



November 1, 2012

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Re: Filter Failure and the Public Interest

Dear Administrator Jackson:

We are writing to urge you to take immediate steps to defeat “filter failure” in the Integrated Risk Information System (IRIS). As you know, this beleaguered but vital program is a fundamental building block for all of EPA’s efforts to control toxic chemicals. Your staff has worked diligently to address discrete concerns raised by the National Research Council. Unfortunately, sensing that the program is vulnerable to broader and more intemperate attacks, chemical manufacturers and their congressional allies are working to ensure that the program never regains its balance.

From our perspective, one of the biggest challenges facing IRIS is how slowly it produces badly needed toxicological profiles. At the rate of six or seven profiles annually, it will take decades for IRIS to produce long overdue toxicological profiles of Hazardous Air Pollutants and drinking water contaminants identified as a priority for regulation by Congress in the 1990’s. (Please see our recent paper [Corrective Lenses for IRIS: Additional Reforms to Improve EPA’s Integrated Risk Information System](http://www.progressivereform.org/articles/IRIS_1009.pdf), available at http://www.progressivereform.org/articles/IRIS_1009.pdf.) Filter failure is one of the major reasons why the program has slowed to a crawl and its viability is threatened.

Filter failure is a new term in the policy literature, coined to describe the lack of any rules to control a tidal wave of irrelevant and duplicative information dumped into public dockets by commenters, especially those representing regulated industries on a fee-for-service basis.¹ Three harms result: (1) public interest groups, individual citizens, and small businesses with considerably fewer resources are stymied in their efforts to keep track of these dockets and file their own views on these issues; (2) EPA’s own scarce resources are wasted; and (3) badly needed regulatory controls are delayed.



¹ Wendy E. Wagner, *Administrative Law, Filter Failure, and Information Capture*, Duke Law Journal, Vol. 59, p. 1321, 2010.

We recommend that EPA take strong steps to establish more effective filters on the deliberate loading of the record with redundant and irrelevant information. The agency should develop criteria for submitting comments and, if submitters do not voluntarily comply with this guidance, the agency should excise the documents filed by egregious violators from consideration. EPA is no less entitled than the judiciary to control the manner in which commenters appear before it to make their arguments. The courts have developed limits on the scope, format, and content of such submissions that greatly facilitate their timely decision-making.

This letter explains the results of our analysis of five IRIS dockets. The five dockets involved trichloroethylene (TCE), dichloromethane, ethylene oxide, tetrachloroethylene, tetrahydrofuran, and platinum. We chose TCE because the IRIS project was alarmingly lengthy. The remaining four were highlighted as being behind schedule by a December 2011 Government Accountability Office report. We analyzed 70 total comments that had 82 attachments and together totaled over 2,800 pages. We excluded comments that were filed anonymously.

Our review revealed that interested parties, particularly industry trade associations, frequently submit comments that do not provide relevant and timely information to EPA, but rather waste EPA's time and resources and delay badly needed public protections. Our analysis revealed the following specific problems:

Redundant Comments: The dockets contain redundant comments that bring no new information to the table. Several of the comments submitted to the trichloroethylene docket provide a clear example of this practice. The Aerospace Industries Association (AIA), for instance, contracted with Exponent to draft comments representing its interests and critiquing EPA's draft assessment. Rather than submitting only one copy of those comments, AIA and Exponent both submitted a copy, the only difference being that AIA included its letterhead with its submission.

Some commenters, particularly industry trade associations, rely on boilerplate language across comments and across dockets. In some cases these comments are drafted by one party and circulated among other interested parties, all of whom may then submit them on different letterhead or with only minimal modifications. In a clear-cut example of boilerplate language, the ethylene oxide docket received at least 14 comments from interested parties that adhered to one of two templates distributed by the American Chemistry Council, an industry trade association. Those 14 comments make up more than 50 percent of the comments submitted to the ethylene oxide docket and yet provide no new information.

Non-germane Issues: Commenters frequently treat the purely scientific IRIS process as though it is the proper forum to detail their policy concerns. They submit multiple statements that are irrelevant to EPA's scientific assessment. For example, the International Precious Metals Institute, an association of producers, refiners, and users of precious metals, tried to steer the discussion toward non-germane issues when it submitted comments to the platinum docket asserting that EPA's scientific determinations might not be fully understood by policymakers and that EPA ought to abandon or significantly relax its proposed reference dose as a result. The Halogenated Solvents Industry Association (HSIA) submitted two copyrighted--and thus available only at EPA's docket center, as opposed to online--attachments that consisted of articles from *Inside EPA* quoting statements made by HSIA's attorney at a listening session regarding the potential economic effects of regulating dichloromethane. HSIA also saw fit to submit the same comments they had previously submitted to the trichloroethylene docket.

Reconsideration of Settled Issues: Some interested parties also demand that EPA reconsider issues that have already been addressed, seemingly in the hopes that EPA will change its mind about its initial determination. Unless they are supported by new data these demands provide no new information and serve only to further delay EPA’s assessments. The European Precious Metals Federation (EPMF), for example, submitted comments asserting that one of the studies EPA relied on in determining its reference concentration for platinum salts did not provide adequate support for establishing a reference concentration at all. EPMF, however, failed to supply any alternate study or data set to support its conclusion and stated that EPA ought to postpone its assessment to await more research.

Unnecessarily Long Submissions: In the absence of page or word limits, some commenters have incentives to pad their submissions to EPA because they prepare them on a fee-for-service basis. For example, in comments on dichloromethane, the HSIA submitted a version of the draft assessment that was sparsely annotated by a contractor but that was more than 1,000 pages long. Requiring EPA and other commenters to go through the draft assessment to find sporadic notes in the margins is far less efficient than submitting comments organized by page and line number.

Recommendations

In order to reassert control over the comment process, we hope that you will consider developing criteria that require comments to:

- focus exclusively on scientific issues raised by an IRIS assessment, with top priority given to questions raised by EPA staff;
- exclude repetitive boilerplate;
- preclude generic comments about the credibility of the program or any ongoing policy debate about how it is run.

EPA may enforce these requirements by discounting, and—after a brief grace period—excluding from consideration comments that violate these criteria. The Administrative Procedure Act (APA) and prevailing case law not only allow such action, but encourage it. APA § 553(c), in describing agencies’ obligations in notice-and-comment rulemaking, states that, “After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose.” In addition, IRIS assessments are not regulations, so the full weight of the APA’s prescriptions regarding notice and comment procedures are inapplicable. Although the Act requires agencies to consider and respond to all significant comments in the rulemaking context, the Fourth Circuit Court of Appeals has noted that “[a]n agency establishing a rule need not respond to every comment. It must, however, reasonably respond to those comments that raise significant problems.”²

Another source of authority for EPA’s efforts to better manage its dockets is the Data Quality Act (DQA). The DQA requires OMB and Federal agencies to issue guidelines that “ensur[e] and maximiz[e] the quality, objectivity, utility, and integrity of information disseminated by Federal agencies.”³ EPA has promulgated its own guidance that “establish[es] administrative

² See, e.g., *North Carolina v. Federal Aviation Admin.*, 957 F.2d 1125 (4th Cir. N.C. 1992).

³ Data Quality Act, §515(a), Pub.L. 106-554.

mechanisms allowing affected persons to seek and obtain correction of information” in addition to guaranteeing the quality of the information disseminated by EPA.⁴ Discounting irrelevant comments would be a useful step in compiling an objective and useful body of scientific evidence to support the toxicological profiles that IRIS produces.

Thank you for considering our recommendations. We look forward to an opportunity to discuss them with you or your staff.

Sincerely,



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⁴ EPA Information Quality Guidelines, <http://www.epa.gov/quality/informationguidelines/>.