

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

Tuesday, June 24, 2014 | 9:00 AM–12:30 PM  
Public Sector Consultants, Lansing, Michigan

## Attendees

TAG Members	
Steve Zayko	PM Environmental
Donal Brady	EnviroSolutions
Christene 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	
Sue Erickson	Department of Environmental Quality
Divinia Ries	Department of Environmental Quality

Project Staff	
Mark Coscarelli	Public Sector Consultants
Katie Van Dorn	Public Sector Consultants

## INTRODUCTION

TAG 2 met on Tuesday, June 24, 2014, at the Public Sector Consultants Inc. (PSC) office. Mark Coscarelli welcomed the TAG members and went over the agenda. The group then reviewed the TAG 2 meeting 1 summary, clarified the role of the TAGs, and then began discussing the questions posed in the White Paper.

## REVIEW OF MEETING 1 SUMMARY

The group had several revisions to the first meeting summary of the Technical Advisory Group (TAG) 2. Of most significance, the group requested that the narrative on MDEQ's values for reasonable maximum exposures include a reference to EPA's acceptable range of the 90th to 98th percentile. While they are not recommending that the MDEQ use a probabilistic method at this time, they will continue the conversation on using probabilistic methods (e.g., Monte Carlo).

All recommended changes have been incorporated into TAG 2's first meeting summary. The summary will be shared with the Criteria Stakeholder Advisory group (CSA) after its approval by the TAG.

## CLARIFICATION OF TAG ROLES

The MDEQ clarified TAG's role in the Part 201 update process, noting that if any of the TAGs have recommendations that may impact the current law, those would go to the legal group. There are no

guidelines or parameters outlining what the legal group will cover, as their agenda will be determined by the TAG groups' requests. The legal group has not yet been convened.

The TAGs are asked by the CSA to use the best available science and methods in making recommendations to the CSA on the Part 201 update. If the TAG thinks that the current statute is wrong, it should be noted and sent to the CSA, which will send it to the legal group. The TAG's recommendations should be based on answering the questions the CSA has posed to the group in the related White Paper. Also, it will be most useful to the CSA if recommendations are as specific and actionable as possible.

For added clarification, the MDEQ provided the TAG with technical support documents (TSD) for review and reference. These 2002 documents supersede the 1998 TSDs. Additionally, two draft tables (Table A: December 2013 Nonresidential Exposure Factors used in Part 201 Generic Cleanup Criteria and Table B: December 2013 Residential Exposure Factors used in Part 201 Generic Cleanup Criteria) were shared with the TAG. These tables combine the TSD information, with the exception of soil ingestion, which is not included. However, several TAG members are not familiar with the current statute and administrative rules associated with Part 201. To better assist those without this background, a link directing TAG members to the most relevant sections of the statute and administrative rules will be sent out.

**Next Steps:** A TAG member will send out the Part 201 statute link to all members of the TAG, and will point members to the sections of the law on the risk assessment framework, which are most relevant to this group. All members are asked to review the relevant sections, and to send links to any missed relevant sections.

## **WHITE PAPER QUESTIONS AND DISCUSSION**

TAG members requested that the White Paper questions be renumbered, and discussed varying aspects and concerns of exposure pathway assumptions. Lastly, the group discussed the first question and recommendations for future meetings. Conversation notes are placed below the question it is most closely related to. TAG recommendations and next steps are noted below each question.

The group also discussed necessary edits in the White Paper. It was pointed out that the White Paper did not define how generic criteria are used by MDEQ. An MDEQ manager attending the meeting provided a list of the uses of generic criteria, which included using the generic criteria as screening values. Several additional uses were also mentioned.

### ***White Paper Questions***

To eliminate confusion over which question is being addressed, the renumbered White Paper questions are reposted below for reference. The revised wording of the questions from the first and second meetings are reflected in the questions below.

#### ***Land Uses: Residential and Nonresidential***

1. What is the most appropriate receptor to use for residential land use criteria?
2. Should the age-dependent adjustment factors (ADAFs) recommended by the EPA be used to address early life exposure from mutagenic carcinogens? This TAG asked that TAG 1 identify those substances to which ADAFs should be applied (i.e., should Chrome VI be listed as a mutagenic chemical?).
3. What is the most appropriate nonresidential scenario for workers, that is, indoor, outdoor, or a combination of both?

### *Data Sources/References*

1. 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, chemical-specific dermal absorption factors, and other dermal exposure assumptions?
2. What are the appropriate data sources for and estimates of exposure frequency, exposure duration, and averaging time?
3. Where available, should the department utilize representative data that is Michigan-specific, rather than nationally representative data? If so, which data should be utilized?
4. 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?
5. In totality, are the pathways, models, and cumulative exposure assumptions reflective of “reasonable and relevant pathways, best science, and realistic conditions?”

### *Numeric Values: Exposure Assumptions*

1. Based on the identified receptors and routes of exposure, what are reasonable values and data sources to use for the various assumptions?
2. Given the range of exposure assumption values, how should the most appropriate number be selected?
3. Do probabilistic approaches have a place in the selection of exposure parameters for generic criteria, and if so, what should that role be?
4. For each pathway calculation recommended, has it been determined to be reasonable and relevant?

### **Question 1: Process for Selecting Most Appropriate Receptor**

Currently, the MDEQ uses a drinking water receptor for adults only, and an “adult plus age-adjusted children” receptor for direct soil contact. The age-adjusted categories for children’s direct soil contact, or “age bins,” are birth to six years, and seven to 31 years. The age bin of seven to 31 years, however, is given the same exposure value as the adults. The group raised concerns that unless more ages and developmental stages are considered in exposure equations susceptible and vulnerable populations will not be as protected as they could be. Members had initial discussions about developmental toxicants, and concerns were raised regarding whether a child-plus-adult receptor would be protective of childhood exposures to developmental toxicants.

One suggestion raised was to have four age bins available, with the ages for each respective bin set as birth–6, 7–11, 12–18, and 19–31 years for soil contact and drinking water exposure values. This would not preclude the MDEQ from using a specific receptor, for children or otherwise, to match identified hazards. The group will do more reading on this topic and continue the conversation on age bins at the next TAG meeting. One citation provided to the group to read on this topic is “Identifying Childhood Age Groups for Exposure Assessments and Monitoring” by Michael Firestone, Jacqueline Moya, Elaine Cohen-Hubal, Valerie Zartarian, and Jianping Xue (Risk Analysis 2007). This article is available through the EPA at <http://www.epa.gov/teach/docs/firestone%20etal%202007-age%20grouping.pdf>. If other papers on this topic are available, however, TAG members were encouraged to send them to the rest of the group for further consideration on this topic.

TAG members brought up the lack of population-representative data necessary for many of the input values for different age groups of children. There are currently 26 Part 201 chemicals with toxicity data based on developmental effects that MDEQ identifies with Footnote “DD” in the Criteria Table. The EPA’s Exposure Factor Handbook identifies values such as body weight and skin surface area for different age groups of children. However, soil ingestion rate for different children age groups is not

described in this handbook. A TAG member indicated that, given department resources, it is not possible for the MDEQ to obtain all of the missing information, noting that it may fall to others outside of the department to provide data to the department as it becomes available.

Additionally, the group will continue the conversation on exposure equation recommendations they will send to the CSA. One concern is that if a recommendation is too broad, meaning it includes all chemicals broken into multiple age groups, it will be too difficult to implement, and result in no consideration of additional age-adjusted exposure equations. One idea raised by the TAG would be to focus on the handful of chemicals known as a concern to children at different ages and developmental stages. This must be balanced, however, against the TAG's responsibility to make recommendation based on the best available science. During the discussion, several TAG members noted that some of the possible options that may best fit the technical requirements of the current statutes are not acceptable to the industrial groups who are on the broader steering committee, and that these TAG members would not be able to recommend them. Other TAG members objected to these types of constraints on the technical information that could be recommended.

It was noted that MDEQ does not currently have a consistent or reliable process on how developmental and environmental toxicants are addressed, or how criteria are generated to protect for that sensitivity. Under statute, the MDEQ does have the authority to do this. The group recommends that the MDEQ create this process, and to ask TAG 1 (Chemical-physical Assumptions and Toxicology) to consider age and developmental impacts of chemical toxicology.

**Recommendation 1\*:** The MDEQ should use age-adjusted children (age 0–18) plus adults (over age 18) as the receptor for all residential soil contact (soil ingestion and soil dermal contact.) In keeping with the objective of identifying the exposure to match the most sensitive endpoint, a child-only receptor may be appropriate or a longer exposure may be appropriate, depending on the health endpoint.

**Recommendation 2\*:** The MDEQ should use age-adjusted children (age 0–18) plus adult (over age 18) as the receptor for residential drinking water. EPA's current approach for deriving MCL's uses the adult only receptor. However, at least one member noted that such an approach would deviate from the current approach where the current approach is consistent with EPA's approach in deriving maximum contaminant levels (MCLs) which were developed without considering children's increased exposures.

\*For developmental toxicants, MDEQ should evaluate if the adult plus age-adjusted child receptor is protective of childhood and early life stage exposures to developmental toxicants. For developmental toxicants where the age-adjusted receptor is not protective of childhood and early life stages, MDEQ should adjust the criteria to a concentration that is protective of children and early life stages.

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**Next steps:** TAG members will share any additional citations they have for papers on the most appropriate ages for child receptors. All TAG members will consider the number of age bins to be considered for both residential soil contact and drinking water, and the ages for each age bin. All TAG members will consider the current values for the two age groups in Table B: December 2013 Residential Exposure Factors used in Part 201 Generic Cleanup Criteria.

### **Question 2: Process for Determining ADAFs for Mutagenic Carcinogens**

The TAG received a list of the chemicals with a mutagenic mode of action for carcinogenesis prior to the meeting. TAG members had concerns about the chemicals that are marked as mutagenic carcinogens, but there was not adequate time prior to the meeting to review this list of chemicals and discuss it further. Members asked TAG 1 (Chemical-Physical Parameters and Toxicity Data) to examine the list of mutagenic chemicals and develop criteria for how and why a chemical ends up on this list. A couple TAG members are especially interested in Chromium VI, and determining if it belongs on the list. Let's plan to discuss this topic at the July 7 meeting.

*Next Steps:* PSC will send the EPA guidance and handbook on ADAFs to the TAG group for their review. All members will review the TSD documents available in the DEQ Part 201 share file. PSC will send the list of chemicals with a mutagenic mode of action for carcinogenesis to TAG 1 with a request to review the list, and to develop criteria for how and why chemicals are included on the list.

### ***Question 11: Determining Role of Probabilistic Methods***

The group further discussed using probabilistic methods, and specifically a Monte Carlo simulation, for establishing acceptable exposure parameters. The probabilistic method is seen as potentially useful, because it could guide the department in knowing if the risk assessment's exposure assumptions are too conservative (compounded conservatism) or not conservative enough. Also, a Monte Carlo approach could be one way to get consensus from the TAG members on the values used in the exposure equations.

Given that most members of the TAG are relatively unfamiliar with using the Monte Carlo method in risk assessment for exposure pathways, though, the TAG requested more information on probabilistic methods. The Ohio EPA's document on the development of generic numerical standards and risk assessment procedures was shared prior to the meeting. The Ohio EPA used the Monte Carlo method in determining some, but not all, of the exposure parameters.

Additionally, while the EPA has a guidance document on probabilistic risk assessment, but the MDEQ does not have one at this time. In the past MDEQ has reviewed a draft EPA guidance document on this topic though MDEQ has not used the probabilistic approach before in determining the Part 201 cleanup criteria, though it could be recommended to do so.

The group noted that if they decide not to use a probabilistic method to check the exposure values, they are left with limited options of (1) individually agreeing on the values or (2) benchmarking the values against other states' values. Benchmarking is discussed further in the next question.

*Next Steps:* A TAG members will send published studies on using probabilistic methods, specifically on Monte Carlo simulations. A TAG member will send out the EPA guidance document on using probabilistic methods for risk assessment.

### ***Question 12: Determining Reasonable and Relevant Pathway Calculations***

The group noted that with or without the use of probabilistic methods, the CSA would like to see some benchmarking of values. The benchmarks recommended are those of the other Region 5 states. Although other states (i.e., California) have good science, data, and values that could be used for benchmarking, it is recommended that opening it up to states outside of Region 5 could become too unwieldy. Studies or sources from other states used to determine exposure assumptions however, including those outside of Region 5 (i.e., California), should be sent to MDEQ, and considered.

Consideration should be given to equations and inputs protective, but not excessively so, of susceptible populations, as discussed in the first question. Within the calculations, there several different kinds of uncertainties. For example, the group noted that there is uncertainty in the amount of exposure of a chemical over time, as well as uncertainty in exposure from multiple chemicals at the same time. The group would like to discuss these issues further.

## **NEXT STEPS**

The group requested to push the third TAG meeting back to Monday, July 7, 2014. It will now be from 1:00–4:00 p.m. at the PSC office at 230 N. Washington Square, Lansing, MI. TAG members requested more time to review the materials in preparation for the next meeting. TAG members will send out

supporting citations, documents, and links by Tuesday, July 7, 2014. It may not be possible to review and send out published papers on Monte Carlo simulation by July 7, though.

Additionally, TAG members requested to review the TAG 2 Meeting 2 summary prior to the meeting, and they will send revisions and feedback through e-mail prior to the July 17 meeting.

The CSA will meet on June 25, and should have feedback and clarification for TAG on the questions it has raised so far. In the next TAG meeting, the group will continue to address the questions presented in the Generic Exposure Pathway Assumptions and Data Sources White Paper.

- A TAG member will send out the Part 201 statute link to all members of the TAG, and will point members to the sections of the law on the risk assessment framework, which are most relevant to this group. All members are asked to review the relevant sections, and to send links to any missed relevant sections.
- TAG members will share any additional citations they have for papers on the most appropriate ages for child receptors. All TAG members will consider the number of age bins to be considered for both residential soil contact and drinking water, and the ages for each age bin. All TAG members will consider the current values for the two age groups in Table B: December 2013 Residential Exposure Factors used in Part 201 Generic Cleanup Criteria.
- PSC will send the EPA guidance and handbook on ADAFs to the TAG group for their review. All members will review the TSD documents available in the DEQ Part 201 share file. PSC will send the list of chemicals with a mutagenic mode of action for carcinogenesis to TAG 1 with a request to review the list, and to develop criteria for how and why chemicals are included on the list.
- A TAG member will send published studies on using probabilistic methods, specifically on Monte Carlo simulations. A TAG member will send out the EPA guidance document on using probabilistic methods for risk assessment.