Center for Regulatory Effectiveness

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September 27, 2002

Mr. Greg Schweer
Office of Science Coordination and Policy (7203M)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Attention Docket ID No. OEI-10014

Dear Mr. Schweer,

The Center for Regulatory Effectiveness ("CRE") files these comments on EPA's *Draft Assessment Factors for Evaluating the Quality of Information from External Sources ("Assessment Factors").* This important document explains how EPA will apply the data quality standards required by the Data Quality Act, 44 U.S.A. § 3516 historical and statutory notes, to information submitted to EPA by parties outside the Agency.

CRE commends EPA for acknowledging that the Data Quality Act's requirements apply to third-party submissions to the Agency. CRE also appreciates the opportunity to comment on the draft *Assessment Factors* . CRE does, however, have some concerns about this draft document.

Appendix 1 Documents

If CRE correctly understands EPA's proposal, then the Agency intends to use the documents identified in Appendix 1 to the *Assessment Factors* to determine whether third-party submissions comply with the Data Quality Act standards. *See Assessment Factors*, pp. 3-4, and Appendix 1. Many of these documents themselves may not meet Data Quality Act standards in toto or in part. There are 85 documents identified in Appendix 1. It is not possible to review each one during this comment period to determine its compliance with Data Quality Act standards, especially during a 21-day comment period. CRE is already familiar, however, with Data Quality Act problems regarding one of these documents.

Appendix 1 at page 13 lists the following document as one that EPA will use to assess third-party submissions under the Data Quality Act: "U.S. Environmental Protection Agency (USEPA) (1998) *Guidelines for Ecological Risk Assessment*, Federal Register 63: 26846-26924, 14 May 1998; also EPA Publication No. EPA/630/R-93/187, December 1993." This document at pages 103-108 approves use of the so-called "Quotient Method" to assess both direct and indirect environmental risks from pesticides and other substances. Yet EPA has acknowledged that the Quotient Method failed peer review; is of questionable utility; and cannot be used to assess indirect or secondary effects. For example, EPA's Pesticides Office explained on its website (emphasis added):

> The [Science Advisory Panel] panel suggested that the current test methodologies and specific endpoints used by OPP in its model assessments were designed to support the relative simplistic process of hazard assessment, not risk assessment. The Panel indicated that the current approach has a number of limitations, *and its utility in risk assessments is of questionable value*. They also pointed out that gaps in the current methodologies must be filled to accomplish effective and comprehensive risk assessments. As a result, they strongly urged OPP EFED to conduct probabilistic assessments (risk assessments) to evaluate the ecological impacts from pesticides.

"Utility" is a fundamental Data Quality Act standard. A risk assessment method that "is of questionable value" does not meet Data Quality Act standards.

In addition, under the Quotient Method EPA first generates a Level of Concern ("LOC") for a pesticide or other product based on available data, then assesses risk based on the frequency of known or projected exceedances of the LOC. EPA's Science Advisory Panel ("SAP")has emphasized its concern "with the notion that the frequency of LOC exceedances is a useful measure." The SAP concluded that the LOC-exceedance standard under the Quotient Method is "essentially an arbitrarily selected threshold." *FIFRA Scientific Advisory Panel, Final Report on a Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Methodology for Conducting Comparative Ecological Risk Assessments," p. 9 (SAP Report No. 99-01A, Jan. 22, 1999).*

"[A]n arbitrarily selected threshold" does not meet the Data Quality Act's quality, objectivity and utility standards because it is not accurate, reliable or useful.

EPA used the Quotient Method in its environmental risk assessment for the pesticide atrazine. On the basis of the Quotient method, EPA concluded that atrazine causes adverse indirect effects: *e.g.*, short-term loss of aquatic vegetation that injures higher tier organisms that depend on the vegetation. *Registration Eligibility Science Chapter for Atrazine: Environmental Fate and Effects Chapter, pp. 3, 12 (April 22, 2002*). Yet EPA itself admitted in response to CRE's comments on the atrazine Risk Assessment that "[c]urrently, there is no methodology...which can model and statistically analyze indirect effects." *EFED Review of*

Public Comments in Response to the EPA EFED Revised Environmental Risk Assessment for Atrazine, p. 3(April 10, 2002).

This is just one example of Data Quality Act problems with the documents listed on Appendix 1. There may be problems with other listed documents. Those problems cannot all be identified during this brief comment period.

Consequently, CRE recommends that EPA amend its *Assessment Factors* to state expressly that the documents listed on Appendix 1 are themselves subject to the Data Quality Act's administrative correction process, and that administrative correction petitions regarding these documents can be filed after the close of the public comment period on the *Assessment Factors.*

Validated Test Methods

The *Assessment Factors* does not require that third-party submissions be based properly validated test methods and protocols. Yet EPA and most other federal agencies have also established a government-wide data quality standard that requires proper validation of tests before their results are used to regulate:

> Before a new or revised test method is used to generate information to support regulatory decisions, it must be (a) validated to determine its reliability and relevance for its proposed use, and (b) determined to be acceptable by one or more regulatory agencies to fill a specific need. Criteria for validation and regulatory acceptance have been prepared and are described in the report, *Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the Ad Hoc Interagency Coordinating Committee on the Validation of Alternative Methods.* Prior to the initiation of any test method development or validation efforts, sponsors are encouraged to consider the validation and acceptance criteria developed by the federal government.

Evaluation of the Validation Status of Toxicological Methods: General Guidelines for Submissions to ICCVAM, Prepared by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), p. v (October 1999).

EPA is a member of the inter-agency committee that established this government-wide validation standard. This standard is a subset of the Data Quality Act's quality, objectivity and utility standards. For example, without proper test validation data cannot be assumed to be accurate, reliable and reproducible.

Consequently, CRE recommends that the *Assessment Factors* be amended to expressly

require that test data and risk assessments be based on properly validated tests and methods.

Influential Scientific, Financial, or Statistical Information

The *Assessment Factors* does not expressly state that third-party submissions of "Influential Scientific, Financial, or Statistical Information" are subject to more rigorous Data Quality Act standards.

OMB's government-wide Data Quality Act guidelines explain that "influential scientific, financial, or statistical information" is subject to especially rigorous quality standards, including reproducibility and transparency:

> If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties.

67 FR 8460 (Feb. 22, 2002).

OMB's government-wide guidelines define the term "influential as follows:

> ``Influential", when used in the phrase ``influential scientific, financial, or statistical information" means that the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions. Each agency is authorized to define ``influential" in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.

67 FR 8460.

OMB's government-wide guidelines define the term "reproducibility as follows:

> ``Reproducibility" means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. For information judged to have more (less) important impacts, the degree of imprecision that is tolerated is reduced (increased). If agencies apply the reproducibility test to specific types of original or supporting data, the associated guidelines shall provide relevant definitions of reproducibility (e.g., standards for replication of laboratory data). With respect to analytic results, ``capable of being substantially reproduced" means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.

67 FR 8460.

OMB's government-wide guidelines further address the reproducibility requirement, distinguishing between "analytic results" and "original and supporting data":

> With regard to original and supporting data related thereto, agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement. Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicable be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints. It is understood that reproducibility of data is an indication of transparency about research design and methods and thus a replication exercise (i.e., a new experiment, test, or sample) shall not be required prior to each dissemination.
>
> With regard to analytic results related thereto, agency guidelines shall generally require sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public. These transparency standards apply to agency analysis of data from a single study as well as to analyses that combine information from multiple studies.
>
> Making the data and methods publicly available will assist in determining whether analytic results are reproducible.

67 FR 8460.

"Influential scientific, financial, or statistical information" is also subject to additional standards for "analysis of risks to human health, safety and the environment maintained or disseminated by the agencies." With respect to this type of information, OMB's government-wide guidelines require that

> agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B)). Agencies responsible for dissemination of vital health and medical information shall interpret the reproducibility and peer-review standards in a manner appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public. Information quality standards may be waived temporarily by agencies under urgent situations (e.g., imminent threats to public health or homeland security) in accordance with the latitude specified in agency-specific guidelines.

67 FR 8460.

EPA proposed Data Quality Act guidelines for Influential Information on April 30, 2002.

Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, pp. 18-21. EPA has not yet promulgated any final Data Quality Act guidelines. Whatever EPA's final Influential Information Guidelines require, those requirements must also apply to third-party submissions of Influential Information.

Consequently, CRE recommends that the *Assessment Factors* be amended to state expressly that third-party submissions are subject to EPA's Data Quality Act guidelines for Influential Scientific, Financial, or Statistical Information.

Proprietary Data and Robustness Checks

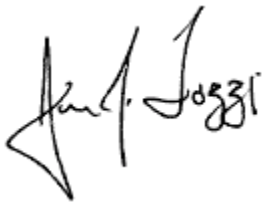
The *Assessment Factors* do not address how EPA will ensure that confidential submissions by third parties will meet Data Quality Act standards. Nor do EPA's proposed Data Quality Act guidelines address this issue.

OMB's government-wide Data Quality Act Guidelines explain that when public access to agency information is impossible for privacy, trade secrets, intellectual property, and other confidentiality protections, the agency shall "(1) perform robustness checks appropriate to the importance of the information involved, e.g., determining whether a specific statistic is sensitive to the choice of analytic method, and, accompanying the information disseminated, to document their efforts to assure the needed robustness in information quality, and (2) address in their guidelines the degree to which they anticipate the opportunity for reproducibility to be limited by the confidentiality of underlying data." 67 FR 8456-57."

EPA's proposed Data Quality Guidelines at pages 20 and 26 acknowledge the need to comply with OMB's government-wide guidelines on this issue, but they do not explain how EPA will comply with this requirement. The *Assessment Factors*, which is devoted application of the Data Quality Act Standards to third-party submissions, is an appropriate forum in which to address this confidential data issue.

Consequently, CRE recommends that the *Assessment Factors* be amended to explain in detail how EPA will ensure that confidential third-party submissions comply with the Data Quality Act standards. This detailed explanation should include a detailed explanation of what robustness checks EPA will perform.

Sincerely,



Jim J. Tozzi
Member. CRE Board of Advisors