UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

CRITICAL DEFICIENCY COMMENTS

On

The Tittabawassee River and Floodplain Remedial Investigation Work Plan and Midland Area Soils Remedial Investigation Work Plan Midland, Michigan (December 2005) Submitted to MDEQ by the Dow Chemical Company, Midland, Michigan
(MID 000 724 724)

February 10, 2006

The United States Environmental Protection Agency, Region 5 (EPA) has identified the following critical deficiencies in the Tittabawassee River and Floodplain Remedial Investigation Work Plan (T-RIWP) and the Midland Area Soils Remedial Investigation Work Plan (M-RIWP) submitted by the Dow Chemical Company, Midland, Michigan (Dow) to the Michigan Department of Environmental Quality (MDEQ) on December 29, 2005.

After a preliminary review of the T-RIWP and the M-RIWP (RIWPs), EPA has determined that the RIWPs are critically deficient and must be amended by Dow and resubmitted to MDEQ prior to the initiation of a detailed and complete review of the documents by MDEQ and EPA. Accordingly, EPA believes that MDEQ must require Dow to promptly remedy the deficiencies set forth below and resubmit amended RIWPs to MDEQ by no later than sixty (60) days from the date that Dow is provided written notice of the deficiencies. In addition, EPA requests that MDEQ not approve either RIWP, in full or in part, until the following changes are made by Dow and reviewed and approved by MDEQ.

TITTABAWASSEE RIVER AND FLOODPLAIN REMEDIAL INVESTIGATION WORK PLAN

Tittabawassee River Sediments

1. The sampling protocol set forth in the T-RIWP by Dow to determine the nature and extent of hazardous constituent contamination in the Tittabawassee River (TR) sediments is severely inadequate. Dow's current proposal to use approximately one sample to characterize each mile of river (25 samples per 22 miles of river) is unacceptable. Because EPA believes that Dow's proposal underestimates a technically supportable sampling density by several orders-of-magnitude, EPA requests that MDEQ require Dow to propose a significantly and substantially more intensive and comprehensive sampling program in the T-RIWP in order to adequately and properly characterize the nature and extent of Principal

Contaminants of Interest (PCOIs) within the TR sediments. In addition, Dow's proposal in the T-RIWP to analyze only a surface sediment composite and one randomly-selected underlying sediment composite is not acceptable. Dow's proposed approach will not define the vertical extent of the PCOIs within the TR sediments. As a result, EPA requests that MDEQ require Dow to analyze all of the soft sediment vertical composites for all the PCOIs.

2. Existing data is insufficient to support Dow's conclusion that sediment contaminant concentrations in the TR are random and that no consistently elevated areas of contamination exist within the TR sediments. Dow's proposal of one sediment sampling location per mile is very likely to be orders-of-magnitude greater than the actual distance of spatial correlation. Consequently, analytical results obtained from sampling locations with a separation of one mile would have a strong tendency to exhibit the unpredictability postulated by Dow. Because spatial correlations between sediment samples in the TR sediments no doubt exist, EPA requests that MDEQ require Dow to submit a sampling protocol to properly define empirically, the parallel and perpendicular correlation distances for the PCOIs in the TR sediments.

Tittabawassee River Floodplain

3. EPA does not consider geospatial modeling as an acceptable substitute to an empirical characterization of the nature and extent of contamination. Dow's proposed characterization protocol for the TR floodplain predominantly relying upon geospatial modeling to establish the nature and extent of the PCOIs in flood plain soils, as set forth in the T-RIWP is, therefore, not acceptable. Because the process of determining the nature and extent of the contamination in the TR floodplain must be essentially empirical, as well as technically supportable, EPA recommends that MDEQ require Dow to implement a significantly more comprehensive and intensive sampling program that will establish the nature and extent of the PCOIs within the TR floodplain.

Tittabawassee River Water Column Sampling

4. Dow's proposal for three surface water sample locations in the TR to be sampled during a base flow and flood event is inadequate. EPA requests that MDEQ require Dow to conduct a more frequent and comprehensive water sampling program in order to determine how, and under what conditions, the PCOIs are migrating within the TR watershed. In addition, water sampling locations should be increased to include, at a minimum, one location immediately downstream from an actively eroding source area within or along the TR that is associated with elevated PCOI concentrations. Further, EPA requests that Dow be required to conduct significant additional sampling during high-flow events, since much of the erosional and sediment transport activities occur during these events. All samples should be separated into a dissolved and suspended-solids phases. Each phase should be analyzed for all of the PCOIs.

Acceptable Preliminary Approach for Tittabawassee Rivers Sediments and Floodplain Soil

5. EPA requests that MDEQ require Dow to undertake the following four sequential steps in order to properly characterize the TR and Floodplain: 1) completion of a thorough PCOI study; 2) completion of a thorough geochemical study on all of the identified PCOIs (or all PCOI chemical groupings) of interest; 3) completion of a pilot characterization study to determine horizontal sampling grid interval for both the River sediments and the floodplain soils (recommended vertical compositing intervals are provided below); and 4) completion of a full characterization study including the preparation of depth-based contaminant-concentration contour maps for all identified PCOIs. As all characterization activities tend to be iterative, EPA proposes that an acceptable preliminary (first iteration) approach to characterize the nature and extent of the hazardous constituents in the TR sediments and floodplain soils would include, at a minimum, the following activities:

1 PCOI Investigation

- All documents and information reviewed in creating the Target Analyte List (TAL) proposed by Dow in the TR-RIWP (Figure 4.3) should be included, with cross references to the appropriate sections, in a new appendix to the T-RIWP. It is necessary for MDEQ and EPA to review all such documents and information in order to verify that the conclusions drawn by Dow in formulating the proposed TAL are accurate and appropriate.

- The proposed sediment, floodplain soil and surface water sampling may be adequate for the purposes of a PCOI investigation, however, PCOI sediment sampling frequency should be increased close to the Midland Plant site. This increased sampling density is necessary due to: 1) the additional (beyond dioxins and furans) PCOIs that have been detected in caged fish studies; 2) the known presence of NAPL at or near Dow's facility; and, 3) the fact that there are likely areas on or adjacent to Dow's facility which potentially serve as continuing sources of contaminants. At all sample locations, the sediment and soil samples collected for PCOI analysis should consist: 1) a surface composite extending from the surface to a depth of six inches (0-6 inches); and, 2) composite samples collected over one foot intervals thereafter until unimpacted material is reached. In addition, the PCOI study should include the analysis of groundwater outside the RGIS system, and free-nonaqueous phase liquid samples from the on-site RGIS.

2 Pilot Characterization and Geochemistry Study

- EPA believes that the limited nature of the existing site characterization information currently precludes establishing a statistical basis for the Pilot

Characterization and Geochemical Studies outlined below. These limitations include: the lack of a completed PCOI investigation; the low density of sampling locations; and inconsistencies within Dow's current site conceptual model. While EPA's proposed Pilot Characterization and Geochemistry studies are not statistically-based, all site characterization activities are iterative in nature. The information these studies will provide will form a firm foundation for either a technically defensible statistical analysis on the nature and extent of PCOI contamination, or will form the basis for the collection of additional information needed to meet the RI objectives, including statistical defensibility. In addition, the proposed approach is consistent with long-standing precedents established by EPA approvals of similar site characterization investigations. Sampling for both PCOIs and geochemistry should be performed on transects across the river at a minimum of 1/4 mile intervals (approximately 100 transects). Core soil and sediment sample spacing along each transect should be at one hundred (100) foot intervals. At all sample locations, the sediment and soil samples collected for PCOI analysis should consist: 1) a surface composite extending from the surface to a depth of six inches (0-6 inches); and, 2) composite samples collected over one foot intervals thereafter until unimpacted material is reached. A minimum of three river sediment samples should be collected per transect. The selection of transect locations should be conducted so that the various land uses and geomorphological characteristics of the River are properly represented. Samples to be analyzed for the geochemistry study should be selected to provide a range of characteristics (e.g. grain size, TOC, mineralogy, contaminant concentration, surface coating on mineral grains, etc.) so as to define parameters which control the fate and transport of the PCOIs.

- Additional grid sampling should be conducted at a significantly higher density at the three scoping areas used by Dow during its preremedial investigation scoping studies in 2003, 2004 & 2005. EPA recommends that the sampling locations be gridded on a one hundred (100) foot interval throughout both the floodplain and the River, extending from one side of the one hundred (100) year floodplain to the other. At a minimum, three river sediment samples should be collected per grid transect; e.g. for every one thousand (1,000) feet of river reach, sediments will be collected from at least 30 locations. Grid locations where only surface sampling was conducted, should be resampled with the core sampling methodology described above.

1 Full Characterization Study

- A final sample methodology, reviewed and approved by MDEQ, shall be based upon the results of the Pilot Characterization and Geochemistry study, unless MDEQ determines further data are required to finalize the sampling methodology. As with the preliminary characterization study, and for consistency and comparability, EPA recommends that the

compositing methodology described above be used for the full characterization study.

2 End Products

EPA recommends that, at a minimum, the final work products of the T-RIWP characterization process include the following:

- 90 ppt TEQ boundary line map (vertical and horizontal).
- Depth based concentration contour maps with a 100 ppt TEQ contour line.
  - 0-6 inch surface TEQ concentration contour map.
  - TEQ concentration contour maps for all underlying 1-foot vertical compositing intervals.
- Comparable boundary lines and maps should be produced for all other PCOIs.

MIDLAND AREA SOILS REMEDIAL INVESTIGATION WORK PLAN (M-RIWP)

6. Dow's proposal in the M-RIWP to delay Phase II sampling until 2008 is not acceptable to EPA. Rather, to avoid this unnecessary delay in the remedial investigation and to minimize any ongoing exposure and associated risks, EPA requests that MDEQ require Dow to initiate the Phase II sampling, described within the M-RIWP, no later than Spring of 2006. This recommended change to the M-RIWP would eliminate the need for the duplicative Preliminary PCOI Investigation component of the Midland Area Representative Soils Sampling and Analysis Plan in Support of the Bioavailability Study.

7. While the January 20, 2005 Framework Agreement between Dow and the State of Michigan does not require Dow to conduct additional off-site D/F nature and extent sampling until risk-based site-specific and/or area-wide cleanup criteria (AWCC) have been developed by Dow and a final determination on such criteria has been made by the State, this multi-year process of developing, reviewing and approving these risk-based and/or area-wide criteria will preclude a thorough evaluation of the extent and intensity of the D/F contamination within the City of Midland. Such a delay in not acceptable or appropriate in light of the significant potential risks posed by the known hazardous constituent contamination in the City of Midland. Rather, EPA recommends a substantially more proactive assessment of such risks, i.e. comprehensive characterization of the contamination starting in 2006 and, if necessary, the implementation of prompt remedial measures to address such contamination and reduce the potential for exposure.

8. EPA requests that MDEQ require Dow to include in the M-RIWP's proposed Phase II sampling plan, soil sampling at the Dow Midland facility. The primary purpose of this on-site sampling would be to evaluate the presence or absence of other PCOIs which have been released from the facility. A complete PCOI list is a prerequisite to a full characterization of the nature and extent of both the on-site

and off-site contamination. On-site sampling at Dow's facility is an simple and efficient way to evaluate the presence or absence of PCOIs.

9. EPA recommends that, at a minimum, the final work products of the M-RIWP characterization process include the following:

    - 90 ppt TEQ boundary line map (vertical and horizontal).
    - Depth based concentration contour maps with a 100 ppt TEQ contour line.
        - 0-6 inch surface TEQ concentration contour map.
        - TEQ concentration contour maps for all underlying 1-foot vertical compositing intervals.
    - Comparable boundary lines and maps should be produced for all other PCOIs.

HUMAN HEALTH RISK ASSESSMENT WORK PLANS

The Human Health Risk Assessment Work Plans (HHRAWPs), as proposed by Dow in the RIWPs, do not comply with EPA risk assessment policy and guidance and, therefore, cannot be approved by EPA. As a result, EPA requests that MDEQ require Dow to substantially amend and revise the HHRAWPs prior to the initiation of a detailed and complete review of these work plans in accordance with the comments provided below.

10. EPA requests that MDEQ require Dow to identify in the RIWPs the likely and potential specific pathways of human exposure to PCOIs in the Midland soils and TR soils and sediments. Such exposure pathways will likely include direct contact to PCOIs and indirect exposure to PCOIs after fate and transport processes have occurred, e.g. consumption of contaminated fish and/or wildlife. In addition, Dow must identify appropriate high-end receptor populations, such as subsistence fish and wildlife consumers and native American populations. MDEQ should also require Dow to include these specific exposure pathways and relevant transport processes in each Site Conceptual Model via appropriate tables and diagrams.

11. EPA requests that MDEQ require Dow to describe in specific detail in the RIWPs how the proposed field data collection and field sampling results will be used in the HHRAWPs. Dow should be required to identify the specific data which will be collected and used to support the exposure assessment portion of the HHRAWPs. In addition, Dow should be required to explain how the PCOI concentrations will be incorporated into the HHRAWPs to determine levels of risk and used for comparison to Cleanup Criteria.

12. EPA policy does not allow probabilistic methods to be used for deriving dose-response parameters. Rather EPA policy requires the long-standing and scientifically supportable method of developing chemical-specific toxicity factors (e.g., cancer slope factors, Reference Doses, TEFs, etc.) based on an analysis of the most sensitive endpoints relevant to human exposure. Dow's proposal, in the

HHRAWPs, to use probabilistic methods for deriving dose-response parameters for the PCOIs is unacceptable. In addition, Dow has not identified the criteria by which the dose-response risk-assessment parameters currently in use by EPA and MDEQ will be determined to be "unreliable." Dow implies that the methodology for applying probabilistic risk assessment (PRA) to dose-response data in HHRAWPs would be straightforward, but this is far from the case. For example, Dow does not explain whether the PRA analysis will use human studies in addition to animal bioassay studies. If data from one animal species were to show a clearly defined (and human related) dose-response effect (positive), but the data from another species did not (negative), it is not clear in the HHRAWPs whether Dow would give the data from the positive species more weight than the data from the negative species, in accordance with EPA policy and guidance. The same questions arise in regard to the use of human data versus animal data, i.e. if the human data were to show a clear or suggestive dose-response effect, it is not clear whether Dow would give more weight to the human data over animal data.

In accordance with the comments above, EPA does not believe that Dow has proposed an adequate or widely accepted methodology for constructing Probability Distribution Functions (PDFs) for dose-response data. Because the establishment of dose-response data and toxicity factors for chemicals has national implications, EPA cannot approve requested deviations on a site-specific basis. National standards are based upon scientific consensus and are established by EPA Headquarters in Washington, D.C. Recognition and use of these standards are a necessary prerequisite to national consistency. As a result, EPA, Region 5 cannot approve a PRA which includes probabilistic methods for deriving dose-response parameters. Specifically, OSWER's program guidance on PRAs states:

"This guidance does not develop or evaluate probabilistic approaches for dose-response in human health assessment and, further, discourages undertaking such activities on a site-by-site basis. Such activities require contaminant specific national consensus development and national policy development. Parties wishing to undertake such activities should contact the OERR to explore ways in which they might contribute to a national process for the contaminant of interest to them." (RAGS Volume 3 Part A - "Process For Conducting Probabilistic Risk Assessment"; December 31, 2001).

As a result, inquiries on the use of alternative toxicity factors are typically referred to the appropriate EPA Headquarters program (e.g., OSWER, ORD, OPPT) for a national expert review in which the Region would participate.

EPA conducts independent external peer reviews of the dose-response data evaluations and provides for public comment on the draft evaluations via several forums, e.g., Federal Register notices, technical workshops, FACA committees, draft RED notices, etc. Hence, there is, has been and will continue to be ample opportunity for Dow to participate in these national review processes.

EPA believes that Dow's proposal to generate a complex PRA as a first attempt to determine cleanup criteria, is inappropriate and unnecessary given the limited nature of the characterization data for the soils and sediments within the proposed study areas. Rather, EPA believes Dow should be required by MDEQ to develop a base-line risk evaluation which is simple and deterministic, e.g. similar to a CERCLA point estimate risk assessment. This simplified risk assessment approach would be more than sufficient to derive any supplemental cleanup criteria for exposure pathways and/or land use not currently included in MDEQ Part 201. In addition, such cleanup criteria could be used during RIWP sampling to assist Dow in development of the Data Quality Objectives. Also, this base-line deterministic risk assessment approach is capable of identifying a chemical contaminant(s) which is (are) present in environmental media: 1) at a concentration level exceeding the existing Part 201 Generic Cleanup Criteria; or 2) at a concentration level exceeding the Part 201 residual risk goals, i.e. cancer risk not above 1E-05; toxic hazard not above 1.0 for an exposure pathway that does not have an existing Part 201 Generic Cleanup Criteria. In summary, Dow's PRA should focus only on the contaminant(s) which exceeds Part 201 Generic Cleanup Criteria or the Part 201 residual risk goals.

13. EPA requests that MDEQ require Dow to follow the guidelines and recommendations set forth in the EPA document titled "Risk Assessment Guidance for Superfund: Volume III - Part A, Process for Conducting Probabilistic Risk Assessment" (U.S. EPA, 2001) in amending its revised HHRAWPs. At a minimum, EPA believes that the following concepts should be incorporated into the HHRAWPs:

    - Dow should use a tiered approach to incorporating PRA into the site risk assessment.

    - Dow should perform a point estimate/deterministic risk assessment prior to developing a PRA.

    - After Dow's deterministic assessment is complete, Dow will need to perform a streamlined sensitivity analysis to identify the key parameters whose variability/uncertainty could significantly affect the calculated results of the deterministic assessment. Next, Dow should be required to focus its efforts on using statistical or probabilistic methods to describe quantitative variability/uncertainty only on these key parameters.

    - After Dow's deterministic risk assessment and the streamlined sensitivity analysis are completed, any inferred potential value (benefit(s)) that would accrue to the risk management decision process through generation of a multi-tiered PRA, must be justified. This justification will need to be evaluated by MDEQ and EPA for scientific/technical appropriateness and supportability.

    - It seems neither appropriate or scientifically necessary for every parameter,

e.g., exposure factor, fate-transport factor, chemical-specific constant, etc. in the PRA to be described by a PDF. Some parameters will probably need to be entered as point estimates due to the lack of sufficient quantitative data to generate a valid PDF or because the preliminary sensitivity analysis indicated that certain parameters have a limited variability and therefore ability to affect the calculated risk estimate. As a result, such PDF parameter estimates should only be used with the approval and at the discretion of MDEQ.

COMPREHENSIVE SCHEDULE

14. A single comprehensive schedule is needed for all activities including: all workplan submittals, all field work, all deliverables, human health risk assessment activities and supporting studies, ecological risk assessment activities and supporting studies, and all deliverables. EPA understands that exact dates cannot be stated for all activities, but it is important for MDEQ and EPA to understand the sequencing and interdependencies of the activities to allow for work planning.