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March 27, 2006

Via Hand Delivery

Debra F. Edwards, Ph.D.
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Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall 2, 6th Floor
Room 604
1801 South Bell Street
Arlington, VA 22202

Re: Preliminary Risk Assessment for the Organic Arsenic Herbicides

Dear Debbie:

I write on behalf of the MAA Research Task Force (Task Force) to express the Task Force's urgent concerns with the preliminary risk assessment (preliminary RA) for the organic arsenic herbicides Reregistration Eligibility Decision (RED), recently issued by the United States Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP), and to request an immediate opportunity to meet with you and pertinent others. As discussed below, the preliminary RA is seriously flawed, and falls well short of the legal standard EPA is required to meet under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in assessing risk, and well short of the Information Quality Act (IQA) and the Office of Management and Budget's (OMB) January 2006 draft *Proposed Risk Assessment Bulletin*, in formulating and communicating risk information. Given past practice, the Task Force is concerned that the fundamental and extensive changes that must be made to the preliminary RA to make it scientifically supported, before it is released to the public, cannot possibly be accomplished by April 6, 2006 (the date set forth in EPA's revised RED schedule) and thus, the preliminary RA will be essentially unchanged before it is released to the public.

[redacted]

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As discussed below, the Task Force believes EPA has options in terms of meeting its Food Quality Protection Act (FQPA) deadlines and discharging its legal duty under FIFRA and the Administrative Procedure Act (APA) to prepare RAs based on all relevant, quality data, and without using flawed published data, which result in flawed RAs. If for whatever reason EPA is unable or unwilling to address the issues summarized below and discussed in detail in the comments the Task Force submitted on March 16, 2006, the Task Force will have no choice other than to pursue all available legal options **[**[redacted]**]**

Summarized below are the major science flaws with the preliminary RA, followed by a summary of the legal bases supporting the Task Force's request that the preliminary RA not be publicly released until it is significantly revised and is scientifically supported. The Task Force also suggests that EPA timely publish food tolerances so as not to compromise EPA's statutory obligations, but to defer all other aspects of the RED until the issues discussed herein and in the Task Force's March 16, 2006, comments can be fully addressed.

Major Science Flaws with the Organic Arsenics Risk Assessment

The following are a few examples of major science flaws with the preliminary RA:

EPA Ignored and/or Discounted Relevant Data -- EPA ignored or discounted data from accepted Good Laboratory Practice (GLP) Guideline studies, and relied on data from non-GLP, non-Guideline published studies containing serious flaws and thus scientifically indefensible conclusions for various subjects in the preliminary RA. For example, GLP studies that were submitted by the Task Force indicate that only a small portion of the organic arsenicals, and only in certain conditions, may be transformed to inorganic arsenic. EPA relies on publications, however, concluding that a substantial portion of organic arsenicals would transform to inorganic arsenic in soil, although these very same publications do not contain the data to support these conclusions. The flaws in the non-GLP, non-Guideline publications are described in detail in the Task Force's comments that were submitted on March 16, 2006. These

flaws are serious, and the data themselves are inconsistent with the GLP Guideline studies EPA ignores or discounts, although these studies had been accepted by EPA. Reliance on these specious data renders EPA's conclusions regarding demethylation without scientific foundation. The unfounded assumption that substantial, or even total demethylation of organic arsenicals occurs is a central tenet running through the preliminary RA, and EPA has adopted it for multiple analyses throughout the draft document. This is a fundamental error and must be corrected, but it is not one that is amenable to a quick fix. The entire document requires major revisions to address this error.

After Assuming That All Organic Arsenic Is Transformed to Inorganic, Thus Assuming Levels of Inorganic Arsenic That Are Exaggerated Several-fold, EPA Wrongly Compares Soil Total Arsenic Levels with SSLs -- EPA inappropriately compares its problematic modeled total arsenic levels in soil to Soil Screening Levels (SSL) and Ecological SSLs to imply that there would be a concern in certain circumstances. This comparison is invalid for several reasons. First, SSLs were developed for soils containing *inorganic* arsenic, not predominantly organic arsenicals, as would result from the use of these compounds as herbicides. An SSL based on the toxicity of the organic arsenicals would be many orders of magnitude greater than the SSL based on the toxicity of inorganic arsenic. Second, SSLs define a level below which there is no concern, not above which there is a concern. Third, the arsenic SSL is *lower* than natural background arsenic levels in most U.S. soils, which demonstrates its lack of ability to identify soils of concern and the utter bias the arsenic SSL contains as a risk assessment tool. It cannot lawfully be used as a risk assessment tool because of this embedded bias.

Another example of EPA ignoring or discounting data from accepted GLP Guideline studies in favor of data of poor or unknown quality from the published literature is the incorrect conclusion that MMA is not a metabolite of DMA. This conclusion is totally inexplicable, and plainly contrary to the published literature. As in the previous example, this is a recurrent theme in the preliminary RA and a serious problem that is not amenable to a quick fix.

EPA Ignores Existing Data and Analytical Methods for Speciation of Arsenic in Food, and Unjustifiably Attributes Inorganic Arsenic in Food and in Various Crops to the Use of the Organic Arsenic Herbicides -- EPA does so even when the cited instances of inorganic arsenics in food are completely irrelevant to the use of the organic arsenicals (for example, rice and fish). Methods for speciation of arsenic in cotton were submitted to EPA in 2002 and in 2003, but these are still "under review" according to the preliminary RA. By any reasonable standard, EPA's review of these methods should have concluded years ago. EPA's failure to review and approve these speciation methods cannot now be used to mask poor science

that falsely attributes "total arsenic" to applications of organic arsenical herbicides, regardless of how improbable the result may be.

EPA's PRZM and PRZM/EXAMS Modeling Is Incorrect -- The modeling EPA used to estimate arsenic concentrations in soil and drinking water is incorrect in several respects: (1) the manner that metabolites were modeled is not scientifically sound; (2) the modeling vastly overestimates the fraction of any watershed that would be treated with organic arsenicals; (3) the model used the erroneous assumption that organic arsenicals are always applied using *broadcast* application, when the master labels require *spot* treatment; (4) organic arsenicals' bioaccessibility is incorrectly treated as though it were constant, ignoring the effect of sorption to soil; and (5) transformation of organic arsenicals was modeled using first-order kinetics, although EPA expressly acknowledges that it is not a first-order process. In fact, modeled results are clearly contradicted by actual worst-case monitoring data, as acknowledged by EPA. EPA should use measured data to ground-truth model results, correcting uncertain model parameters so that the results are consistent with, not contradicted by, measured data.

The aggregate result of these problems is that modeled drinking water arsenic concentrations are overestimated at least by an order of magnitude. Because these results were used as the basis of subsequent risk calculations and comparisons to regulatory benchmarks (*e.g.*, Maximum Contaminant Level (MCL), SSL), the preliminary RA is embedded with recurrent and significant errors and require substantial revision to correct the cascade of subsequent errors incurred in the preliminary RA as a result of these modeling errors.

EPA Wrongly Assumed Arsenic in Soil Is Completely Bioavailable -- EPA wrongly, consistently, and inexplicitly assumes in the preliminary RA that 100% of arsenic in soil is bioavailable, despite *overwhelming* scientific evidence and regulatory precedent indicating that the bioavailability is *significantly lower*. The effect of combining the many EPA errors in the selection of data for the assessment of arsenic exposure in soil is a multiplication of the overestimates. For example, combining three of the errors is demonstrated in the following paragraph.

Specifically, EPA overestimates the area treated annually with organic arsenicals by a factor of at least 15 (*i.e.*, at least three applications must be spot treatments, which are likely 1/5th the area treated using broadcast application, at most). The biotransformation of organic arsenicals to inorganic arsenic is overestimated by at least 5 (*i.e.*, EPA assumes 100% transformation when the maximum transformation extent supported in the reliable scientific studies is no more than 20%, or 1/5). The bioavailability is overestimated by at least a factor of 3 as well, which results in a total overestimate of exposure to inorganic arsenic in soil of 225 (*i.e.*, $15 \times 5 \times 3$) just from these three issues.

EPA Wrongly Uses Chronic Effects to Assess Short-term Exposure -- EPA uses chronic effects to assess short-term exposures in several scenarios through the document. For example, EPA's ecological exposure modeling incorrectly assesses chronic effects using the single-day maximum MMA or DMA concentration, and also uses the completely erroneous assumption that organic arsenicals are *always* applied using *broadcast* application, when the master labels require *spot* treatment. Chronic effects are also used for assessing toddlers' risk although EPA defined toddlers' exposure as short-term.

EPA Wrongly Disregards the Turf Transferable Residue (TTR) Study -- In the preliminary RA, EPA uses default values and ignores the TTR study conducted by the Task Force, which has previously been accepted by EPA. The arguments given for ignoring the study are not relevant and all were refuted in the Task Force's March 16, 2006, comments (Comment # 132). The results of this study are directly relevant to the analysis and should be used. The study results materially impact the occupational, residential, and ecological risk assessments and the inclusion of the TTR study favorably impacts the risk analysis.

EPA's Dietary Risk Estimates Are Based on Overly Conservative Assumptions -- This is true for several reasons. First, dietary estimates are based on conversion of methylated arsenic compounds to inorganic arsenic in food. Dietary risk estimates rely on overly conservative assumptions regarding the transformation of organic arsenic to inorganic arsenic. Dietary risk estimates should not be presented until *scientifically* accurate information is available. EPA's analysis of dietary intake of inorganic arsenic derived from demethylation of organic arsenic herbicides is based on a hypothetical screening analysis (*i.e.*, what would the risk be if a certain percent of inorganic arsenic in food was from organic arsenic herbicides). Such a screening analysis may be useful only in demonstrating that a risk is *de minimis.* Should a screening analysis demonstrate risks potentially exceeding a *de minimis* level, then it is essential that further analysis be conducted. In this situation, EPA has not provided evidence from laboratory studies, field studies, or surveys that such a pathway from application of organic arsenic herbicides has even resulted in inorganic arsenic in meat or any food. Based on currently available information, it is reasonable to conclude that the contribution of organic arsenic herbicides to inorganic arsenic in meats, and the diet in general, is likely to be quite minimal. For example, MSMA is commonly used in treating lawns; it is unlikely that residential lawns will be used in growing crops or in raising animals for commercial production. In fact, in 2004 EPA determined that there were "no reasonable expectations of finite residues in or on meat, milk, poultry, or eggs" for cacodylic acid.[1] As another example, rice is one of the foodstuffs containing higher levels of inorganic arsenic. In the United States, rice is cultivated in fields

[1] *See* 69 Fed. Reg. 6561 (Feb.11, 2004).

surrounded by levees or dikes, and, as a result, are flooded with water throughout the growing season.[2] Such areas are unlikely to have also been treated with MSMA. Because of the inadequate foundation for such an analysis, all dietary assessments for inorganic arsenic theoretically derived from organic arsenic demethylation should be removed from the assessment and a more scientifically supported analysis should be conducted.

Second, EPA's use of the cancer slope factor is wrong -- dietary risk estimates rely on overly conservative assumptions regarding the estimate of arsenic's carcinogenic potency (a Q* of 3.36 with linear extrapolation to determine risks). Dietary risk estimates should not be presented until scientifically accurate information is available. The cancer slope factor (*i.e.*, Q* of 3.36) used to make risk determinations is an unpublished, provisional value that has not been accepted by EPA. In fact, the Task Force finds no support or documentation in the preliminary RA or elsewhere regarding an oral Q* for arsenic of 3.36. Moreover, the carcinogenic potency of arsenic, as well as the assumption that inorganic arsenic cancer risk is linear at low doses is currently being re-evaluated by a Science Advisory Board (SAB) Scientists Panel. The Panel has suggested that current estimates of inorganic arsenic carcinogenic potency may significantly overestimate cancer risk. Although an accepted carcinogenic mechanism for inorganic arsenic has not been established, all the proposed carcinogenic mechanisms for arsenic have a nonlinear dose-response. Furthermore, epidemiological evidence confirms that inorganic arsenic-induced cancers are increased only in populations exposed to over 200 μg/L arsenic in drinking water.[3] In light of these findings, the Panel has recommended additional modeling analyses, including evaluation of a sublinear component in the low dose region. Since the carcinogenic potency of arsenic, as well as the low dose linearity assumption, is still under consideration, the evaluation of dietary risks should not be included in the preliminary RA until the SAB's re-evaluation of the carcinogenic potency of arsenic is complete.

These concerns are illustrative of the types of problems with the preliminary RA, and are not an exhaustive summary of the errors and omissions.

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2 *See* http://www.riceland.com/consumers/all_about/; http://www.wholehealthmd.com/refshelf/ foods_view/1,1523,75,00.html.

3 Brown, K (2006). Memorandum to G. Matanoski (EPA SAB Arsenic Review Panel) re: Comments on the EPA SAB Report Regarding Inorganic Arsenic. 6 p.; Lamm, SH, Engel, A, Penn, CA, Chen, R, Feinleib, M. (2006). "Arsenic Cancer Risk Confounder in SW Taiwan Dataset." *Environ. Health Perspect.* (In press); Schoen, A, Beck, B, Sharma, R, Dubé, E. (2004). "Arsenic toxicity at low doses: Epidemiological and mode of action considerations." *Toxicol. Appl. Pharmacol.* 198:253-267.

Legal Deficiencies with the Preliminary RA

As EPA knows well, its regulations implementing FIFRA require that EPA, when considering a registration under FIFRA Section 3(c)(5), "review[] *all relevant data* in the possession of the Agency."[4] As EPA has stated:

> Universally accepted scientific principles require that all relevant information, not an arbitrary selected subset of information, be considered in making risk/benefit decisions. The Agency has consistently adhered to this principle. The Agency rejects any interpretation of the statute that would limit the scope of the information reviewed or compromise the integrity of its scientific decisionmaking process.[5]

For purposes of reregistration, EPA must "conduct a thorough examination of all data submitted under [FIFRA Section 4] concerning [the] active ingredient listed under [FIFRA Section 4(c)(2)] and of all other available data found by [EPA] to be relevant."[6] In the context of this reregistration proceeding, the Registrants have submitted to EPA many studies and data that show clearly and unequivocally that organic arsenicals have modes of action and toxicity profiles that are considerably different than those for inorganic arsenic. The Registrants have also submitted significant data expressly addressing the environmental fate of the organic arsenical herbicides, showing that only under certain conditions, and only to a small extent, these compounds may be transformed to inorganic arsenic. There is no scientific support for EPA using data on inorganic arsenic. EPA thus errs legally and scientifically in ignoring the data on

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4 40 C.F.R. § 152.112(b)(emphasis added); *see also* 21 U.S.C. § 346a(b)(2)(D) (Section 408(b)(2)(D) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by FQPA, the controlling authority for the Risk Assessment regarding dietary exposure, requires that EPA consider, among other relevant factors, "(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue; (ii) the nature of any toxic effect shown to be caused by the pesticide chemical . . . in such studies; [and] (iii) available information concerning the relationship of the results of such studies to human risk").

5 49 Fed. Reg. 30884, 30902 (Aug. 1, 1984).

6 FIFRA § 4(g)(1), 7 U.S.C. § 136a-1(g)(1).

organic arsenicals in favor of a subset of data, in some instances non-GLP, non-Guideline data that address inorganic arsenic, a compound that EPA acknowledges has many differences from organic arsenic compounds. EPA is legally required to use and rely upon the submitted data specific to organic arsenic, which is the active ingredient at issue here, rather than data on inorganic arsenic, data that arguably might be relevant in the absence of the more specific data, but cannot lawfully be used in place of those more specific, scientifically sound, and available data.[7] EPA must correct the preliminary RA and make its risk determinations on organic arsenicals based on the best, most specific, and most relevant data available. Reliance on the toxicity data for inorganic arsenic, which is not the active ingredient at issue, does not pass muster under FIFRA, the FFDCA, the APA, or OMB Guidance.[8]

In the preliminary RA, OPP chooses to evaluate organic arsenicals in terms of "total arsenic" and compares levels estimated in the environment to criteria that were set for inorganic arsenic, arguing that the Office of Water (OW) and the Office of Solid Waste and Emergency Response (OSWER) have existing levels -- an OW-established MCL and OSWER-established SSLs -- for total arsenic (*i.e.*, levels that do not distinguish between organic arsenic and inorganic arsenic). These levels for total arsenic are *not* relevant for OPP's assessment of organic arsenic products, for the reasons stated above given the data specific to organic arsenic products that the Registrants have supplied. Moreover, the OSWER and OW levels for total arsenics were developed by those EPA offices before the large and scientifically irrefutable

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7 *See, e.g., NCAMP v. Thomas*, 809 F.2d 875, 882 (D.C. Cir. 1987) (EPA acted arbitrarily and capriciously under the FFDCA by failing to give appropriate consideration to the relevant factors), *on remand*, 815 F.2d 1579, 1582 (D.C. Cir. 1987) (finding that EPA on remand gave proper attention to the relevant factors); *see also CMA v. EPA*, 28 F.3d 1259, 1265-66 (D.C. Cir. 1994) (EPA's use of a generic air dispersion model was arbitrary and capricious where EPA did not adequately rebut evidence in the record indicating that the substance did not act in the manner the model assumed); *Nat'l Treasury Employees Union v. Horner*, 854 F.2d 490, 498-99 (D.C. Cir. 1988) (agency's failure to "'examine the relevant data'" was arbitrary and capricious (*quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

8 *See, e.g., Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) (an agency decision is arbitrary and capricious where the decision was not based on a consideration of the relevant factors); *Love v. Thomas*, 858 F.2d 1347, 1358-63 (9th Cir. 1988) (EPA suspension decision on dinoseb was arbitrary and capricious because EPA failed to evaluate information in its possession about impacts of the suspension on Pacific Northwest agriculture), *cert. denied sub nom., AFL-CIO v. Love*, 490 U.S. 1035 (1989).

database that OPP now has become available. This database shows, as EPA itself now puts it, that "the target organs and toxicological effects are dissimilar, as well as the magnitude of the toxicity."[9] Rather, EPA promulgated the MCL over five years ago, and published guidance setting forth the generic SSL for arsenic over three years ago.[10] OPP has ignored the new data, inappropriately using MCLs and SSLs that were developed before analytical methods could distinguish between the various forms of arsenic. As noted above, the SSLs are so inherently biased, they cannot lawfully be used for any risk assessment purpose, let alone support a reregistration determination.

It cannot be overemphasized that the scientific understanding of the different forms of arsenic has progressed and is no longer what it was several years ago. In conducting its risk assessment of organic arsenicals, OPP, unlike OW when it was developing the MCL and OSWER when it was developing the SSL, has the benefit of and must, as a matter of law, use this enhanced scientific knowledge. OPP cannot bury its head in the ground or pretend these data do not exist.

For example, the SAB recently agreed that DMA carcinogenicity is not related to inorganic arsenic and should be assessed separately. The science speaks for itself, and as stated earlier, EPA is obligated to consider *all* relevant data in this reregistration proceeding. EPA cannot rely on inorganic arsenic data merely because OW and OSWER established total arsenic levels several years ago in unrelated regulatory contexts, for unrelated other regulatory reasons. At EPA's specific request, the Task Force and its member companies have provided EPA with data specific to organic arsenic, the active ingredient at issue here -- data that were unavailable several years ago and thus call into question the OW and OSWER levels. Under the law, the active ingredient-specific data, not any less specific data on inorganic arsenic, must form the basis for EPA's risk determinations under FIFRA and the FFDCA. The Task Force therefore

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9 EPA, "HED Combined Chapter of the Reregistration Eligibility Decision Document (RED)" at 7-8.

10 *See* 66 Fed. Reg. 6975 (Jan. 22, 2001); EPA, "Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites" (Dec. 2002), available at http://www.epa.gov/superfund/resources/soil/. It is worth noting that the generic arsenic SSL cited by EPA in the preliminary RA, 0.4 ppm, is for a residential scenario, not a commercial/industrial scenario. The generic SSL for a commercial/industrial scenario is either 4 ppm (indoor worker receptor) or 2 ppm (outdoor worker receptor), an order of magnitude higher. *Id.* at A-10, A-13.

strenuously contests the preliminary RA insofar as it ignores sound science and seeks now to draw risk conclusions on the flawed basis of total arsenic.

Indeed, EPA has emphasized on numerous occasions its policy of basing decisions on sound science.[11] In fact, EPA is under a legal obligation to follow its own guidelines and policies and base its decision-making on sound science absent a rational explanation for departure from such precedent.[12]

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[11] *See, e.g.*, EPA, *Guidelines for Carcinogen Risk Assessment*, at 1-7 (Mar. 2005), available at http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=116283 ("[T]hese cancer guidelines adopt a view of default options that is consistent with EPA's mission to protect human health while adhering to the tenets of sound science."); EPA, *General Principles for Performing Aggregate Exposure and Risk Assessments*, at 58 (Nov. 28, 2001), available at http://www.epa.gov/pesticides/trac/science/aggregate.pdf ("Transparency in environmental decision-making, clarity in communication, consistency in core assumptions and science policies from case to case, and reasonableness are important elements of risk characterization"); EPA, U.S. Environmental Protection Agency Fiscal Year 2000 Annual Report (Mar. 2001) at cover letter and Report at II-32 (EPA will use "the best available science in the review of new and existing pesticides" and base its "policies and decisions on sound science and meaningful peer review").

[12] *Western States Petroleum Ass'n v. EPA*, 87 F.3d 280, 284 (9th Cir. 1996) ("EPA 'may not depart, sub silento, from its usual rules of decision to reach a different, unexplained result in a single case.'") (citation omitted); *Northwest Airlines, Inc. v. U.S. Dep't of Transp.*, 15 F.3d 1112, 1121 (D.C. Cir. 1994) ("An agency should not gloss over or swerve away from prior precedent without discussion."); *Japan Air Lines Co., et al. v. Dole*, 801 F.2d 483, 486 (D.C. Cir. 1986), *cert. denied*, 480 U.S. 917 (1987) ("[T]here exists a presumption against unexplained changes in agency interpretations"); *Lucas v. Hodges*, 730 F.2d 1493, 1504 n.20 (D.C. Cir. 1984) ("it is a familiar principle of federal administrative law that agencies may be bound by their own substantive and procedural rules and policies, whether or not published in the Federal Register, if they are intended as mandatory"), *vacated as moot*, 738 F.2d 1392 (D.C. Cir. 1984); *National Conservative Political Action Comm. v. FEC*, 626 F.2d 953, 959 (D.C. Cir. 1980) ("Agencies are under an obligation to follow their own regulations, procedures, and precedents, or provide a rational explanation for their departures."); *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970), *cert. denied*, 403 U.S. 923 (1971) (footnote omitted) ("[A]n agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored, and if an

Since it is a fundamental principle of administrative law that an agency must follow its own precedents, absent a rational explanation for departure from such precedent, EPA must ensure that it comports with the APA and its own policies by basing the preliminary RA on sound science and correcting fundamental errors. Failing in these regards when a highly technical scientific issue is under consideration not only violates EPA's obligations under the APA to follow its own policies, but is also contrary to well-established principles of sound science. Moreover, requirements established by the APA -- including the need to provide adequate opportunity to comment and the need to consider fully all available data, as discussed more fully below -- are all intended to ensure that agencies do not issue flawed documents.[13]

In addition, to issue a risk assessment that contains substantive errors and misleading information would be inconsistent with EPA's guidelines under the IQA, which affirm that "EPA is dedicated to the collection, generation, and dissemination of high quality information."[14] The IQA thus requires that EPA disseminate information that it believes to be accurate, or at the least, avoid disseminating information that it knows to be inaccurate.[15] EPA's

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agency glosses over or swerves from prior precedents without discussion it may cross the line from the tolerably terse to the intolerably mute").

13 5 U.S.C. §§ 551, 553 (setting forth notice and comment framework and procedural conditions).

14 EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency*, at 10 (Oct. 2002), available at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

15 Moreover, Congress enacted the IQA to ensure the consistency and quality of information disseminated by federal agencies. The IQA requires OMB to develop government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." 67 Fed. Reg. 8452 (Feb. 22, 2002). Another integral part of OMB's information quality assurance initiative is its "Final Information Quality Bulletin for Peer Review," which establishes peer review principles for federal agencies government-wide. OMB, "Issuance of OMB's Final Information Quality Bulletin for Peer Review" (Dec. 16, 2004), available at http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf. On January 9, 2006, OMB issued a document entitled "Proposed Risk Assessment Bulletin," which is intended "to enhance the technical quality and objectivity of risk assessments

stated policy regarding "sound science" requires that EPA rely upon the best science studies available and cure the errors related to uncertainty factors, modeling, and dose-response, as well as other errors set forth within this comment document.

Discussed in the Task Force's March 16, 2006, comments are significant critical scientific errors in the preliminary RA based on the review that the Task Force has been able to conduct to date, despite the inadequacies of the comment opportunity EPA has provided. The abbreviated time period given in the error-only phase of the RED process is intended to address modest computational or other simple errors. The errors in the preliminary RA are the result of embedded, fundamental mistakes that require more than the allotted 30 days to expose. As stated, the Task Force intends to supplement its comments once it has had adequate time to review all the documents EPA has provided. The Task Force reserves all rights to do so, and to pursue all available options to protect its interests in this matter.

In this regard, the Task Force wishes to be explicit about its concerns with the release of the preliminary RA without significant revisions, which the Task Force doubts EPA can accomplish in a few short weeks. **[** [redacted]

prepared by federal agencies by establishing uniform, minimum standards." OMB, "Proposed Risk Assessment Bulletin," at 3 (Jan. 9, 2006), available at http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf. Although this is only a proposed Bulletin, EPA should apply the guidelines in it to ensure the quality and objectivity of its risk assessment.

[redacted].

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The Task Force is well aware of the pressure on EPA to meet the FQPA statutory deadline of August 2006 to reevaluate organic arsenical tolerances. As the Task Force has suggested previously, EPA can achieve its deadline and address the serious and fundamental flaws in the preliminary RA by separating out the organic arsenicals tolerances from the other portions of the documents and risk assessments on which EPA is now working. That way, EPA can proceed with what it must do under FQPA, while addressing its statutory obligations to the Registrants to get the preliminary RA correct, and take the time that will be needed to do so properly.

The Task Force believes this is a sensible and realistic way to proceed. If EPA has other options, we would welcome an opportunity to discuss them with EPA. In any event, absent EPA's assurance that the critical flaws in the preliminary RA will be addressed in a way that comports with FIFRA, the APA, the IQA, and sound science as the Task Force suggests, the Task Force will have no option other than to pursue all available legal options **[**[redacted]**]**

Thank you for your consideration. I will call you shortly to discuss this.

Sincerely,

Lynn L. Bergeson

cc: MAA Research Task Force (via e-mail)
Mr. James J. Jones (via hand delivery)
Brenda Mallory, Esquire (via hand delivery)