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Subject: EPA Docket Control Nos. OEI-2003-0025 and OEI-2003-0026 (OMB Nos. 2070-0093 and 2070-0143); Comments on EPA's request for renewal of OMB approval of its Information Collection Requests for TRI Forms R and A (ICRs 1363.13 and 1704.07) (68 FR 39071-78, July 1, 2003; 68 FR 43427, July 22, 2003)

On March 10, 2003, OMB's Office of Information and Regulatory Affairs (OIRA) approved predecessor ICRs with an expiration date of October 31, 2003. OIRA granted approval for such a short time in order, as it stated in the "New Terms of Clearance" for both TRI forms, to "provide EPA with an opportunity to examine in more detail several issues that were not adequately addressed during the current review cycle, [including] opportunities for . . . enhancing the practical utility of the data."

In its January 13, 2003 comments on those predecessor ICRs that were approved until Oct. 31, 2003, CRE had asserted that the ICRs raised significant issues of "practical utility" under the PRA, and related issues of "utility" and "objectivity" under the Data Quality legislation and guidelines. Our comments today reiterate and expand on those assertions with regard to the new ICRs.

In particular, these comments contend that EPA cannot certify to the practical utility of the ICRs until it revises and clarifies its current TRI listing guidance, because that guidance allows EPA to subject to TRI and PRA requirements chemicals, such as the diisononyl phthalates category ("DINP"), which cannot reasonably be anticipated to pose a risk of toxicity to humans. The current listing guidance cannot produce objective and useful listing decisions which comply with the Data Quality legislation and guidelines because the guidance is contradictory, confusing, and subjective (*i.e.*, not objective, as required), and it does not allow listing decisions to be capable of being

substantially reproduced. In addition, application of the existing guidance to listing decisions cannot ensure and maximize the "utility" of the TRI data to its intended users, because it does not ensure that the listed substance can be reasonably anticipated to be "toxic" to humans under a realistic exposure scenario.

While the *Federal Register* notice for the ICRs asks for comments on "practical utility" and "quality, utility, and clarity" of the information to be collected, the EPA ICRs themselves do not address the issue of "practical utility" in terms of the objectivity and reproducibility of the listing guidance used to produce the information. With regard to "utility", the ICRs contain extensive discussion of how the TRI information is widely used by individuals, activists, and state and local governments, apparently assuming that all TRI information meets quality standards, and they do not address the issue of whether the assumed utility has "practical" utility because it is accurate, clear, reliable, and reproducible.

Applicability of the Data Quality Legislation and Guidelines

Under the information quality legislation and guidelines, PRA clearances will not be given by OMB unless the information requested by an agency would meet the new information quality standards. This was stated clearly in the Administrator's June 10, 2002 Memorandum for the President's Management Council (sec. IV):

> [E]ach agency is already required to demonstrate the "practical utility" of a proposed collection of information in its PRA submission, i.e., for draft information collections designed to gather information that the agency plans to disseminate. Thus, we think it important that each agency should declare in its guidelines that it will demonstrate in its PRA clearance packages that each such draft information collection will result in information that will be collected, maintained, and used in a way consistent with the OMB and agency information quality standards. It is important that we make use of the PRA clearance process to help improve the quality of information that agencies collect and disseminate. **Thus, OMB will approve only those information collections that are likely to obtain data that will comply with the OMB and agency information quality guidelines.** [Emphasis added.]

EPA's final information quality guidelines, issued on October 3, 2002, reflect this OMB requirement:

> For all collections of information that will be disseminated to the public, EPA intends to demonstrate in our Paperwork Reduction Act clearance submissions that the proposed collection of information will result in information that will be collected, maintained and used in ways consistent with the OMB guidelines and these EPA Guidelines.

Sec. 6.5.

Both the OMB and EPA guidelines require that information disseminated by the Agency be "objective". Objectivity, as defined by both OMB and EPA, "focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance is accurate, reliable, and unbiased."[1] "Influential" scientific information[2] requires more rigorous application of these quality standards,[3] and EPA's ICRs for forms R and A set out a strong case for TRI information being "influential". In addition to the quality standard of objectivity, influential scientific information is subject to the requirement that it be "reproducible". "Reproducibility" requires that there be a high degree of transparency regarding "the analytic methods applied"[4] such 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."[5]

The StatutoryTRI Listing Provisions and the Current TRI Listing Guidance for Chronic Health Effects

EPCRA section 313(d)(2)(B), commonly known as the chronic health effects section, provides EPA with the authority to list a chemical on the TRI if –

> (B) The chemical is known to cause or **can reasonably be anticipated** to cause **in humans**
> (i) cancer or teratogenic effects, or
> (ii) serious or irreversible
> . . . .
> (IV) other chronic health effects

42 U.S.C. § 11023(d)(2)(B).

Use of the term "toxics" in the statute carries the necessary implication that level of exposure at which adverse effects might occur will be considered, since it is fundamental to toxicology that a substance is "toxic" only in relation to dose. This is undoubtedly the understanding of the layman,

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[1] OMB final government-wide guidelines at 67 FR 8453 and 8459 (Feb. 22, 2002). And see the EPA final guidelines at section 5.1 (http://www.epa.gov/oei/qualityguidelines/EPA_OEI_IQG_FINAL_10-2002.pdf).

[2] "Influential" means that "the Agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions." EPA guidelines sec. 6.2.

[3] EPA guidelines sec. 6.3; OMB guidelines at 67 FR 8455 2d col.

[4] EPA guidelines sec. 6.3.

[5] OMB guidelines at 67 FR 8460 3d col.

also – *i.e.*, that listing of a substance on the "Toxics Release Inventory" means that releases of the substance are likely to be toxic.

The issue of whether, or the extent to which, EPA would consider likely levels of exposure in determining whether to list a substance on the TRI was raised prominently in 1994 when EPA proposed to add a large number of chemicals to the list. Many commenters argued that it was necessary under the statute for EPA to consider likely levels of exposure. EPA's response has constituted its guidance for listing since that time.

With regard to the listing decisions made for the many specific chemicals in the 1994 notice, EPA explained that it had conducted "hazard assessments" for each, in which "the number, severity, and significance of the effects induced by the chemical, **the dose level causing the effect**, and the quality and quantity of the available data, including the nature of the data (*e.g.*, human epidemiological, laboratory animal, field or workplace studies) and confidence level in the existing data base, were all considered." EPA then explained how it made its final listing determination:

> Where a careful review of the scientific data for a particular chemical results in a high level of confidence that the chemical causes an adverse effect **at relatively low dose levels**, EPA believes that this evidence is sufficient for listing the chemical under section 313. EPA also believes that where a review of the scientific data indicates that the chemical will cause various adverse effects **at moderate dose levels**, the total weight-of-the-evidence indicates that there is sufficient evidence for listing the chemical under EPCRA section 313. EPA believes that **both types of chemicals described above exhibit moderately high to high toxicity** based on a hazard assessment.

59 FR at 61432, 61433, Nov. 30, 1994 (emphasis added). There was no explanation of how the Agency would determine what constitutes "relatively low dose levels" or "moderate dose levels". The term "relatively" certainly indicates that the dose levels causing adverse effects in the data would have to be considered "low" relative to some other dose level. One would think that this other dose level would most likely be the dose level that might reasonably be expected from human exposures in the vicinity of facilities releasing the chemical.

In this 1994 notice, EPA then proceeded to consider whether assessment of likely human exposures should be considered in listing decisions. EPA noted that many comments had been received arguing that EPA should consider human exposure levels in making listing decisions based on (a) the wording of the listing criteria, which implied consideration of exposure, (b) the legislative history, which indicated Congressional intent that exposure should be considered, and (c) EPA's prior practice of considering exposure in making listing and delisting decisions. EPA responded to these arguments as follows:

> In light of the many comments received on this issue, EPA has reviewed its positions in this area, and agrees with many of the commenters that there are limited

> circumstances under which it is appropriate for EPA to consider exposure factors for listing decisions under section 313 (d) (2). **The Agency believes that exposure considerations are appropriate in making determinations under [(d) (2) (B)] for chemicals that exhibit low to moderately low toxicity based on a hazard assessment (i.e., those chemicals for which the value of listing on the EPCRA section 313 list on hazard along is marginal) . . . . The Agency believes that exposure considerations are not appropriate in making determinations . . . under section 313 (d) (2) (B) for chemicals that exhibit moderately high to high human toxicity.**

59 FR at 61441 (emphasis added). EPA then considered that the purpose of the TRI provisions was to allow communities to "estimate local exposure and local risks" as opposed to risk which might be based on generic exposure considerations, and "to move the determination of what risks are acceptable from EPA to the communities in which the releases occur". *Id*. It also determined that because the conference report on the legislation stated that the Agency "may, but is not required to conduct new studies or risk assessment or perform site-specific analyses to establish actual ambient concentrations . . . ", Congress did not intend EPA to conduct exposure studies or perform risk assessments. *Id*. Based on these considerations, EPA concluded:

> EPA believes that it has the discretion under both section 313 (d) (2) (B) and . . . (C) to consider, where appropriate, those exposure factors that may call into question the validity of listing any specific chemical on TRI. . . .
>
> **For listing determinations made pursuant to EPCRA section 313 (d) (2) (B), in instances where the hazard assessment indicates that the value of listing on EPCRA section 313 on hazard alone is marginal (i.e., a chemical is of low toxicity and unrealistic exposures would be necessary for it to pose a risk to communities), EPA may use exposure considerations in its listing decisions. Only chemicals for which the hazard assessments indicate moderately high to high toxicity are being added in today's action to the EPCRA section 313 list pursuant to section 313 (d) (2) (B). None of these chemicals are chemicals for which the consideration of exposure factors would be appropriate**.

59 FR at 61442 (emphasis added).

To summarize the requirements of the statute and the interpretations contained in the 1994 listing guidance --

1. The statute requires consideration of the "reasonably anticipated" impact of a chemical "in humans"

2. Impact "in humans" cannot be determined without consideration of exposure and dose.

3. EPA's guidance states that it will consider the relative level of dose ("relatively low" or

"moderate") in determining whether a chemical is of high or moderately high toxicity. However, it says that it will not consider exposure if it has determined that a chemical is of high or moderately high toxicity.

4. EPA's guidance states that it will consider whether the value of listing is marginal because a chemical is of low toxicity and unrealistic exposures would be necessary for it to pose a risk to communities.

These listing guidance statements are contradictory and circular, and are incongruous with the statutory provisions. Dose to humans (and "toxicity") cannot be considered without also considering realistic exposure levels, as reflected partially in the statement regarding "unrealistic exposures". EPA states that "low" toxicity can be determined by considering realistic exposure and dose levels for communities, but high or moderately high toxicity can be determined only by considering dose, but not exposure. On its face, this guidance makes no sense. Realistic exposure levels must be considered in all cases in order to determine whether the toxicity potential of a chemical is low, moderate, or high. There is no way to determine that the toxic potential of a chemical is "high" or "moderately high" for humans without considering the levels that they might be exposed to and the dose that would result. The TRI is intended to provide information useful to humans on potential toxicity to humans. EPA says such determinations will be based on dose in all cases, but not on exposure in some cases. Dose to humans cannot be considered without also considering exposure in all cases. Determining the degree of toxicity based on dose but not exposure is not possible. In other words, toxicity, as EPA recognizes, depends on dose; but dose "in humans" cannot be considered without considering reasonably anticipated levels of exposure, which EPA does not recognize.

Data Quality Deficiencies

The flawed nature of the current listing guidance will inevitably lead to flawed listing decisions – *i.e.*, ones that are based on subjective determinations regarding degree of toxicity that do not have practical utility for the intended users of the listing data, whereas the Data Quality legislation and guidelines require that information be objective. Users can be lead to believe that a particular chemical is "toxic" when unrealistic exposure levels would be necessary to induce any adverse effects, but EPA has determined that the degree of toxicity is "high" or "moderately high" without considering whether the exposure levels required to produce toxicity are unrealistic.

The data quality guidance requires that TRI information, as "influential" scientific information, meet a high standard of "objectivity". It must be "accurate", "clear", "reliable", and "reproducible". Application of the current listing guidance ensures that listings will not meet any of these standards:

1. Listings cannot be "accurate" in any scientific sense because level of dose (and toxicity) is determined without consideration of the levels of human exposure.

2. TRI listing information cannot be considered "clear" because under the listing guidance

toxicity is determined based on whether the dose is "relatively low", but no guidance is given for determining what is "relatively low" (*i.e.*, relative to what?), and no guidance is given on how to determine level of dose "in humans" without considering realistic (*i.e.*, "reasonably anticipated") exposure levels.

3. The listing information is not "reliable" because the listing guidance is inaccurate, unclear, and subjective.

4. Finally, the listing determinations are not "reproducible", because it is not possible to determine how the Agency has decided whether a particular chemical has "high", "moderately high", or "low" toxicity.

As a consequence of these data quality deficiencies, application of the current guidance cannot be certified by EPA to produce information which has "practical utility" (or "utility") under the Paperwork Reduction Act and the information quality guidelines.

An Example

In September 2000, EPA proposed TRI listing for the diisononyl phthalates (DINP) category of chemicals, which are very widely used in consumer plastics products. 65 FR 5368, Sept. 5, 2000. The proposal contained the preliminary determination that DINP was "high" to "moderately high" in toxicity because its database showed toxicity (in animals) "at relatively low doses". The proposal did not consider how doses determined to be potentially toxic compared to realistic ("reasonably anticipated") exposures and doses "in humans", referring to the 1994 guidance discussed above as authority for not considering exposure and dose in humans.

Subsequently, EPA received comments from dozens of chemical and plastics companies objecting to the listing on grounds that the Agency's analysis showed that even if there were any toxic effects, they occurred only at doses that were tens of thousands to millions of times higher than could ever be expected in humans.

The latest Unified Regulatory Agenda indicates that EPA expects to take final action on the proposal to add DINP to the TRI by November 2003. (68 FR 31065, May 27, 2003.)

Bypassing of PRA Review for Significant New Listing Determinations

The DINP comments also observed that EPA claimed that it had already been granted Paperwork clearance by OMB under the clearances for generic forms R and A, and therefore did not have to submit ICRs for the DINP listing proposal to OMB for clearance and undergo a Data Quality challenge to the information collection. The generic clearances were being used, the comments claimed, as a way to circumvent Paperwork and related Data Quality review, and they requested that OMB attach terms of clearance to any clearance of the generic forms that would require the Agency to submit any significant new TRI additions to Paperwork and Data Quality review by OMB.

Ongoing Review of the TRI Listing Guidance

EPA has informed companies concerned with the DINP proposal that they were considering possible revisions/clarifications to the TRI listing guidance, and that a decision on this would be make in the near future. Thus, EPA is aware of the issues raised herein to some extent. Nevertheless, there is no discussion of such issues in the form R and A ICRs, and to date there has been no indication of any EPA action on this matter.

Summary

The current (1994) EPA guidance for new TRI listings is fatally flawed because it does not consider realistic ("reasonably anticipated") exposure and dose "in humans" in making determinations of toxicity. Application of the guidance results in dissemination of "influential" information that cannot satisfy the Data Quality requirements of OMB and EPA because it is not objective, accurate, clear, reliable, and reproducible, and lacks utility. Consequently, the current ICRs for TRI forms R and A cannot meet the "practical utility" requirements of the Paperwork Reduction Act. Approval of the ICRs would permit EPA to make new TRI listing determinations that do not satisfy the Paperwork Reduction Act and Data Quality guidelines requirements, and circumvent OMB review for compliance with those requirements, as it has proposed to do in the case of the DINP category.

Recommendations

While we do not recommend that EPA withdraw, or OMB reject, the form R and A ICRs in their entirety, thereby bringing the TRI program to a halt, we do contend that before they can be approved, the ICRs, or OMB terms of clearance, must commit to the following in order to satisfy the "practical utility" requirements of the Paperwork Reduction Act and the quality and utility standards of the Data Quality guidelines:

1. EPA must revise its listing guidance to provide that the Agency will consider realistic/reasonably anticipated human exposure and dose in relation to the doses which might have elicited potential adverse effects in the database.

2. The revisions to the listing guidance must be developed through public notice and comment.

3. The revisions to the listing guidance must be finalized within two years.

4. The revisions to the listing guidance must undergo OMB review under E.O. 12866.

5. Until new listing guidance is finalized, EPA cannot make any new TRI listing determinations.

6. Any new EPA proposed or draft final TRI listing determinations which have raised significant Data Quality or "practical utility" issues in the public comments must be submitted to OMB with a new ICR and pursuant to E.O. 12866 after the listing guidance has been revised.

The principal CRE contact for these comments is William G. Kelly, Jr., wgkelly@tetontel.com, (208) 354-3050. Please contact Mr. Kelly if you have any questions concerning these comments or wish to discuss them.

Thank you for considering these comments and recommendations.

Sincerely,

WGK

William G. Kelly, Jr.
CRE Western Representative

cc: SBA Office of Advocacy
OMB/OIRA