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March 10, 2010

Via E-Mail

Mr. Anthony F. Maciorowski
Deputy Director
EPA Science Advisory Board Staff Office
1200 Pennsylvania Avenue, N.W.
Mail Code: 1400F
Washington, D.C. 20460

Re: Notification of SAB Workgroup Public Meeting for the
Toxicological Review of Inorganic Arsenic

Dear Mr. Maciorowski:

I am writing on behalf of the Organic Arsenical Products Task Force (OAPTF), a group of registrants of pesticide products that contain monosodium methanearsonate (MSMA), to request that the Science Advisory Board (SAB) reschedule the public meeting of a workgroup to conduct a review of the draft document entitled "Toxicological Review of Inorganic Arsenic: In Support of the Summary Information on the Integrated Risk Information System (IRIS)" (EPA/635/R-10/001). This meeting has currently been scheduled for April 6 and 7, 2010, in a notice published on March 1, 2010.¹

The contents of the draft U.S. Environmental Protection Agency (EPA) document to be reviewed are a matter of vital interest to the members of the OAPTF. The interest of MSMA registrants in EPA's review of the mode of action for the carcinogenic effects of inorganic arsenic was addressed by specific provisions in an Agreement in Principle between the MSMA registrants and the Office of Pesticide Programs (OPP) that was executed on January 16, 2009. That Agreement provides in relevant part:

OPP agrees that it will strive to take the issue of the mode of action for carcinogenic effects by inorganic arsenic to a joint review by the EPA Science Advisory Board (SAB) and the FIFRA Science Advisory Panel (SAP) in the first half of 2012. ... EPA agrees that in determining whether to present the mode of action issue to the SAB, the Agency will consider any relevant scientific data or

¹ 75 Fed. Reg. 9205 (Mar. 1, 2010).



Mr. Anthony F. Maciorowski
March 10, 2010
Page 2

information submitted by the Task Force or its members, or any other person, addressing the issue of whether the state of the science has advanced sufficiently to justify an SAB role in this peer review process, provided that data or information is submitted to EPA sufficiently in advance of the peer review to be scheduled in the first half of 2012.²

The members of OAPTF recognize that this Agreement with OPP does not constrain the ability of EPA to evaluate the same issues as part of the IRIS process, but the provisions of this Agreement clearly establish the vital interest the registrants of MSMA products have in this matter.

As you know, the EPA SAB is an advisory committee chartered under the Federal Advisory Committee Act (FACA). FACA expressly requires that “[i]nterested persons shall be permitted to attend, appear before, or file statements with any advisory committee...”³ While FACA does not establish any mandatory timeframes for advance notice of advisory committee meetings, EPA has adopted a Public Involvement Policy⁴ that clearly addresses this issue. The SAB Staff Office has published a pamphlet in which it cites this policy and affirms that it will work “to meet EPA’s public involvement goals in the management of its advisory committees by providing timely, accessible, and accurate information about meetings and including consideration of public comments in the advisory process.”⁵

² Agreement in Principle to Implement the Organic Arsenicals Reregistration Eligibility Decision (RED) (Jan. 16, 2009) at Paragraph 3, *available at* <http://www.regulations.gov/search/Regs/contentStreamer?objectId=090000648099c82d&disposition=attachment&contentType=pdf>.

³ 5 U.S.C. app. § 10(a)(3).

⁴ EPA, Office of Policy, Economics and Innovation, “Public Involvement Policy of the U.S. Environmental Protection Agency,” EPA 233-B-03-002 (May 2003) (Public Involvement Policy), *available at* <http://www.epa.gov/publicinvolvement/policy2003/finalpolicy.pdf>.

⁵ EPA, SAB Staff Office, “Advisory Committee Meetings and Report Development; Process for Public Involvement,” EPA-SABSO-04-001 (Sept. 2004) at 7 (SAB Process for Public Involvement), *available at* [http://yosemite.epa.gov/sab/SABPRODUCT.NSF/WEBSABSO/part-mtgs-reports/\\$File/sabso_04_001.pdf](http://yosemite.epa.gov/sab/SABPRODUCT.NSF/WEBSABSO/part-mtgs-reports/$File/sabso_04_001.pdf).



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BERGESON & CAMPBELL, P.C.

Mr. Anthony F. Maciorowski
March 10, 2010
Page 3

The notice of the SAB workgroup meeting concerning the Toxicological Review of Inorganic Arsenic was published in the *Federal Register* on March 1, 2010, and the workgroup meeting is currently scheduled to commence on April 6, 2010, which is only 36 days later. This timeframe does not conform to the EPA Public Involvement Policy. Under that policy, the draft document under review is considered a “public outreach” document, and all advisory committee meetings are considered to be “public involvement processes.” The EPA policy states that there should be at least 45 days notice for public hearings, and that “the comment period for public review of unusually complex issues or lengthy documents generally should be no less than 60 days.”⁶

The 575 page IRIS assessment was published in the *Federal Register* on February 19, allowing a comment period of 60 days (until April 20). This indicates to the Task Force that EPA appears to acknowledge that this is a complex issue and a lengthy document. The same notice provides, however, that only comments submitted to EPA by March 26 (within 35 days) are guaranteed to be read by SAB members reviewing the document. The 60-day comment period is, thus, illusory as the real comment period is 35 days.

There is an expectation that EPA may establish a more expedited schedule when an emergency or imminent danger to public health requires it. There is no legitimate basis for emergency action concerning a document that is only one step in an ongoing IRIS process for inorganic arsenic which has already stretched over many years.

The members of the OAPTF have an ongoing interest in EPA’s efforts to evaluate the mode of action for the carcinogenic effects of inorganic arsenic. There is no evidence that the use of registered MSMA products results in any inorganic arsenic exposure through consumption of food or feed, but the EPA OPP has expressed concern about the possibility that MSMA may be transformed to inorganic arsenic by soil bacteria and then enter surface waters that may be consumed by humans. The magnitude of the risk (if any) that could be associated with this potential route of human exposure depends in the turn on the selection of an appropriate dose/response modeling methodology for inorganic arsenic.

The members of the OAPTF are carefully reviewing the document that will be the subject of the workgroup meeting, and have also engaged independent consulting firms to assist them in this task. There can be no reasonable question that this draft is the sort of “complex issue or lengthy document” concerning which it is EPA policy to provide no less than 60 days for review. Moreover, although EPA’s Office of Research and Development (ORD) has

⁶ Public Involvement Policy at 20, 25.



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BERGESON & CAMPBELL, P.C.

Mr. Anthony F. Maciorowski
March 10, 2010
Page 4

identified some specific subject areas concerning which ORD is seeking SAB's advice, the issue of modeling the carcinogenicity slope factor is not identified as a charge to the panel. The Public Involvement Policy mentioned above urges EPA to put specific issues before the committee. Members of the OAPTF urge SAB to conduct a thorough scientific review of the document and believe that SAB should not limit its review to those subjects specifically identified by ORD.

Given the nature of the advisory committee process, it is important for SAB also to allow adequate time for submission of written comments in advance of the workgroup meeting. The SAB Process for Public Involvement states:

It is best to submit written comments in advance of the meeting because those comments will be available to the members before and during deliberations. The earlier comments are received, the more opportunity the members will have to consider them prior to the meeting.⁷

The members of OAPTF would like to submit written comments on the draft document at least two weeks before the meeting.

The accelerated schedule for the workgroup meeting to consider this draft document is not adequate to allow time for proper review of the document and for preparation and submission of written comments in advance of the meeting. The amount of advance notice that SAB has provided for this draft document and the meeting at which it will be discussed does not conform to the established EPA policy concerning review of "public outreach materials" and advance notice for "public involvement processes." Moreover, while EPA policy would permit a more expedited schedule when there is an emergency or an imminent hazard to public health, there is no justification in this instance for SAB to adopt a schedule that severely constrains the ability of interested parties to participate fully in the scientific dialogue.

If SAB intends to afford a meaningful opportunity for public involvement in conformity with the Public Involvement Policy, SAB should allow at least 75 days for review of the draft document and submission of written comments prior to the workgroup meeting. Also, the SAB should be allowed at least two weeks to review comments on such a complicated document. Although SAB has characterized the intended review as "expedited," there is no emergency or other justification for SAB to deviate in such a material manner from the EPA Public Involvement Policy, a policy that it has committed to uphold. The workgroup meeting

⁷ SAB Process for Public Involvement at 7.



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BERGESON & CAMPBELL, P.C.

Mr. Anthony F. Maciorowski
March 10, 2010
Page 5

must be rescheduled to afford interested members of the public at least 75 days for review of this important draft document and for preparation and submission of written comment on the scientific issues it presents.

Sincerely,

Lynn L. Bergeson

cc: The Honorable Paul Anastas, Ph.D. (via e-mail)
Vanessa Vu, Ph.D. (via e-mail)
Steven P. Bradbury, Ph.D. (via e-mail)
Peter W. Preuss, Ph.D. (via e-mail)