CENTER FOR REGULATORY EFFECTIVENESS'S
INITIAL COMMENTS ON EPA'S PROPOSED DATA QUALITY GUIDELINES
DOCKET OEI-10014

The Center for Regulatory Effectiveness ("CRE") submits the following comments on the United States Environmental Protection Agency's proposed data quality guidelines, 67 FR 21234 (April 30, 2002).

In addition to these EPA-specific comments, we are attaching as Exhibit A CRE's Generic Comments to all Federal Agencies Related to Data Quality Guidelines ("CRE Generic Comments"). CRE's Generic comments are incorporated by reference into CRE's comments on EPA's proposed data quality guidelines. CRE's Generic Comments, while not limited to EPA, address several issues presented by EPA's proposed guidelines.

While CRE has comments on several specific aspects of EPA's proposed guidelines, we wish to emphasize one general comment on the guidelines.

EPA Cannot Exempt Publicly Disclosed Information From the Data Quality Guidelines

EPA's proposed data quality guidelines violate clear congressional intent that they must apply to all information that EPA has in fact made public. Rather than complying with the statutory mandate, EPA proposes to exempt much of the Agency's public information from coverage by the guidelines. *E.g.*,

- Proposed Guidelines, pages 14-17(exemptions from the definitions of dissemination and information)

- Proposed Guidelines, page 23 (exempting rulemakings from the guidelines' administrative correction process).

- Proposed Guidelines, page 16 (exempting information distribution related to adjudicative processes, with "adjudicative processes" defined extremely broadly)

EPA's proposed data quality guidelines are required by the Information Dissemination provisions of the PRA. 44 U.S.C. §§ 3504(d)(1); 3516 note; 66 FR 49718 (Sept. 28, 2001). Attached as Exhibit B is a legal memorandum prepared by Multinational Legal Services, PLLC, for CRE. This memorandum is incorporated by reference into CRE's comments on EPA's proposed data quality guidelines. This memorandum examines the relevant statutory text and legislative history, and concludes that neither the Office of Management and Budget ("OMB") nor any other federal agency has any authority or discretion to exempt any publicly disclosed information from coverage by the data quality guidelines required by the Information Dissemination provisions of the Paperwork Reduction Act.

EPA's proposed data quality guidelines are also inconsistent with the definition of "information" in OMB Circular A-130, which defines the term at page 3 to mean "any

communication or representation of knowledge such as facts, data, or opinions in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms." There is no rational basis for using a different, conflicting definition of "information" for the data quality guidelines required by the PRA's Information Dissemination requirements. OMB Circular A-130 is issued pursuant to the PRA's Information Dissemination requirements and eight other federal statutes, as well as three Executive Orders. Consistent with congressional intent, OMB's Circular A-130 Information dissemination definition of "information" is much broader than OMB's definition of "information" for purposes of the PRA's separate Collection of Information requirements. *Compare* OMB Circular A-130, at 3 *with* 5 CFR 1320.3(h)(OMB's definition of "information" for PRA Collections of Information).

In regard to this issue, CRE further incorporates by reference Exhibit A to CRE's comments, including but not limited to pages 2-10; and Exhibit B to CRE's comments.

Consequently, CRE requests EPA to revise its proposed data quality guidelines to state explicitly that they apply to any and all information that EPA in fact makes public.

EPA Cannot Exclude Rulemakings and Adjudicative Processes From the Data quality Standards and Petition Process

EPA's proposed guidelines, at pages 22-23, appear to exclude most rulemaking records from the Data Quality Act petition and correction process:

> ... where a mechanism by which to submit comments to the Agency is already provided. For example, EPA rulemakings include a comprehensive public comment process and impose a legal obligation on EPA to respond to comments on all aspects of the action. These procedural safeguards assure a thorough response to comments on quality of information. EPA believes that the thorough consideration required by this process meets the needs for the correction of information process. A separate process for information that is already subject to such a public comment process would be duplicative, burdensome, and disruptive to the orderly conduct of the action.
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> If EPA cannot respond to a complaint in the response to comments for the action (for example, because the complaint is submitted too late to be considered along with other comments or because the complaint is not germane to the action), EPA will consider whether a separate response to the complaint is appropriate. EPA may consider frivolous any complaint which could have been submitted as a timely comment in the rulemaking or other action but was submitted after the comment period.

These proposed exclusions could, as a practical matter, remove all EPA rulemaking records from coverage under the Data Quality Act. This exclusion is contrary to the letter and intent of the Act, as explained in Exhibit B to these comments, which is incorporated herein by reference.

Moreover, many rulemakings are very lengthy proceedings. Information in a rulemaking public docket may be publicly available for years before the agency takes any action on comments on the information in its proposed rules and docket. Not allowing a Data Quality guidelines petition to correct this information before promulgation of final rules would violate OMB's interagency Data Quality guidelines, which require a timely correction process for correcting errors in all agency information made publicly available, including "preliminary information" used in agency rulemakings:

> ... agencies shall establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, *timely correction of information* maintained and disseminated by the agency that does not comply with OMB or agency guidelines. These administrative mechanisms shall be flexible, *appropriate to the nature and timeliness of the disseminated information*, and incorporated into agency information resources management and administrative practices.
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> i. *Agencies shall specify appropriate time periods* for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made.
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> ii. If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), the person may file for reconsideration within the agency. The agency shall establish an administrative appeal process to review the agency's initial decision, *and specify appropriate time limits* in which to resolve such requests for reconsideration.

67 FR 8452, 8459 (Feb. 22, 2002)(emphasis added).

> OMB does not believe that an exclusion for preliminary information is necessary and appropriate. It is still important that the quality of preliminary information be ensured and that preliminary information be subject to the administrative complaint-and-correction process.

Similarly, EPA's definition of "dissemination" at page 16 excludes publicly disclosed information "related" to "adjudicative processes." EPA's definition of "adjudicative processes" at pages 16-17 is so broad that it includes most EPA information that is not included within EPA's rulemaking exemption. These two exemptions, when combined with the other proposed

exemptions, exclude from the data quality guidelines most information that EPA makes public.

CRE's legal memorandum attached as Exhibit B to these comments explains that these exemptions from the data quality standards are not permitted under the Data Quality Act amendments to the Information Dissemination requirements of the Paperwork Reduction Act.

Application of the SDWA Health Risk Assessment Standards

EPA's proposed guidelines at page 9 state that EPA will only adapt the SDWA risk assessment standards, without explaining how or why. Moreover, EPA proposes to defer any action regarding the SDWA standards for environmental and safety risk assessments, without explaining why.

OMB's February 22nd agency-wide guidelines stated that the science quality and risk assessment standards contained in the 1996 amendments to the Safe Drinking Water Act (SDWA), 42 U.S.C. § 300g-1(b)(3)(B), should be adopted or adapted by federal agencies. Agencies should adopt both the SDWA science quality and risk assessment standards unless they conflict with the other federal statutory requirements. If such conflicts do arise, agencies should make every efforts to reconcile the SDWA standards with the conflicting statutory requirements.

There are only two valid reasons why a federal agency should not adopt these standards:

- The agency does not conduct these types of risk assessments; or
- The SDWA risk assessment standards conflict with the specific risk assessment standards of another federal statute governing the agency.

In the latter case, the agency should identify the conflicting specific risk assessment standards; make every effort to reconcile the conflicting standards with the SDWA standards; and request public comment on both the conflict and the attempt at reconciliation.

The SDWA risk assessment standards, and compliance with other data quality standards (e.g., quality, objectivity and utility) are especially critical for EPA environmental risk assessment standards. EPA's own SAP and virtually every one else who has reviewed the Agency's practice in this area agree that EPA's current environmental risk assessments do not meet Data Quality Act standards in large part because EPA does not use probabilistic risk assessments.

For example, EPA's Office of Pesticide Programs explains on its website (emphasis added):

> In May 1996 the Environmental Fate and Effects Division (EFED) of the Office of Pesticide programs (OPP) presented two pesticide risk assessment case studies to EPA's Scientific Advisory Panel (SAP) and asked them to address the agency's current pesticide

> risk assessment methodology. *The SAP commented that while the current process is believed to be cautious and protective in terms of adverse environmental effects, it best serves as a screen because it provides little information on the likelihood of damage. The SAP recommended that the pesticide risk assessment process be expanded to include probabilistic assessments of risk and to identify the uncertainties associated with the assessment.*

EPA's Ecological Committee on FIFRA Risk Assessment Methods ("ECOFRAM") published in 1999 an Aquatic Report which on page 3 summarized the SAP's conclusions in part as follows (emphasis added):

> The panel suggested that the current test methodologies and specific endpoints used by OPP in its model assessments were designed to support the relatively 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.*

In sum, the type of lower-tier analyses used by EPA for environmental risk assessments have been subject to formal, independent, external peer review and found lacking in this context. By contrast, a probabilistic risk assessment is the type of analysis found necessary by formal, independent, external peer review.

The PRA Data Quality guidelines require that all information disseminated by EPA to the public have "utility." The OMB definition of "utility" explains that this term "refers to the usefulness of the information to its intended users, including the public." As noted above, EPA's own SAP emphasized that the type of lower-tier analyses used by EPA, instead of a probabilistic risk assessment, has "utility...of questionable value." EPA's own SAP urged the Agency "to conduct probabilistic assessments (risk assessments) to evaluate the ecological impacts from pesticides." The SAP further cautioned that the lower-tier analysis "best serves as a screen because it provides little information on the likelihood of damage." In fact, as the SAP pointed out, this type of lower-tier analysis "is designed to support the relatively simplistic process of hazard assessment, not risk assessment." EPA itself admits that its lower-tier analysis does "not imply any quantification of magnitude or probability of effect." Yet EPA still relies on this type of risk assessment to determine environmental risks.

OMB's Guidelines also require "objectivity" in information EPA disseminates to the public. The OMB definition of "objectivity" explains (emphasis added), "In a scientific or statistical context, the original or supporting data shall be generated, and the analytical results shall be developed, *using sound statistical and research methods.*" 67 FR 8452, 8459 (Feb. 22, 2002).

EPA's SAP has concluded that the type of lower-tier analysis used by EPA is not a sound

statistical and research method for ecological risk assessments. In fact it is only a hazard assessment, not a full-fledged risk assessment. Probabilistic risk assessments are the sound statistical and research method in this context.

There other examples of EPA risk assessment practices that are inconsistent with the SDWA risk assessment standards and other data quality standards. One of these is EPA's categorical prohibition on the consideration of third party clinical human test data pending NAS review of these types of tests. Attached as Exhibit C to CRE's comments is a Petition CRE filed with EPA on this issue. This CRE petition is incorporated by reference into CRE's comments on EPA's Data Quality Guidelines.

CRE's Petition explains that third party clinical human test data are among the best available data regarding any substance or product's risk to human health. EPA's categorical ban on consideration and use of such data violates the SDWA risk assessment standards and other Data Quality requirements: *e.g.*, objectivity, utility and quality.

CRE hopes that EPA's decision regarding adoption and use of the SDWA risk assessment standards is not influenced by whatever concerns motivated its categorical ban on third party clinical human test data. In any event, EPA cannot promulgate final data quality guidelines that comply with the required data quality standards while still maintaining its categorical ban on use and consideration of third party clinical human test data.

Reproducibility Of Original Data

EPA's proposed Data Quality Act guidelines at page 8 recognize the importance of reproducibility as a fundamental test of science: "As a regulatory agency with a strong science program and function, EPA takes reproducibility of data and results very seriously and understands the importance of ensuring that data and methods are transparent and credible."

EPA's proposed Data Quality Act Guidelines request public comment on a number of reproducibility issues, including the following at page 25: "What types of original and supporting data do you believe should or should not be subject to a reproducibility requirement given ethical, feasibility, or confidentiality constraints?"

In response to this question, the original and supporting data for all laboratory animal studies should be capable of being reproduced. EPA relies heavily on animal studies in many of its regulatory contexts, and animal studies are often the primary basis for EPA regulatory action. The original and supporting data from these animal tests are often the most influential data used by EPA in regulating. Consequently, EPA's guidelines should be revised to state that if a qualified laboratory using the same test protocols achieves significantly different results in regard to the data generated by the original test, then EPA will assume that the original test does not meet data quality standards. CRE believes that requirement could be implemented, and the original test shown invalid, primarily through third party administrative petitions. If the information in question has to be part of a public record under the APA or some other law or

regulation, then any correction petition, EPA action on it, and the results of any judicial review of the petition, should all be in the public record. There are no ethical or feasibility obstacles to such a requirement. Confidentiality issues are discussed in CRE's Generic Comments at pages 23-25.

CRE also comments that any animal test results that cannot be reproduced do not meet the required data quality standards of objectivity, quality, and utility. Consequently any such test should be subject to an administrative correction petition on these grounds.

Retroactive Application of the Data Quality Guidelines

In regard to this issue, CRE incorporates by reference Exhibit A to CRE's comments, including but not limited to page 5; and Exhibit B to CRE's Comments.

Third-Party Submissions of Data to An Agency

In regard to this issue, CRE incorporates by reference Exhibit A to CRE's comments, including but not limited to page 10; and Exhibit B to CRE's Comments.

Definition of "Affected Persons"/Definition of a "Person"

In regard to this issue, CRE incorporates by reference Exhibit A to CRE's comments, including but not limited to page 10; and Exhibit B to CRE's Comments.

Deadline for Deciding a Petition

In regard to this issue, CRE incorporates by reference Exhibit A to CRE's comments, including but not limited to page 13; and Exhibit B to CRE's Comments.

Who Decides the Initial Petition?

In regard to this issue, CRE incorporates by reference Exhibit A to CRE's comments, including but not limited to page 14; and Exhibit B to CRE's Comments.

Who Decides Appeals?

In regard to this issue, CRE incorporates by reference Exhibit A to CRE's comments, including but not limited to page 15; and Exhibit B to CRE's Comments.

Must the Agency Correct Information When It Agrees with a Petition?

In regard to this issue, CRE incorporates by reference Exhibit A to CRE's comments, including but not limited to page 16; and Exhibit B to CRE's Comments.

What is the Standard for Rebutting the Presumption of Objectivity Resulting from Peer Review?

In regard to this issue, CRE incorporates by reference Exhibit A to CRE's comments, including but not limited to page 17; and Exhibit B to CRE's Comments.

How is "Influential Information" Defined?

In regard to this issue, CRE incorporates by reference Exhibit A to CRE's comments, including but not limited to pages 18-19; and Exhibit B to CRE's Comments.

What is "Objective" and "Unbiased" Information on Risks to Human Health, Safety and the Environment?

In regard to this issue, CRE incorporates by reference Exhibit A to CRE's comments, including but not limited to pages 20-22; and Exhibit B to CRE's Comments.

Robustness Checks for CBI

In regard to this issue, CRE incorporates by reference Exhibit A to CRE's comments, including but not limited to page 23; and Exhibit B to CRE's Comments.

Use of Third-Party Proprietary Models

In regard to this issue, CRE incorporates by reference Exhibit A to CRE's comments, including but not limited to pages 24-25; and Exhibit B to CRE's Comments.