Corrective Lenses for IRIS:

Additional Reforms to Improve EPA's Integrated Risk Information System

By CPR Member Scholars Rena Steinzor and Wendy Wagner and CPR Policy Analysts Lena Pons and Matthew Shudtz

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This white paper is a collaborative effort of the following Member Scholars and Staff of the Center for Progressive Reform: **Rena Steinzor** is a Professor of Law at the University of Maryland School of Law, with a secondary appointment at the University of Maryland Medical School's Department of Epidemiology and Preventive Medicine, and the President of the Center for Progressive Reform; **Wendy Wagner** is the Joe A. Worsham Centennial Professor at the University of Texas School of Law, Austin Texas, and a Member Scholar of the Center for Progressive Reform. **Lena Pons** is a Policy Analyst and **Matthew Shudtz** is a Senior Policy Analyst with the Center for Progressive Reform.

For more information about the authors, see page 23.

www.progressivereform.org

For media inquiries contact Matthew Freeman at mfreeman@progressivereform.org or Ben Somberg at bsomberg@progressivereform.org.

For general information, email info@progressivereform.org

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View of the Seattle Skyline through glasses courtesy of WikiCommons.

Executive Summary

The Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) is the most important toxicological database in the world. Not only is it the single most comprehensive database of human health information about toxic substances, it also serves as a gateway to regulation, as well as to a range of public and private sector efforts to protect against toxic substances. IRIS "profiles" of individual substances include a number of scientific assessments of the substance's toxicity to humans by various means of exposure – by inhalation, contact with the skin, and so on. Federal regulators rely on the assessments to do their important work protecting the public, as do state and local environmental protection authorities, and industry itself.

For EPA, the assessments conducted to complete profiles of particular toxic substances for IRIS provide the authoritative underpinnings for a wide range of regulatory actions under the Clean Air Act (CAA), the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), and the Safe Drinking Water Act (SDWA). At the state and local level, IRIS profiles are the basis for regulation of toxic substances. For example, the Oregon Department of Environmental Quality used IRIS values in its Portland Air Toxics Assessment, conducted in 2006.[1] The Portland Air Toxics Assessment modeled ambient air concentrations of 12 pollutants at a highly localized level. Rather than having to rely on EPA's county-level assessment of toxic air pollutants, Oregon officials can now estimate exposure and risk at a neighborhood level and set permit allowances accordingly. In the private sector, IRIS information may be used in toxic tort suits, or by individuals or public interest groups to advocate for lower permissible permit levels under Title V of the CAA.

Unfortunately, IRIS is woefully incomplete. EPA is many years behind in meeting statutory mandates for completing profiles of at least 255 chemicals, and as a result regulatory and enforcement action related to those chemicals has been stalled. Some chemical profiles in IRIS are missing information essential to regulatory action. In addition, 77 of the hazardous air pollutants (HAPs) listed in IRIS are missing the most important piece of information – an assessment of how much of the substance may be safely inhaled. In all, some 109 chemical profiles that EPA was required by the Clean Air Act Amendments of 1990 to have completed by 2008 are either included in IRIS but missing critical elements, or entirely absent from the database. So severe is the delay in the IRIS process that a 2008 Government Accountability Office (GAO) report warned that the Bush Administration's approach to IRIS, which resulted in just two completed profiles per year, left the database at risk of becoming obsolete.[2]

In May 2009, newly appointed EPA Administrator Lisa Jackson introduced reforms she predicted would improve EPA's performance with respect to IRIS that included making it harder for other agencies of the federal government to slow down or exert undue influence over EPA's assessment of the environmental health effects of substances listed in IRIS. The Administrator's stated goal was to ensure completion of new assessments in 23 months, but she made no promises about how many assessments EPA would complete in a year. Neither

did she present any plan for clearing the backlog of the 478 assessments that are in process, nor mention that EPA has long since been required by statute to complete, or have been identified as out of date by EPA staff.[3]

In the year since the new process has been in effect, EPA has made only modest progress completing assessments, finishing nine assessments in 2009 – up from the Bush pace of two per year – but still slow enough that, if it does nothing to improve its performance, EPA will not catch up with its backlog for another 55 years. Moreover, it is not clear from information available to the public whether the agency is fulfilling Jackson's 23-month pledge on individual IRIS assessments.

One area of particular concern is that the Administrator's new IRIS process left in place many of the roadblocks GAO had previously identified, including interagency review of individual assessments, multiple reviews by outside science panels, and prioritization of a few high-profile assessments at the expense of faster assessments.[4] The consequence is that significant data gaps are still a serious problem.

Specifically, the IRIS database is missing important human health information about the toxicological effects of HAPs, drinking water contaminants, and chemicals commonly found in Superfund toxic waste sites.

- **Thirty-two HAPs regulated under the CAA are not listed in IRIS at all, and 77 HAPs lack inhalation values, hampering the air office's ability to do the "residual risk assessments" that ensure technology-based standards provide an "ample margin of safety."[5]**

The Human Consequence of the IRIS Breakdown

The ramifications of the large-scale breakdown of the IRIS process are very real. For example, residents of the Marine Corps Base Camp Lejeune have been exposed to high levels of trichloroethylene for decades. A Navy-funded study of increased cancer risk for children born at Camp Lejeune found 14 cases of Acute Lymphocytic Leukemia in a cohort of 10,000-12,000 births, or more than 100 times the expected rate.

EPA drafted an updated IRIS assessment of trichloroethylene in 2001, but it was challenged by the Department of Defense (DOD). Under pressure from DOD, EPA commissioned a National Academy of Sciences Review of trichloroethylene. In 2007, five Senators introduced a bill instructing EPA to complete the trichloroethylene assessment and issue a drinking water standard for trichloroethylene. The bill was reported in the Senate, but has not passed in either chamber.

The Department of Defense objects to lowering the exposure limit for trichloroethylene because of the resulting increased cleanup costs. DOD estimates it would cost $5 billion more to clean up trichloroethylene if the drinking water standard went from five parts per billion to one part per billion.

Toward that end, DOD submitted 72 pages of comments to EPA's Nov. 2009 draft assessment of trichloroethylene. The new draft assessment will undergo review by the Science Advisory Board in 2010.

Meanwhile, EPA's IRIS assessment of trichloroethylene is still pending. Residents of Camp Lejeune continue to be exposed to high levels of trichloroethylene in drinking water, and cannot successfully prove these levels are harmful until EPA finishes this work.

— House of Representatives Committee on Science and Technology. Toxic Communities: How EPA's IRIS Program Fails the Public. (Jun. 12, 2008).

— Department of Defense. Comments on the Review of Trichloroethylene. (Aug. 25, 2009).

- **Three of 71 contaminants regulated under the SDWA are not listed, and an additional 64 of 156 substances nominated to the Contaminant Candidate List, slowing EPA's ability to develop enforceable standards for drinking water contaminants.**
- **Of the 275 substances the Agency for Toxic Substances and Disease Registry has identified as "high profile" based on their frequency of occurrence at Superfund sites, toxicity, and potential for human exposure, 87 (32 percent) are not listed.[6]**

The sources of delay have not changed: priority treatment of complex, high-profile assessments at the expense of other needed assessments; excessive interagency review; involvement of the Office of Information and Regulatory Affairs (OIRA); industry interference; and recursive, formalized outside review continue to contribute to the small number of IRIS assessments completed each year.

The interagency review process is one of the largest sources of delay. It provides agencies, which are often also potentially regulated entities, with multiple opportunities to influence and soften EPA's risk assessments and reduce future regulatory burdens. Even under the new process, federal agencies, coordinated by OIRA, have two special opportunities to comment on draft IRIS assessments. EPA has the discretion to terminate the interagency review process, which is unusual and would not be tolerated at other agencies. The DOD, for example, would not allow EPA to comment on decisions about training because of concerns about hazardous pollution.

To close data gaps and reestablish IRIS's credibility as a cutting-edge database, EPA needs to make four changes. First, EPA should reduce the procedural burdens that were formalized during the Bush administration. Second, EPA must articulate clear, statute-driven priorities about which assessments to complete to ensure that data gaps in statutory mandates would be more quickly addressed. Third, the IRIS process must be restructured to allow for timely assessments made based on the weight-of-the-evidence at the time an assessment is undertaken. Fourth, EPA must also have adequate resources and make better use of its resources to complete a much larger number of assessments than it is currently finishing each year.

Administrator Jackson has repeatedly emphasized her commitment to use EPA's chemical management program to reinvigorate the agency's public health responsibility.[7] The IRIS program has featured prominently in her discussion of these efforts. EPA has substantial latitude to reforms the program and remove these obstacles to make it more productive. For Administrator Jackson to be successful with chemical management, she will need to impose further reforms on the IRIS process.

Tables 1 *and 2: Hundreds of millions of pounds of highly toxic chemicals are released each year without IRIS numbers that would allow EPA, state and local officials, the media, and community groups to gauge public health hazards.*

Table 1: Top Ten Hazardous Air Pollutants with No IRIS Information[1]

Chemical	Total Air Releases (lbs)
Chromium compounds	58,875,719
Ethylene oxide	19,326,422
Chloroprene	6,917,570
Diethanolamine	5,292,937
Ethyl acrylate	4,536,125
Cobalt compounds	4,502,987
Titanium tetrachloride	3,603,494
Cadmium compounds	1,736,020
O-Toluidine	626,844
Hydrogen fluoride	526,486
Total	**105,944,603**

Table 2: Top Ten Hazardous Air Pollutants with No Inhalation Values in IRIS[2]

Chemical	Total Air Releases (lbs)
Methanol	112,091,055
Carbonyl sulfide	353,389
Formaldehyde	313,659
Chlorine	270,468
Dichloromethane	205,328
Phenol	53,622
Trichloroethylene	48,130
Tetrachloroethylene	40,888
Lead compounds	14,478
Chloroform	12,191
Total	**113,413,298**

Figure 1,2 &3: *Hearing on Fixing EPA's Broken Integrated Risk Information System, Before the Subcomm. on Oversight and Investigations of the H. Comm. on Science and Technology* (Jun. 11, 2009).

Introduction

The IRIS database provides a number of important pieces of information about the human health effects of specific toxic substances. These include specific oral and inhalation "reference doses," accounting for the effects of ingestion and inhalation of the substance, as well as a "cancer slope factor" that measures the risk of cancer associated with exposure to increasing concentrations of a substance. EPA relies on this information in developing regulations to protect Americans from a variety of risks, fulfilling its statutory mandate under several laws, including parts of the Clean Air Act (CAA), Safe Drinking Water Act (SWDA), Superfund and other statutes. IRIS is widely used, not just by EPA, but also by state, local, and international public health experts, as well as toxic tort attorneys. In all, the online version of IRIS receives approximately 20,000 hits per day.

Originally, IRIS was an internal EPA database, aggregating human health information collected by various offices within the agency. But the assessments grew to be so vital to the regulatory process and other risk-management decisions, that advocates for industry and the public interest began targeting IRIS assessments. In response, EPA has restructured the IRIS process three times since 2004. In doing so, EPA struggled to balance the need to complete IRIS assessments quickly with the desire to produce assessments that are so robust as to be immunized against criticism from outside interests.

EPA has failed to develop a process that can achieve this balance between providing information in a timely fashion so that the agency can get on with its work and attempting to generate definitive answers that demand a level of finality and precision that science cannot produce. The resulting IRIS assessment process has injected additional burdens, including interagency review coordinated by the White House Office of Information and Regulatory Affairs (OIRA) and recursive critique by outside scientists. These additional requirements slowed EPA productivity so significantly that although the IRIS program received increased funding from 2000 to 2007, the number of assessments completed in this period fell from an average of five per year to two per year.[8] After the Bush Administration's final round of reforms to the IRIS assessment process, congressional overseers estimated that it would take EPA six to eight years to clear all of the procedural hurdles between initiation of an assessment and its final posting in the public database.[9]

The Government Accountability Office (GAO) and the U.S. House of Representatives Committee on Science and Technology identified three primary problems with the Bush-era IRIS process: interagency review, multiple layers of science review, and EPA's choice to focus considerable resources on a few high profile assessments at the expense of progress on others.[10] In response, EPA Administrator Lisa Jackson announced a new IRIS process in May 2009. Jackson promised to regain control over interagency review and streamline each step so that assessments would be completed in 23 months. She explained that the new process would restore timely, transparent assessments in service of other actions to protect public health.[11] But Jackson's focus on completing assessments in 23 months rather than

whittling down the prodigious backlog of uncompleted assessments suggests that it might be decades before the agency meets current statutory requirements whose deadlines have long since passed.

Indeed, the new IRIS process has failed to meet these goals precisely because it retained many of the same features of the old process. Interagency review of individual assessments, industry efforts to hijack the process through Data Quality Act petitions, overuse of science advisory boards, and a focus on high profile and complex assessments have all prevented EPA from completing assessments in a timely and transparent way. For example, under the new process, EPA releases written comments provided in the interagency review process, but the documents do not provide a full picture of what transpires between the agencies because they do not provide a record of telephone calls and other communications. And EPA's agenda for IRIS assessments has become less transparent, with less information available about which substances will be assessed and the projected timeline for doing so.

It might be decades before the agency meets current statutory requirements whose deadlines have long since passed.

With that in mind, this paper proposes five specific reforms to the IRIS process to make the program more productive and able to complete a greater number of assessments each year:

1. **EPA should adopt a transparent, statute-driven process for selecting substances to be assessed.**
2. **EPA should eliminate the interagency review process, which has largely served to create additional opportunities for industry interference, without adding significantly to the scientific discussion that should be at the heart of EPA's regulatory decision-making.**
3. **EPA should put faith in its own scientific expertise and rely on outside science review only in the most complex cases.**
4. **EPA Administrator Lisa Jackson should advocate for adequate resources for IRIS and ensure they are used to the greatest possible effect.**
5. **EPA should announce these reforms in a memorandum that also sets out a streamlined six-step process for developing an IRIS profile: (1) publish a notice of assessment in the Federal Register; (2) open a docket for public to add studies during staff literature review; (3) draft an assessment; (4) publish the draft for public and agency comment; (5) revise the draft based on input during the public comment process, and; (6) publish the final assessment to IRIS.**

History of the EPA's IRIS Process

EPA has restructured the IRIS process three times since 2004. During the Bush administration, additional steps were added that provided OMB and other federal agencies a special opportunity to influence the process. EPA's current IRIS process eliminates some steps; however, some of the steps in the new IRIS process are not contained in the chart. Under the current process, OMB and federal agencies still have an opportunity to review IRIS assessments before the public comment period.

Figure 1: The original IRIS profile development process.

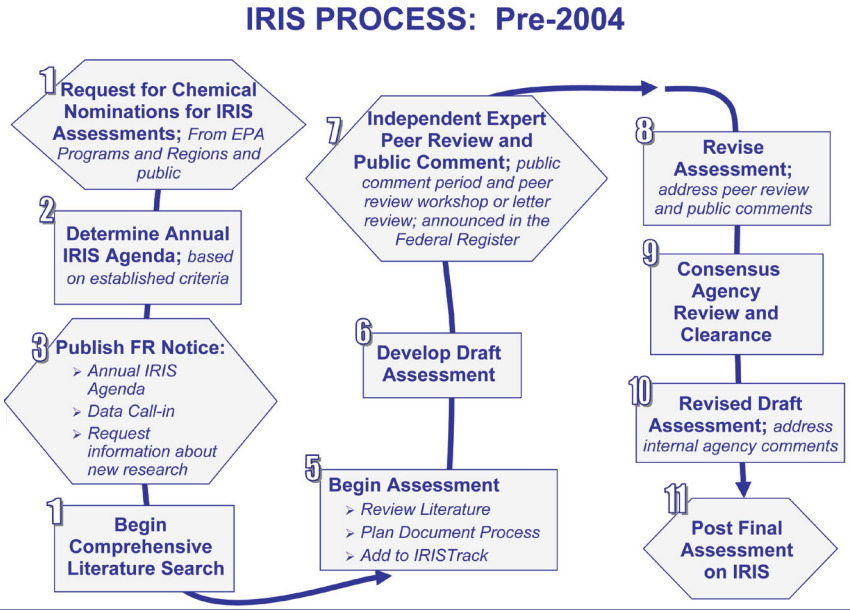
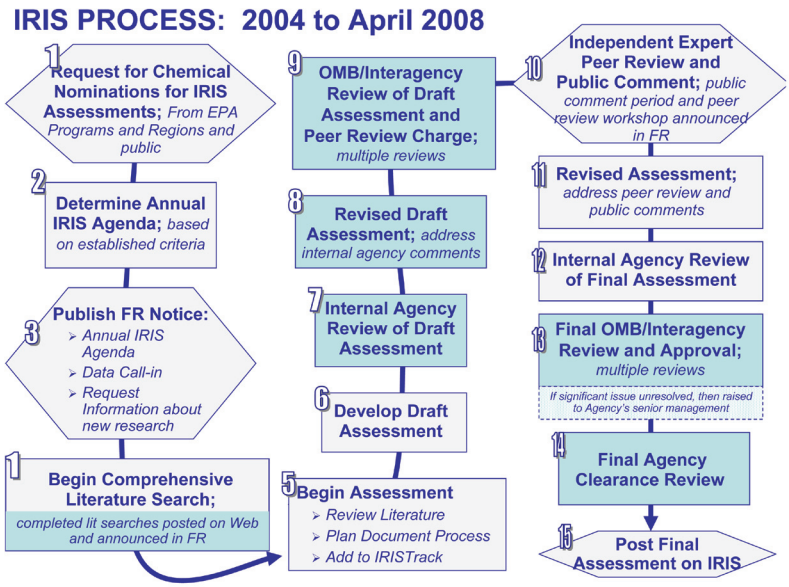


Figure 2: The process after the Bush Administration's first revisions.



Figures courtesy Environmental Protection Agency.

Figure 3: The process after the Bush Administration's second revisions.

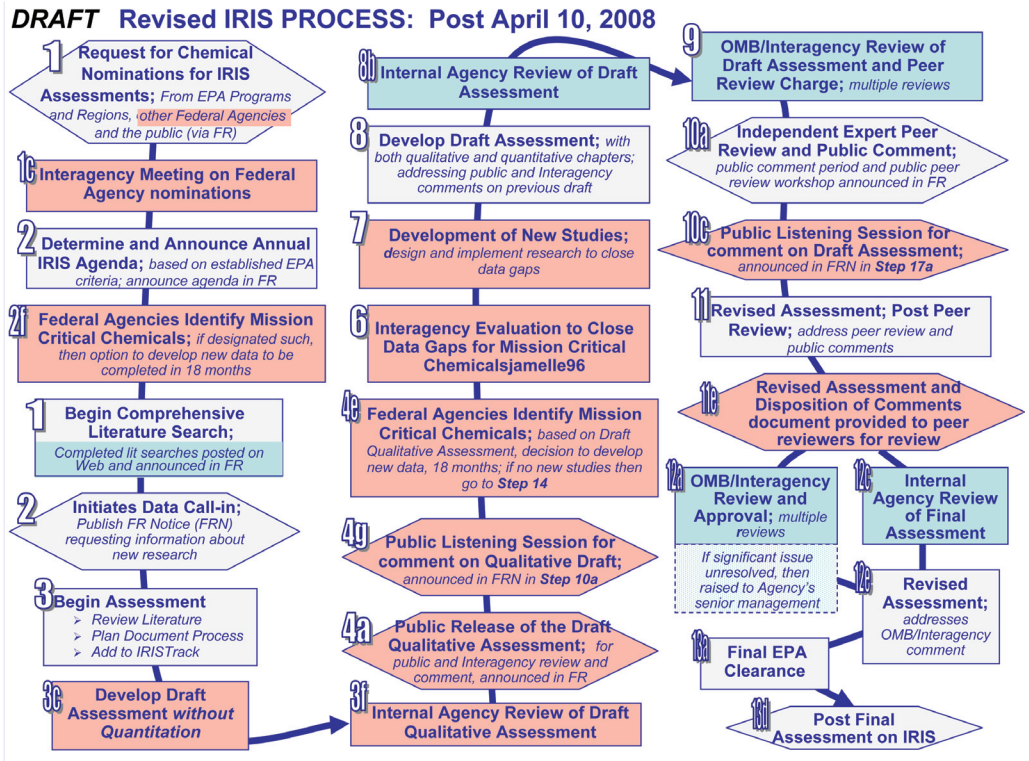


Figure 1,2, & 3: Hearing on Fixing EPA's Broken Integrated Risk Information System, Before the Subcomm. on Oversight and Investigations of the H. Comm. on Science and Technology (Jun. 11, 2009)."

Figure 4: The current process.

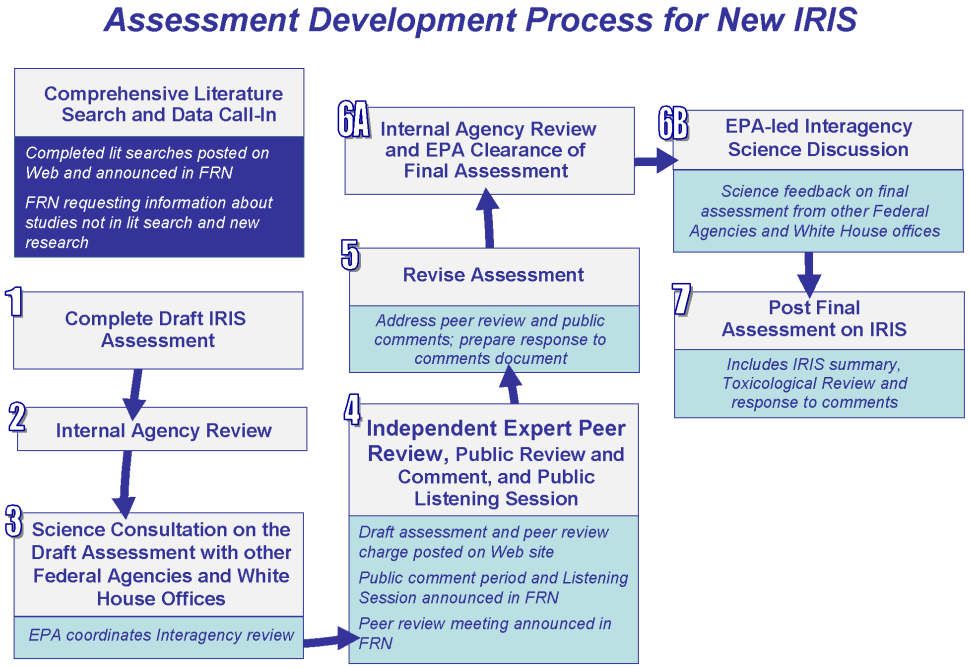


Figure 4: ENVIRONMENTAL PROTECTION AGENCY, NEW PROCESS FOR DEVELOPMENT OF INTEGRATED RISK INFORMATION SYSTEM (May 21, 2009), available at http://epa.gov/iris/process.htm.

Improving the Process for Setting the IRIS Agenda

The principal purposes of the IRIS database are to identify hazards and help EPA and other agencies prioritize toxic substances that are of concern. The basic toxicology information contained in IRIS assessments along with other information collected by EPA, such as the Toxics Release Inventory, provide a basis for making decisions about chemical management. But the risk management process has its own set of procedural requirements for determining how best to protect the environment and public health from hazards related to toxic chemicals. These decisions are essentially separate from the risk assessment process, and need not be made during the IRIS process.

Given the gaping holes in the IRIS database, it is essential that EPA develop and pursue a well-considered process for completing the assessments necessary to complete IRIS profiles. That process ought to reflect communication and cooperation between IRIS staff and other EPA program officers, it ought to seek to balance of statutory needs and priorities of the program offices, and it ought to be transparent so that the public and various stakeholders will know what is under consideration. So far, however, EPA has focused on a few high-profile IRIS assessments, without offering up to the public any explanation for why these assessments have been chosen at the expense of others.

EPA program offices that regulate toxic substances rely heavily on IRIS assessments to help carry out their statutory responsibilities. The CAA's HAPs program regulates emissions of toxic substances.[12] Under the program, EPA establishes standards for sources of toxic air pollutants and then determines the residual risk associated with these substances once industry implements the regulations. EPA program staff makes residual risk determinations based on health hazard analyses, exposure data, and dose-response characterizations.[13]

The IRIS database should provide key information for those determinations, but it has critical data gaps. **Thirty-two of the 188 HAPs listed in the CAA have no IRIS assessment at all, and 77 pollutants are listed in IRIS but do not have inhalation risk information**. As a result, EPA cannot easily evaluate residual risk for 109 of 188 listed substances.

Similarly, EPA program staff's implementation of the SDWA relies on human health information for prioritizing substances to set primary drinking water standards. Their work is also dependent on public health information for health risk reduction and cost analysis in setting standards. Quantitative risk information is supposed to be included in IRIS, and, indeed, IRIS provides information on all but three substances currently regulated under the SDWA. In addition, 64 substances that have been nominated for regulatory consideration do not have IRIS assessessments. Included in the most recent Contaminant Candidate List are a range of pesticides and estrogen-like hormones for which there are no IRIS profiles.[14] These missing assessments, as with HAPs, hinder EPA's work in implementing the SDWA.

IRIS is also critical in cleaning up Superfund sites. EPA guidance for using human health information in risk assessments for Superfund states that if an IRIS assessment is available, EPA need not seek out additional human health information.[15] **Unfortunately, IRIS assessments are not available for 87 of the 275 high-priority substances the Agency for Toxic Substances and Disease Registry (ATSDR) identified in 2007.** For these substances, EPA must look to other sources and make determinations about the quality of the information before a risk assessment can be completed. Risk assessments are used to determine whether cleanup action is warranted, to establish protective cleanup levels, and to estimate residual risk after cleanup.

The IRIS database should be a resource for other program offices. The IRIS staff should encourage open communication with other program offices to ensure that the IRIS database is most useful to the program offices. For example, the CAA Amendments of 1990 direct EPA to develop emissions standards for 188 specific HAPs, and then assess the "residual risk" posed by the pollutants after industry has instituted the pollution controls needed to meet the standards. The law provides only limited guidance to EPA on which assessments to undertake first. The Office of Air and Radiation should consult with IRIS staff to help develop such priorities.

EPA has generally provided lists of substances whose IRIS assessments had been completed in the previous year, new substances nominated for assessment in a specific year, and ongoing assessments that EPA expected to complete that year.[16] In 2009, EPA only provided information about substances for which literature searches had been completed.[17] EPA provides additional information about the progress of assessments through IRISTrack, but does not provide detailed information about how it has selected and prioritized assessments, nor does it explain its strategy or goals for working through the large number of assessments indicated by program offices.

The Obama administration has expressed a commitment to transparency through the Open Government Directive, which lays out several goals for improving transparency, including publishing information online, creating a culture of open government, and making legislative, budgetary and regulatory materials more accessible. EPA should explain its priorities for the IRIS program and account for data gaps on substances program offices need to carry out their missions. In effect, EPA is providing data without providing the underlying rationale for its decision-making, defeating the objective of the President's transparency initiative.

Recommendation

EPA should publish a clearly articulated IRIS agenda in the *Federal Register* each year. It should describe in its agenda how it plans to complete the large number of assessments needed to make the database current. When EPA develops this plan, it should give consideration, where possible, to conducting assessments of similar or related chemicals

at the same time. The agency should divide the assessments into groups based on factors related to how complex they will be to complete and use those groupings to divide the workload more evenly. EPA should also explain how it will complete high-profile assessments without preventing the agency from completing all the other assessments.

Removing the Barrier of Interagency Review

The interagency review process is a significant contributor to delay of IRIS assessments. From 2003 to 2007, the number of full-time staff devoted to IRIS rose from 10 to 35. In this period, the number of draft assessments set for interagency review rose from zero to 15, but the number of completed assessments was relatively stagnant – with five assessments completed in 2003 but just two in 2007.[18]

Not only does the interagency review process contribute greatly to gumming up the works of IRIS assessments, it also gives agencies that are themselves potentially regulated entities the opportunity to assert undue influence or delay assessments by years or even decades. The Department of Defense (DOD), for example, is the nation's biggest polluter, yet the interagency review process affords it a preferred seat at the table in establishing standards by which it will be regulated, something no corporate polluter could even hope to achieve.

In her 2009 reforms, Administrator Jackson chose to keep in place two opportunities for interagency review. The first is what is labeled "Step 3" in the new process: "Science consultation on the draft assessments with other Federal Agencies and White House Offices."[19] In a 2009 report, GAO noted that EPA's use of the phrase, "White House offices," is vague, and does not provide sufficient information about what White House offices are to be involved in this process. But based on the interagency review comments available for substances assessed under the new process, the White House Office of Management and Budget (OMB) seems to be the main driver, notwithstanding the fact that it only employs two professional scientists. The second opportunity for interagency review in Administrator Jackson's 2009 process is labeled, "Step 6B," "EPA-led Interagency Science Discussion." In brief, with this reform, Jackson asserted EPA control over the interagency review process, where previously OMB coordinated interagency review through OIRA.

The core problem with interagency review is that it provides agencies that may have conflicts of interest an opportunity to influence and delay risk assessments under the IRIS process. One example is the reassessment of trichloroethylene, long-term exposure to which has been linked to liver and kidney cancer and nerve damage. The substance is used as an industrial degreaser by many industries, as well as by the DOD, Department of Energy (DOE) and National Aeronautics and Space Administration (NASA). In 2004, EPA commissioned a joint study from the National Academy of Sciences (NAS) with DOD, DOE, and NASA on human health effects of trichloroethylene.[20] In response to the NAS report, NASA released a bulletin discussing the potential impact of regulatory actions related to trichloroethylene, including clean-up action.[21] NASA and other agencies were then given an opportunity to comment on the trichloroethylene draft assessment, a plain conflict of interest for the agencies, since the agencies themselves, and their contractors, are subject to the eventual regulation. Of course, public and private polluters are entitled to offer their views and provide information to regulators during the public comment period. The issue here is whether polluters should be given an up-front opportunity to comment on EPA scientists' findings about the hazards of the pollutants they discharge.

Interagency review not only slows IRIS assessments, it also lets agencies that are potentially regulated push for favorable standards and cause delay.

As that example demonstrates, the interagency review process provides other federal agencies with a disruptive opportunity to inject policy considerations into the scientific assessments developed under IRIS. For example, this year, OMB submitted comments to the 2,3,7,8-tetrachlorodibenzo-p-dioxin (dioxin) reassessment expressing its disappointment that EPA did not calculate a "margin of exposure" in proposing a reference dose (RfD) for dioxin.[22] OMB argued: "Because the exposures of a proportion of the U.S. population would be above any RfD, it would have been useful for EPA to define the nature and magnitude of the risks at different levels of intake, the groups of the population most at risk, and the major sources of exposure for any at-risk groups." But decisions about whether and how to subdivide the exposed population for purposes of an IRIS assessment are science policy choices that do not belong in the IRIS process. These decisions should be made through the regulatory process, based on the strength of data and other factors without influence from potentially regulated parties, whose policy views are likely more informed by potential cleanup costs than by unbiased scientific considerations.

By retaining this interagency review process, EPA signaled that it continues to support the treatment of IRIS assessments as if they were themselves regulatory actions, rather than the scientific underpinnings for subsequent regulatory actions. For example, interagency review panels often call for additional explanation of factors related to regulatory action. In comments on the draft dioxin assessment, agencies asked for EPA to provide additional support for toxicity equivalent factors, which EPA explained were not used for the purposes of making IRIS assessments, but would be useful for future regulatory applications.[20] EPA leadership of the interagency science review process should have resulted in better balancing of EPA's interests with those of other federal agencies, but since the new IRIS process took effect, interagency comments have still resulted in delay, additional layers of analysis and calls for more and more science review.[23] The additional information supplied by federal agencies could be provided during a public comment period, so the delay created by interagency review does not justify the value of additional information shared by agencies.

A second problem with interagency review is that it provides additional avenues for industry interests to influence or delay the IRIS process. Industry interests commonly devote substantial resources to exploiting procedural opportunities to slow the process. And indeed, delay is at least a partial victory for industry, because assessments often provide significant basis for future regulations on toxic substances. As long as an industry can produce the appearance of a controversy around a substance, it can delay any regulatory action, and put off the day when it will have to conform to stricter regulation.

Industry tactics for delaying IRIS assessments are the product of years of experience fighting regulations. The guiding principle for delaying regulations and any government action that would protect people from hazards is to create a public perception of uncertainty in the link between chemical exposure and adverse effects. Industry has used this strategy for decades to delay regulations, win less stringent controls, and generate skepticism about

science from the agencies, including EPA.[25] Although industry manufactures this sense of doubt in many ways, at the core, each tactic is related to the overarching strategy of delay.

Recent actions by the American Forest and Paper Association (AF&PA) and the Methanol Institute exemplify how industry can manipulate the interagency review process to sow doubt and promote regulatory delay. EPA posted its original IRIS profile for methanol in 1988. The agency updated the profile in 1993, however it still lacks the two most critical data points for a CAA HAP—an inhalation reference concentration and a cancer slope factor. In 2002, EPA began the process of developing these numbers, and by 2009 had come up with a draft of a new profile. At that point, AF&PA and the Methanol Institute instituted a coordinated attack on EPA's draft. AF&PA attacked the individual studies EPA used to support the new inhalation reference concentration and the new cancer slope factor.[26] The Methanol Institute took on the studies that EPA used to support the overall conclusion that methanol is likely to be a human carcinogen.[27] Those studies were conducted by the Ramazzini Institute, an Italian lab that specializes in long-term carcinogenesis studies that industry believes overestimate chemicals' carcinogenic potential. In its comments attacking the Ramazzini methanol studies, the Methanol Institute went so far as to demand an audit of the lab. Soon thereafter, the National Toxicology Program (NTP), an interagency program housed in the Department of Health and Human Services, made a visit to the Ramazzini labs and issued a report that was critical of the labs' pathology practices.[28] The report also suggested that EPA conduct additional review of the Ramazzini results used in various IRIS profiles. Immediately after receiving the report, EPA announced it would suspend its assessment of methanol and three other chemicals currently under review in the IRIS program.[29]

The agency could devote more resources to completing assessments if IRIS staff was not developing draft assessments to clear interagency hurdles.

The delay brought on by NTP's review of the Ramazzini labs may be evidence of a shrewd manipulation of the interagency review process by affected industry. At the very least, it will provide them with the opportunity to dump additional studies that they have funded into the docket. For instance, AF&PA hired a consulting company to conduct a review of EPA's draft IRIS assessment for methanol. The company, Exponent, has a long history of science for hire that stretches back to tobacco industry efforts to generate research to discredit the connection between smoking and cancer.[30] Since then, Exponent has been involved in a number of high-profile, industry-sponsored efforts to create a public perception that research linking products to hazards is controversial, including tests of laminated glass for Ford, which the company uses in litigation.[31] Such industry-sponsored studies are not subject to the guidelines set by the agencies and OMB for "quality, objectivity, utility, and integrity." Indeed, regulated industry has significant incentives to pay for studies that challenge agency results that recommend regulation. Such studies affect the IRIS process in two major ways – they slow it by requiring agencies to respond to petitions for correction of information, and they foster a perception of scientific disagreement. Industry interests have several opportunities to critique and discredit government science, but agencies are not provided with the same capacity to critique and re-analyze research presented from outside entities.

Public access to federally funded research is much greater than privately funded research. Under the Data Access Act, federally funded research is subject to the Freedom of Information Act, giving private entities the opportunity to request underlying data and other information about federally funded studies. But privately funded studies are subject to no such disclosure requirements. As a result, industry-funded studies like the one conducted by Exponent for the AF&PA are effectively shielded from scrutiny by the media, the public, public interest organizations, and even the agencies themselves.

Without such checks on their work, there can be little assurance that industry-funded research meets the high standards of quality, objectivity, and independence required for use in the IRIS program. For instance, AF&PA also attached to its comments a study critical of EPA's assessment published in the journal *Regulatory Toxicology and Pathology*. The journal is sponsored by the industry-funded International Society of Regulatory Toxicology and Pharmacology, and has been criticized by a group of toxicologists for lacking transparency and editorial independence.[32]

One straightforward way to reduce the likelihood that bought-and-paid-for research finds its way into the IRIS process is to require a simple conflict disclosure, modeled after existing conflict disclosures adopted by scientific journals. Conflict disclosure would allow EPA, other agencies, and outside observers to quickly and easily consider potential conflicts of interest and account for any bias that might be built into industry-sponsored studies.[33] Apart from the problem of conflicts of interest, industry's ability to delay the regulatory process using research that is difficult to verify undermines EPA's ability to do its job in a timely manner.

In short, the interagency review process delays assessments without contributing to the IRIS process in a productive way. EPA expends resources in responding to interagency review comments and refining assessments multiple times before they are made available to a broader public for further comment. The agency could devote more resources to completing assessments if IRIS staff was not developing draft assessments to clear interagency hurdles—concerns that are often motivated by risk management concerns that are more appropriately raised during the development of actual regulations, rather than the development of a scientific assessment of possible harms. In addition, because EPA divides the review process into multiple steps, each of which requires EPA to wait and then re-evaluate its assessment, the agency sometimes is forced to respond to the same objections more than once.

Recommendations

The interagency review process should be eliminated and agencies should be given an opportunity to comment during a public comment period that is made equally available to all stakeholders. If significant science issues are raised in these public comments, EPA could then choose to initiate a more formal process for agencies to share information and resolve disputes.

In addition, EPA should assert more authority to question or re-analyze industry-sponsored research or at least to be able to take conflicts of interest into account when considering weight-of-the-evidence determinations about toxic substances. A conflict disclosure requirement that provides information about identity of sponsors, what kind of support they provided, the role of the sponsor in the research process, and the sponsors' level of control over the study and data, would enable EPA to make such assessments.

Limiting Redundant Review

In her 2009 memo announcing the new IRIS process, Administrator Jackson wrote that EPA would occasionally seek outside scientific review from the NAS and EPA's Science Advisory Board (SAB), but only in high-profile assessments of major importance.[34] Since then, however, EPA has chosen to focus the bulk of its IRIS energies on a handful of high-profile assessments, with the result that six assessments expected to be completed this year have been recommended for SAB review: dioxin, arsenic (inorganic), arsenic (non-cancer effects), trichloroethylene, polycyclic aromatic hydrocarbons, and methanol. Half of these assessments have already been reviewed by at least one outside panel of scientific experts: inorganic arsenic, dioxin and trichloroethylene have had SAB reviews previously. Inorganic arsenic was previously reviewed by the SAB from 2005-2006. Dioxin was previously reviewed by SAB in 1995 and by NAS in 2006. Trichloroethylene was previously reviewed by SAB in 2001 and by NAS in 2006. Often OMB encourages these science advisory board meetings during the interagency review process.[35]

To be sure, NAS and SAB review can add an additional layer of scientific expertise to the process. But it is a process that has already incorporated the expertise of EPA scientists, who are, among other things, assessing existing scientific literature based on expert research. In addition, the extra layer of review comes at the cost of greatly slowing down the process, sometimes by years. In the case of trichloroethylene, the two SAB reviews have taken nine years – the first SAB review was initiated in 2001, and the second SAB review has not yet been completed.

Between the outside peer review process, public comments and additional reviews of EPA's scientific judgment delay assessments by focusing on details that may not be relevant to the risk assessment task at hand, and contribute to cascading delays, making delay of assessments so lengthy that new research emerges in the interim, requiring EPA to start again from the beginning. All scientific questions can be studied virtually indefinitely. At some point, assessments must be entered into the IRIS database so that regulators can get to work protecting the public from harm. While it is important that IRIS assessments provide the best available scientific information, the science advisory process furthers the myth that IRIS assessments can be static answers about human health effects. EPA's decision to wait for unassailable answers undermines the goal of IRIS to be broadly informative. In addition, redundant layers of review can have a demoralizing effect on EPA staff that prompts them to rely only on the most deeply entrenched studies preventing them from incorporating new research.

EPA could easily incorporate more expert advice without halting the process to wait for additional SAB and NAS review, by inviting additional experts to comment on individual assessments as part of the public comment period. Instead of asking these experts to come to a consensus opinion, as NAS and the SAB do, EPA could simply solicit opinions and comments on any problems with EPA's draft. This would keep the assessment process

moving forward and would prevent peer review from delaying the process. Including such comments in the public comment process would also promote transparency of the peer review process. Comments from outside experts would be published to a docket for the assessment and therefore could be reviewed by all interested parties.

Recommendations

EPA should attempt to limit SAB review to the greatest extent possible. There will be difficult and complicated assessments, where input from the SAB may add value, reduce conflicts and provide EPA staff with needed oversight and outside expertise. But EPA should strive to avoid multiple reviews by SAB and NAS. Further, EPA should make decisions about how and when it will consult outside scientific expertise, not OMB. One place where outside science review could add genuine value is when broader scientific questions are raised, such as the development of toxicity equivalence factors, which compare the relative toxicity of individual chemicals within a family of similar chemicals, or review of classes of chemicals. In these cases, the expert opinions and additional guidance to EPA provides clear added value, as such determinations are complex and may require additional scrutiny, particularly in cases where EPA is evaluating techniques or approaches it has not used previously.

If and when EPA program offices act on IRIS information and propose a regulatory action, specific procedures under the Administrative Procedure Act, executive orders governing review of regulatory actions, and statutory requirements under each specific statute should govern the promulgation of regulations. This process is well-developed and provides regulated industry and other stakeholders with ample opportunity to evaluate EPA's proposal and present information and perspectives to the process. EPA should forgo outside science review aimed at resolving questions that are related to potential regulatory actions or risk management decisions, rather than to the science underlying those decisions.

A nimbler IRIS process would also make it easier for EPA to revise assessments if new research becomes available. In fact, EPA staff undertook the task in 2003 of identifying assessments in the IRIS database that should be revised because of new research.[33] At its best, the IRIS database should be responsive to new information, and be flexible enough that that EPA can incorporate new information to existing assessments relatively quickly. Because other program offices rely so heavily on information in the IRIS database, EPA should err on the side of information and provide the greatest possible amount of information that is scientifically credible.

In short, expert peer review can be an important tool for supporting the findings of EPA, but the agency should strive to keep redundant reviews of IRIS assessments by outside science advisory boards to an absolute minimum.

While it is important that IRIS assessments provide the best available scientific information, the science advisory process furthers the myth that IRIS assessments can be static answers about human health effects.

Putting EPA's Resources to the Greatest Effect

EPA's IRISTrack program paints a compelling portrait of just how much work remains before IRIS is truly current. A compilation of status reports on EPA's IRIS assessments currently in progress, IRISTrack shows that 67 IRIS assessments are currently in process, while 255 substances need assessments for EPA program offices to fulfill statutory mandates, and 169 substances currently listed in the database have been identified by EPA staff as being in need of updating to account for new information. EPA must complete a significantly greater number of assessments each year to quickly clear the backlog of assessments. If EPA were to complete these assessments in five years, it would have to complete approximately 84 assessments each year – nine times the number of assessments per year that it completed in the past year. Assessments cost money, and even if EPA streamlines its process along the lines recommended in this paper, the agency will require an increase in its IRIS budget from its current level of $14.5 million to approximately $100 million, with a commensurate increase in the number of full time staff to allow EPA to complete enough assessments for the database to stay current.

Although the IRIS program has received increases in funding and staff since 2000, it has not been able to complete enough assessments to meet the needs of EPA program officers and other users of the database. The low level of productivity of the IRIS program was the subject of House Science Committee hearings in 2009. The briefing memo for the hearing suggested that 20 assessments per year was the bare minimum level of productivity for the IRIS database to be relevant.[37] Even that is, in all likelihood, an understatement of what is needed. To complete the 478 assessments listed above at the rate of 20 per year would take 24 years. If the schedule includes the 77 HAPs listed but still missing inhalation values, it would take EPA 25 years to complete all the statutorily-indicated assessments, without taking on any new assessments. By contrast, at EPA's current pace of nine assessments per year, it will take 55 years for the IRIS program just to clear its backlog.

Simply dumping more money into the IRIS program will not fix the problem. EPA must make more effective use of its resources. In fiscal year 2010, the IRIS program received $5 million additional dollars and 10 additional staff to carry out its work.[38] In 2010, six assessments were referred for interagency review, eight are expected to complete the draft development phase, and EPA expects to complete nine assessments this year.[39]

The unfortunate reality is that EPA's new process for completing IRIS assessments has not addressed root causes of delay: the interagency review process, interference from regulated industry, excessive and redundant science review and inadequate strategic planning. Ideally, EPA would strive to reduce burdens on the assessment development process by focusing on a smaller number of key goals: reviewing toxicology information on toxic substances and providing an opportunity for peer review and public comment on the agency's assessment. Reducing these burdens would ensure that interested parties would have an opportunity to participate in the assessment development process and provide key oversight consistent with the requirements of the scientific community.

Recommendations

EPA should pursue two principal budget objectives with respect to IRIS. First, it should devote a limited amount of resources to high-profile IRIS assessments. Doing so would ensure that these high-profile or complex assessments are completed, but that they do not interfere with EPA's completion of other, easier-to-assess substances. The fraction of IRIS program resources devoted to high-profile chemicals should have a firm cap, so as to put an end to the current dynamic, in which EPA works on just a handful of the most difficult-to-complete assessments.

Second, EPA should develop a budget request that relies on a determination of what would actually be required to complete a target number of assessments. It should then add funding for ongoing assessments of high-profile substances. Such an approach would ensure that EPA would continue to complete assessments at a pace to keep the database up to date without high-profile assessments cannibalizing resources.

Administrator Jackson has an important opportunity to back up her assertion that the IRIS program is a key part of her chemical management strategy. The program needs sufficient resources and support so that the database can support the work of other program offices at EPA. Streamlining and simplifying the IRIS process would allow EPA to devote more of the agency's resources to completing assessments rather than responding to interagency comments and submitting to outside science review. If the agency divided priorities between a few high-profile assessments and a larger number of assessments that could be completed more quickly, EPA could complete more assessments while still making progress on the small number of high-profile assessments.

Finally, Congress should provide the IRIS program with the resources necessary to make sure IRIS is able to meet the needs of the program offices, and to keep the database up to date.

Conclusion

The reforms to the IRIS program implemented by EPA in May 2009 have not made the IRIS program productive enough to support EPA's statutory responsibilities with respect to IRIS, or to the regulatory programs that rely on it so that they can do the important work of protecting Americans from toxic substances. In particular, by prioritizing a small number of high-profile assessments, retaining interagency review, and overusing NAS and SAB review, EPA has fallen into the trap of continuing the appallingly low completion rate for IRIS assessments.

EPA has the authority to implement all of these changes recommended in this paper, with the exception of funding requests that will require appropriation by Congress. EPA's principles for chemical management state that "[c]lear, enforceable and practicable deadlines applicable to the Agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive sub-populations."[40] Under the EPA's current IRIS process, there is no way to set a clear or enforceable deadline for chemical review. If Administrator Jackson wants to achieve a better, more protective chemical management strategy, it is imperative that the IRIS program become nimbler and better able to fulfill the needs of other offices at EPA to carry out their statutory responsibilities.

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About the Authors

Rena Steinzor is the President and a Director of the Center for Progressive Reform and a Professor of Law at the University of Maryland School of Law, with a secondary appointment at the University of Maryland Medical School Department of Epidemiology and Preventive Medicine. Professor Steinzor has published widely in the areas of environmental federalism, the implications of industry self-regulation on the protection of the environment and public health, and so-called "market based" alternatives to traditional regulation. Her most recent book, *The People's Agents and the Battle to Protect the American Public*, co-authored with CPR Member Scholar and Wake Forest Law Professor Sidney Shapiro, was published by the University of Chicago Press in May 2010.

Wendy Wagner is a Member Scholar of the Center for Progressive Reform and the Joe A. Worsham Centennial Professor at the University of Texas School of Law, Austin Texas. Prior to joining the University of Texas Law faculty, Professor Wagner was a professor at the Case Western Reserve University School of Law and School of Management, and was a visiting professor at the Columbia Law School and the Vanderbilt Law School. Professor Wagner is also trained as an ecologist. After majoring in biology at Hanover College (graduating summa cum laude), she received a masters degree from the Yale School of Forestry and Environmental Studies and began (but did not finish) a Ph.D. in ecology from the University of Virginia School of Environmental Science. Professor Wagner has published widely in the areas of law and science, and presented a number of papers in a wide variety of academic and practice-based settings.

Matthew Shudtz is a Senior Policy Analyst at the Center for Progressive Reform, providing research, drafting, coordination and other staff assistance to CPR's Clean Science and Corporate Accountability Issue Groups. Prior to joining CPR, Mr. Shudtz worked as a legal intern for the Natural Resources Defense Council and as a legal/legislative intern for the Chesapeake Bay Foundation.

Lena Pons is a Policy Analyst at the Center for Progressive Reform, with experience in regulatory agencies and regulatory process issues. Prior to joining CPR, she worked on regulatory policy matters for four years at Public Citizen, covering transportation safety and energy policy and worker protections. She also worked on regulatory process issues involving the Office of Information and Regulatory Affairs of the Office of Management and Budget. Ms. Pons graduated from the University of Wisconsin-Madison with a B.S. in chemistry.

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