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OEI-10014

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ONE HUNDRED SEVENTH CONGRESS

**U.S. House of Representatives**
**Committee on Energy and Commerce**
**Washington, DC 20515–6115**

C4-003

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DAVID V. MARVENTANO, STAFF DIRECTOR

June 7, 2002

The Honorable Christine Todd Whitman
Administrator
US Environmental Protection Agency
Docket ID No. OEI-10014
Northeast Mall, Room B607
401 M Street, NW
Washington, DC 20460

Re: Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency; Docket ID No. OEI-10014

Dear Administrator Whitman:

We are writing to comment on the Environmental Protection Agency's ("EPA's") "Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency" (the "Draft Guidelines").[1] We are very concerned about statements in the Draft Guidelines, particularly with respect to risk assessments. The preamble states:

> In reviewing EPA's experience with the SDWA [Safe Drinking Water Act] principles, existing policies in place at EPA, and the applicability and appropriateness of the SDWA language with regard to the variety of risk assessments conducted by the Agency, EPA has decided to adapt the SDWA principles with minimal changes for use with all human health risk assessments . . . However, the Agency intends to adapt the SDWA principles for human health assessments and work further to refine the applicability of these principles across program areas.[2]

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Section 3.4 of the Draft Guidelines states:

> With respect to influential scientific information regarding human health risk assessments, EPA should ensure, to the extent practicable and in conformance with Agency guidelines, the

[1] Notice at 67 Fed. Reg. 21,234 (April 30, 2002). Draft Guidelines available at www.epa.gov/oei/qualityguidelines.

[2] Draft Guidelines at 9.

> objectivity of this information disseminated by the Agency by adapting the quality principles found in the SDWA amendments of 1996. [3]

Section 3.4 also alters the SDWA standards themselves by adding the phrase "as appropriate" after the terms "best available, peer-reviewed science." In addition, section 3.4 only provides for use of data collected by the best available methods if "the nature of the decision justifies use of the data."[4] Finally, the Draft Guidelines provide no basis at all to understand what the Agency's proposal is for objectivity as it relates to environmental and safety risks.

We are concerned that the preamble statements and section 3.4 of the Draft Guidelines are inconsistent with law and contain too many loopholes to be useful.

**1. EPA's Draft Guidelines Would Be Inconsistent with Law.**

EPA's proposal would be inconsistent with law and it leaves completely open-ended loopholes for EPA not to follow the SDWA principles or any principles of objectivity. First, we note that the placement of the qualifiers "should" (versus "shall"), "to the extent practicable," and "in conformance with Agency guidelines" cannot legally modify the requirement to meet the Congressional objectivity requirements set out in the legislative data quality language in section 515 of the Fiscal Year 2001 Treasury, Postal Service and General Government Appropriations Act ("FY 2001 Treasury, Postal Act").[5] The legal requirement is for guidance to meet objectivity standards. There is no exception.

The Office of Management and Budget ("OMB") has, in its guidelines, provided an initial interpretation of what those standards are:

> With regard to analysis of risks to human health, safety, and the environment maintained or disseminated by the agencies, 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. [6]

Accordingly, EPA should specifically explain what its proposed adaptation of the SDWA standards are along with the specific reasons and basis for any changes from the SDWA standards. Whatever the final version, EPA must issue guidelines "ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency." [7] EPA has explained what it proposes to do for human health risks but has provided no specific reasons or examples for why it should modify the SDWA standards. Moreover, the Agency has provided no proposal for safety and environmental risks.

EPA's proposal on human health risks states that EPA "should" ensure "objectivity." The statutory standard, on the other hand, is that the guidelines must ensure objectivity.[8] The qualifier that meeting standards of objectivity should only be "to the extent practicable" is also

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[3] Id. (emphasis added)
[4] Id.
[5] Pub. L. No. 106-554.
[6] 67 Fed. Reg. 8,451 (February 22, 2002).
[7] Section 515 of the FY 2001 Treasury, Postal Act.
[8] Id.

inconsistent with the statutory mandate. Moreover, no rationale or example has been given for why "objectivity" should be "to the extent practicable." There is no reason for risk assessment information not to meet the standard of "objectivity." Finally, it is impermissible and irrational to provide that compliance with such a standard is only where it is "in conformance with Agency guidelines." Agency guidelines must be in line with the applicable statutory requirement, not the other way around.

**2. EPA's Proposal Provides No Rationale or Record Why Human Health Risk Assessments Should be Treated Differently under Risk Assessments Related to Drinking Water Versus Other Human Health Risk Assessments at EPA.**

The Agency also proposes to weaken the SDWA language without any explanation as to why human health risk assessments under the SDWA should be treated one way and other human health risk assessments at the Agency should be treated another. The SDWA language itself obviously applies without such exceptions to human health risk assessments under SDWA.[9] The Agency, on the other hand, proposes to weaken the language further by the use of the terms: (1) "involves the use of"; (2) "as appropriate" after the terms "peer-reviewed"; and, (3) "if the . . . nature of the decision justifies the use of the data."[10] The SDWA language has no such qualifiers. The Agency has neither given an explanation as to why any of these qualifiers are appropriate nor has it provided any examples of why the exact language of the Safe Drinking Water Act should not simply be adopted for human health risks.

We further note EPA's reference to the "nature of the decision." This reference appears to address risk management issues that extend beyond the scope of the risk assessment itself. The purpose of risk assessment is to assess risks. The nature of subsequent risk management decisions cannot undermine or create an exception to principles of objectivity for the risk assessment itself. As discussed below, the point EPA appears to be making is inconsistent both with the SDWA principles and the recommendations of the Commission on Risk Assessment and Risk Management (the "Risk Commission").

**3. EPA's Proposal Provides No Rationale or Record Why Human Health Risk Assessments Should be Treated Differently under Risk Assessments Related to Drinking Water Versus Environmental and Safety Risk Assessments and Has Provided No Opportunity for Comment on EPA's Intended Adaptations.**

The SDWA requires use of the "best-available peer-reviewed science" and "sound and objective" scientific practices. We fail to see why the exact SDWA language cannot be fully adopted for environmental and safety risks. The Agency has neither put forth any specific rationale for this failure nor presented any specific proposal for adaptation. This approach denies the right to public comment, since we have no idea what adaptations EPA proposes. We request that, if the Agency plans to propose adaptations in this area, such adaptations be presented for public comment.

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[9] See 42 U.S.C. 300g-1(b)(3)(A), (B).
[10] Draft Guidelines, section 3.4 at 20-21.

**4. The Record Supports Adoption of the SDWA Principles and the Recommendations of the Risk Commission to Present and Use the "Weight of the Scientific Evidence" in all Risk Assessments.**

As discussed below, prior Congressional and Executive Branch statements support full adoption of the SDWA principles for human health risk assessments as well as environmental and safety risk assessments. The record also supports -- and we recommend -- adoption of specific language requiring that all risk assessments present and employ the weight of the scientific evidence.

Under section 515 of the FY 2001 Treasury, Postal Act, OMB must "provide policy and procedural guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information)." There are a number of sources which provide further guidance on these terms.

First, Executive Order 12866 states:

> Each agency shall base its decision on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for and consequences of the intended regulations.[11]

This language is fully consistent with related legislative mandates. For example, the Safe Drinking Water Act Amendments of 1996 state in part:

> [T]he Administrator shall use --- (1) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices.[12]

The SDWA provision further states that:

> [T]he Administrator shall, in a document made available to the public in support of a regulation promulgated under this section, specify, to the extent practicable --
>
> (ii) the expected risk or central estimate of risk for the specific populations;...
>
> (v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data.[13]

The 1997 Recommendations of the Risk Commission support this objective and unbiased approach in several instances:

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[11] E.O. 12866, section (1)(b)(7) (emphasis added).
[12] 42 U.S.C. 300g-1(b)(3)(A) (emphasis added).
[13] 42 U.S.C. 300g-1(b)(3)(B) (emphasis added).

> A good risk management decision . . . [i]s based on a careful analysis of the weight of scientific evidence that supports conclusions about a problem's potential risks to human health and the environment.[14]
>
> [T]he Commission's Risk Management Framework is intended to: ...[e]nsure that decisions about the use of risk assessment and economic analysis rely on the best scientific evidence .[15]
>
> Making judgments about risk on the basis of scientific information is called 'evaluating the weight of the evidence.'.... It is important that risk assessors respect the objective scientific basis of risk and procedures for making inferences in the absence of adequate data.[16]
>
> Because so many judgments must be made based on limited information, it is critical that *all* reliable information be considered. Risk assessors and economists are responsible for providing decision-makers with the best technical information available or reasonably attainable, including evaluations of the weight of the evidence that supports different assumptions and conclusions.[17]

Risk assessments may also form the basis for cost-benefit analyses even where such assessments must address issues of uncertainty. A March 22, 2000 OMB memorandum (The Lew Memorandum) addresses this issue:[18] This memorandum states in part:

> Normally, you should calculate benefits (including benefits of risk reductions) that reflect the full probability distribution of potential consequences. Where possible, present probability distributions of benefits and include the upper and lower bound estimates as compliments to central tendency and other estimates.[19]

The Lew Memorandum further states:

> If fundamental scientific disagreement or lack of knowledge prevents construction of a scientifically defensible probability distribution, you should describe benefits under plausible assumptions and characterize the evidence underlying each alternative.[20]

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[14] The Presidential/Congressional Commission on Risk Assessment and Risk Management; Framework for Environmental Health Risk Management, Final Report, Volume 1 at 4 (1997) (emphasis added).
[15] Id. at 5 (emphasis added).
[16] Id. at 23 (emphasis added).
[17] Id. at 38 (emphasis added).
[18] Memorandum from OMB Director Jacob J. Lew to the Heads of Departments and Agencies concerning "Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements" (March 22, 2000).
[19] Id. at 9 (emphasis added).
[20] Id. (emphasis added).

A 1996 Memorandum on Best Practices Guidelines for Executive Order 12866 further defines principles of objectivity and states:

> Risk management is an activity conceptually distinct from risk assessment . . . The risk assessment should generate a credible, objective, realistic, and scientifically balanced analysis . . . The data, assumptions, models, and inferences used in the risk assessment to construct quantitative characterizations of the probabilities of occurrence of health, safety, or ecological effects should not reflect unstated or unsupported preferences for protecting public health and the environment, or unstated safety factors to account for uncertainty and unmeasured variability. Such procedures may introduce levels of conservatism that cumulate across assumptions and make it difficult for decision-makers to evaluate the magnitude of the risks involved.

As you, Governor Whitman, aptly stated in your confirmation hearing to be Administrator of the Environmental Protection Agency:

> Scientific analysis should drive policy. Neither policy nor politics should drive scientific results.[21]

It is clear that the context of a regulatory decision should not alter the objectivity requirement for risk assessments themselves.

**5. EPA Should Include the Language from the Definition of "Quality" as Specifically Applying to Information from Risk Assessments.**

It is insufficient to apply the standard of being "accurate" and "unbiased" only to "the substance of information," as EPA currently proposes. EPA's proposed section 2.1 provides that the definition of objectivity "focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner." This standard should explicitly apply to the presentation of risk information. The standard that information is "comprehensive," "informative," and "understandable" does not adequately convey the objectivity requirement.

**6. The Agency Should Clarify the Application of Objectivity Principles with Respect to Assumptions with the Greatest Scientific Weight.**

As discussed above, risk information must be based on an objective scientific process. Safety factors or measures based on assumptions designed to produce an overestimate of risk are statements of policy and not themselves scientific assessments of risk. It is important that Federal agencies maintain the distinction between true risk assessments and risk management policy measures.

In order to provide to meet the standards of the statutory provisions for quality, objectivity, utility, and integrity of risk information, Federal agencies must present a more complete and clear package of information to the public. Best estimates based on assumptions

[21] Statement of the Honorable Christine Todd Whitman before the Senate Committee on Environment and Public Works, Senate Hearing 107.3 at 31 (Jan. 17, 2001).

with the greatest weight of scientific evidence are critical pieces of information to provide quality, objectivity, utility and integrity. Best estimates are important for cost-benefit analyses and for comparisons among risks. Moreover, by avoiding the decision criteria of "conservatism" such estimates carry more scientific integrity than measures than mix science and public policy. Such best estimates must be an anchor to risk assessment information presented to the public.

Accordingly, EPA should, among other estimates or measures, present risk estimates or measures which are based on assumptions that have the greatest support in the weight of scientific evidence and are based on the best science. This is the baseline objective of risk assessment. Information purporting to state risks to human health or the environment should contain this information.

Along with the baseline best estimate, other risk measures may be useful as indicators of uncertainty and variability. Such measures may also be useful in setting forward a screening process to determine whether further analysis is worthwhile. Moreover, choosing a given risk measure to achieve a program objective depends on the policy and legal context. But, such choices do not themselves become risk assessments or risk information. The failure to present measures reflecting the greater weight of the scientific evidence and best available science evades the Congressional mandates of quality, objectivity, utility, and integrity of information purporting to be a risk assessment.

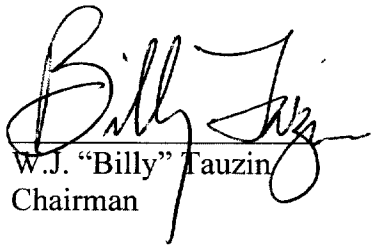
Revisions to the Draft Guidelines should be directed at, among other areas, information about competing assumptions. When there are competing assumptions in a risk assessment those assumptions should be disclosed to the public. Federal agencies should indicate their view on which assumption has the most support in view of the best available science. At least one risk measure should be produced based on the weight of the scientific evidence. When assumptions have equal support, it is acceptable to provide measures based on each such assumption. Measures should not be identified as central tendency measures where such measures are based on assumptions designed to overstate the risk.

A recent General Accounting Office ("GAO") report examined risk assessment guidance documents and procedures at EPA, the Food and Drug Administration, the Occupational Health and Safety Administration, and the Department of Transportation to determine whether the agencies stated a specific scientific or policy basis for their choices.[22] The GAO study showed that there are problems with current practices. First, the report found gaps in agency explanations. Agency guidance did not explain the basis for significant assumptions approximately a quarter of the time. The agencies provided information on the likely effects of using particular assumptions or methods in only about half of the examples. When that information was provided, it was usually in the context of whether and to what extent the agencies' choice could be considered precautionary. The agencies acknowledged that such practices can result in "multiple conservatisms" and that some of these choices are likely to overstate risk by an unknown amount. It is unclear whether such assessments provide decision-makers or the public with risk information based upon assumptions that are supported by the greater weight of scientific evidence or that rely on the best available science. The guidelines must assure that such information is provided to the public.

[22] Chemical Risk Assessment: Selected Federal Agencies' Procedures, Assumptions, and Policies (Aug. 6, 2001 GAO-01-810).

We ask that you make modifications in any final guidelines consistent with our foregoing comments.

Sincerely,



W.J. "Billy" Tauzin
Chairman

Paul E. Gillmor
Chairman
Subcommittee on Environment and
Hazardous Materials