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Access to Chemical Data Used in Regulatory Decision Making

http://dx.doi.org/10.1289/ehp.1206438

It is clear from our commentary (Goldman and Silbergeld 2013), that we disagree with Lutter et al. (2013) about whether the public disclosure of all raw data used by the U.S. Environmental Protection Agency (EPA) for making regulatory decisions for chemicals is necessary to ensure the scientific basis for such decisions, and about the extent to which preemptive disclosure (prior to any request) is practical. However, the most important disagreement between us is the basis asserted by Lutter et al. in their commentary for this change in policy. Lutter et al. argued that it is necessary for the U.S. EPA—and anyone else who desires to do so—to reanalyze all data used in their assessments in order to "replicate" the findings and conclusions of the original investigators.

Lutter et al. (2013) repeatedly used the terms "replicability" and "replication" as synonymous with an "independent analysis" of raw data from an existing study. Replication in science is quite different; it involves performance of an independent study with the same hypothesis and then testing the extent to which this independent study reaches the same conclusions. Recalculation of study statistics or other reanalysis of an existing study data set is not a replication. Designing and conducting a replication study does not require access to raw data from the original study; this would abrogate the concept of independence. Moreover, an independent study will by definition utilize different sets of animal models or human populations, and as a consequence may employ different statistical techniques.

Their second argument is that disclosure of raw data will assist in identifying sources of scientific bias. We consider this unlikely because the most important sources of bias are usually related to problems in study design or limitations of the data collected. This is not identifiable through data recalculation; however, this type of bias can usually be identified in the text of the original study publication.

Lutter et al. (2013) noted (correctly) that applicants to the U.S. EPA for pesticide registrations must provide raw data from regulatory testing as part of the package submitted to the U.S. EPA. This is a very special case, in that these studies are neither peer reviewed nor accessible to the public because of the protection sought by industry and extended by law for confidential business information (CBI). The assumption of bias related to these studies is not unreasonable, given that they are conducted by or on behalf of commercial entities seeking to obtain pesticide registration. These studies are rarely published in the scientific literature or in any way subject to independent peer review other than review by the U.S. EPA. Many scientists and public policy practitioners consider the CBI cloak as a major impediment to transparency and confidence. Industry could demonstrate their commitment to transparency by declining this protection, thereby increasing the confidence of all.

Finally, Lutter et al. (2013) attempted to support their proposal by claiming that journals [*Nature* and the *Proceedings of the National Academy of Sciences of the United States* (*PNAS*)] and an expert body (the Bipartisan Policy Center) agree with them. However, these bodies have neither supported the concept of requiring that all raw data be reported to the the U.S. EPA nor that the U.S. EPA carry out its own independent recalculation. Rather, *Nature* and *PNAS* require authors to agree to make data sets (as well as materials and protocols) available to editors, and to others, upon request (Nature Publishing Group 2012; PNAS 2012). One of us (L.R.G.) was a member of the Science for Policy Project; its final report (Bipartisan Policy Center 2009) also recommended this practice. Many journals require data, such as DNA and protein sequences, macromolecular structures, microarray data, and crystallographic data, to be made available on publicly accessible databases, but most of these are not "raw data" in the sense that Lutter et al. proposed. *Nature* also recommends that authors submit clinical trials data to external clinical trials databases (Nature Publishing Group 2012).

In summary, we disagree with the argument that raw data from every study used by the U.S. EPA to support a regulatory assessment should be made available to the agency and to the public. This proposal does not serve the purpose of "replication" or identification of bias, as asserted by Lutter et al. (2013). In practice, it may generate obstacles to good science and discourage researchers from studying issues of importance in environmental health. This proposal would also limit the U.S. EPA from using the results of research published in the peer-reviewed scientific literature by placing studies off-limits if the authors did not submit raw data sets to the the U.S. EPA.

Finally, there is no obvious need for these changes. When the U.S. EPA has determined a need to reanalyze data, the current regulatory practice has not impeded such activities. Past history indicates that difficult cases are rare and do not warrant an intrusive and burdensome new requirement for the automatic submission of data from all studies.

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The authors declare they have no actual or potential competing financial interests.

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Access to Chemical Data: Lutter et al. Respond

http://dx.doi.org/10.1289/ehp.1206438R

We appreciate the attention paid by Goldman and Silbergeld (2013) to the issue of data disclosure and agree that there has been "increased demand for transparency and disclosure of the data used by the U.S. EPA [Environmental Protection Agency] to make evaluations that support regulatory decisions."

In their letter, Goldman and Silbergeld contend primarily that "replication" in science means to independently repeat a prior study to see if the same results can be obtained. They suggest that public availability of the prior study's data is unnecessary because a subsequent study will generate its own data. In 2011, a special section of *Science* (Vol. 334, No. 6060) addressed replicability and reproducibility and made two general points. First, "replication," as defined by Goldman and Silbergeld, while perhaps the cornerstone of the scientific method, can be difficult in many settings because of the uniqueness of the precise conditions surrounding field observations, the expense and time required to collect data (e.g., for longitudinal studies), and ethical constraints (e.g., Jasny et al. 2011). Second, in those cases where conduct of a second experiment may be impossible or infeasible, review and reanalysis of the first study's data is still a meaningful step along the "reproducibility spectrum," assists in understanding the differences between competing analyses, and "may be sufficient to verify the quality of the scientific claims" (Peng 2011; see also Ioannides and Khoury 2011; Santer et al. 2011).

Other empirical work also supports the view that data availability promotes reproducibility. In empirical economics, a discipline that uses large-scale statistical models broadly similar to those of epidemiologists, a famous study of replication of peer-reviewed research suggested that inadvertent errors may be "commonplace rather than rare occurrences" (Dewald et al. 1986). The *American Economic Review* (AER 2013) subsequently adopted a policy "to publish papers only if the data used in the analysis are clearly and precisely documented and are readily available to any researcher for purposes of replication." Further, the *AER* conducted a recent evaluation of its policy and reported that about 80% of 39 sampled papers met the spirit of the data availability policy (Glandon 2010). Importantly, independent efforts at replication of 9 selected papers found no serious errors (almost exact replication for 5 studies and "several small discrepancies … immaterial to the conclusions" for another 4.) This result represents a marked improvement relative to the results of the original 1986 study of replication. The difference is presumably attributable, at least in part, to the difference in care and quality of work associated with the *AER*'s current policy of data availability. Although analytic methods underlying papers published in the *AER* are different from those used in chemical evaluation, the experience of the *AER* suggests that there is merit in promoting data availability for the purpose of improving the reliability of the results of published, peer-reviewed scientific papers, at least in disciplines that use complex statistical models.

Finally, we, like Goldman and Silbergeld, "disagree with the argument that raw data from every study used by the U.S. EPA to support a regulatory assessment should be made available to the agency and to the public." Unlike Goldman and Silbergeld, we recommend that the U.S. EPA, when it uses results of a published study in a regulatory assessment, ask the authors for underlying data (Lutter et al. 2013). If the U.S. EPA does not receive such data, it should explain how it used the study results in light of the fact that data sufficient to assess reproducibility was not forthcoming. We believe our approach would facilitate and not obstruct good science and that it would not discourage researchers from studying issues of importance in environmental health. Moreover, it would not, as Goldman and Silbergeld state,

> limit the U.S. EPA from using the results of research published in the peer-reviewed scientific literature by placing studies off-limits if the authors did not submit raw data sets to the U.S. EPA.

R.L., an independent consultant, consults for CropLife America (CLA) and received financial support from the CLA to moderate a forum and serve as principal author of this letter. C.B. consults for Dow AgroSciences LLC, an R&D-based agrochemical producer, registrant, and marketer. C.J.B. received CLA funding to review and analyze scientific literature on data quality. J.W.C. has previously received funding from the American Chemistry Council to author work on the quality of scientific research evaluating chemicals. D.E. consults for a variety of pesticide manufacturers and for the CLA. A.F. has consulted with nonprofit organizations funded by the CLA about pesticide issues.

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