



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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OFFICE OF
ENVIRONMENTAL INFORMATION

Ms. Lynn L. Bergeson
Bergeson & Campbell, P.C.
1203 Nineteenth Street, N.W., Suite 300
Washington, D.C. 20036-2401

Re: Request for Reconsideration – Risk
Assessment for Metam Sodium
(RFR #05004A)

Dear Ms. Bergeson:

This letter is in response to your Request for Reconsideration (RFR) dated October 11, 2005, filed on behalf of the Metam Sodium Alliance (MSA) under EPA's Information Quality Guidelines (EPA IQGs), and received by the Environmental Protection Agency (EPA) via e-mail on October 12, 2005. In your letter, you request reconsideration of the Agency's July 11, 2005, response to your June 24, 2005, Request for Correction (RFC) of information contained in EPA's January 31, 2005, draft document entitled "Human Health Risk Assessment: Metam Sodium" (Risk Assessment) that the Agency had provided only to metam sodium registrants for the pre-public review under Phase-1 of the 6-Phase Public Participation Process for Pesticide Reregistration¹.

Your RFR reiterates the request you made in your RFC that EPA correct the pre-public release draft document dated January 31, 2005, and also requests that EPA correct the preliminary Risk Assessment that was made available to the public on July 13, 2005, for review under Phase-3 of the 6-Phase Public Participation Process for Pesticide Reregistration. Your RFR disputes the Agency's response to the RFC and reiterates concerns regarding the model used for metam sodium's preliminary Risk Assessment, both the January 31, 2005, pre-release draft document and the July 13, 2005, public review document. MSA asserts that the model used by EPA to inform metam sodium's preliminary Risk Assessment has been chosen at the exclusion of another model. MSA requests that EPA use a different model in metam sodium's Risk Assessment [i.e., replace the Probabilistic Exposure and Risk Model for Fumigants

¹ EPA is evaluating five soil fumigants, including metam sodium, using a 6-Phase Public Participation Process for Pesticide Reregistration that was established to encourage public involvement starting early in and continuing throughout the evaluation process. For additional information about the public participation process for soil fumigants, go to http://www.epa.gov/oppsrrd1/reregistration/soil_fumigants/index.htm#pub_process.

(PERFUM) with the Fumigant Exposure Modeling System (FEMS)]. MSA submitted comments identical to these in response to EPA's solicitation of public comments on July 13, 2005, which initiated Phase-3 of the 6-Phase Public Participation Process for Pesticide Reregistration. That public comment period ended on October 12, 2005. Your RFR does not otherwise provide any additional or new information that has not already been addressed by EPA and placed in the public docket established for the reregistration of metam sodium.²

In accordance with the administrative process described in the EPA IQGs³, your RFR was considered by a three-member Executive Panel comprised of the Agency's Science Advisor to the Administrator, the Economics Advisor to the Administrator, and myself. The Executive Panel carefully reviewed your June 24, 2005, submission, EPA's July 11, 2005, response, your RFR, and other relevant materials. The Executive Panel concludes that EPA's July 11, 2005, response was consistent with the EPA IQGs.

The Agency's well-established 6-Phase Public Participation Process for Pesticide Reregistration provides ample opportunity for registrants and the public to identify concerns about information quality as part of the comments they submit to EPA during the development of the document, and for EPA to consider those comments to make any necessary corrections in preparing final documents. OMB's Information Quality Guidelines⁴ recognize that an agency may already have a process in place to respond to public concerns and the Information Quality Guidelines are not intended to create administrative mechanisms that disrupt such an agency process. The process in place has provided you with a written response to the concerns expressed in the RFC and the RFR.

As you know, the pre-public release draft document dated January 31, 2005, that was provided to the metam sodium registrants under Phase-1, was superseded by the preliminary Risk Assessment that was made available to the public on July 13, 2005, for public review under Phase-3. In addition, both of the models cited in your letter (i.e., PERFUM and FEMS) were peer reviewed by the FIFRA Scientific Advisory Panel (SAP), a process that also includes a public comment opportunity, and both models were found to be scientifically sound. Although both models were considered during the development of the preliminary Risk Assessment, as explained in the July 13, 2005, public review draft, the Agency chose to use the PERFUM model

² Both your comments and EPA's responses are available in the public docket. To view the docket, go to <http://www.regulations.gov/>, select "Docket Search" under "Advance Search" and then enter docket ID No. EPA-HQ-OPP-2005-0125 in the "Docket ID Number" field.

³ Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, EPA, 2002. (67 FR 63657)
http://www.epa.gov/qaality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf

⁴ Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, OMB, 2002. (67 FR 8452)
<http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf>

in the preliminary Risk Assessment. The Agency notes that both models provide information that may, along with many other types of information, ultimately be useful in characterizing and managing by-stander risk from soil fumigants.

We appreciate MSA's efforts to enhance the utility of the FEMS model. The FEMS model assessment developed by MSA and submitted during the Phase-3 public comment period is one of the documents in the public docket for the Agency's metam sodium Risk Assessment. Your RFC and the Agency's June 30, 2005, and July 7, 2005, letters that respond to those comments were added to the public docket for the preliminary Risk Assessment that was made available for public comment on July 13, 2005. Your subsequent comments, which reiterated the comments provided in your June 24, 2005, request, were received during that public comment period and were placed in the public docket. A copy of the February 2, 2006, presentation by MSA to EPA and a brief summary of the February 2, 2006, meeting are also in the public docket.

As part of the Agency's 6-Phase Public Participation Process for Pesticide Reregistration, all comments received during all phases (which involve several iterative opportunities for public review and comment), are carefully considered by EPA before it disseminates a risk assessment that represents a final Agency viewpoint or is used to formulate and support the Agency's final decision or position. MSA's concerns – along with all of the other public comments that were submitted during Phase-3 – are now being evaluated and considered as part of the 6-Phase Public Participation Process for Pesticide Reregistration. EPA will then revise the preliminary Risk Assessment as appropriate. At that point, should MSA's review of the revised (yet still pre-decisional) Risk Assessment identify information that needs correction, either because you are not satisfied with how EPA addressed your previously expressed concerns or because you have identified new concerns, MSA can avail itself of the existing mechanisms under the Public Participation Process for Pesticide Reregistration and provide EPA with further comments. Additionally, Phase-5 of the 6-Phase Public Participation Process for Pesticide Reregistration involves the release of a document that responds to public comments submitted under Phase-3, and another public review and comment opportunity of the draft pre-decisional revised Risk Assessment, and, if appropriate, preliminary risk reduction options.⁵ After considering the public comments submitted under this additional formal public comment opportunity, EPA will address the public comments, as appropriate, through revisions to the Risk Assessment itself, in a letter to the commenting registrant, as part of the Agency's decision document, or in a separate response to comment document. The final Risk Assessment represents a final Agency viewpoint and will then be used to formulate and support the Agency's final decisions on the reregistration of metam sodium.

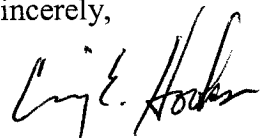
⁵ Under Phase-5, EPA publishes a Federal Register notice announcing the availability of the revised risk assessment and response to comments. EPA also releases and invites public comment during the next 60 days on preliminary risk reduction options, a qualitative impact discussion (if EPA has identified risks of concern), and a discussion of any potential transition issues. The public is encouraged to suggest risk management proposals. Additionally, during this Phase, Federal agencies begin a dialogue with stakeholders on risk reduction and risk management. See the full description of the 6-Phase process at http://www.epa.gov/oppsrrd1/public_summaries.htm#6phase.

These pre-decisional review opportunities afforded by EPA's reregistration process will help ensure the quality of information incorporated into the Agency's final decisions on the reregistration of metam sodium. As we continue to move forward with the 6-Phase Public Participation Process for Pesticide Reregistration, we would like to emphasize that Phase-3 of the process is intended to elicit comments and information that help the Agency refine the preliminary risk assessments. At this point in the process, the draft document issued for public comment does not represent a final Agency decision. EPA's experience over the last six years is that the public discussion and input on these draft documents at this early stage of the regulatory process enhances everyone's understanding of both science and policy issues and provides a sound basis for the Agency's subsequent risk management discussions in Phase-5, as well as for the Agency's final decision.

EPA values input from the public on the quality of information it produces or utilizes and embraces opportunities for improvement. We appreciate your active participation in the Agency's well established public participation process for the reregistration of metam sodium. As an active participant in that process, the Agency will continue to keep you informed of the activities related to the reregistration of metam sodium.

EPA is committed to promoting transparency in the Agency's processes and providing the public with information that is objective and useful. If you have any questions about our response to this RFR, please do not hesitate to contact Reggie Cheatham, Director, Quality Staff, at (202) 564-6830.

Sincerely,


for Linda A. Travers
Acting Assistant Administrator
and Chief Information Officer

cc: George Gray, Assistant Administrator for Research and Development
Brian Mannix, Associate Administrator for Policy, Economics and Innovation
Susan Hazen, Principal Deputy Assistant Administrator for Prevention, Pesticides,
and Toxic Substances
James Jones, Director of Pesticide Programs, Office of Prevention, Pesticides,
and Toxic Substances