

# Part 201 TAG 2 Meeting 6

## Exposure Pathway Assumptions and Data Sources

Tuesday, August 26 | 9:00 AM–12:00 PM  
Public Sector Consultants

### AGENDA

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- |      |                                                        |            |
|------|--------------------------------------------------------|------------|
| I.   | <b>Proposed Framework for Updating Exposure Values</b> | Group      |
| II.  | <b>Summary Answers to White Paper Questions</b>        | Group      |
| III. | <b>Recommended Values for Tables A and B</b>           | Group      |
| IV.  | <b>CSA Presentation</b>                                | Group      |
| V.   | <b>Timeline</b>                                        | Coscarelli |

# PART 201 Technical Advisory Group 2: *Exposure Pathway Assumptions Meeting 6 Summary*

Tuesday, August 27, 2014 | 9:00 AM–12:00 PM  
Public Sector Consultants, Lansing, Michigan

## Attendees

TAG Members	
Steve Zayko	PM Environmental
Donal Brady	EnviroSolutions
Christine Jones	Barr Engineering
Patricia Koman	University of Michigan
Francis Ramacciotti	ENVIRON Corporation
Kory Groetsch	Department of Community Health
Christine Flaga	Department of Environmental Quality

MDEQ Staff	
Divinia Ries	Department of Environmental Quality
Sue Erickson	Department of Environmental Quality

Project Staff	
Mark Coscarelli	Public Sector Consultants
Jon Beard	Public Sector Consultants

## INTRODUCTION

TAG 2 met on Tuesday, August 27, 2014, at the Public Sector Consultants, Inc. (PSC) office. Mark Coscarelli welcomed the TAG members and presented the final report format.

A member suggested that the idea of an executive summary preceding the body of the report would be helpful and that he supports the PSC format in terms of having the discussion in the body of the report. Mark indicated that the summary can be drawn from the report.

## DECISION-MAKING FRAMEWORK

The revised framework diagrams were sent to all the members prior to the meeting. The group discussed the framework and potential options for identifying and verifying proposed numbers. One of the options offers more flexibility and indicates that although EPA values are good starting point, the use of Michigan-specific information should not be precluded. A member cited that the TAG 1's decision-making framework for toxicity is clear when it comes to the tiered sources and asks the question "Is this the best available information". Another member suggested that the framework should create more defined question that can be answered by a YES or NO. For example, "Is the number relevant? Is the EPA value current or indicative of Michigan condition?"

The member who prepared the draft frameworks noted that the TAG 1 question in Appendix B "Is this the best available information" is similar to the question being asked in the draft TAG 2 framework, i.e. "Does the value meet data quality objectives (DQOs)?" Many of the TAG 2 members agreed to start with

the “EPA value” as the primary source and not specify in the diagram which EPA source would be used. The group could not reach consensus regarding whether the primary source should be RSL only or OSWER source. One member suggested that the group should start with the current MDEQ number. Another emphasized the question: Does it meet the DQOs and can we explain the number? In response to an inquiry regarding what “best available value” means to the stakeholder process, MDEQ representative explained that MDEQ wants the TAG to recommend a process for determining values and if possible recommend specific values (for exposure assumptions) but emphasized that the development of the process is more important.

A member noted that DQOs are relevant and the draft framework is a good starting point; however, he suggested that “reasonable and relevant” considerations should be included. To illustrate this, this member presented an alternative framework diagram. The member noted that this diagram presents questions such as: “Have the EPA numbers been updated?” followed by the question, “Is it relevant to the Part 201?” and then “Are the EPA numbers reflective of Michigan-specific conditions?” A member inquired about the box “Derive proposal for relevant Part 201 scenario and document” and how it would respond to questions relating to DQOs and note that the RSL as a source is missing in the diagram. The author of diagram 3 responded that RSL is not always correct; hence it was not included. A member suggested that OSWER and RSL should both be considered as primary sources to which another member stated that there is a difference between screening level and criteria in relation to objectives; one difference cited was that the generic cleanup criteria is more site-specific or more state-specific. The Diagram 3 author noted that the step after Tier 1 is more Michigan specific. The TAG reached consensus that the diagram should not include a reference to either OSWER or RSLs.

A member proposed another framework format which presents a decision tree in a yes-no format and incorporates the technical standard document (TSD) process in Diagrams 1 or 2. The diagram starts with EPA exposure values, followed by the question “Michigan-specific number available?”. If yes, MI value is evaluated with questions: 1) Does it meet DQOs? 2) Is it representative? and 3) Is it the best available data?. If no, EPA number is evaluated with similar questions. If EPA or MI value is not available, the next step is “Other sources”. If No value is found, a number is developed using the TSD process suggested in Diagrams 1 or 2. The group agreed that Christine and Kory will develop a revised framework.

In Appendix G (table showing which parameters used upper bound (high-end) or mid-range (mean or 50<sup>th</sup> percentile) values, 2 parameters were added, i.e., dispersion factor and wind speed, which were not present in Tables A and B. Dispersion factor and wind speed are parameters required to develop the soil to ambient air criteria. A member noted that these parameters are fate and transport numbers and not exposure assumptions. A member suggested putting these parameters under “undiscussed points”.

## **DRAFT SUMMARY ANSWER AND RECOMMENDATIONS TO THE WHITE PAPER QUESTIONS**

### ***Question 1: What is the most appropriate receptor to use for residential land use criteria?***

A member indicated she has more comments to provide for this question.

### ***Question 2: Should the age-dependent adjustment factors (ADAFs) recommended by the EPA be used to address early life exposure from mutagenic carcinogens? The ADAFs would be applied to those substances that have been identified by the***

**EPA to be mutagenic carcinogens (approximately 10 substances on the current Part 201 list of hazardous substances and cleanup criteria).**

TAG members said that they would provide additional comments to Mark via email.

**Question 3: What is the most appropriate nonresidential scenario for workers that is indoor, outdoor, or a combination of both?**

A member suggested that for the nonresidential scenario, the CSA/MDEQ consider the issue that the nonresidential DWC brings inconsistency with other DEQ programs.

A member noted that the group appeared to have agreed to present both indoor and outdoor workers scenario, to which a member agreed but the differences should be pointed out. A member noted that a sensitivity analysis prepared by this member showed that there is not much difference between these 2 receptors, to which a member suggested the use of the more protective worker scenario. A member agreed to the suggestion adding that this would be easier to communicate to the public. It was also suggested that data sources for defining the worker, e.g. Department of Labor, should be included in the report.

The group agreed that both worker scenarios will be presented. However, a member dissented noting that his agreement will depend on the values/numbers the DEQ would propose. To this, a member pointed out that the simplistic risk assessment used to derive the generic cleanup criteria requires a level of conservatism since the criteria is generated without considering cumulative risk, pregnant workers, and tracked in soil among others. Another member pointed out that it was thought the group will not talk about cumulative exposures, etc. and that numbers and justification will be presented, to which the member replied that the point was to use the high-end for sensitive parameters.

For nonresidential scenario, it was suggested that options for data sources for developing Michigan-specific exposure frequency be included, e.g. MSU Extension Service frozen soil data, NOAA, etc. The MDEQ representative commented that if the group can't get a consensus on the issue, that it should be parked. The MDEQ clarified that explaining how and why the number was developed is needed but the department needs to be able to explain the number using a layout on how to get to the number.

Relating to this question, a member asked whether a pregnant worker is protected by the current criteria. MDEQ considers known reproductive effects of chemicals to a pregnant worker by adjusting certain assumption in the same way criteria for developmental toxicants are adjusted.

A member indicated that he doesn't agree with the exposure frequency number value, 225 days, in Table A (nonresidential exposure assumptions). A member reiterated the use of the frozen soil data, to which a member objected since it does not represent "reasonable and relevant" conditions, e.g. a worker running out in shorts and short sleeves-shirts when the ground is frozen or covered with snow, and suggested the use of 160 days for exposure frequency instead. Another member pointed out that the group would not get a consensus on this factor because members are looking at it from different points of view. The MDEQ representative noted that this issue goes back to a process (or decision making framework), to which a member indicated that the process and the options could be used to present what the group thinks can provide the best available data.

On Coscarelli's inquiry if the group has consensus on presenting numbers for the exposure factors, several suggestions were offered:

- The numbers, which the group had consensus on, could be presented
- Use the broad framework process to determine values
- Recommend that DEQ or a DEQ-organized smaller work group to discuss the issues on numbers

The MDEQ representative noted that if the group lay-out the process, MDEQ can follow the process, e.g. evaluating an EPA value, to which a member asked whether CSA would consider this and whether this can be a part of the 4-year review.

At the end of the discussions, the group recognized that it had reached consensus on the process to evaluate nonresidential exposure factors but did not reach consensus on all levels. The group agreed to include two alternatives (for each exposure factor where consensus is not reached) for consideration by the CSA. The group agreed that the final report should describe which values the TAG has agreed on and identify those where consensus has not yet been reached and include a justification on why the different perspectives were reached. Don volunteered to work on language for inclusion in the report that would address the group's discussion and include the "protection of public health" and "reasonable and relevant" considerations.

It was suggested that recommendation # 6 for Question 3 should be moved somewhere else in the report.

***Question 8. Should the "algorithms, exposure assumptions" be consistent with or based upon federal (i.e., U.S. EPA) methodology and data? If yes, are there any circumstances under which deviations from the federal methodology and data should be allowed? If no, what methodology and data should be used?***

Suggested revisions of Q.8 and summary answer are:

- Should the "algorithms, exposure assumptions" **be the same as** the EPA methodology and data?
- It depends on the conceptual site models....differently than the **EPA**.
- Remove the first sentence from the summary answer.

A member suggested that the summary answer should include a statement that TAG 2 was asked by CSA not to consider equations. The group agreed that the answer to Question 8 is YES. Chris will provide the language about the equations. Kory and Christene will revise the framework.

***Question 5. What are the appropriate data sources for the estimates for exposure assumptions such as drinking water ingestion rates, soil ingestion rates, body weights for the selected age groups, relative source contribution factors, and other dermal exposure assumptions?***

Suggested changes to the summary and the recommendations are:

- Summary Answer, 2<sup>nd</sup> sentence: As a starting point, the group agreed to recommend "EPA exposure values" in lieu of EPA's OSWER Directive and the EPA RSLs and allow the CSA to discuss the issue and propose a recommendation to the MDEQ.
- Recommendation 1 – The TAG supports recommending EPA values as beginning data sources...
- Recommendation 2 – The first of DQOs will be rewritten by PSC to incorporate comprehensiveness; credibility, and peer-reviewed in the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> DQOs, respectively.

A member suggested that "reasonable and relevant" be included in the summary, to which a member asked where "reasonable and relevant" would fit in the framework because you would have 2 questions, one for reasonable and relevant, and another for DQOs. A member noted that relevant is already included in the "Applicability and Utility" DQO. A member indicated that "reasonable" is considered by site managers. In response to the suggestion to adding the question whether the value is reasonable and relevant, a member indicated that these should be a consideration in the application of the criteria to a site.

**Question 6. What are the appropriate data sources for and estimates of exposure frequency, exposure duration and averaging time?**

The group agreed that this will be placed in the Appendices section. On the first recommendation concerning data source, Chris will provide a brief description of the OSWER and RSL and the difference between these sources. The group has a consensus to use EPA values. A member suggested that the response to Question 5 should be incorporated in the Discussion portion.

**Question 7. Where available, should the department utilize representative data that is Michigan-specific, rather than nationally representative data? If so, which data should be utilized?**

The group agreed to a YES response. The summary answer will be revised to: Yes, data that is representative of Michigan, when available is preferred so long as it meets the DQOs outlined in Question 5. The consideration of Michigan-specific data is included in the draft framework. TAG members suggested that a non-comprehensive list of potential sources of Michigan specific data for consideration could be identified (e.g. weather data, body weight data, etc.).

**Question 9. Based on the identified receptors and routes of exposure, what are reasonable values and data sources to use for the various assumptions? Given the range of exposure assumption values, how should the most appropriate number be selected?**

Two members suggested that the summary answer should be crafted to include RME, i.e. the values (for the various assumptions) satisfy the RME. The Summary Answer will be revised to include the RME, for example: The objective/intent of the update is to have a representative value for a RME that is reached by using a high-end value or an average (central tendency) value, depending on the parameter's sensitivity, uncertainty and variability. Steve and Trish will revise the Summary.

**Question 10. Do probabilistic approaches have a place in the selection of exposure parameters for generic criteria, and if so, what should that role be?**

The Summary Answer will be revised to: Yes, probabilistic approach could be used to validate the combination of selected point estimate exposure factors to ensure that the intake falls between the 90<sup>th</sup> to 98<sup>th</sup> percentile exposures. Steve and Trish will further improve this Summary

A member objected to the summary in relation to the phrase "could be used to either derive individual exposure factors" because the group did not discuss this use and the recommendation was the use of this approach in relation to benchmarking and validating selected set of exposure values.

The group agreed that probabilistic approach could be used as an alternative tool for benchmarking and validation of exposure values. It was also noted that this approach can be used in site-specific assessments and to describe the distribution of the variable, e.g. exposure frequency.

**Question 11. For each pathway calculation recommended, has it been determined to be reasonable and relevant?**

For the recommendation, the group changed “Ontario and region 5” to Great Lakes Region. A member suggested adding EPA as another benchmark.

On the issue of “reasonable and relevant”, a member noted that that group will have to agree to disagree. A member noted that the Framework/approach they have discussed could be used; however, the group does not have time to develop numbers.

**Question 4. In totality, are the pathways, models, and cumulative exposure assumptions reflective of “reasonable and relevant pathways, best science, and realistic conditions?”**

Steve and Trish agreed to write the summary. Coscarreli noted the red lines on this section will be considered by PSC.

**Next Steps**

- PSC will send all TAG 2 members comments provided by Steve, Kory, and Francis
- PSC will send all TAG 2 members the TAG 1 presentation to the CSA
- Kory will redraw the decision framework for a process to develop exposure values including a short accompanying narrative
- Don will develop language regarding a recommendation to the CSA regarding Question 3 and the process to evaluate nonresidential exposure factors and include two options for consideration. The final report will describe which values the TAG has agreed on and identify those where consensus has not yet been reached and include a justification on why the different perspectives were reached
- Steve and Trish will work together to provide revised language regarding use of probabilistic approaches (Question 10)
- Steve and Trish will draft language responding to question 4
- Chris F. will draft language with a basic description of RSLs and OSWER Directive
- **August 28:** Comments from TAG members due to PSC
- **September 4:** PSC provide a revised draft to TAG members
- **September 8:** TAG members provide any final comments on the updated draft
- **September 12:** CSA meeting 9:00am –noon. Kory and Don will present the TAG’s overview and recommendations. All TAG members are encouraged to attend.

The meeting was adjourned at 12:45 p.m.