Allan Taylor - Draft Notice of Deficiency--Remedial Investigation Work Plans

From: George Bruchmann
To: Ben Baker
Date: 2/10/2006 5:27 PM
Subject: Draft Notice of Deficiency--Remedial Investigation Work Plans
CC: Allan Taylor; Cheryl Howe; Deborah Mackenzie-Taylor; Delores Montgomery; dgustafson@dow.com; Jim Sygo; Liane Shekter Smith; Phillips.Gerald@epamail.epa.gov; rudloff.gregory@epa.gov

Please acknowledge receipt of this e-mail and attachment. If this does not go through, we will upload the attachment to e-project.

Attached are MDEQ "high level" review comments on the TR RIWP and the Midland RIWP submitted by Dow to MDEQ for review and approval. Please note that the MDEQ is in substantial agreement with U.S. EPA's comments of February 10, 2006 (also attached) and that the comments below are intended to supplement the U.S. EPA comments.
These comments are not intended to be all inclusive. These do represent significant deficiencies that must be addressed in order to obtain MDEQ approval and to move forward with a more detailed technical review. As you are aware, we will be receiving public comment and comments from the NRDA Trustees until March 15, 2006. The comments below have benefited from public comment received at the February 9, 2006 Town Hall Meeting.

In order to keep this process moving forward, on February 9, 2006, the MDEQ granted approval with modifications of the Priority 2 Mailing Package and Property Lists. This will allow Dow to begin pursuing property access while completing the necessary modifications to the RIWPs.

MDEQ is continuing its administrative and technical review of the RIWPs. Pending discussion of these comments with you and your consultants on February 14 and 15, 2006 and considering any associated clarification and resolution of the concerns identified in the attached, MDEQ will final our Notice of Deficiency accordingly.
George Bruchmann, Chief
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MDEQ High Level Comments
(Administrative and Technical Deficiencies)

Major Items and Issues for the Tittabawassee River and Midland RIWPs (TR RIWP and Midland RIWP)

1) General. The RIWP must contain a single comprehensive schedule that consolidates the major work activities proposed by the RIWP and associated studies. A single "master" schedule needs to be developed showing the work that is proposed under the RIWP, the Human Health Risk Assessment, the Ecologic Risk Assessments, the Bioavailability Studies, the Midland Bioavailability Study and PCOI Investigation, and any other Study Dow is proposing to conduct or plans to propose during the overall Remedial Investigation process. This is essential to ensure coordinated sequencing of various data gathering and data evaluation to meet identified deadlines in the Framework, the Operating License, the Scope of Work, and within the RIWP itself.

2) General. In addition to lacking detail on the overall RI process, the new schedule proposed in the RIWP is not consistent with the schedule in the approved Scope of Work for the Tittabawassee River. In particular it was noted that the Phase I RI Report is scheduled for submission by Dow in April of 2007. The approved SOW indicates the Phase I RI report is to be submitted in September of 2006. This proposed schedule will make it difficult or impossible to conduct "Phase II" work during the 2007 field season – effectively postponing Phase II work until 2008. Note also that the Phase I report does not propose key exposure pathway investigation work, which had been specifically identified to Dow by the DEQ back in September, October and December 2005 during the Exposure Work Group meetings.

The approved SOW requires this information to be collected during the first phase of the RIWP as this information is necessary to develop cleanup criteria. Without adhering to the SOW schedule, this information would not be collected under Dow RIWP schedule until 2007 or 2008. This is a significant schedule deviation from the approved SOW which requires a formal request for modification with adequate justification for the revision. At this time the MDEQ does not see the value of reprioritizing the collection of this information – as shown by the four previous written communications to you on this 'data inclusion issue' from the DEQ.

3) The RIWP Conceptual Site Model or Current Conditions report does not address or list the specific exposure pathways that are currently known to be present or identify other exposure pathways that may be present and require investigation. The approved Scope of Work and the operating license requires Dow in the initial phase of the RI to "To identify and collect exposure data to

support the Human Health Risk Assessment." It is not clear in the RIWP what data Dow will propose to collect to support the HHRA or the time frame on which the data will be collected. Again, a master schedule with milestones for all of the work to be used in the RI process needs to be provided.

Summary tables developed by the Exposure Work Group (EWP) were not included in the RIWP as committed to by Dow. These tables identified the known relevant exposure pathways and identified data needs to be addressed in the initial phase of the RI. It is not clear why the summary tables were not included as these tables were developed by the work group and conceptually approved by Dow.

4) PCOI Identification. The RIWP does not address comments previously provided to Dow on the PCOI identification process. For example, for the proposed sediment PCOI list, the target analyte list appears to exclude contaminants that were previously detected in caged fish studies conducted adjacent to the Dow facility. In addition, the proposed sediment core sampling density needs to be increased adjacent to the Dow facility in order to more completely evaluate the suspected release area (i.e. tighter PCOI sampling closer to the suspected source area).

5) Soil Sampling. The RIWP proposes the collection of soil samples randomly distributed throughout the Tittabawassee River floodplain for PCOI identification and to provide data to develop a geospatial model to predict the distribution of dioxins and furans in the floodplain. Based on the review of this process we have the following concerns that must be directly addressed:

- The first phase of the RIWP data collection must be focused on the collection of detailed information on the residential properties that are of highest concern – Priority 1 IRA properties and high use areas of Priority 2 properties. These are the areas where greatest exposure to the highest levels of contamination is to be expected. It is also logical and necessary to determine if there are other PCOIs present at levels of concern in these areas. It is also necessary to determine whether any chemical associations exist between any identified PCOIs and/or other physical or chemical properties.

  The MDEQ is not opposed to the concept of developing a geospatial model to predict levels of contamination in appropriate portions of the floodplain. However, it would not be appropriate to use a model to predict concentrations on properties where we have the highest level of concern. In these areas, actual soil concentration data, rather than modeled results, is necessary to ensure adequate protection of human health.

  Therefore, direct investigation of contaminant concentrations must be conducted first on the Priority 1 and high use Priority 2 properties. This

information can then be used with the other sampling that Dow has proposed to construct the model. This work should be integrated with EPA's requirement to sample the floodplain and river on periodic transects (e.g., 1/4 mile transects at intervals of approximately 100 feet as described in EPA's attached comments). The sequence of this type of sampling will also partially satisfy the SOW requirement to collect information to support the HHRA by providing a population of sample concentrations from the areas of highest human exposure concern. This would represent a reasonable high end residential scenario.

We recognize that this will increase the number of samples. However, we remain open to the use of screening technologies, where appropriate, to reduce costs.

- For other proposed random samples, the RIWP must provide information on the targeted locations and land uses so it can be determined if the different land uses (such as residential, agricultural, etc.) are being adequately sampled and to provide a basis for the collection of more detailed information in the future. For example, farm fields with varying levels of contamination need to be identified to focus data collection on the "blowing dust" pathway.

6) Geospatial Modeling. If Dow proposes to conduct geospatial modeling as part of the RIWP, the following information must be directly included in the work plan for review and approval:

- The statistical basis for the sampling grid (the point to area spatial representation) and a clear basis for proposing the sample population(s) for the study areas. Dow needs to show how the proposed grid intervals are appropriate for their intended purposes. Any references and calculations need to be provided in the proposal.

- The processes and equations upon which the model is built. A report documenting the development and application of the model must be presented for review. The report must include all data used in developing and calibrating the model, and the results of all pertinent model simulations. This information needs to be included in text, table and figure format.

- The process by which the model will be calibrated to the n samples. Model calibration consists of changing values of model input parameters, within a reasonable range, in an attempt to match observed concentrations. Calibration simulations are needed to narrow the range of variability in model input data since there may be numerous choices of model input data values which may result in similar model solutions. At a minimum, model calibration must include comparisons between model-simulated conditions and field conditions for the n samples.

- Verification of the model by demonstrating that it also matches existing data. The predictive aspects of the model must then be evaluated to determine if it can accurately estimate the concentrations in areas where there is no data. The DEQ and U.S. EPA will direct the testing of the predictive capabilities of the model by selecting locations to collect new samples and compare the modeled results to the actual concentrations in the soil samples.

7) Sediment Sampling. Dow is proposing to collect 25 sediment samples for PCOI identification (see comments in number 4) and to test their theory that sediment levels of dioxin are "random." The workplan needs to provide detail to describe how the hypothesis of randomness is to be tested and at what scale this hypothesis may apply. A sampling design suitable for estimating a semi variogram at varying scales would be a more appropriate to test for randomness. Specific tests of spatial randomness are readily available. However the spacing of data described in the RI are much too wide to adequately identify the scale of spatial continuity within the river. MDEQ is willing to discuss alternative approaches to determine if there are spatially aggregated deposits of contaminants within depositional zones or if contaminant distributions are truly random. The proposed design is not adequate for these purposes.

As previously communicated to Dow (DEQ comments on Flow and Solids Monitoring Workplan, 2003 and more recently in June and November of 2005), a critical first step in this process is to determine if there are physical or chemical properties in the sediments that are controlling the distribution of dioxins and furans – before designing and implementing a test to assess "randomness."

For comparison purposes, the DEQ's 2002 Sampling Strategies and Statistics Training Materials Document (the S3TM) would indicate a random sampling grid for this long, narrow area would be a 80 to 100 foot grid. This would be the basis for a random grid which would provide the foundation for additional systematic and possibly stratified sampling. Any meaningful random sampling approach, especially over such a large area, would require a much larger sample population than is currently proposed by the RIWP.

8) The RIWP does not address Preliminary Feasibility Study Planning or data needs as required by III.F of the approved SOW and as discussed in Dow's "Performance Based Approach" proposal.

9) The RIWP needs to specifically include mapping and sampling of erosional areas (e.g. cut banks). This is necessary to determine how large a continuing source these features are for remedial planning purposes.

10) The Midland PCOI investigation strategy needs to be reevaluated as indicated by U.S. EPA. In addition, the "blind – blind" strategy proposed continues to be deficient. MDEQ recommends a different approach using a

boxed random sampling along the proposed Phase II transects. Samples from multiple properties within the box would be collected, totally blinded to all parties, and a subset analyzed for the target parameters and/or physical properties. This allows for a general location reference, while protecting the identity of the property. It also provides an immediate mechanism to evaluate the occurrence of a PCOI at a level of concern – the other box samples can be analyzed without "unlocking" the code or remobilizing for sampling. If any PCOI concentrations are of concern, the concern is limited to the geographic area of the "box."

11) DQOs These will need to be revised to reflect required modifications to the RIWPs.

Major Items and Issues for the Human Health Risk Assessment Work Plans (HHRA WP)

1) Review and approval process for components of the HHRA WP. A review and approval process for the individual workplan for each component of the HHRA work plan is necessary. As Dow has proposed in the HHRA WP, several components do not include review and approval process for the work plan for that component. Many of these components merely indicate the work plan will be shared or provided to the DEQ. This is not acceptable. DEQ has already stated that HHRA is not subject to a "results-based" or "performance-based" process. This type of human health risk assessment is not considered appropriate. The proposed approach is also in conflict with the review and approval process in the approved SOWs.

Another example of this problem is in the Introduction of the HHRA WP in the Midland RIWP. In item number 5. the Operating License language is misquoted. Section XI 3B(3)(iv) of the operating license language requires proposal of steps (work plan) for the development of site specific criteria. Dow proposed HHRA states that license allows them to propose an SSCC.

2) Preliminary Conceptual Site Model (PCSM) The PSCM must describe known and expected human and ecological exposure pathways for each land use including transport mechanisms or migration routes known or expected to occur between environmental media (e.g., soil and sediment) and receptor populations. Neither the RI WP PCSM nor the HHRA WP include this information. A conceptual site model is "a three-dimensional "picture" of site conditions that illustrates contaminant distributions, release mechanisms, exposure pathways and migration routes, and potential receptors." *Ref. EPA SSL Guidance User's Guide*

3) Identification of Exposure Pathways The approved Scopes of Work (SOWs) state that "The RI Work Plan will include identification of potential exposure pathways for each relevant land use," and "The RIWP will propose

potential Tittabawassee floodplain exposure pathways that will need to be fully addressed in the RI. All exposure pathways evaluated will be identified and the rationale for inclusion or exclusion in the final human health risk assessment will be provided." However, the proposed RI WPs or proposed HHRA Work Plan appendices do not identify specific exposure pathways and media by land use to be evaluated. Exposure pathways identified with previously concurrence with MDEQ, MDCH, MDA, and EPA Region 5 for dioxins and furans through the Exposure Pathways workgroup must be identified for the HHRA WP and PCSM sections of the RIWP. Exposure pathways may be different for other PCOIs. These other pathways will need to be determined after identification of other PCOIs, if present.

4) Exposure Data Collection The SOW states that "the initial phase of the RI is anticipated to include collection of data to… identify and collect exposure data to support the human health risk assessment (HHRA)." The proposed RIWP or HHRA WP does not identify any specific preliminary exposure data needs or specific approaches to evaluate these exposure data needs. Consideration of exposure units and adequate representation of media concentrations for each exposure unit is also necessary for development of sampling plans to collect environmental media concentration data for the HHRA. Collection of data must be initiated to begin addressing known pathways in a prioritized manner.

5) Exposure Inputs to HHRA Equations The HHRA WP states that all inputs to the risk assessment must have probability distributions. This is not an accurate statement according to EPA Probabilistic Risk Assessment (PRA) Guidance or an efficient use of time and/or resources. EPA PRA guidance recommends that PRAs start out with a preliminary evaluation of the sensitivity of each exposure assumption. This sensitivity analysis can be done with distributions if readily available and/or by using high-end, central and low-end tendencies. In this way, the risk assessors can determine the most important inputs for quantifying risk for each pathway. The most sensitive assumptions may be appropriate to spend the time and resources in developing and evaluating representative probability density functions in lieu of point estimates.

The HHRA WP specifically states it will not include background dietary exposures. Dow claims that the HHRA process in practice does not address risks from other sources. There was concurrence in the EPW that this was relevant as part of the exposure necessary to be included for non-cancer risk assessment. Part 201 specifically includes the consideration of non-release sources in evaluation on non-cancer risk. It specifically requires it when "compound and site specific data are available to demonstrate that a different source contribution is appropriate." (MCL 324.20120a(4)) and MAC R 299.5703(d) " "Relative source contribution factor" or "RSC" means that portion of a person's total daily intake of a noncarcinogenic hazardous substance that comes from the medium being addressed by the cleanup criterion." The RSC is included in MAC R 299.5710(3) Equation for noncarcinogens and MAC R

299.5720(1) and (2) Equation for noncarcinogens. The RSC is included to account for other sources of exposure (predominantly considered for dietary exposure).

The HHRA WP does not include breast milk exposure in text or algorithms. This exposure pathway is important for evaluation of the risk posed for developmental effects, which is a sensitive effect of dioxins and furans. Breast milk exposure is likely to be a major component to total exposure for infants and young children, sensitive subpopulations exposure to and non-cancer effects of dioxins and furans.

6) Toxicity values MDEQ concurs with EPA Region 5 comments that Dow's proposed approach for developing probability density functions for toxicity values is not acceptable. Combining of data from multiple studies typically is carefully done using meta analysis, not a Monte Carlo approach, and assuring only studies appropriate for combining in a meta-analysis are used. This proposal is contrary to Part 201 requirements which requires the use of 95% upper bound on cancer risk and based on most sensitive effect. Michigan law, Part 201 (20120a((4)), requires 95% upper bound estimate of cancer risk not "most likely" or maximum likelihood estimate and that criteria must be based on the most sensitive effect. The proposed approach does not comply with these requirements.

7) Toxic Equivalency Factors (TEFs) The MDEQ considers the WHO international consensus TEF values as "best available science" for use in human health risk assessment. The HHRA WP proposes to develop or use toxic equivalency factors (TEFs) and/or relative potency factors (RPFs) different from WHO international expert consensus values. These alternate values would be developed using probability distributions or other separate studies. Dow's justification for proposing this approach cites EPA ecological risk assessment guidance. Citation from draft EPA Eco Risk Guidance document also states "In most cases, it is reasonable to use the TEFs (WHO). They reflect careful scientific judgment following expert review of the existing database. Other RPFs can be derived for a particular species "(consider ecological risk basis of language). It may be appropriate to use a different RPF only if specific to most sensitive endpoint for specific congener, better reflects human toxicity and is incorporated into the additivity requirements of Part 201.

However, the MDEQ will consider updated WHO TEFs, expected to be released soon, with evaluation of new data, including the NTP bioassay for 2,3,4,7,8-pentachlorodibenzofuran, to represent "best available science" .

8) Screening Level Risk Assessment (SLRA) Dow proposes to use SLRA to eliminate exposure pathways that will not exceed Part 201 cleanup criteria and associated requirements. This approach makes sense to the MDEQ, but the SLRA should be moved to the beginning of the process for all PCOIs (see

comment 14a.). However, the proposed approach for conducting the SLRA is unacceptable because it is likely to eliminate exposure pathways and PCOIs that may have representative environmental media concentrations that exceed Part 201 cleanup criteria as described below.

Part 201(20a(4)) requires the use of 95% upper bound on cancer risk and all criteria based on most sensitive effect. Dow's proposal for the SLRA proposes to use maximum likelihood cancer and non-cancer toxicity values. This proposal is contrary to these Part 201 requirements and not an acceptable approach to assure that PCOIs concentrations and exposures will not exceed the requirements of Part 201. Non-cancer distributions are proposed to include multiple endpoints, although it is not clear if these would include both sensitive and insensitive effects. This may not meet the requirements of Part 201 that the most sensitive endpoint be the basis for cleanup criteria and by extension human health risk assessment. In addition, the SLRA, as proposed by Dow, allows use of any values from the distribution, which could include less conservative exposure inputs from the distributions, resulting in underestimating risk and the exceedance of cleanup criteria.

EPA typically uses maximum exposure media concentrations for screening level risk assessments in order to determine the critical exposure pathways and PCOIs. Dow's SLRA proposes using a 95% upper confidence level from environmental media concentrations. This approach could be acceptable if there was representative sampling of each exposure unit available (i.e. each property or MDEQ approved representative subset of properties in the contaminated areas, especially the Priority 1 properties). Without having this data available, using the maximum media concentration ensures that exposure pathways are not eliminated inappropriately. Evaluation of appropriate representative sampling by exposure unit is necessary prior to use in an exposure medium probability distribution or 95% UCL concentration calculation. Sampling to represent exposure units should be done only after the critical exposure pathways and PCOIs are identified. This will ensure data collection is focused on critical exposure pathways to efficiently conserve time and limited resources.

9) Forward-looking Probabilistic Risk Assessment The PRA is titled as population based and individual. However, the content describes a population based approach and states the approach can provide a central tendency and reasonable maximum exposure from the general population distribution and does not include an individual. The algorithms portion of HHRA states will use age adjusted average values as inputs for the equations. This approach does not account for susceptible subpopulations (e.g. fetuses and children when most sensitive noncancer effects are developmental) for noncancer endpoints. Also, this approach is not likely to adequately account for high-end exposures (e.g., families using local fish as a major protein source – environmental justice issue).

10) Area Wide Cleanup Criteria (AWCC) and Site Specific Cleanup Criteria (SSCC) Further discussion of the Area Wide Cleanup Criteria concept is necessary. As described in the RIWP, the AWCC appears to conflict with Part 201.

11) Soil and Sediment Concentrations related to food-chain pathways The HHRA WP includes some major category exposure equations, but only for intermediate exposure media (e.g., fish vegetable, meat concentrations). The HHRA WP must include equations for determining critical exposure media concentrations (e.g., soil, sediment) necessary for determining cleanup levels.

12) Identification of other PCOIs Further discussion is necessary on the following items:

a. Proposes to only use generic human benchmark values (clearly site specific pathways and ecological risks are likely to be necessary for this contaminated facility) for analytical methods, detection limits and elimination of analytes.
b. Proposes use of trend analysis and mapping to eliminate analytes as not being related to releases from Dow.
c. Proposes using background threshold values (95% Upper Prediction Limits) for natural and anthropogenic analytes from reference areas to eliminate analytes. This needs to be evaluated with the Part 201 definition of "background."
d. Proposes substituting benchmark risk values with PQLs, not ensuring DQOs for PQLs meet benchmark risk values as technically feasible.
e. Excludes analytes present in fewer than 5% of samples (regardless of concentration in samples that analyte is detected).

13) Citations and/or references need to be included for all applicable Part 201 regulatory requirements or EPA guidance.

14) Sequence of proposed HHRA WP components The sequence of components in the proposed HHRA is not logical and does not follow EPA guidance. It would be best to try to optimize this risk assessment process to address only the most critical pathways, exposure parameters and PCOIs in the time and resource intensive type of approach similar to that proposed in the HHRA WP. This emphasis on the most critical aspects of the risk assessment should allow the risk assessment and the oversight for the risk assessment to proceed more expeditiously.

a. The critical exposure pathways and PCOIs should be determined prior to development of all exposure pathway inputs and toxicity criteria, as proposed in the Dow HHRA WP. Conducting the SLRA

first will allow time and resources to be focused on critical exposure pathways and PCOIs instead of using time and resources on exposure pathways that will not be risk drivers. As mentioned previously, to determine the critical exposure pathways and PCOI, the maximum or otherwise appropriate exposure unit based environmental media concentrations should be evaluated with generic cleanup criteria for the applicable land use. For relevant exposure pathways identified without generic criteria or PCOIs without generic criteria, a Screening Level Risk Assessment (SLRA) should be performed using point estimates for exposure and toxicity inputs. This is necessary to determine exposure pathways and PCOIs that should be subject to further risk assessment. This process needs to be separated as the SLRA can be conducted first for dioxins and furans while Dow begins to identify the PCOIs for risk assessment from sampling in the study areas. The HHRA process for additional PCOIs without generic cleanup criteria can follow this process following collection of data to identify or eliminate additional PCOIs.

b. Once an SLRA is conducted, a sensitivity analysis can be used for the remaining exposure pathways and PCOIs to determine exposure assumptions that are critical and should be the focus for development of probability distributions. It is critical for this to be done early also to determine exposure data that needs to be collected as part of the RI.

c. Further discussion of the sequencing of the rest of the process is necessary.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGIONS 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

REPLY TO THE ATTENTION OF:

CERTIFIED MAIL: 7001 0320 0006 1558 2242
RETURN RECEIPT REQUESTED

DW-8J

Mr. James Sygo
Associate Director
Michigan Department of Environmental Quality
P.O. Box 30241
Lansing, Michigan 48909

Re: *U.S. EPA Comments on the Tittabawassee River and Floodplain Remedial Investigation Work Plan and Midland Area Soils Remedial Investigation Work Plan submitted to the State of Michigan on December 29, 2005 by the Dow Chemical Company, Midland, Michigan*

Dear Jim:

In accordance with EPA's oversight role under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901 et seq., the United States Environmental Protection Agency, Region 5 (EPA or the Agency) has conducted a preliminary review of the Tittabawassee River and Floodplain Remedial Investigation Work Plan (T-RIWP) and the Midland Area Soils Remedial Investigation Work Plan (M-RIWP) submitted to Michigan Department of Environmental Quality (MDEQ) by the Dow Chemical Company, Midland, Michigan (Dow) on December 29, 2005. As detailed in the attached comments, the Agency has determined that the T-RIWP and M-RIWP (RIWPs) are critically deficient.

Prior to the submission of the Agency's comments, EPA and MDEQ staff conferred and agreed that the RIWP deficiencies set forth in EPA's comments need to be addressed by Dow prior to initiation of a more comprehensive review of these documents. Of particular note, Dow's Human Health Risk Assessment Work Plans are fundamentally flawed, and it would not be a wise or efficient use of either agency's resources to attempt to approve them with modifications in their current form. As a result, EPA requests that MDEQ require Dow to promptly address the deficiencies detailed in the attached comments and then require Dow to resubmit amended RIWPs to the State of Michigan no later than sixty (60) days from the date that Dow is provided written notice of the subject deficiencies. EPA also requests that MDEQ not approve either RIWP, in full or in part, until all of the requested changes are made by Dow and such changes have been reviewed and approved by MDEQ.

I want to thank you again for all of the hard work you and your staff have devoted to this matter and MDEQ's continuing efforts to protect human health and the environment throughout the State of Michigan. EPA considers MDEQ to be a valuable partner in protecting the environment and the

Agency will continue to work closely with the State of Michigan in its oversight capacity in order to ensure that Dow timely complies with its RCRA license and all applicable federal laws.

Please contact me at (312) 886-0399 if you have any questions concerning this letter or the attached comments.

Sincerely,

Margaret M. Guerriero, Director
Waste, Pesticides and Toxics Division

cc: George Bruchmann, MDEQ
Frank Ruswick, MDEQ

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:

- **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.

- **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.

- **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.

- **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.