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June 24, 2005

Via E-Mail

Information Quality Guidelines Staff
Mail Code 2811R
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Request for Correction -- Risk Assessment for Metam Sodium

Dear Sir or Madam:

This request for the correction of information (RFC) is submitted on behalf of the Metam Sodium Alliance (Alliance), which consists of Amvac Chemical Corporation; Taminco, Inc., and Tessenderlo Kerley, Inc., under the Information Quality Act (IQA)¹ and the implementing guidelines issued, respectively, by the Office of Management and Budget (OMB)² and the United States Environmental Protection Agency (EPA).³ Each of the Alliance companies is a registrant and producer of metam sodium. As discussed below, the Alliance seeks the correction of information disseminated in EPA's January 31, 2005, "Human Health Risk Assessment: Metam Sodium" (Risk Assessment). To the extent that similar information is contained in a revised version of the Risk Assessment, to be issued by EPA on or about June 29, 2005, the Alliance seeks the pre-dissemination correction of that information as well.

This RFC seeks the correction of EPA's Risk Assessment in its reliance upon the Probabilistic Exposure and Risk Model for Fumigants (PERFUM) as applied to metam sodium and in EPA's corresponding omission of any analysis based upon the demonstrably superior

¹ Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, P.L. 106-554; 44 U.S.C. § 3516 (notes).

² 67 Fed. Reg. 8452 (Feb. 22, 2002).

³ EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency, EPA/260R-02-008 (Oct. 2002) (Guidelines).



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Fumigant Exposure Modeling System (FEMS) model. EPA's failure to address the FEMS model in the current draft Risk Assessment and to include the relevant modeling results based on FEMS is a basic error that requires immediate correction, in both the January 31, 2005, document and the forthcoming revised Risk Assessment. In short, EPA must make use of such pertinent and credible information before it, and any Risk Assessment it disseminates concerning metam sodium -- whether the current draft or the one to be issued shortly -- must be revised to incorporate what is lacking. In this instance, what is missing is no less than the "best available science," specified under the Guidelines. Absent the inclusion of the FEMS model data, the utility and the objectivity of both the current draft and upcoming Risk Assessment will be fundamentally compromised and EPA's IQA obligations will go unmet.

The Guidelines "contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information we disseminate" as well as specifically describing "new mechanisms to enable affected persons to seek and obtain corrections from EPA regarding disseminated information that they believe does not comply with EPA or OMB guidelines."⁴ Thus, the Guidelines expressly contemplate and enable a process for the correction of information disseminated by EPA that falls short of the "basic standard of quality, including objectivity, utility, and integrity," enunciated in its own Guidelines or those issued by OMB.⁵

Of these three prongs that go to the quality of information EPA disseminates, "objectivity" and "utility" both are implicated by the errors the Alliance seeks to correct. As does OMB, EPA views the focus of "objectivity" to be "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."⁶ The term "utility" refers to "the usefulness of the information to the intended users."⁷ The information of concern here, moreover, is indisputably "influential scientific . . . information," which under the EPA Guidelines, like those of OMB, is subject to "a higher degree of quality (for example, transparency about data and methods)."⁸

⁴ *Id.* at 3.

⁵ *Id.*

⁶ *Id.* at 15; OMB Guidelines § V.3, 67 Fed. Reg. at 8459.

⁷ EPA Guidelines at 15; OMB Guidelines § V.2, 67 Fed. Reg. at 8459.

⁸ *Id.* at 20; OMB Guidelines §§ V.3(b)(ii) and V.9, 67 Fed. Reg. at 8460.



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In the context of the Risk Assessment for metam sodium, EPA's reliance on the PERFUM modeling results to the exclusion of those from the application of the FEMS model means that the Risk Assessment fails to meet the "accuracy" and "completeness" aspects of "objectivity" under the Guidelines. For the reasons noted below and discussed more fully in previous submissions by the Alliance, the FEMS model is far more accurate than the PERFUM model when applied to metam sodium; experience in the field confirms that the PERFUM modeling results are unreliable.

Even assuming that there is some value in disseminating the PERFUM-based results in the Risk Assessment, the assessment is incomplete as a viable information source due to EPA's failure to include the FEMS results. In view of its inadequacies on grounds of accuracy and completeness, the Risk Assessment necessarily fails to meet the standard in the Guidelines for "utility" as well.

With specific reference to ensuring the "objectivity" of "influential scientific risk assessment information," the EPA Guidelines have adapted the quality principles in the Safe Drinking Water Act Amendments (SDWA) of 1996⁹ to provide as follows:

- (A) The substance of the information is accurate, reliable and unbiased. This involves the use of:
 - (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and
 - (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data).

- (B) The presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, is comprehensive, informative, and understandable.¹⁰

⁹ 42 U.S.C. § 300g-1(b)(3)(A) and (B). The OMB Guidelines, § V.3(b)(ii)(C), direct federal agencies to "adopt or adapt" the SDWA principles for these purposes. 67 Fed. Reg. at 8460.



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For the reasons summarized below, EPA's omission of the FEMS model analysis in favor of the PERFUM model in its Risk Assessment is contrary to the SDWA principles incorporated into the Guidelines. It is the FEMS model -- with the resulting Monte Carlo analysis -- that represents "the best available science and supporting studies conducted in accordance with sound and objective scientific practices," consistent with (A) of the SDWA principles quoted above. By contrast, the PERFUM model yields a cruder screen that is out of line with consistent and robust field test results. For the same reasons, the FEMS model also represents the "best available method" of data collection under SDWA. The FEMS model, as noted below, was peer-reviewed favorably by EPA's Scientific Advisory Panel (SAP) last summer and has been enhanced since then, in accordance with the SAP's suggestions. Without inclusion of the FEMS modeling results, the Risk Assessment cannot be considered "comprehensive" or even sufficiently "informative" under (B) of the above-quoted SDWA principles either.

The Alliance previously has discussed in detail the deficiencies in the PERFUM model on which the current draft Risk Assessment relies, as well as the reasons why the FEMS model enables a more accurate and realistic assessment. Most recently, the Alliance has addressed these points in its "error-only" comments on the Risk Assessment.¹¹ The modeling-related errors identified by the Alliance for purposes of the April 2005 comments and its previous submissions also support this RFC, in that they go to the analytic foundation of the Risk Assessment, as well as to the results of that analysis.¹²

¹⁰ EPA Guidelines at 22.

¹¹ Letter from Lynn Bergeson, Esquire, Bergeson & Campbell, P.C., to CDR Mark J. Seaton, USPHS, EPA Chemical Review Manager/OPP/SRRD (Apr. 4, 2005) (Error-Only comments or April 2005 comments), citing also the Alliance's comments of May, August, November 1, and November 17, 2004. The portions of these comments relating to EPA's choice of model and the modeling results for metam sodium are incorporated by reference to this RFC. Appendix A to the Error-Only comments specifically addresses EPA's application of the PERFUM model to metam sodium, as well as a comparison of modeling results obtained from the PERFUM model as applied by EPA with those results that the FEMS model would yield.

¹² While this RFC is directed to the basic modeling issues, the additional errors identified in the Alliance's April 2005 comments -- whether directed to specific modeling concerns or other errors -- remain on the table.



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As EPA's Risk Assessment states, EPA decided to use the PERFUM model because of the availability of inputs, because modifications suggested by the SAP were completed, and because the computer processing time would be less than with either FEMS or another model. Not only has EPA's choice of model produced an erroneous and incomplete picture, it contravenes IQA principles in that EPA also chose to exclude from its analysis a more suitable modeling tool that was, and continues to be, available. Unless EPA includes a FEMS-based analysis in its Risk Assessment, the latter will fall short as a viable piece of information and its modeling-driven conclusions will remain suspect.

As discussed in the Alliance's Error-Only comments, the FEMS model produces, for both emissions and meteorological data, a true Monte Carlo analysis -- the undisputed gold standard and one that cannot be attained with the PERFUM model.¹³ The PERFUM model may have been fully available earlier than the FEMS, but this ignores the facts that the FEMS model was nevertheless timely available *and* that the PERFUM model was inappropriate in the first place. The FEMS model, in prototype form, was reviewed in August 2004 by EPA's FIFRA SAP, which commented favorably upon its capabilities and features.¹⁴ Specific technical suggestions for refinement the SAP made were incorporated promptly. Currently, not only does the FEMS model run more rapidly than does PERFUM, it is clearly superior to PERFUM, because it applies Monte Carlo features to more model variables than does PERFUM.¹⁵

¹³ See Error-Only comments at 5 and Appendix A.

¹⁴ Meeting Minutes, FIFRA Scientific Advisory Panel Meeting, August 26-27, 2004 held at the Holiday Inn-National Airport, Arlington, Virginia, "*A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Fumigant Bystander Exposure Model Review: The Fumigant Exposure Modeling System (FEMS) Using Metam Sodium as a Case Study*," SAP Report No. 2004-07 (Nov. 9, 2004), available at <http://www.epa.gov/scipoly/sap/2004/august2/aug2004final.pdf>.

¹⁵ The Guidelines state as follows:

In applying [the SDWA] principles, "best available" usually refers to the availability at the time an assessment is made. However, EPA also recognizes that scientific knowledge about risk is rapidly changing and that risk information may need to be updated over time. When deciding which influential risk assessment should be updated and when to update it, the Agency will take into account its statutes and the extent to which the updated risk assessment will

(Footnote continued on the next page . . .)



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Additionally, the unrealistically conservative buffer zone results for metam sodium yielded by PERFUM are contrary to decades of field experience, as confirmed by California Technical Information Bulletin provisions, as well by California Department of Pesticide Regulation (CDPR) action.¹⁶ Application of PERFUM to metam sodium has produced screening-type results at best. To base a risk assessment on such a crude analysis is inconsistent with sound science particularly when, as here, a better tool is available. Accordingly, IQA principles call for EPA's Risk Assessment to incorporate modeling results using FEMS in addition to -- or, preferably, in lieu of -- those based on the PERFUM model.

Going forward with the requested correction also is necessary to preclude significant and unjustified harm to the interests of the registrants of metam sodium and the grower constituents they serve. As it stands, the PERFUM-driven modeling analysis in the current draft Risk Assessment threatens to undercut the commercial viability of metam sodium in projecting -- unjustifiably -- that a buffer zone of more than one mile is necessary to protect against human health risks due to exposure. The PERFUM model results, however, are wholly at odds with many years of operational experience in California and with the 500-foot buffer zone that has earned the approval of the California regulatory authorities. The more refined FEMS modeling results, by contrast, represent the "best available science" and dovetail with

have a clear and substantial impact on important public policies or private sector decisions. In some situations, the Agency may need to weigh the resources needed and the potential delay associated with incorporating additional information in comparison to the value of the new information in terms of its potential to improve the substance and presentation of the assessment.

EPA Guidelines at 23.

It should be noted that, in contrast to the situation addressed in the above-quoted passage, the Alliance's RFC does not seek to update a Risk Assessment that was once satisfactory but has become outdated. Instead, it seeks inclusion of "best available science" in a Risk Assessment that should not have excluded the FEMS model data or relied solely on the PERFUM model in the first place. The issue here goes to correction rather than updating, and it is undisputed that the FEMS model is fully available and that the associated data have been available to EPA for some time.

¹⁶ Error-Only comments at 6, citing CDPR Enforcement Letter 2000-44 (Nov. 15, 2000).



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real-world experience. It is thus clearly erroneous to omit them from the Risk Assessment, as “influential scientific information” disseminated by EPA.

To satisfy the IQA and the implementing Guidelines, EPA should act promptly upon the Alliance’s RFC and should correct these data in both the January 31, 2005, draft Risk Assessment and the updated version for release on or about June 29, 2005.

Sincerely,

Lynn L. Bergeson

cc: Ms. Susan B. Hazen (via e-mail)
Mr. James J. Jones (via e-mail)
Debra F. Edwards, Ph.D. (via e-mail)
CDR Mark J. Seaton (via e-mail)
Ms. Margaret J. Rice (via e-mail)
Ms. Linda Keola P. Murray (via e-mail)