the methodology used for analyzing the stakeholders' claims is flawed. From the response quoted above, it appears that EPA looked only at chemicals that were actually nominated for new assessments to determine whether public health concerns are being adequately addressed. However, the stakeholders' concerns were with those chemicals that engender public health concerns but were *not* nominated because of the inadequacies of the current nomination process. Thus, EPA's response does not adequately respond to stakeholders' concerns.

At the stakeholder workshop it was also suggested that EPA should make "the IRIS priority-setting process more transparent by including information concerning why each chemical substance was selected for an assessment."<sup>48</sup> In response to this concern, EPA now lists the reason for each new assessment in its annual IRIS agendas.

### *Screening Level Literature Review*

The Fiscal Year 2004 Agenda notes that EPA recently completed a "screening-level review" of the IRIS database.<sup>49</sup> This review was aimed at determining which chemicals in the IRIS database had been the subject of new toxicity or carcinogenicity studies since their last significant IRIS update. All 460 chemicals in the IRIS database that were not being reassessed at that time were included in the review. The review was conducted by Eastern Research Group and was completed in three phases, the last phase finished in August, 2003. In each phase, Eastern Research Group searched titles and abstracts in web-based databases and in certain authoritative secondary sources for new literature regarding IRIS chemicals.<sup>50</sup> The researchers identified "new health effects information" for 169 chemicals (37% of those reviewed) that, "if evaluated in detail, could possibly result in a change to an existing value."<sup>51</sup> Additionally, the researchers found studies that could possibly fill data gaps for 210 chemicals (46% of those reviewed) whose IRIS entries are currently incomplete. Researchers refrained from extending the scope of their study, choosing not to evaluate whether the studies of these 210 chemicals were of sufficient quality to warrant derivation of data suitable for filling holes in IRIS entries.<sup>52</sup>

The data gaps identified in the literature review, the concerns posed by stakeholders, and EPA's inability to efficiently update the database suggest that IRIS may not be robust enough to support the weight it must bear as a preeminent source of toxicological information. This need not be the case. EPA recognizes the need to transform the IRIS system. By starting that transformation with their own ideas and incorporating the suggestions of this paper, EPA can strengthen IRIS to support the demands it must meet.

## The Future of IRIS

### EPA's IRIS "Needs Assessment"

In 2001, while working on the EPA appropriations bill, the Senate requested that EPA assess the future needs of IRIS in terms of how current entries are updated and how new chemicals will be added to the database.<sup>53</sup> The Senate instructed EPA to conduct this "needs assessment" with public input, so EPA published a notice in the Federal Register requesting comment on July 20, 2001.<sup>54</sup> EPA received comments from only 38 respondents, 16 of whom were from within the Agency.<sup>55</sup>

In the report, EPA recognizes the shortcomings of IRIS, particularly the slow pace of database updates. Two reasons for this problem are presented: a lack of staff and funds, and the widening scope of what constitutes "an assessment." These problems complicate not only the development of new assessments, but the reassessment of existing entries. To combat these problems, EPA suggested a three-part solution.

To begin, EPA needs more resources, including both money and personnel, to work on IRIS assessments. This issue has been addressed recently, with the number of employees working on IRIS updates rising from eight several years ago to 16 in late 2003, and funding for IRIS jumping from just \$2.3 million in FY 2003 to the fully requested \$7 million in FY 2004.<sup>56</sup> This increased funding will likely help to pay salaries for new researchers, as the President requested that an additional 19 full-time employees be assigned to this task beginning in FY 2004.<sup>57</sup> In FY 2005 and 2006, EPA continued to seek additional resources for IRIS. In its budget requests for these fiscal years, EPA sought an additional \$1.65 million and 10 full-time employees over President Bush's FY 2004 budget.<sup>58</sup> These additional resources, dubbed "redirections" by EPA, are actually funds taken from other Agency programs.<sup>59</sup> Nonetheless, the additional funding for IRIS is essential to expansion of the database.

EPA's second component to improve IRIS has also been implemented. Prior to 2002, researchers working on IRIS were spread throughout the agency, but now a centralized group at ORD's National Center for Environmental Assessment (NCEA) has been formed to lead or co-lead most IRIS assessments.

The third part of the design for an improved IRIS, regarding the nomination process, has yet to reach fruition. EPA recommended that a change should be made to the process by which chemicals are nominated for updates, and suggested three possible approaches. The first solution was a "user-need based approach." Under this system the 40 most requested chemicals in the IRIS database would be updated every four years, the next 80 most requested chemicals would be updated every eight years, and the remaining chemicals would be put on less frequent update schedules or not updated at all.<sup>60</sup>

The second approach was called the "systematic approach." Here, EPA suggested three ideas. First was to use the screening-level literature review completed in 2003 to create a list of chemicals whose assessments would be updated on a timetable based on resource availability and desired rate of updating. Second was to set a specific rate at which updates would be completed (e.g., 55 or 110 per year), and update this number of assessments annually regardless of need or availability of new pertinent literature. The final idea was to use a list of all chemicals of potential interest from all major EPA programs and use this list as a starting point for choosing which assessments to update.<sup>61</sup>

Ultimately, EPA came up with a third approach that blended the user-need and systematic approaches. The plan would involve a set rate of 50 new or updated assessments per year, but the chemicals selected for review would be a combination of chemicals specially reviewed based on user need and chemicals systematically chosen because of the age of their last assessments. This plan would also involve the archiving of enough assessments each year to counter-balance the new assessments added to the database. EPA provides an example:

[A] 10-year plan might be for 300 chemicals to undergo a 10-year cycle update, 100 chemicals to undergo two 5-year cycle updates, 20 chemicals to undergo special reviews when needed, 20 new chemicals to be added to the data base, and 100 chemicals to be archived from the data base. Under this approach, 320 chemicals (those on the 10-year cycle and those chosen for special review) would be reassessed once within 10 years, 100 would be reassessed

twice, 20 would be assessed for the first time under the IRIS Program, and 100 would be removed from consideration for reassessment based on diminished interest from IRIS users or the Agency.<sup>62</sup>

Implementing this system would require a full staff of at least 25 researchers and a substantial budget. EPA believes that the \$7 million appropriated for FY 2004 will go a long way towards that end.

### *OMB's Peer Review Bulletin*

Created ostensibly to ensure that regulatory agencies base their policies on sound science and good data, the Office of Management and Budget (OMB) recently proposed a new system of peer review. The proposal requires all information published by certain regulatory agencies to undergo a process of peer review prior to publication in addition to already established agency review processes. In the case of IRIS, the effect of this new program is not entirely clear. In the most recent proposal, regulatory agencies have significant control over their peer review programs for any "influential scientific assessments," but scientific assessments deemed "highly influential" are subject to peer review requirements that are highly scrutinized by the OMB.<sup>63</sup> The influential/highly influential distinction is made as follows:

A scientific assessment is considered "highly influential" if the agency or the OIRA Administrator determines that the dissemination could have a clear and substantial impact on important public policies (including regulatory actions) or private sector decisions with a potential effect of more than \$500 million in any one year or that the dissemination involves precedent setting, novel and complex approaches, or significant interagency interest.<sup>64</sup>

The uncertainty in how this new program will affect IRIS database updates arises out of the fact that OMB fails to define how the potential \$500 million effect will be calculated or even what constitutes a "precedent setting" dissemination, a "novel and complex approach" to dissemination, or a "significant interagency interest." It is somewhat unlikely that the \$500 million potential effect criteria will be used to trigger heightened peer review standards, as only three regulatory actions

reviewed by OMB in FY 2003 had estimated potential effects greater than \$500 million.<sup>65</sup> However, any of the other criteria could trigger heightened peer review standards, especially for controversial chemicals like dioxin, PCBs, and MTBE, all of which are currently being assessed.

The prospect of IRIS assessments being subject to the peer review standards for "highly influential" disseminations is disconcerting. Under these standards OMB has great control over how peer review is conducted, particularly how reviewers are chosen. The standards set by OMB presume a conflict of interest where scientists have received research funding through EPA, placing them lower in the list of potential peer reviewers. Thus, there is a significant bias in favor of industry scientists, who have no presumed conflicts of interest, even if their employer will be greatly affected by the proposed dissemination. Although the effects of this new program on IRIS are not immediately clear as the requirements of the Bulletin have only recently taken effect,<sup>66</sup> peer review is just one of several efforts by the White House to increase OMB oversight of scientific work that leads to regulatory action.<sup>67</sup>

An interesting dynamic will develop in the near future, as these anti-regulatory efforts by the White House take effect at the same time EPA funnels more resources towards IRIS and attempts to streamline the processes by which the database is updated. With any luck, this apparent conflict will be resolved in a way that allows this important toxicological database to grow without undue influence from OMB bureaucrats.

### *Criticisms of IRIS*

There are a number of criticisms of IRIS. Addressed here are 1) data gaps, 2) resource allocation issues, 3) failure to update, and 4) priority setting criteria.

#### *IRIS Data Gaps*

Despite its great importance and worldwide use, IRIS is riddled with significant gaps caused in part by EPA's infrequent updates and inadequate criteria for prioritizing such updates. Compared to almost any other list of environmentally significant chemicals, IRIS falls short. A startling example is provided by the lack of IRIS assessments for many chemicals EPA is responsible for regulating under the Clean Air, Safe Drinking Water, and

Emergency Planning and Community Right to Know Acts.

Under the Clean Air Act, EPA is responsible for regulating emissions of 188 chemicals referred to as Hazardous Air Pollutants (HAPs). Remarkably, though, over one-fifth of the HAPs are missing from IRIS. Assessments for the 149 HAPs that are present in the IRIS database are, on average, almost 12 years old.<sup>68</sup>

Likewise, under the Safe Drinking Water Act (SDWA) EPA has promulgated National Primary Drinking Water Standards (Maximum Contaminant Levels) for 87 viral and chemical contaminants. Over one-fifth of these contaminants are absent from the IRIS database, including eleven chemical contaminants.<sup>69</sup> Four of the eleven missing chemical contaminants are currently being

assessed for inclusion in the IRIS database, though two – dioxin and arsenic – are listed as unlikely to be finished any time soon because of the complexity of assessing the risks these chemicals present. On April 2, 2004, EPA announced the Draft Contaminant Candidate List 2, which represents the final list of additional contaminants for which EPA will make regulations “in the 2006 time-frame.”<sup>70</sup> Of the 51 contaminants on this list, only 28 have assessments available on the IRIS database. Thus, of the 131 contaminants that will eventually be regulated under the SDWA, 41 do not have assessments in IRIS. Only seven of these 41 contaminants are scheduled to be updated within the next two to three years.<sup>71</sup>

Similarly, under the Emergency Planning and Community Right to Know Act’s annual Toxics Release Inventory (TRI), EPA collects data on releases and transfers of 667 toxic chemicals and chemical categories. At present, IRIS assessments are available for less than half of these chemicals.<sup>72</sup>

Examination of lists of toxic or carcinogenic chemicals compiled by groups outside of EPA, on the state and international level, shows even more striking gaps in the IRIS database. Perhaps the best example is California’s

Prop 65, which requires the state to publish an annual list of chemicals known to the state “to cause cancer or birth defects or other reproductive harm.”<sup>73</sup> California updates this list on an annual basis, and businesses are required “to notify Californians about significant amounts of chemicals in the products they purchase, in their homes or workplaces, or that are released into the environment.”<sup>74</sup> The Prop 65 list of carcinogens and developmental toxicants now contains 710 chemicals, only 24% of which can be found in the IRIS database.<sup>75</sup> This is due, in part, to the fact that IRIS assessments often contain more detailed information about a chemical than does the Prop 65 database (e.g., oral reference doses or inhalation reference concentrations). Nonetheless, the disparity between the two databases is striking.

---

***Under the Clean Air Act, EPA is responsible for regulating emissions of 188 chemicals referred to as Hazardous Air Pollutants (HAPs). Remarkably, over one-fifth of the HAPs are missing from IRIS. Assessments for the 149 HAPs that are present in the IRIS database are, on average, almost 12 years old.***

---

Likewise, when compared to the list of known, probable, and possible carcinogens published by the International Agency for Research on Cancer (IARC), IRIS is also seriously deficient. IARC publishes Monographs containing carcinogenicity data for 900 agents, mixtures, and exposures,<sup>76</sup> but IRIS assessments are only available for 186 of these 900 entries.

Shockingly, only 14 of IARC’s known carcinogens have IRIS assessments.<sup>77</sup> The discrepancy between the IRIS database and the IARC Monographs is likely the result of EPA providing more detailed information in each IRIS entry, such as quantitative information on actual doses or levels of exposure and their correlative risks for carcinogenicity, while IARC Monographs only characterize an agent, mixture, or exposure as a known, probable, possible, or unlikely carcinogen. This explanation, however, does not excuse the fact that more than 85% of IARC *known* carcinogens are not present in the IRIS database.

Based on the comparisons between the chemicals listed in the IRIS database and those chemicals recognized or suspected of causing adverse health effects, and between the chemicals in the IRIS database and the various chemicals the EPA is responsible for regulating, it is clear that IRIS suffers from serious deficiencies in the number

of assessments available. Thus, research to fill IRIS data gaps would appear to be a federal research priority. However, as detailed below, that is not actually the case.

### *Resource Allocation*

Two primary reasons IRIS has not been updated more frequently in recent years were a lack of resources and inefficient allocation of available resources. Until recently, updates to IRIS assessments were conducted by a few researchers on limited budgets spread throughout EPA. In the past two years, however, EPA has increased the number of researchers working on IRIS updates, increased the funding earmarked for this work, and centralized the work within ORD's NCEA. These changes have enabled the IRIS program staff to increase the resources directed toward updating the database.

### *Currency*

As previously noted, one of the primary criticisms of the IRIS database is the infrequency with which it is updated. Currently, the average age of IRIS assessments is over 13 years old. In fact, over 43% of the assessments date to the late 1980s. While old data are not inherently inadequate, as noted above, the literature review conducted by Eastern Research Group suggests there is substantial new information available that could be used to update existing IRIS assessments. IRIS is utilized by a wide variety of groups and individuals in the public and private sectors. To ensure that the decisions they make are based on the best available information, IRIS needs to be updated more often.

### *Priority Setting Criteria*

EPA's stated criteria for prioritizing IRIS updates are statutory, regulatory, or program need, availability of scientific data, and agency interest.<sup>78</sup> Noting the data gaps discussed above, it is evident that there is significant disparity between these stated criteria and the actual priority-setting procedures employed by EPA. For example, it is unclear why IRIS lacks assessments for many of the toxins regulated under the CAA and SDWA when statutory need is listed as the first criterion for choosing chemicals for inclusion in the database. Furthermore, the literature review conducted by Eastern Research Group uncovered a significant amount of new scientific information that could be used for updating existing assessments. It seems, then, that agency interest

must be the only true criterion for choosing chemicals that will be added to the list or whose assessments will be updated.

In addition to the simple lack of important assessments, EPA's decision to start the short-term exposure pilot program evidences improper priority-setting procedures. Since the program's inception, the IRIS database focused on the potential adverse health effects of chronic exposure to toxic chemicals. In contrast, the new program aimed at developing short-term exposure assessments is likely to result in less stringent oral reference doses and inhalation reference concentrations for many toxic chemicals. As a matter of precautionary regulation, EPA should concentrate on first filling the most egregious data gaps (e.g., the lack of chronic exposure assessments for all HAPs) before working to update assessments to make them more favorable to industry.

Comparing the chemicals listed in the IRIS database to virtually any other list of chemicals important to the regulatory or public health fields highlights substantial inadequacies in EPA's central source of risk assessment information.<sup>79</sup> In recent years, a lack of funding and personnel has prevented EPA from keeping IRIS as up-to-date as would be expected for a key source of information for U.S. policy decisions. These problems are currently being addressed by centralizing IRIS assessment research within EPA's NCEA, increasing the number of employees whose sole responsibility is to conduct IRIS assessments, increasing funding for IRIS assessments, and devising new methods for prioritizing assessment updates. OMB's Peer Review Bulletin may also have an effect on how EPA updates IRIS, as EPA's own peer review requirements could be replaced by an entirely different system pronounced by OMB. All of the new programs that will affect IRIS are currently in their infancy, so their full effect will not be discernible for at least another year or two. Potential solutions for improving IRIS are detailed at the end of this paper.

## ***The Data Gaps Dilemma: Causes and Concerns***

Data gaps in IRIS reflect the struggle of important federal environmental programs to fight off the forces of declining budgets, competing priorities, and an increasingly hostile private sector. Using air toxics as

context, this section evaluates the budget and planning process at EPA's Office of Research and Development (ORD) to illustrate how data gaps are created and exacerbated. While the budget and planning process alone might be sufficient to cripple a good program, there are also increasing attacks on IRIS and other science-based toxicological programs that further threaten the integrity and existence of this critical database. Meanwhile, air toxics remain a top environmental health threat.

Air toxics was chosen as an example because vast data gaps in this field flout the statutory mandate to control HAPs and leave public health at stake. In passing the 1990 Amendments to the CAA, Congress was motivated by continued adverse health effects from air pollution. In fact, the Senate's first committee hearing on CAA changes was titled "Health Effects of Air Pollution."<sup>80</sup> At this hearing, a former American Public Health Association President testified that "air pollution is one of the greatest risks to public health. It causes, contributes to, and aggravates a long list of diseases and dysfunction..."<sup>81</sup> Spurred by the failure of EPA to control toxic air pollutants and concern over the resulting health effects, Congress specifically addressed the control of hazardous air pollutants by adding a new approach to their regulation.<sup>82</sup> The CAA's new Title III listed 191 HAPs and required that EPA issue technology-based emission standards for major sources of those pollutants.<sup>83</sup> Following technology-based controls, EPA was required to evaluate and control any remaining health risks through the residual risk program.<sup>84</sup>

Yet, fifteen years later there are almost 40 HAPs missing from the IRIS database, many of which have substantial annual emissions. In 2002, combined air emissions from the 40 missing HAPs was over 412 million pounds.<sup>85</sup> Exposures are also high as EPA estimates that the cumulative cancer risk from 33 air toxics placed more than 200 million people (approximately 2/3 of the U.S. population) at a lifetime cancer risk exceeding 10 in one million, and exceeded 100 in one million for 20 million people, both significantly higher than EPA's goal of one in one million.<sup>86</sup> Moreover, these figures address only cancer risks. The National Air Toxics Assessment revealed that almost the entire U.S. population is subject to respiratory irritation from the pollutants studied.<sup>87</sup> Given such high emission and exposure rates, it is

startling that the health effects of air toxics remains a recognized but unmet research need.<sup>88</sup> ORD acknowledges such gaps, writing that an "accounting of cancer and non-cancer dose-response assessments in the Integrated Risk Information System (IRIS) reveals many missing values for high priority air toxics."<sup>89</sup>

Choosing to focus on air toxics allowed us to dissect how a top threat to public health remains plagued by data gaps years after Congress specifically mandated their control. ORD's air toxics research program thus provides a case study ripe for analysis and reveals a suite of problems that contribute to data gaps. These problems include 1) a declining and constrained federal budget, 2) a planning process with too many priorities, and 3) political pressure to weaken toxics control.

## *Federal Research Budget*

### *Size, Scope, and Breakdown*

In 2003, the U.S. spent a total of \$284 billion on research and development (R&D), 63% of which was spent by private firms.<sup>90</sup> The federal portion of R&D has been declining steadily since the 1980s, when the federal government funded the majority of the nation's research.<sup>91</sup> Nonetheless, federal spending on R&D will reach an all time high of \$132.2 billion in FY 2005, the majority of which goes to defense, including spending in the Departments of Defense, Energy, and Homeland Security.<sup>92</sup> Meanwhile, non-defense R&D budgets fared variably. Highlighted below is FY 2005 budget information for EPA's ORD and NIEHS' NTP, chosen because their work represents the bulk of federal research on toxics. Together, these two programs represent six-tenths of one percent of the entire proposed federal R&D budget for FY 2005.

### *Environmental Protection Agency, Office of Research and Development*

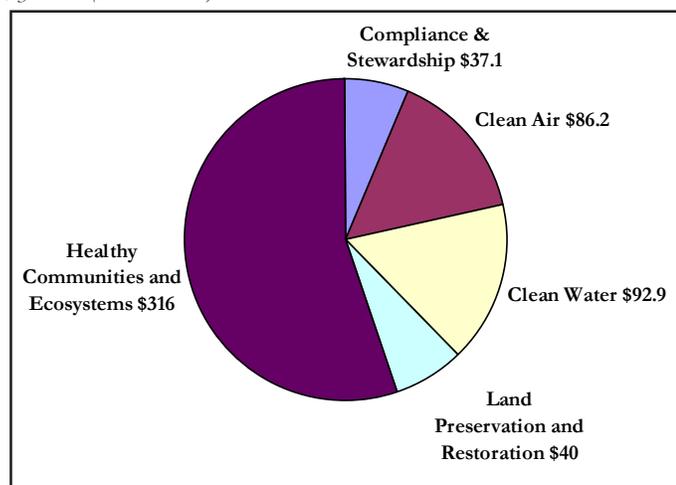
While Congress increased EPA's R&D budget above the Presidential request, the final amount is a decrease from FY 2004, and determining how this money will be parsed within ORD is difficult because of a lack of transparency. The President's proposed FY 2005 budget for ORD was \$572 million, a 7.1% decrease from the previous year,<sup>93</sup> while the final VA-HUD Appropriations Bill allocates \$598 million for ORD, a 2.8% decrease from FY 2004.<sup>94</sup> To place this amount of money in context, EPA's

research allocation is less in absolute dollars and was cut more in the last budget cycle than the budgets of most other non-defense agencies (Table 1). Further, it is noteworthy that in constant FY 2004 dollars EPA's R&D budget has declined from \$743 million in 1976 to \$591 million in 2005.<sup>95</sup> For FY 2006, EPA has been targeted for an agency wide decrease of 6% while its R&D budget would decline by 0.7%.<sup>96</sup>

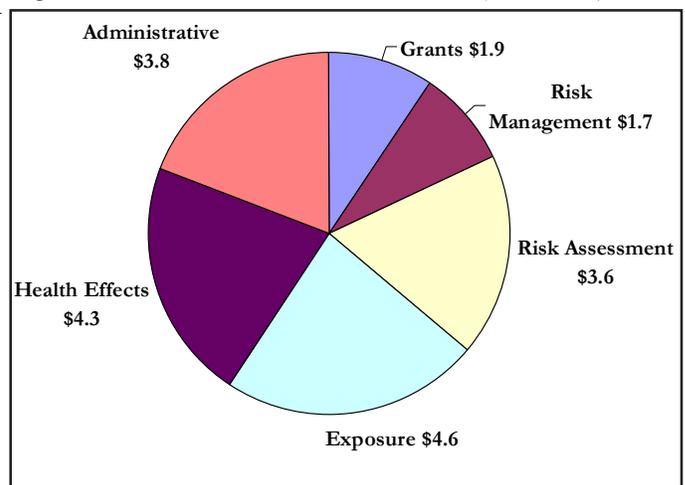
How EPA actually proposes to use their research money is a harder question to answer given that such information is “not normally available to the public”<sup>97</sup> as CPR was informed by a staff budget director. Indeed, as we discovered, past a coarse budget breakdown, further detail is in fact not publicly available. After research, a meeting with EPA staff, and further correspondence in an attempt to determine a more detailed and meaningful division of ORD's budget proved fruitless, CPR decided to narrow the focus to the details of the air toxics program as a case study. Even within the relatively small Air Toxics research program (\$17.6 million), however, we could not derive sufficient information to understand research budget allocations. Only after Senators Mikulski and Sarbanes requested and received information from EPA were we able to better understand the Air Toxics budget. As described below, this lack of transparency undoubtedly contributes to data gaps.

Readily available budget information is as follows. Initially, EPA breaks their budget into categories aligned with their five strategic goals of clean air and global climate change, clean and safe water, land preservation

**Figure 1:** President's Proposed FY 2005 ORD Budget by Goal (\$ in millions)



**Figure 2:** ORD Air Toxics Resources - FY 2003 (\$ in millions)



and restoration, healthy communities and ecosystems, and compliance and environmental stewardship (Figure 1).<sup>99</sup> This broad categorization is further broken down into Program Project research areas.<sup>100</sup> For example, under ORD's Clean Air goal, \$17.6 million is proposed for allocation to Air Toxics, \$63.7 million is allocated to Particulate Matter, and \$4.9 million is allocated to Tropospheric Ozone. Other goals with larger budgets make this breakdown even less telling – for example, under Healthy Communities and Ecosystems, \$177.4 million is allocated to Human Health and Ecosystems, a vague category at best. For air toxics, an intermediate level of budget detail was also readily available for FY 2003 (Figure 2), however any information about funding for specific projects, programs, or constituents remained obscure.

Upon receiving more detailed information from EPA via Senators Mikulski and Sarbanes, it became apparent that EPA “does not budget at the level of annual performance goals (APGs)” or annual performance measures as used in EPA's planning documents.<sup>101</sup> These specific targets are used only as “indicators of progress” and cannot be aligned with a budget allocation.<sup>102</sup> Another factor adding to the difficulty of understanding how ORD money is used is the occasional realignment of programs. For instance, EPA's response reveals that a sharp decline in Air Toxics research funding from \$24.5 million in FY 2003 to \$16.9 million in FY 2004 was a result of a realignment of some air toxics research to Human Health Risk Assessment.<sup>103</sup> However, this does little to clarify how the Air Toxics money is being used. Finally, the IRIS budget, housed in ORD's National

Center for Environmental Assessment, has increased over the last several years from \$2.3 million in FY 2003 to \$6.9 million in FY 2004, but it is not discernible how much of that amount is focused on air toxics.<sup>104</sup>

#### *National Institute of Environmental Health Science, National Toxicology Program*

NIEHS had a FY 2005 budget request of \$650 million<sup>105</sup> that was maintained in the Omnibus Appropriations bill.<sup>106</sup> Although toxics are researched through several of the NIEHS programs (e.g. Toxigenomics Research Consortium), the primary vehicle for such research is the National Toxicology Program (NTP) whose aim is to “expand the scientific basis for making public health decisions on the potential toxicity of environmental agents.”<sup>107</sup> Funding for NTP was \$183.7 million in FY 2003,<sup>108</sup> and it is not clear how much this has changed for 2005.<sup>109</sup> Similar to EPA, it is ambiguous how research money is used within the NTP.

#### *Budget Trends*

There are three trends that are notable for their potential effect on the data gaps problem. First, federal funding for environmental research is declining, and arguably becoming less focused, as money is diverted for homeland security purposes. Second, Congressional earmarks continue to dilute agency priorities. Third, the executive branch is attempting to impose a private sector management approach onto federal scientific research, with potential adverse effects for programs that cannot show short-term results.

#### *Declining and Inadequate Federal Research Budgets*

First, although federal funding in FY 2004 constant dollars for non-defense R&D has increased from \$29.9 billion in 1976 to \$56.5 billion in 2005, funding for EPA

R&D has declined during this same period.<sup>110</sup> Non-defense increases during this period are attributable to expansion in the National Institutes of Health R&D budget.<sup>111</sup> Looking forward, EPA’s R&D budget for FY 2006 is targeted for a 0.7% decrease,<sup>112</sup> and is projected to decline by 15% in FY 2009.<sup>113</sup> Air toxics research would decline to \$16.3 million in FY 2006.<sup>114</sup> These cuts are part of a broader trend to cut domestic discretionary spending whereby funding for natural resources and environmental programs is projected to decline by 23% in 2010 alone, and thus EPA can expect to receive only cuts in their research budget.<sup>115</sup> Further, within EPA’s FY 2006 budget, spending on homeland security is tripling (for decontamination and drinking water security research), thereby diluting EPA’s existing environmental research needs.<sup>116</sup> Finally, the implications of recent changes in the Congressional appropriations committee structure whereby EPA’s appropriations have moved from VA-HUD to the Interior subcommittee, also raise questions as to EPA’s funding future.<sup>117</sup>

EPA’s Science Advisory Board (SAB) observed of the FY 2005 budget that “the investments in EPA’s research go beyond erosion to the point of drastic cuts... which will eventually lead to a knowledge crisis...”<sup>118</sup> Likewise, in the draft 2006 report, the SAB notes that the “[f]ailure to fund a credible science and research program will lead to greater, not reduced regulatory burdens.”<sup>119</sup> In the air toxics research arena, the SAB also recognizes the resource disparity, characterizing the Air Toxics Program as “sorely under funded if the Agency is serious about achieving the long-term goals of the program.”<sup>120</sup>

#### *Earmarks*

Second, budgetary earmarks will continue to affect federal environmental programs. Otherwise known as “pork,” earmarks occur when a legislator designates funds for a certain pet project with or without adding money to cover the expense. If additional funds are not added some existing agency projects or programs must be cut to stay within spending limits. There are 873 earmarks worth \$488.2 million in EPA’s FY 2005 budget, a 7% decrease from the previous year.<sup>121</sup> Although President Bush is proposing to eliminate earmarks for EPA’s FY 2006 budget, this seems highly unlikely given the continued reliance on earmarks by local governments, trade associations, and others.<sup>122</sup> In fact, because of decreases to state revolving funds for

*Table 1: R&D Funding for Selected Agencies<sup>98</sup>*

Agency/Department	FY 2005 R&D Budget (\$ in millions)	% Change from FY 2004
Agriculture	\$2414	+7.8
Veteran's Affairs	\$813	-0.8
Transportation	\$718	+1.5
NOAA	\$684	+10.7
Interior	\$672	-0.5
EPA	\$598	-2.8
Nuclear Regulatory Commission	\$61	+0.9

drinking water and water quality, earmarks will likely increase as state and local governments attempt to compensate for this loss of infrastructure funding.<sup>123</sup> Unfortunately, this means that agency priorities based on certain criteria such as water quality improvements may be disrupted.<sup>124</sup>

Likewise, earmarks are also used for R&D projects, and up to 10% of EPA's R&D budget has been earmarks in recent years, causing agency staff to worry that areas of basic research will be neglected altogether.<sup>125</sup> For FY 2005, Congress again included a slew of earmarks in EPA's budget ranging from \$500,000 to the North Carolina State University Turfgrass Research Center to \$1.7 million to the Canaan Valley Institute to develop ecological prioritization and restoration tools for the protection of the Mid Atlantic Highlands.<sup>126</sup> Two earmarks specifically address air toxics research and are additions to ORD's FY 2005 R&D budget. First, is \$1.5 million to the Mickey Leland National Urban Air Toxics Research Center in Houston,<sup>127</sup> a center which was authorized by Congress and is funded by EPA and the chemical and oil industries.<sup>128</sup> Second, is \$900,000 for the study of Air Toxics Metals at the Energy and Environment Research Center, a business housed at the University of North Dakota.<sup>129</sup> Such earmarks are problematic regardless of whether these programs add to ORD's budget or cut into it because they can confuse priority-setting efforts.<sup>130</sup> In this case, where funds are supplemental, questions arise about the relationship between this external research and ORD's research goals. It is uncertain, for example, how projects funded by these two earmarks fit into ORD's strategic plan for Air Toxics, and whether these centers will best produce this research without going through the competitive grant making process. The Leland Center, for example, has emphasized that EPA does not "control our research agenda."<sup>131</sup>

#### *Private Sector Management Approach to Federal Research*

Finally, the third trend potentially affecting agency research budgets is the application of private sector management concepts to federal scientific research. Both the Bush administration's Program Assessment Rating Tool (PART) and a proposed fee-for-service arrangement for ORD are examples of this approach and have the potential to undermine federal scientific research programs.

First is PART, an Executive Branch tool intended to evaluate agency program effectiveness and inform budget decisions, which may be especially inappropriate for evaluating scientific research programs. Originating from the President's Management Agenda, PART was specifically created as part of the Budget and Performance Integration Initiative with the first round of PART reviews taking place in 2002.<sup>132</sup> A questionnaire designed by OMB, PART is used to rate a program's effectiveness and to "give true effect to the spirit as well as the letter" of the Government Performance and Results Act (GPRA).<sup>133</sup> PART places the burden on federal managers to continuously justify their funding by showing program results.<sup>134</sup> Much like the GPRA, however, PART drains agency staff time and becomes a game of procedural compliance that detracts from accomplishing an agency's mission and programs.<sup>135</sup>

Although program ratings are supposed to "enrich" budget recommendations and not lead to automatic funding decisions,<sup>136</sup> the current budget states that "[l]ow priority and low performing programs are generally proposed for reduction or elimination, and the funding is redirected to higher performing alternatives. Programs that are high priorities, but that need improvement are subjected to reforms that will produce better results."<sup>137</sup> Although the Bush Administration claims that PART results do not lead to automatic funding decisions, there is some evidence to the contrary.<sup>138</sup> Because of this Administration's close ties to industry and desire to cut government, any move to operate the government on business terms instead of as a public entity is suspect. Performance management like PART, for instance, is an attempt to transfer corporate management techniques, focusing on efficiency, results, and "market-like" discipline to the government.<sup>139</sup> Unlike the private sector, however, government does not work to make a profit, and federal programs have many, varied goals in addition to promoting equity, efficiency and other objectives,<sup>140</sup> such as long-term, unbiased scientific research.

Although this is just one in a string of performance measures used by various administrations, there are concerns that PART is politically motivated and inappropriate for evaluation of scientific research programs. First, the PART "examiners" are under the supervision of OMB staff and agency political appointees,<sup>141</sup> giving rise to the impression that examiners

come into the process with a politically motivated outcome.<sup>142</sup> Additionally, unlike GPRA there is no role for either public participation or Congressional input into PART, thus increasing control over agency programs by the executive branch, sometimes to the extent of undermining a program's underlying statutory mandate.<sup>143</sup> As an illustration of the potential conflict between PART evaluations and EPA's statutory mandates, EPA's Air Toxics Regulatory Program was evaluated in 2004 and was rated as "results not demonstrated."<sup>144</sup> For instance, the program received a zero score for the question whether "all regulations issued by the program/agency are necessary to meet the stated goals of the program..."<sup>145</sup> The explanation given for the zero score is that "[s]ome sources subject to MACT regulations do not have a significant impact on public health. EPA has the flexibility to achieve a more cost-effective regulation of air toxics within the current Clean Air Act requirements for air toxics."<sup>146</sup> This statement seems to indicate a disregard for Congress' 1990 decision to include the list of HAPs in the text of the CAA for the very reason that toxics posed a yet unaddressed health threat.

Finally, PART review may be especially inappropriate for scientific research because of the tool's emphasis on demonstrating short-term outcomes when research is by definition oriented towards long-term information collection and results.<sup>147</sup> Indeed, the three ORD programs that have been evaluated (ecological research, pollution prevention and technology research, and particulate matter research) have all received "results not demonstrated" scores.

Another tool that has just been proposed as a pilot is the "fee-for-service" program as part of ORD's budget believed viewed by some as moving ORD towards a contract mindset.<sup>148</sup> Under this program, part of ORD's research money would be allocated to program offices to use to contract with ORD for pressing research needs.<sup>149</sup> Overall the administration plans to shift \$20 million from ORD to program offices in the areas of air, water, solid waste, emergency response, pesticides, and policy.<sup>150</sup> Funds would be used for applied science to support regulatory needs and would focus on short-term results.<sup>151</sup> Although this could help alleviate certain regulatory backlogs, there are concerns that this contract approach will redirect existing ORD priorities to

program offices where a political agenda is being pushed and result in a "private sector" mentality.<sup>152</sup> In fact, responding to some of these concerns as voiced by the House Science Committee, House appropriators cut this program from their bill.<sup>153</sup>

Although it is unclear what effect these corporate-like management tools will ultimately have on scientific research budgets, it will be important to track as the Bush administration continues to impose a business model on the government. For instance, while Congress, as of yet, has not strictly followed PART-based recommendations, this tool may have serious adverse implications for agency budgets, including scientific research budgets, if PART is allowed to play a central role in funding allocations.<sup>154</sup> This could happen as there are now serious efforts to codify PART in the Program Assessment and Results Act (PARA) currently making its way through the House.<sup>155</sup> The impacts of the fee-for-service program are similarly unclear. On one hand, the program could allow program offices to direct research to fill data gaps as part of program needs, or alternatively it could divert ORD away from their research priorities to filling immediate information needs meanwhile eroding EPA's scientific base.<sup>156</sup>

In summary, EPA's budget suffers from an opacity that makes it difficult to analyze. Only after Congressional assistance was CPR able to understand the Air Toxics budget in any significant detail. What is clear, is that EPA's R&D budget, already among the lowest of the non-defense agencies, will continue to erode and, at least under this administration, will increasingly be measured by a private sector yardstick, one that is likely ill-suited to serve public environmental research needs.

### *Establishing Research Priorities*

Next, and even more labyrinthine than the budget process was the EPA research priority process. EPA has long been criticized for lacking a systematic method for setting research priorities which have instead been set in a piecemeal fashion.<sup>157</sup> Priority-setting is especially critical for toxics research given the great number of toxics lacking requisite information for the risk assessment process.<sup>158</sup> EPA does, in fact, have a voluminous strategic planning process, which is explained below. Unfortunately, it is hampered by several flaws that lead to data gap problems. These flaws include

an unrealistic set of “priorities” that are then cut haphazardly, a failure to truly prioritize by risk, and an apparent lack of coordination and integration within EPA and between EPA and other agencies.

*Research Priorities at EPA ORD*

While EPA may not be closing all the data gaps, it is not for a lack of planning and priority-setting documents (Figure 3). At the broadest level is the EPA agency-wide Strategic Plan with five strategic goals.<sup>159</sup> Focusing on air toxics within this document, the broad goal of “Clean Air and Global Climate Change” has two relevant sub-objectives. First, under the objective of healthier outdoor air, sub-objective 1.1.2 is focused on “reduced risks from toxic air pollutants” through a variety of tools including MACT, Clear Skies, and “market oriented methods.”<sup>160</sup> Second, under the objective to enhance science and research, sub-objective 1.6.2 is to conduct air pollution research including development of air quality models, cost effective pollution prevention and research designed to “answer critical scientific questions that will result in more certain risk assessments and more effective risk management practices...”<sup>161</sup>

**Figure 3:** Relationship of EPA Planning Documents for Air Toxics



At the next level, although not much more informative, is the ORD strategic plan.<sup>162</sup> Because this document was written before the current agency strategic plan, it no longer matches with overall agency goals although some general approaches likely persist. For example, ORD’s process for setting research priorities is based on scientific feasibility, resource constraints, existing expertise, ability to make a contribution, and activities to support risk reduction.<sup>163</sup>

More meaningful are the next two layers of planning documents: the Air Toxics Research Strategy (ATRS) and the Air Toxics Multi-Year Plan (MYP), although they have been criticized for a lack of integration and transparency<sup>164</sup> (research center and lab plans are not readily available and were not evaluated). The ATRS was designed to provide a framework for identifying the highest priority research needs based on risk, uncertainty, and research questions to support EPA’s activities and regulations under the CAA.<sup>165</sup> Towards this end, ORD developed five principles to guide selection of priority toxics (Figure 4),<sup>166</sup> and, using these principles, identified a priority list of 50 (out of the CAA’s 188) HAPs that are “crosswalk” constituents meeting many of the criteria.<sup>167</sup>

Ultimately the crosswalk list is the overlap between chemical structure groups and program priority groups. For example, following Principle 1, HAPs can be divided into 17 chemical groups or 11 chemical structure/reactivity groups, and from these ORD chose four groups on which to focus based on either their importance to EPA regulatory programs or because they represent areas of research uncertainty.<sup>168</sup> This process was then repeated for program priorities by compiling all HAPs previously identified as priorities by EPA programs (urban HAP list, mobile source air toxics, indoor air toxics, and HAPs subject to early residual risk standards).<sup>169</sup> Health and exposure risk was addressed as part of program priorities, assuming these programs had already integrated health and risk factors. However, the ATRS acknowledges that the crosswalk list is hampered by data gaps as “there are a number of other compounds found in both indoors and ambient environments that could not be evaluated due to a lack of health data.”<sup>170</sup> Only nine of the 39 HAPs missing from IRIS are on the crosswalk priority list.<sup>171</sup>

**Figure 4:** ATRS Principles (from *Air Toxics Research Strategy*)

- Principle 1.** Increase the usefulness of the research program by grouping air toxics initially based on physicochemical properties to assist in future studies of structure-activity relationships (SARs).
- Principle 2.** Focus research and development on the greatest risks to people and the environment.
- Principle 3.** Focus research on reducing major uncertainties in risk assessment and improving cost effectiveness in risk prevention and management.
- Principle 4.** Undertake and foster multidisciplinary research.
- Principle 5.** Ensuring an appropriate balance between near-term research and long-term research.

Following the ATRS, is the Air Toxics MYP, which provides more detail, though not enough to determine how budget resources are allocated or when research projects will actually begin.<sup>172</sup> Written by an ORD Research Coordination Team, MYPs are intended to provide more detail about a research program via long term goals, annual performance goals and measures, and research priorities.<sup>173</sup> The Air Toxics MYP, for instance, has two rather broad long term goals,<sup>174</sup> 17 annual performance goals, and 131 annual performance measures for 2003-2010. Each measure has a description, a projected completion date, and the lab or center responsible for the research.<sup>175</sup> Although the MYP is supposed to be linked with the ATRS, EPA's Science Advisory Board notes that there is not a "sufficient level of planning integration to effectively inform research priorities."<sup>176</sup> Specifically, there is no mention of any of the priority HAPs identified in the ATRS nor does the MYP explain how the ATRS' five strategic principles are applied.<sup>177</sup> As a result, despite ostensibly working under the risk management paradigm, the MYP fails to emphasize "those HAPs that pose the greatest health risks to exposed populations..."<sup>178</sup>

### **Political Meddling with Toxicity Values**

Because of the incredibly high use of the IRIS database, its good reputation, and its role as a consensus value for setting regulatory standards, those who produce and use toxics have found ways to undermine IRIS. Such political interference, often under the auspices of "sound science" threatens IRIS' integrity with the potential result of weakening public confidence in IRIS values. Industry has influenced a downgrade for some IRIS values, and

when that has not worked they have challenged the "quality" of EPA's data. Another tactic is to have EPA forsake the use of IRIS altogether when industry is displeased with the cancer potency value. Finally, when all else fails, those responsible for chemical contamination can always advocate for more review and oversight by OMB.

Industry has successfully influenced the downgrade of several IRIS values, illustrated by the cases of vinyl chloride and 1,3 butadiene (butadiene). For two years before EPA even published a public notice requesting input, the Chemical Manufacturers Association worked with the agency on a revised vinyl chloride assessment, urging the use of an industry model that ignored all cancers except liver cancer despite a broad scientific consensus that vinyl chloride causes other cancers.<sup>179</sup> Additionally, the chemical industry got EPA to drop an uncertainty factor, ultimately resulting in a 10-fold lower IRIS value.<sup>180</sup> Consequently, not only will workers be allowed to be exposed to higher levels of vinyl chloride, but vinyl chloride manufacturers facing toxic tort suits and superfund clean up liability have made life less costly for themselves.<sup>181</sup> Similarly, industry was also successful at lowering IRIS' protective value for butadiene, an extremely hazardous air pollutant associated with leukemia.<sup>182</sup> By exerting their influence through EPA's Scientific Advisory Board (SAB), panelists with ties to the chemical industry were able to restrict the use of animal studies that may have informed the dose-response determination, instead limiting the dose-response (i.e. potency) calculation to an industry sponsored occupational study with admittedly poor exposure data.<sup>183</sup> As a result, the IRIS cancer potency estimate for butadiene was weakened 8-fold from the previous government value and 4-fold from the value derived from the most recent animal data despite a General Accounting Office report criticizing the financial conflicts of interest of SAB panel members.<sup>184</sup>

Next, when such informal methods to manipulate IRIS values and underlying science are unsuccessful, industry can turn to the Information Quality Act (IQA) petition process. Under the IQA groups can petition an agency ostensibly to correct information disseminated by the agency. In reality, this law (passed as a two paragraph appropriations rider) has become another tool for industry to avoid and delay regulatory actions and

question agency policy decisions.<sup>185</sup> Using just this tactic, the Chemical Products Corporation (CPC) filed an IQA petition requesting the withdrawal of EPA's IRIS value for barium.<sup>186</sup> CPC claimed that EPA's value did not represent the consensus position and specifically requested inclusion of an industry funded study in order to raise the oral reference dose.<sup>187</sup> Ultimately EPA rejected the petition, but agreed to a panel to peer review barium data to determine whether a reassessment was warranted.<sup>188</sup> Thus, although their IQA petition failed, CPC was able to inject sufficient uncertainty into the IRIS process to divert EPA time and resources away from other IRIS priorities.

Another strategy to undermine the IRIS process is to question whether IRIS values should be used at all in regulatory decisions when it would be unfavorable to industry. For example, the Formaldehyde Council successfully urged EPA's Air Office to use a risk value derived from a Chemical Industry Institute of Toxicology (CIIT) model in place of the IRIS value under development as EPA was considering risk-based exemptions to CAA control requirements.<sup>189</sup> Consequently, plywood makers were granted an exemption when EPA used the CIIT recommended risk value that was 10,000 times lower than the previously posted IRIS value.<sup>190</sup> The Formaldehyde Council further used their success at the federal level to oppose more stringent state plans to control air toxics,<sup>191</sup> and EPA's use of the CIIT value generates uncertainty for states normally relying on IRIS.<sup>192</sup> Although not all such efforts to disregard IRIS are winning, they nonetheless help confuse the purpose and credibility of IRIS. Another industry group, the Residual Risk Coalition, unsuccessfully advocated use of industry data in place of IRIS values as part of the residual risk setting process for coke ovens.<sup>193</sup> Yet because the Coalition argued in part that the IRIS value was outdated, they raise reasonable concerns about IRIS even if their motives or data are suspect, thus striking at IRIS credibility.

Finally, chemical industry officials support recently proposed plans to increase OMB oversight of IRIS.<sup>194</sup> Objections were raised by the Department of Defense (DOD) following the release of draft IRIS perchlorate values that some states used to set cleanup standards stricter than the final IRIS value.<sup>195</sup> Increased interagency review may be one result, possibly stalling IRIS review

and creating a conflict of interest in cases such as perchlorate where DOD is likely a potentially responsible party.<sup>196</sup> Certainly, OMB will have more oversight and ability to interfere in what should be a scientific, not a political, risk assessment. Already OMB will start reviewing draft assessments prior to public review, raising a red flag for agency scientists and environmental groups who are concerned that OMB's lack of scientific expertise can only undercut the IRIS process.<sup>197</sup>

## **Analysis – Sources of Data Gap Problems**

Because there are a number of air toxics data gaps, ORD's air toxics research program provides a good example for analysis and reveals a suite of problems that contribute to data gaps. One of the recognized unmet research needs in this area is the health effects of air toxics.<sup>198</sup> An indication of the scope of these data gaps, as mentioned earlier, is that there are almost 40 HAPs missing from the IRIS database, many of which have substantial annual emissions.<sup>199</sup> Additionally, nine of the "crosswalk" HAPs delineated as priorities in the ATRS are not in IRIS (although three are currently in the assessment process). Cobalt, for instance, listed as a priority HAP in the ATRS, is not mentioned in the MYP nor is information available for it on IRIS. According to the Toxics Release Inventory (TRI), more than six million pounds of cobalt compounds were released in 2002,<sup>200</sup> and the International Agency for Cancer Research (IARC) has classified cobalt as a possible human carcinogen.<sup>201</sup> ORD recognizes such gaps, writing that an "accounting of cancer and non-cancer dose-response assessments in the Integrated Risk Information System (IRIS) reveals many missing values for high priority air toxics."<sup>202</sup> Nonetheless, despite the fact that one of the services provided by ORD is "defendable IRIS toxicity values and exposure models...", IRIS is mentioned in only two of the MYP's performance measures.<sup>203</sup>

This data gap dilemma stems from at least four flaws in the federal planning and budget process. First, there are too many priorities established in the ATRS and the MYP to make them meaningful or reasonable given budget realities. The ATRS crosswalk list, for instance, narrows the HAP list from 188 to 50, and the Air Toxics MYP includes 131 annual performance measures.

Further, while the MYP purports to answer key research questions, many annual performance goals become research priorities as part of “backroom deals.”<sup>204</sup> Compiled by a Research Coordination Team with representatives from ORD, Labs and Centers, and the Regions, and ultimately approved by the Assistant Administrator, budgeting is “about people” who have a stake in protecting certain programs or projects.<sup>205</sup> Thus the priorities, as embodied by the crosswalk list and performance goals, may not be consequential even initially.

Further, because there is insufficient money to achieve all of the MYP’s goals, the order in which items are cut is arguably as important as affirmatively stated priorities. While the SAB recognizes that it is “imperative that the Agency be willing to reprogram funds among laboratories as the need arises,”<sup>206</sup> such cuts are currently made in a haphazard manner. ORD has a “contingency pool” that establishes which items are cut when there are budget reductions, a process that is not transparent and can be extremely subjective.<sup>207</sup> Lab and Center Directors, for instance, can opt to cut entire programs or skim a set percentage across all programs, regardless of the initial priority-setting process.<sup>208</sup> Because MYPs are written to a flat budget in a time of decreasing budgets, use of the contingency pool is common and may have a significant effect on research plans.

Second, another flaw contributing to data gaps is that despite following a risk-based priority-setting process, the ATRS and the MYP are criticized for failing to “set research priorities based on those HAPS that pose the greatest risk to exposed populations.”<sup>209</sup> While the second ATRS prioritization principle is to focus R&D “on the greatest risks to people and the environment,” the SAB observes that this principle is not well-defined.<sup>210</sup> Perhaps capturing the essence of the data gaps dilemma is the SAB’s recognition that one “should not assume that because little is known about a compound there is little risk for adverse health and ecological outcomes.”<sup>211</sup> This problem was acknowledged in the ATRS, which was hampered in setting priorities by gaps in health effects data. Ideally, a first level of minimal information should be collected on as many air toxics as possible and used to select certain compounds for further study.<sup>212</sup> Without this baseline of information, priority setting becomes rather hollow.

A third flaw is the apparent lack of coordination within EPA and between EPA and other agencies.<sup>213</sup> Initially, there is a lack of integration within the air toxics planning process. For instance, there is no evidence that the ATRS crosswalk constituents are actually being prioritized for research in the MYP. A search of the Air Toxics MYP revealed no specific mention of any of the 50 crosswalk HAPS by name although structural groups are addressed. While this is not determinative, it indicates that strategic planning efforts may have been disregarded. Next, planning between divisions within EPA is also missing. Some metals classified as HAPS, for example, are addressed under the Particulate Matter MYP, but because that research is not referenced in the Air Toxics MYP it is unclear whether this research is coordinated.<sup>214</sup> Another example of special relevance to data gaps is the lack of any systematic link between Air Toxics (and presumably other research areas) and the National Center for Environmental Assessment that manages IRIS.<sup>215</sup> IRIS is on a one-year planning cycle and does not request research from other ORD branches that could provide data to complete assessments. Finally, coordination between EPA and other agencies working on air toxics is also absent. While the Air Toxics MYP acknowledges the need to coordinate research with outside organizations such as NTP,<sup>216</sup> the planning documents do not address how this will be accomplished.

Fourth, IRIS is vulnerable to political attack from industry and other branches of government displeased with the liability they derive from IRIS values. Already, industry has successfully influenced IRIS values and raised questions concerning when IRIS values are used. This will likely only increase as OMB takes more control of the IRIS review process. This outside meddling with toxicity values thus contributes to data gaps by delaying and questioning the government process through a variety of tactics.

Although it is not possible to determine ORD’s exact research projects from the MYP or how much money is being spent on them, an initial analysis reveals that EPA’s strategic planning process has the potential to target data gaps. On the bright side, this is good news given the important role of federally funded research on toxics. Unfortunately, as reflected by the Air Toxics case study, this potential is apparently unfulfilled. While almost 40 HAPS remain unlisted in IRIS, there is no indication

that these constituents have been prioritized for research. Only nine of the 39 HAPs missing from IRIS are on the ATRS crosswalk list, and none of the 50 HAPs from the crosswalk listed are specifically mentioned in the Air Toxics MYP. Data gaps in this context are engendered in several ways. First, there are an excessive number of goals given EPA's tightening budget in tandem with a subjective process for cutting from stated priorities. Second, risk based planning is hampered by a lack of baseline information on all HAPs. Third, there is a lack of coordination within EPA and between EPA and most prominently, NTP, and fourth, forces outside EPA work to cripple IRIS by undermining the scientific research process. Both the EPA budget and specific research items suffer from a lack of transparency that limits evaluation. Because it is certain that EPA will see further erosion in R&D funding, however, it is critical to highlight these processes to identify ways to better target data gaps in future planning cycles.

## **Closing Data Gaps – Thinking About Solutions**

Both because critical health and environmental issues can only be addressed if there is information to do so and because IRIS is a preeminent internationally respected toxicological database, CPR presents the following ideas as a starting point to close data gaps.

### **Improving the IRIS Database**

The most egregious problem with IRIS – its significant data gaps – is the result of three systemic flaws – insufficient resource allocation, ossified peer review, and confused prioritization.

*Increase IRIS Funding* – the first of these problems has been addressed in recent years. As discussed above, EPA has centralized work on IRIS at NCEA and increased the number of full-time employees assigned to IRIS work. Further, the IRIS allocation in the President's budget for FY 2004 more than doubled the actual IRIS budget in FY 2003. While these improvements are moving in the right direction, they do not completely address the lack of resources that is at the root of IRIS data gaps. In the Needs Assessment drafted for the Senate, EPA suggested that 50 new or updated assessments would have to be completed each year in order to meet user needs.<sup>217</sup> In recent years, EPA has

only been able to complete roughly ten assessments per year. Assuming there is a strong correlation between EPA resources dedicated to IRIS assessments and the rate at which EPA produces new assessments, *EPA might need at least \$25 million dollars per year and 50 full time researchers working on IRIS updates.*

*De-ossify the IRIS Peer Review Process* – analysis of the state of IRIS assessments currently in progress suggests that a large increase in resource allocation may not actually be necessary to completely close IRIS data gaps. The IRIS Chemical Assessment Tracking System reveals that almost one third of assessments currently in progress are stuck in the agency-wide peer review stage of development. Many of these assessments have been undergoing agency peer review for several years. And this is just the second of three levels of peer review. Once the agency-wide peer review is complete, the assessment must be redrafted and submitted for external peer review. The ossification of the IRIS peer review process has resulted in a system in which a substantial number of the IRIS assessments in progress, begun in 1998, will likely not be completed until 2006.

Two possible solutions for speeding up the peer review process involve deadlines and collapsing the process into a single stage. The first solution would be simpler to implement. *Rather than merely distributing a draft assessment throughout EPA and waiting for the various program and regional offices to respond, NCEA should set deadlines.* Allowing these offices a set amount of time – say, eight or ten months – to respond would greatly reduce the bottleneck that currently hampers the issuance of new IRIS assessments. *A more drastic measure would be to collapse the ORD, agency, and external peer review stages into a single stage peer review.* While this would eliminate the need to redraft the assessment three times during the peer review process, the sheer volume of discussion from all spheres of interested parties could make single-stage peer review unwieldy, particularly for an undersized and underfunded NCEA staff. Perhaps, though, an increase in researchers and funding, combined with a more streamlined peer review process (including deadlines for responses from all interested parties) could help close the data gaps.<sup>218</sup>

*Revise the IRIS Prioritization Scheme to Reflect Statutory and Regulatory Needs* – besides ossified peer review and insufficient resources, the third major flaw in the IRIS

system that must be addressed is the improper prioritization for IRIS updates. As noted above, the first criterion in EPA's list of factors to consider in determining chemicals to add to IRIS is statutory need. Despite this, many chemicals that must be regulated under the Clean Air Act and Safe Drinking Water Act are missing from IRIS. Furthermore, contrary to another factor listed for consideration in determining which assessments to update, there is abundant new toxicological information that could be used to update a significant percentage of existing assessments.

These flaws show that EPA's system of prioritization should be revised. A simple solution would be to create a master list of chemicals that will be assessed or whose assessments will be updated sequentially. *At the top of the list should be those regulated chemicals for which no IRIS assessment currently exists.* Next should be regulated chemicals for which information is available that would fill gaps in the current IRIS assessment. These regulated chemicals should be followed by those non-regulated chemicals that are missing IRIS assessments but are important to the regulatory community. A simple revision of the prioritization process like this, combined with an improved peer review process and allocation of additional resources to IRIS assessments would have a significant impact in closing the data gaps that devalue this important database.

### ***Improving the Budget and Research Planning Process***

*Elevate and Integrate IRIS in the ORD Planning Process* – while there are plenty of annual performance goals as part of EPA planning documents, at least in the area of air toxics, there is no systematic plan for research to close IRIS data gaps. IRIS research on the remaining air toxics missing from IRIS should be a priority for two reasons. First, the CAA set a statutory mandate to regulate these pollutants, and second, EPA's planning process, based to a large degree on addressing risk, cannot be accurate without baseline information on all of the HAPs. These will require better and more transparent coordination

and cooperation within ORD and between ORD and other EPA divisions and agencies. NCEA should have an intra/inter-agency coordinator to facilitate this work. Additionally, IRIS should have a long-term planning process more similar to the rest of ORD, providing the opportunity to identify areas of research that IRIS needs to complete an assessment that the rest of ORD could provide.

*Establish a Systematic Method by which Projects are Cut* – in an era of declining funding for EPA programs and research, it is critical to have a way to cut programs that will minimize harm to programs, staff, and research priorities. Thus, research projects should be cut in order of least to most priority to best address data gaps.

*Insulate EPA's Scientific Research from Political Pressure* – as described above, IRIS values are under intense political pressure and scrutiny that undermines the integrity of this internationally renowned toxicity database. Regulated industries as well as some government agencies are continually battering IRIS, and attempting to bend IRIS values to their liking. Whether through OMB's peer or PART review or industry attempts to replace IRIS with their own science, IRIS is certainly under siege. The IRIS process must occur, instead, within strict boundaries that disallow conflicts of interest and prohibit gratuitous review processes used to delay IRIS assessments. This further underscores the recommendation to increase ORD's IRIS budget as it is even more clear that industry funded science comes with inherent conflicts.

*Improve Transparency of EPA's Budget* – while the public, after much diligence and assistance from U.S. Senators, can view how ORD's money is allocated to a certain level, it is still unclear what portion of the air toxics budget is used for IRIS research or other data gap closing efforts. Budget documents should first, be available to the public, and second, indicate what portion is used to provide information about the effects of toxics chemicals to which we are all exposed.

## Appendix A

### CAA Hazardous Air Pollutants not in IRIS

Acetamide	Ethyl acrylate	2,3,7,8-Tetrachlorodibenzo-p-dioxin
2-Acetylaminofluorene	Ethylene oxide	Titanium tetrachloride
4-Aminobiphenyl	Hexamethylphosphoramide	2,4-Toluene diisocyanate
Bis(2-ethylhexyl)phthalate (DEHP)	Hydrazine	o-Toluidine
Calcium cyanamide	Hydrogen fluoride (Hydrofluoric acid)	o-Xylenes
Catechol	Methyl hydrazine	m-Xylenes
Chloroacetic acid	4,4-Methylene bis(2-chloroaniline)	p-Xylenes
Chloroprene	4,4'-Methylenedianiline	Cadmium Compounds
Diethanolamine	4-Nitrobiphenyl	Chromium Compounds
3,3-Dimethoxybenzidine	N-Nitroso-N-methylurea	Cobalt Compounds
Dimethyl aminoazobenzene	N-Nitrosomorpholine	Glycol ethers
Dimethyl carbamoyl chloride	p-Phenylenediamine	Manganese Compounds
Dimethyl formamide	1,3-Propane sultone	Fine mineral fibers
1,1-Dimethyl hydrazine	Styrene oxide	Polycyclic Organic Matter
4,6-Dinitro-o-cresol, and salts		

### About the Authors

**Rena I. Steinzor** is a tenured full Professor at the University of Maryland School of Law, where she directs the University of Maryland's Environmental Law Clinic. She has published widely in the areas of (1) environmental federalism, including so-called "unfunded mandates" imposed on state and local governments by the federal government and the impact on public health of devolving authority and responsibility for solving environmental problems; (2) the implications of industry self-regulation on the protection of the environment and human health; and (3) so-called "market-based" alternatives to traditional regulation; and the soundness of the science used by EPA to make regulatory decisions. Prior to entering academia, Professor Steinzor was associated - first as "of counsel" and ultimately as the partner in charge of the environmental practice - at Spiegel & McDiarmid, a 45-lawyer, Washington, D.C. firm representing numerous cities, counties, states, and public agencies in the energy, environmental, communications, and transportation fields. Before entering private practice, Professor Steinzor served as Staff Counsel, Subcommittee on Commerce, Transportation, and Tourism of the Energy and Commerce Committee, U.S. House of Representatives (James J. Florio, Chairman). She was the primary staff person responsible for legislation that became the "Superfund Amendments and Reauthorization Act of 1986" and the "Asbestos Hazard Emergency Response Act." She also prepared legislation to reauthorize the Toxic Substances Control Act during the 98th Congress.

**Katherine Baer** is a Policy Analyst at the Center for Progressive Reform. Ms. Baer is a 2004 graduate of the University of Maryland School of Law and earned her master's degree in Conservation Ecology from the University of Georgia. Prior to attending law school, she was Director of Headwaters Conservation for the Upper Chattahoochee Riverkeeper.

**Matt Shudtz** will earn his J.D. from the University of Maryland School of Law in May 2006, with a concentration in environmental law. He earned his Bachelor of Science in Earth and Environmental Engineering from Columbia University.

### Acknowledgments

The authors would like to thank John Applegate, Michael Paul, Jennifer Sass, and Katherine Squibb for their assistance with and review of this report.

## Endnotes

- <sup>1</sup> EPA *Analysis of Test Data Availability for HPV Chemicals*, 22 Chem. Reg. Rep. 261 (1998).
- <sup>2</sup> U.S. EPA, Toxic Air Pollutants <<http://www.epa.gov/air/toxicair/newtoxics.html>> (last updated Oct. 2003).
- <sup>3</sup> David B. Peden, *Pollutants and Asthma: Role of Air Toxics*, 110 Env. Health Persp. No. 4 (2002).
- <sup>4</sup> Center for Children's Environmental Health, *New Study Reveals that Prenatal Exposure to Urban Air Pollutants can Cause Genetic Alterations in Babies In Utero* <[http://www.ccceh.org/news-events/ChromMutationsReleaseFinal\\_Emb-2-15.htm](http://www.ccceh.org/news-events/ChromMutationsReleaseFinal_Emb-2-15.htm)> (last accessed Mar. 9, 2005).
- <sup>5</sup> Jerry Phelps, *Fair Air*, 110 Env. Health Persp. No. 8 (2002).
- <sup>6</sup> US EPA, Technology Transfer Network National Air Toxics Assessment, *Summary of Results* <<http://www.epa.gov/ttn/atw/nata/risksun.html>> (last updated Sept. 2002).
- <sup>7</sup> Sen. Rpt. 101-228, at 128-133 (Dec. 20, 1989).
- <sup>8</sup> Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 Duke L.J. 1619, 1628 (2004).
- <sup>9</sup> US EPA, Web Statistics for iriswebp <[http://www.epa.gov/reports/objects/iriswebp/iriswebp/iriswebp-February\\_2005.html](http://www.epa.gov/reports/objects/iriswebp/iriswebp/iriswebp-February_2005.html)> (last accessed Mar. 9, 2005).
- <sup>10</sup> *Id.*
- <sup>11</sup> See U.S. EPA, *IRIS Substance List* <<http://www.epa.gov/IRIS/subst/index.html>> (last updated Feb. 18, 2005) and Appendix A.
- <sup>12</sup> Steve Gibb, *Perchlorate Dispute Prompts Effort for Broader Federal Toxics Review*, InsideEPA.com Risk Policy Report (Mar. 3, 2005), and *EPA May Overhaul Toxic Reviews to Minimize Interagency Disputes*, InsideEPA.com Risk Policy Report (Apr. 8, 2005).
- <sup>13</sup> Wagner, *supra* n. 8 throughout.
- <sup>14</sup> See e.g. John S. Applegate, *The Government Role in Scientific Research: Who Should Bridge the Data Gap in Chemical Regulation?* In *Rescuing Science from Politics*, Wendy Wagner and Rena Steinzor, eds., Cambridge University Press (forthcoming 2005).
- <sup>15</sup> U.S. EPA, *Web Server Statistics for iriswebp* <[http://www.epa.gov/reports/objects/iriswebp/iriswebp/iriswebp-February\\_2005.html](http://www.epa.gov/reports/objects/iriswebp/iriswebp/iriswebp-February_2005.html)> (last accessed Mar. 9, 2005).
- <sup>16</sup> U.S. EPA, *U.S. EPA's Process for IRIS Assessment Development and Review*, <<http://www.epa.gov/iris/process.htm>> (last updated Nov. 18, 2004).
- <sup>17</sup> See Integrated Risk Information System (IRIS); Announcement of 2004 Program; Request for Information, 69 Fed. Reg. 5971, 5975 (Feb. 9, 2004); Integrated Risk Information System (IRIS); Announcement of 2005 Program; Request for Information, 70 Fed. Reg. 10616, 10619 (Mar. 4, 2005).
- <sup>18</sup> See 7 Del. C. §7402A(15)(b) (2003), 415 I.L.C.S. 5/58.2 (2004), N.J.S.A. 58:10B-12(b)(5) (2004).
- <sup>19</sup> See West online citation: S.C. Reg. 1131 (SN), see, e.g., Notice of Final Rulemaking, 49 D.C. Reg. 3012, 3033 (Department of Health) (Apr. 5, 2002).
- <sup>20</sup> West online citation: S.C. Reg. 1131 (SN).
- <sup>21</sup> See California Office of Environmental Health Assessment, *Proposition 65 in Plain Language!* <<http://www.oehha.ca.gov/prop65/background/p65plain.html>> (last visited March 18, 2005). The Carcinogen Identification Committee and the Developmental and Reproductive Toxicant Identification Committee, who are responsible for adding new chemicals to the Prop 65 list, have designated EPA an "authoritative body." This designation means that any chemical identified by EPA to cause cancer or developmental or reproductive harm will automatically be added to the Prop 65 list.
- <sup>22</sup> See, e.g., Notice of Final Rulemaking, 49 D.C. Reg. 3012, 3033 (Dept. of Health) (Apr. 5, 2002).
- <sup>23</sup> John L. Payne & David B. Farer, Case Study: Acquisition and Development of a Brownfields Property, American Law Institute – American Bar Association Continuing Legal Education, SH033 ALI-ABA 1289, 1337-8 (Oct. 17 – 18, 2002).
- <sup>24</sup> See, e.g., Notice of Proposed Rulemaking, 50 D.C. Reg. 8842, 8867 (Dept. of Health) (Oct. 17, 2003).
- <sup>25</sup> 2001 WL 303106 (S.D. Ala. 2001).
- <sup>26</sup> *Id.* at \*1.
- <sup>27</sup> *Id.* at \*50-56.
- <sup>28</sup> U.S. EPA, *Web Server Statistics for iriswebp* <[http://www.epa.gov/reports/objects/iriswebp/iriswebp/iriswebp-March\\_2005.html](http://www.epa.gov/reports/objects/iriswebp/iriswebp/iriswebp-March_2005.html)> (last accessed Apr. 21, 2005).
- <sup>29</sup> See U.S. EPA, *IRIS Substance List* <<http://www.epa.gov/IRIS/subst/index.html>> (last updated May 12, 2005).
- <sup>30</sup> U.S. EPA, *IRIS Chemical Tracking System* <<http://cfpub.epa.gov/irisstrac/index.cfm>> (last updated June 13, 2004).
- <sup>31</sup> See *id.* at <<http://cfpub.epa.gov/irisstrac/index.cfm?fuseaction=listChemicals.showList&letter=ALL>> (last updated June 13, 2004).
- <sup>32</sup> Integrated Risk Information System (IRIS); Announcement of 2003 Program, 68 Fed. Reg. 5870, 5871 (Feb. 5, 2003).
- <sup>33</sup> Announcement of 2004 Program, 68 Fed. Reg. at 5872.
- <sup>34</sup> Announcement of 2005 Program, 70 Fed. Reg. at 10617.
- <sup>35</sup> Announcement of 2004 Program, 69 Fed. Reg. at 5973.
- <sup>36</sup> *Id.*
- <sup>37</sup> The chemicals on this list are: ammonium perchlorate (and other perchlorate salts), inorganic arsenic, asbestos (noncancer effects), ethylene oxide (cancer effects), formaldehyde, methyl tert-butyl ether (MTBE), tetrachloroethylene (perchloroethylene), polychlorinated biphenyl (PCBs – noncancer endpoints), 2,3,7,8-TCDD (dioxin), and trichloroethylene (TCE).
- <sup>38</sup> Appendices on file with authors.
- <sup>39</sup> Announcement of 2003 Program, 68 Fed. Reg. at 5871.
- <sup>40</sup> Announcement of 2004 Program, 69 Fed. Reg. at 5974.
- <sup>41</sup> *Id.*
- <sup>42</sup> *Id.*
- <sup>43</sup> U.S. EPA, *EPA's Risk Assessment Process For Tolerance Reassessment, Staff Paper #44* <<http://www.epa.gov/oppfeed1/trac/paper44.pdf>> (Oct. 8, 1999) (last visited July 8, 2004).
- <sup>44</sup> Announcement of 2004 Program, 68 Fed. Reg. at 5872.
- <sup>45</sup> Integrated Risk Information System (IRIS); 2003/2004 Program, 68 Fed. Reg. 48359, 48,360 (Aug. 13, 2003).
- <sup>46</sup> *Id.* At present, "[c]hemicals are selected based on one or more of the following factors: (1) Agency statutory, regulatory, or program implementation need; (2) the availability of new scientific information or methodology that might significantly change current IRIS information; (3) interest to other levels of government or the public; (4) most of the scientific assessment

work has been completed while meeting other Agency requirements, and only a modest additional effort will be needed to complete the review and documentation for IRIS.” U.S. EPA, *U.S. EPA’s Process for IRIS Assessment Development and Review* <<http://www.epa.gov/iris/process.htm>> (last updated July 8, 2004).

<sup>47</sup> 2003/2004 Program 68 Fed. Reg. at 48,360.

<sup>48</sup> *Id.*

<sup>49</sup> Announcement of 2004 Program, 69 Fed. Reg. at 5975.

<sup>50</sup> Screening Level Review of the Recent Health Effects Literature for IRIS Chemicals, obtained from IRIS hotline (Oct. 2003).

<sup>51</sup> Screening Level Review of Toxicity Information Contained in the Integrated Risk Information System (IRIS) Database Summary of Phase I, II, and III Findings, Prepared by Eastern Research Group for U.S. Environmental Protection Agency, 1 (Aug. 6, 2003).

<sup>52</sup> *Id.* at 2.

<sup>53</sup> Sen. Rpt. 106-410, at 90 (June 30, 2000).

<sup>54</sup> Integrated Risk Information System; Notice; Request for Information, 66 Fed. Reg. 37,958 (July 20, 2001).

<sup>55</sup> U.S. EPA, *Needs Assessment for U.S. EPA’s Integrated Risk Information System*, at 5. EPA/635/R-02/004 (Sept. 2003) <[http://www.epa.gov/iris/iris\\_needs.pdf](http://www.epa.gov/iris/iris_needs.pdf)>.

<sup>56</sup> Pat Phibbs, *EPA Says It Should Add Information on 50 Chemicals Per Year to Database*, 27 Chem. Reg. Rep. (BNA) No 37, at 1115 (Sept. 22, 2003).

<sup>57</sup> U.S. EPA Science Advisory Board, *Review of the FY2004 Science and Technology Budget Request for the U.S. Environmental Protection Agency: An EPA Science Advisory Board Review*, EPA-SAB-EC-03-006 (Apr. 2003) <<http://www.epa.gov/sab/pdf/ec03006.pdf>>. The Board notes that the President requested 19 additional FTE, or full-time equivalents.

<sup>58</sup> See U.S. EPA. FY 2005 Annual Performance Plan and Congressional Justification at IV-162 <<http://www.epa.gov/ocfopage/budget/2005/g04final.pdf>> (last visited Mar. 18, 2005); and FY 2006 Annual Performance Plan and Congressional Justification for Science and Technology at 30 <<http://www.epa.gov/ocfopage/budget/2006/sciencetech.pdf>> (last visited Mar. 18, 2005).

<sup>59</sup> *Id.* FY 2006 Annual Performance Plan and Congressional Justification for Science and Technology at 49, 61, 83.

<sup>60</sup> Needs Assessment for U.S. EPA’s Integrated Risk Information System, at 7.

<sup>61</sup> *Id.* at 7-8.

<sup>62</sup> *Id.* at 9.

<sup>63</sup> Revised Information Quality Bulletin on Peer Review, 69 Fed. Reg. 23,230 (Apr. 28, 2004).

<sup>64</sup> *Id.* at 23,236-7.

<sup>65</sup> Letter from U.S. Chamber of Commerce to Dr. Margo Schwab, re: Comments on OMB’s Revised Information Quality Bulletin on Peer Review, at n.4 (May 28, 2004) <<http://www.uschamber.com/government/comments/040528peerreview.htm>>.

<sup>66</sup> Office of Management and Budget, Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005).

<sup>67</sup> Steve Gibb, *Perchlorate Dispute Prompts Effort for Broader Federal Toxics Review*, InsideEPA.com Risk Policy Report (Mar. 3, 2005).

<sup>68</sup> Appendices on file with authors.

<sup>69</sup> Appendices on file with authors.

<sup>70</sup> U.S. EPA, *Drinking Water Contaminant Candidate List* <<http://www.epa.gov/safewater/ccl/cclfs.html>> (last updated June 4, 2004).

<sup>71</sup> Appendices on file with authors.

<sup>72</sup> Appendices on file with authors.

<sup>73</sup> California Office of Environmental Health Assessment, *Proposition 65 in Plain Language!* <<http://www.oehha.ca.gov/prop65/background/p65plain.html>> (last visited March 18, 2005).

<sup>74</sup> *Id.*

<sup>75</sup> Appendices on file with authors.

<sup>76</sup> International Agency for Research on Cancer, *LARC Monographs on the Evaluation of Carcinogenic Risks to Humans* <<http://monographs.iarc.fr/>> (last updated June 14, 2005).

<sup>77</sup> Appendices on file with authors.

<sup>78</sup> See *supra* n.16.

<sup>79</sup> Appendices on file with authors.

<sup>80</sup> Sen. Env. & Pub. Works Comm., Subcomm. Env. Prot., *Health Effects of Air Pollution*, 101<sup>st</sup> Cong. (Apr. 18, 1989).

<sup>81</sup> *Id.* Statement of Dr. Bailus Walker, Past-President, Am. Public Health Assoc.

<sup>82</sup> Sen. Rpt. 101-228, at 128-130 (Dec. 20, 1989). Note that Congress was especially concerned with the inequitable distribution of health effects from toxic air pollution.

<sup>83</sup> *Id.* at 133. Codified at 42 U.S.C. §7412 (2005). Note that list now has 188.

<sup>84</sup> 42 U.S.C. §7412(f) (2005).

<sup>85</sup> U.S. EPA TRI Explorer <<http://www.epa.gov/triexplorer>> (last accessed Dec. 4, 2004).

<sup>86</sup> U.S. EPA, Technology Transfer Network National Air Toxics Assessment, *Summary of Results* <<http://www.epa.gov/ttn/atw/nata/risksum.html>> (last updated Sept. 2002).

<sup>87</sup> *Id.* Note that EPA calculated this figure using a “respiratory hazard index” assuming that irritation effects could be added and that such irritation occurs by the same mechanism for all air toxics.

<sup>88</sup> Advisory Report on the Science and Research Budgets for the U.S. Environmental Protection Agency for Fiscal Year 2005; A Report by the EPA Science Advisory Board at 6. EPA-SAB-ADV-04-003 (March 2004).

<sup>89</sup> U.S. EPA, Air Toxics Multi-Year Plan, ORD at 9 (Apr. 2003) <<http://www.epa.gov/osp/myp/airtox.pdf>> (last accessed Nov. 29, 2004) (hereinafter “Air Toxics Multi-Year Plan.”).

<sup>90</sup> Intersociety Working Group, *AAAS Report XXIX Research and Development FY 2005*, 6 (2004). Hereinafter AAAS XXIX. This publication can be accessed at <<http://www.aaas.org/spp/rd/rd05main.htm>>.

<sup>91</sup> *Id.* at 7.

<sup>92</sup> AAAS, *Defense and Homeland Security R&D Hit New Highs in 2005; Growth Slows for Other Agencies, AAAS R&D Funding Update Nov. 29, 2004 – FY 2005 Final Appropriations*, <<http://www.aaas.org/spp/rd/upd1104.htm>> (last updated Nov. 29, 2004). In fact, eighty percent of the nation’s \$6.0 billion R&D

increase from FY 2004 to FY 2005 is for defense. Note, however, that the President's proposed Federal R&D budget for FY 2006 is \$132.3 billion, which is a 0.6% increase and not sufficient to keep up with inflation. AAAS, *Re&D Programs Face Another Rough Year in 2006: Cuts for Many, Gains for Space, Homeland Security, AAAS Preliminary Analysis of FY 2006 Budget* <<http://www.aaas.org/spp/rd/prel06p.htm>> (last accessed Feb. 15, 2005).

<sup>93</sup> AAAS XXIX at 51.

<sup>94</sup> *Defense and Homeland Security R&D Hit New Highs in 2005*, *supra* n. 92.

<sup>95</sup> AAAS, *AAAS Re&D Funding Update Nov. 29, 2004 – FY 2005 Final Appropriations*, Table 2 Historical Data on Federal R&D, FY 1976-2005 <<http://www.aaas.org/spp/rd/hist05c2.pdf>> (last updated Nov. 29, 2004). This is in contrast to federal R&D spending on defense which has increased from \$30 billion to \$74 billion over the same time period.

<sup>96</sup> AAAS, *EPA Boosts Homeland Security Research, Proposes Modest Increases for R&D Programs* <<http://www.aaas.org/spp/rd/epa06p.htm>> (last updated Mar. 2, 2005). Note that House appropriation bills would restore a small portion of that decrease while Senate appropriations would decrease cuts further. See AAAS, *Senate Cuts EPA R&D* <<http://www.aaas.org/spp/rd/epa06s.htm>> (June 17, 2005).

<sup>97</sup> Phone conversation with Howard Cantor, Director of Budget, ORD (Oct. 20, 2004).

<sup>98</sup> AAAS, *AAAS Re&D Funding Update Nov. 29, 2004 – FY 2005 Final Appropriations*, Table 1 <<http://www.aaas.org/spp/rd/upd1104tb.htm>>.

<sup>99</sup> These goals were developed as part of EPA's 2003-2008 Strategic Plan available at <<http://www.epa.gov/ofco/plan/2003sp.pdf>>.

<sup>100</sup> The following information was provided to CPR by ORD staff as part of a presentation and is on file with the authors. Note that these allocations have since been modified by Congress, but are presented here as an illustration of the level of analysis that is readily available to the public.

<sup>101</sup> Letter to Professors Rena Steinzor and Katherine Squibb, University of Maryland, from US EPA in response to information request from Senator Barbara Mikulski, Jan. 25, 2005. On file with authors.

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> Testimony of Kenneth Olden, NIEHS Director, before the Senate Subcommittee on Labor-HHS-Education Appropriations, April 1, 2004. <<http://www.hhs.gov/budget/testify/b20040401q.html>>.

<sup>106</sup> H.R. Conf. Rpt. 4818, Consolidated Appropriations Act, 2005, H10321 (Nov. 19, 2004).

<sup>107</sup> National Toxicology Program Update, Oct. 2004.

<sup>108</sup> National Toxicology Program website <<http://ntp-server.niehs.nih.gov/index.cfm?objectid=720163D9-BDB7-CEBA-FA4A02388C4D8B50>> (last accessed Dec. 4, 2004).

<sup>109</sup> For purposes of this memo, the FY 2005 NTP budget will be assumed to be the same at \$183.7 million.

<sup>110</sup> AAAS R&D Funding Update Nov. 29, 2004 – FY 2005 Final Appropriations, AAAS Table 2 Historical Data on Federal R&D, FY 1976-2005 <<http://www.aaas.org/spp/rd/hist05c2.pdf>>.

<sup>111</sup> *Id.*

<sup>112</sup> AAAS, *EPA Boosts Homeland Security Research, Proposes Modest Increases for R&D Programs* <<http://www.aaas.org/spp/rd/epa06p.htm>> (last updated Mar. 2, 2005).

<sup>113</sup> AAAS XXIX at 28.

<sup>114</sup> U.S. EPA, *Summary of EPA's FY 2006 Budget, Appendix D: Budget Tables* <<http://www.epa.gov/budget/2006/2006bib.pdf>> (last accessed Mar. 28, 2005).

<sup>115</sup> Center on Budget and Policy Priorities, *Assessing the Administration's Five-Year Appropriation "Caps"* <<http://www.cbpp.org/2-28-05bud.htm>> (last updated Mar. 1, 2005).

<sup>116</sup> AAAS Report XXX: Research and Development FY 2006, Ch. 13 – R&D in Selected Agencies <<http://www.aaas.org/spp/rd/06pch13.htm>>. Note that the administration proposes to eliminate all earmarks, which would allow some growth in core research if implemented.

<sup>117</sup> See e.g. *Bond Reassures City Water Officials of Senate Funding Changes*, InsideEPA.com (March 8, 2005).

<sup>118</sup> Advisory Report on the Science and Research Budgets for the U.S. Environmental Protection Agency for Fiscal Year 2005; A Report by the EPA Science Advisory Board. EPA-SAB-ADV-04-003 (March 2004).

<sup>119</sup> Draft Advisory Report on the Science and Research Budgets for the U.S. Environmental Protection Agency for Fiscal Year 2006; A Report by the EPA Science Advisory Board <[http://www.epa.gov/sab/pdf/sci\\_and\\_res\\_budget\\_fy2006\\_circulated\\_032205.pdf](http://www.epa.gov/sab/pdf/sci_and_res_budget_fy2006_circulated_032205.pdf)>.

<sup>120</sup> EPA's Air Toxics Research Strategy and Air Toxics Multi-Year Plan, EPA Science Advisory Board Review, EPA-SAB-05-002 at 14 (Oct. 2004).

<sup>121</sup> Susan Bruninga, *Escalating 'Earmarks' Trend Spurs Concern About Maintaining Budget Process Balance*, 36 Env. Rpt. (BNA) No. 10, at 509 (Mar. 11, 2005).

<sup>122</sup> *Id.* For example, some groups, such as the American Water Works Association and the National Biosolids Partnership, receive regular annual earmarks.

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> Robert E. Gropp, *Washington Watch: Pork: The Other Research*. American Institute of Biological Sciences <[http://www.aibs.org/washington-watch/washington\\_watch\\_2004\\_07.html](http://www.aibs.org/washington-watch/washington_watch_2004_07.html)> (July 2004).

<sup>126</sup> H.R. Conf. Rpt. 4818, Consolidated Appropriations Act, 2005, H10847 (Nov. 19, 2004).

<sup>127</sup> *Id.* at H10848.

<sup>128</sup> Mickey Leland National Urban Air Toxics National Research Center website <<http://www.sph.uth.tmc.edu/mleland/Pages/about.htm>> (last updated Nov. 11, 2004). Note that the Leland Center has been criticized for failing to study the link between air toxics and cancer in Houston because of industry influence, see Leigh Hopper, *In Harm's Way: Too Little Research*, Houston Chronicle, Jan. 18, 2005 <<http://www.chron.com/cs/CDA/ssistory.mpl/special/04/toxic/2989505>>.

<sup>129</sup> H.R. Conf. Rpt. 4818, Consolidated Appropriations Act, 2005, H10848 (Nov. 19, 2004).

<sup>130</sup> Robin Shifrin, *Not By Risk Alone: Reforming EPA Research Priorities*, 102 Yale L.J. 547, 550 (1992).

<sup>131</sup> Andrew Lawler, *1998 Budget: Bipartisan Mood in Congress Opens Door for Pork*, 277 Science 1195-1196 (Aug. 1997).

<sup>132</sup> Clinton T. Brass, *The Bush Administration's Program Assessment Rating Tool (PART)*, CRS Report for Congress RL32663 at 3 (Nov. 5, 2004). See the President's Management Agenda at <http://www.whitehouse.gov/omb/budget/fy2002/mgmt.pdf> and the Budget and Performance Integration Initiative at <http://www.whitehouse.gov/results/agenda/budgetperformance.html>.

<sup>133</sup> *Rating the Performance of Federal Programs, The Budget for Fiscal Year 2004* at 49. <http://www.gpoaccess.gov/usbudget/fy04/pdf/budget/performance/pdf>.

<sup>134</sup> *Id.* at 47. To date, 607 programs have been evaluated and there are plans to evaluate all programs by FY 2008, see Amelia Gruber, *Program Assessments Factor into Bush Plan to Trim Deficit*, Govexec.com (Feb. 7, 2005) [http://govexec.com/story\\_page.cfm?articleid=30504](http://govexec.com/story_page.cfm?articleid=30504).

<sup>135</sup> See e.g. Rena I. Steinzor & William F. Piermattei, *Reinventing Environmental Regulation Via the Government Performance and Results Act: Where's the Money?* 28 ELR News & Analysis 10563, 10564 (1998) and Laurence E. Lynn Jr., *Requiring Bureaucracies to Perform: What Have We Learned from the U.S. Government Results and Performance Act (GPRAP)?* Second revised draft for presentation at the International Research Conference of the Journal Politiques et Management Public, May, 1998. Available at [http://harrisschool.uchicago.edu/About/publications/working-papers/pdf/wp\\_lynn.pdf](http://harrisschool.uchicago.edu/About/publications/working-papers/pdf/wp_lynn.pdf).

<sup>136</sup> *Rating the Performance of Federal Programs, The Budget for Fiscal Year 2004* at 51. <http://www.gpoaccess.gov/usbudget/fy04/pdf/budget/performance.pdf>.

<sup>137</sup> *Rating the Performance of Federal Programs, The Budget for Fiscal Year 2006* at 51. <http://www.whitehouse.gov/omb/budget/fy2006/pdf/budget/effective.pdf>.

<sup>138</sup> An analysis by the Performance Institute correlated positive PART ratings with proposed budget increases and vice versa. For instance, agency programs with an "effective" rating received an average 7.18% increase in the President's FY 2005 budget whereas programs deemed "ineffective" saw their budgets cut by an average of 37.68%. See *Lessons from the Use of Program Assessment Rating Tool (PART) in the '05 Budget*, The Performance Institute <http://www.transparentgovernment.org/tg/fy05budget.htm> (last accessed Nov. 29, 2004). Likewise, Gilmour and Lewis report that a PART score increase of 10 points translates into a proposed budget increase of 4-5% for the same time period while others estimate a larger impact. John B. Gilmour & David E. Lewis, *Assessing Performance Assessment for Budgeting: The Influence of Politics, Performance, and Program Size in FY 2005*. Paper prepared for presentation at the American Political Science Association (2004), and see, Robert Olsen and Dan Levy, *Program Performance and the President's Budget: Do PART Scores Really Matter?* Presentation at the Association for Public Policy Analysis and Management (Oct. 2004). <http://www.appam.org/>

[conferences/fall/atlanta2004/sessions/downloads/4301.pdf](http://conferences/fall/atlanta2004/sessions/downloads/4301.pdf) and GAO, *Performance Budgeting: Observations on the Use of OMB's Program Assessment Rating Tool for the Fiscal Year 2004 Budget*. GAO-04-174 (Jan 2004).

<sup>139</sup> Beryl A. Radin, *The Government Performance and Results Act (GPRAP): Hydra-Headed Monster or Flexible Management Tool?* 58 Pub. Admin. Rev. 307 (1998).

<sup>140</sup> Beryl A. Radin, Draft, *The Dark Side of Performance Assessment, Unanticipated Consequences or Faulty Assumptions?* Paper presented to the 26<sup>th</sup> Annual Research Conference Association for Public Policy Analysis and Management, Oct. 2004. Available at <http://www.appam.org/conferences/fall/atlanta2004/sessions/PM-14.html>.

<sup>141</sup> Brass, *supra* n. 132, at 6.

<sup>142</sup> Conversation with anonymous ORD Employee, Nov. 2004 and see *Statement of Dr. Genevieve Matanoski, Board Member, U.S. Environmental Protection Agency Science Advisory Board*, Before the Subcommittee on Environment, Technology and Standards, Committee on Science. U.S. House of Representatives, (Mar. 11, 2004) (stating her concerns that examiners subjectivity and bias affect PART scores).

<sup>143</sup> Brass *supra* n. 132 at 16, 21.

<sup>144</sup> Environmental Protection Agency PART Assessments, <http://www.whitehouse.gov/omb/budget/fy2005/pma/epa.pdf>. For a sample of PART assessment language.

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> *Statement of Dr. Genevieve Matanoski, Board Member, U.S. Environmental Protection Agency Science Advisory Board*, Before the Subcommittee on Environment, Technology and Standards, Committee on Science. U.S. House of Representatives, March 11, 2004.

<sup>148</sup> Manu Raju, *EPA Budget Plan Would Force Program Offices to Fund ORD Research*, InsideEPA.com (Feb. 10, 2005).

<sup>149</sup> US EPA, *Summary of EPA's 2006 Budget* <http://www.epa.gov/ocfo/budget/2006/2006bib.pdf>. For example, the Office of Air and Radiation will receive some of ORD's air research funds.

<sup>150</sup> *Administration's Plan Shifts Some Research into EPA Air, Water, Other Program Offices*, 36 BNA Env. Rpt. 7 at 338 (Feb. 18, 2005).

<sup>151</sup> Manu Raju, *EPA Budget Plan Would Force Program Offices to Fund ORD Research*, InsideEPA.com (Feb. 10, 2005).

<sup>152</sup> *Id.*

<sup>153</sup> *House Appropriators Cut EPA's FY05 Homeland Security Funds, Research Plan*, InsideEPA.com (May 11, 2005).

<sup>154</sup> These concerns are expressed by EPA's Scientific Advisory Board in EPA-SAB-ADV-04-003, *Advisory Report on the Science and Research Budgets for the U.S. Environmental Protection Agency for Fiscal Year 2005*; A Report by the EPA Science Advisory Board (March 19, 2004).

<sup>155</sup> H.R. 185, 109<sup>th</sup> Cong. (2005), and see OMB Watch, *House Committee Approves Government Performance Rating Bill* <http://www.ombwatch.org/article/articleview/2747/1/312?TopicID=1> (Mar. 21, 2005).

<sup>156</sup> *Draft Advisory Report on the Science and Research Budgets for the U.S. Environmental Protection Agency for Fiscal Year 2006*; A Report

by the EPA Science Advisory Board at 7 <[http://www.epa.gov/sab/pdf/sci\\_and\\_res\\_budget\\_fy2006\\_circulated\\_032205.pdf](http://www.epa.gov/sab/pdf/sci_and_res_budget_fy2006_circulated_032205.pdf)>.

<sup>157</sup> Shifrin, *supra* n. 130 at 549.

<sup>158</sup> John S. Applegate, *Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control*, 9 Yale J. on Reg. 277, 285-286 (1992).

<sup>159</sup> U.S. EPA 2003-2008 Strategic Plan <<http://www.epa.gov/ofco/plan/2003sp.pdf>>.

<sup>160</sup> *Id.* at 13 <<http://www.epa.gov/ofco/plan/2003sp.pdf>>.

<sup>161</sup> *Id.* at 27.

<sup>162</sup> U.S. EPA ORD Strategic Plan. <<http://epa.gov/osp/stplan.htm>> (Jan. 2001).

<sup>163</sup> *Id.* at 25.

<sup>164</sup> EPA's Air Toxics Research Strategy and Air Toxics Multi-Year Plan, EPA Science Advisory Board Review, EPA-SAB-05-002 at 1 (Oct. 2004).

<sup>165</sup> EPA Air Toxics Research Strategy, External Review Draft, US EPA ORD, EPA 600/R-00/056 (May 2002). Available at <[http://www.epa.gov/ord/htm/documents/Air\\_Toxics.pdf](http://www.epa.gov/ord/htm/documents/Air_Toxics.pdf)>. Note that while this document is officially a draft, according to agency staff it is the working version used by EPA.

<sup>166</sup> *Id.* at 3.

<sup>167</sup> *Id.* at 38.

<sup>168</sup> *Id.* at 17, 32. The four groups are: halides, aldehydes, metals, and POM/hydrocarbons.

<sup>169</sup> *Id.* at 34.

<sup>170</sup> *Id.* at 39.

<sup>171</sup> The nine HAPs missing from IRIS that are also on the crosswalk list are: Manganese compounds, some Chromium compounds, Cadmium compounds,\* Cobalt compounds, P-xylenes, M-xylenes,\* O-xylenes,\* Chloroprene, Polycyclic organic matter (\*These HAPs are currently in the IRIS assessment process).

<sup>172</sup> Air Toxics Multi-Year Plan. Note that letter from EPA to Professors Rena Steinzor and Katherine Squibb details when projects are slated to begin.

<sup>173</sup> *Id.*

<sup>174</sup> The EPA Science Advisory Board characterizes the long term goals as "so broad as to be almost meaningless." EPA's Air Toxics Research Strategy and Air Toxics Multi-Year Plan, EPA Science Advisory Board Review, EPA-SAB-05-002 at 10 (Oct. 2004).

<sup>175</sup> Air Toxics Multi-Year Plan at 21.

<sup>176</sup> EPA's Air Toxics Research Strategy and Air Toxics Multi-Year Plan, EPA Science Advisory Board Review, EPA-SAB-05-002 at 1 (Oct. 2004).

<sup>177</sup> *Id.* at ii.

<sup>178</sup> *Id.*

<sup>179</sup> Jennifer Beth Sass, Barry Castleman, & David Wallinga, *Vinyl Chloride: A Case Study of Data Suppression and Misrepresentation*, 7 Env. Health Persp. 809-812 (Mar. 2005) <<http://ehp.niehs.nih.gov/docs/2005/7716/abstract.html>>.

<sup>180</sup> *Id.*

<sup>181</sup> Linda Greer & Rena Steinzor, *Bad Science*, The Env'tl. Forum., ELI (2002).

<sup>182</sup> Jennifer Beth Sass, *Butadiene Assessment: A Case of Insufficient Safeguards*, Intl. J. Occup. Health (forthcoming, 2005).

<sup>183</sup> *Id.* Note that similar lobbying by industry was successful in getting the International Agency for Research on Cancer to classify butadiene as a Group 2A probable human carcinogen following a narrow and controversial second vote where an initial vote had classified it as a Group 1 human carcinogen. See O. Axelson, B. Castleman & S. Epstein, *Re: Implementation of WHO Guidelines on Disclosure of Interest by Members of WHO Expert Panels*, 8 Intl. J. Occup. & Env'tl. Hlth. 271-273 (2002).

<sup>184</sup> *Id.*, and see U.S. Government Accounting Office, *EPA's Scientific Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance*, GAO-01-536 (2001).

<sup>185</sup> See Thomas O. McGarity, Sidney A. Shapiro, Rena I. Steinzor, Joanna Goger, & Margaret Clune, *Truth and Science Betrayed: The Case Against the Information Quality Act*, CPR Publication #502 (Mar. 2005) <<http://www.progressiveregulation.org/articles/iqa.pdf>>.

<sup>186</sup> OMB Watch, *Data Quality Challenge on Barium*, <<http://www.ombwatch.org/article/articleprint/1231/-1/219/>> (Dec. 23, 2003).

<sup>187</sup> Clean Air Report, *EPA Rejects Barium Petition, Defers Atrazine Decision* (Feb. 13, 2003).

<sup>188</sup> OMB Watch, *Data Quality Challenge on Barium*, <<http://www.ombwatch.org/article/articleprint/1231/-1/219/>> (Dec. 23, 2003).

<sup>189</sup> Clean Air Report, *EPA Decision to Delay Formaldehyde Risk Review Sparks Uncertainty* (Dec. 30, 2004).

<sup>190</sup> *Id.*

<sup>191</sup> Formaldehyde Council, *letter to Louisville Metro Air Protection Control District*, Feb. 14, 2005. <[http://www.apcd.org/star/comments2/formaldehyde\\_council.pdf](http://www.apcd.org/star/comments2/formaldehyde_council.pdf)>.

<sup>192</sup> Clean Air Report, *Industry Raises Data Quality Concerns Over 'Residual Risk' Standard* (Oct. 21, 2004).

<sup>193</sup> *Id.*

<sup>194</sup> Steve Gibb, *Perchlorate Dispute Prompts Effort for Broader Federal Toxics Review*, InsideEPA.com Risk Policy Report (Mar. 3, 2005).

<sup>195</sup> *Id.*

<sup>196</sup> *Id.* and see EPA May Overhaul Toxic Reviews to Minimize Interagency Disputes, InsideEPA.com Risk Policy Report (Apr. 8, 2005), and EPA Toxics Review Plan to Allow Error Correction by Outside Groups, InsideEPA.com (Jun. 10, 2005). These concerns were also voiced by U.S. Senators Jeffords, Boxer, and Lautenberg. See *Letter to EPA Administrator Johnson from Senators Jeffords, Boxer, & Lautenberg*, July 6, 2005 <<http://epw.senate.gov/pressitem.cfm?party=dem&id=240231>> (expressing concerns that proposed changes to EPA's IRIS process will undermine credibility, result in delay, and risk politicizing EPA technical decisions).

<sup>197</sup> *Id.*

<sup>198</sup> Advisory Report on the Science and Research Budgets for the U.S. Environmental Protection Agency for Fiscal Year 2005; A Report by the EPA Science Advisory Board at 6. EPA-SAB-ADV-04-003 (March 2004).

<sup>199</sup> U.S. EPA TRI Explorer <<http://www.epa.gov/triexplorer>> (last accessed Dec. 4, 2004).

<sup>200</sup> *Id.*

<sup>201</sup> IARC Cobalt Monograph <<http://www-cie.iarc.fr/htdocs/monographs/vol152/11-cobaltandcobaltcomp.htm>> (last

updated Nov. 17, 1997).

<sup>202</sup> Air Toxics Multi-Year Plan at 9.

<sup>203</sup> *Id.* at 4. IRIS is mentioned in Annual Performance Measure 92: “Develop for external review four dose-response assessments intended for the IRIS and which support NATA including residual, urban, mobile source, indoor air or other risk assessments,” and in Annual Performance Goal 38 as part of the assessment of the need for additional regulatory options for mobile source air toxics. Further, nor are any of the crosswalk HAPs specifically mentioned in the MYP although some projects target the chemical structure groups identified in the ATRS.

<sup>204</sup> Conversation with anonymous ORD Employee, Nov. 2004.

<sup>205</sup> *Id.*

<sup>206</sup> EPA’s Air Toxics Research Strategy and Air Toxics Multi-Year Plan, EPA Science Advisory Board Review, EPA-SAB-05-002 at 14, 11 (Oct. 2004).

<sup>207</sup> *Id.* Interestingly, there is nothing written about contingency planning in either the ATRS or MYP. This is in contrast to a list of “additional research desired” if additional funding were available that was included in the MYP (see Air Toxics Multi-Year Plan at 18).

<sup>208</sup> Conversation with anonymous ORD Employee, Nov. 2004.

<sup>209</sup> EPA’s Air Toxics Research Strategy and Air Toxics Multi-Year Plan, EPA Science Advisory Board Review, EPA-SAB-05-002 at 2 (Oct. 2004).

<sup>210</sup> *Id.* at 7.

<sup>211</sup> *Id.*

<sup>212</sup> *Id.*

<sup>213</sup> *Id.* at 2. This may be only a lack of articulation as the Science Advisory Board was shown an illustration of the relationship between some research programs.

<sup>214</sup> *Id.* at 8.

<sup>215</sup> Conversation with anonymous ORD Employee, Nov. 2004.

<sup>216</sup> Air Toxics Multi-Year Plan at 18.

<sup>217</sup> U.S. EPA, *Needs Assessment for U.S. EPA’s Integrated Risk Information System*, at 1. EPA/635/R-02/004 (Sept. 2003) <[http://www.epa.gov/iris/iris\\_needs.pdf](http://www.epa.gov/iris/iris_needs.pdf)>.

<sup>218</sup> An additional benefit that would flow from collapsing the peer review process would be that it would force EPA to make science policy decisions on IRIS assessments in a more public venue. Currently, such decisions are made during the first two stages of peer review, before a draft assessment is available to the public.

## About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization 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.



1200 New York Ave., NW, Suite 400, Washington, DC 20005

202-289-4026 (phone) / 202-289-4402 (fax)

[www.progressivereform.org](http://www.progressivereform.org)

© Center for Progressive Reform