

Michigan Department of Environmental Quality
Response to Recommendations
Criteria Stakeholders Advisory Group Final Report
July 15, 2015

Overview

The Michigan Department of Environmental Quality (MDEQ), Remediation and Redevelopment Division (RRD) has reviewed the Final Report of the Criteria Stakeholders Advisory Group (CSA) prepared by Public Sector Consultants and submitted to the MDEQ. The following review comments are organized as they are presented in the Final Report.

Updating Chemical/Physical Parameters and Toxicity Data
Technical Assistance Group (TAG) 1

CSA Recommendation 1.1

The CSA recommends implementation of the CSA-modified TAG 1 decision frameworks for toxicity values and chemical-physical parameter values.

RRD Alternative Recommendation: The RRD supports this recommendation with respect to the toxicity value component of the recommendation. The RRD recommends that rather than repositioning the phrase “DEQ Value (existing)” from Tier 1 to Tier 4, as proposed by the CSA, that it instead be repositioned to Tier 3 to better conform to the structure of other identified “existing value” references within the decision framework (i.e., Tiers 1-3). Tier 4 identifies the scenario in which a toxicity value does not currently exist and would have to be developed by the MDEQ.

Outcome:

The RRD alternative recommendation was discussed with the CSA members during the April 20, 2015, meeting convened by Director Wyant. See Exhibit 1. Consensus was reached that the RRD alternative recommendation is acceptable and the RRD is proceeding accordingly.

CSA Recommendation 1.2

The CSA recommends that the MDEQ publish the literature reference for each of the toxicity and chemical/physical values used in the development of the Part 201 generic cleanup criteria. The CSA further recommends that the MDEQ identify and publish the measured or modeled origin of each of the chemical/physical value entries.

RRD Response: The RRD supports this recommendation.

CSA Recommendation 1.3

The CSA recommends that the MDEQ provide more opportunity for stakeholders to give feedback on what data and methodology could be considered in selecting parameters or developing toxicity values when the MDEQ determines it is necessary for the agency to develop such values.

RRD Response: The RRD supports this recommendation.

CSA Recommendation 1.4

The CSA recommends that the MDEQ have more flexibility, considering best available science and practices, in the selection of inhalation toxicity values used to develop the Part 201 generic cleanup criteria.

RRD Response: The RRD supports this recommendation.

CSA Recommendation 1.5

The CSA recommends that the MDEQ should adopt the CSA modified chemical-physical value decision framework identified in Exhibit 3 of the CSA Final Report.

RRD Alternative Recommendation:

The RRD noted that the CSA recommendation would prevent the use of more recent and robust data available from other sources, including the United State Environmental Protection Agency (USEPA) EPI Suite tool. The RRD proposed a revision to the decision framework that would allow consideration of a broader range of data sources.

Outcome:

The RRD alternative recommendation was discussed with CSA members during the April 20, 2015 meeting convened by Director Wyant. The CSA members expressed concern about the RRD's alternative. Further discussions with CSA members subsequent to the meeting led to the development of a revised alternative decision framework. See Exhibit 2. This revision has been reviewed by CSA members and they have indicated concurrence. The RRD is proceeding accordingly.

CSA Recommendation 1.6

The CSA recommends that the MDEQ publish chemical information datasheets as a communication tool.

RRD Response: The RRD supports this recommendation.

CSA Recommendation 1.7

The CSA recommends that the tiered approach as recommended by TAG 1 adequately addresses the use of international data sources when North American data sources do not provide adequate information on specific chemicals.

RRD Response: The RRD supports this recommendation in the context of its alternative to Recommendation 1.1.

CSA Recommendation 1.8

The CSA recommends that the MDEQ make use of data sources for toxicity and chemical/physical parameter values that are consistent with the data source characteristics

MDEQ Response to CSA Workgroup Final Report and Recommendations

presented in the final CSA report (i.e., peer-reviewed, subject to notice and comment, derived through relevant and accepted methods, consistency, credible data, regularly maintained, and based on experimental data).

RRD Response: The RRD supports this recommendation.

CSA Recommendation 1.9

The CSA recommends that the MDEQ apply age-dependent adjustment factors to toxicity values for those carcinogenic chemicals identified as mutagenic.

RRD Response: The RRD supports this recommendation.

CSA Recommendation 1.10

The CSA recommends that the MDEQ identify whether a chemical is considered carcinogenic by the USEPA or the International Agency for Research on Cancer (IARC) before developing carcinogenic toxicity values.

RRD Response: The RRD supports this recommendation.

CSA Recommendation 1.11

The CSA recommends that the criteria should be footnoted to denote whether the carcinogenic or non-carcinogenic algorithms are used to calculate the final criteria for a chemical.

RRD Response: The RRD supports this recommendation.

CSA Recommendation 1.12

The CSA recommends that the MDEQ be allowed to deviate from the USEPA methodology where there is appropriate justification to do so and where opportunity for public input and comment on the outcome of the methodology deviation is provided.

RRD Response: The RRD supports this recommendation.

Updating Exposure Pathway Assumptions and Data Sources **Technical Assistance Group (TAG) 2**

CSA Recommendation 2.1

Receptor: Use an age-adjusted child plus adult receptor that, at present, assumes exposure across two age bins, except in the case of developmental toxicants.

RRD Response: The RRD supports this recommendation.

CSA Recommendation 2.2

Use the USEPA information to develop a process to account for those chemicals, or classes of chemicals, that have documented developmental or reproductive effects.

RRD Response: The RRD supports this recommendation with the understanding that it is not intended to limit the RRD's consideration of other credible references as necessary to assure that criteria are protective for the most sensitive adverse effects.

CSA Recommendation 2.3

Use current Part 201 rules (R299.49 (DD)) that allow the agency to regulate developmental and reproductive toxicants to protect sensitive subpopulations from these substances on a chemical-specific basis. For developmental and reproductive toxicants, the MDEQ should evaluate if the age-adjusted child plus adult receptor is protective of childhood and early-life-stage exposures on a chemical-specific basis.

RRD Response: The RRD supports the intent of this recommendation with a correction of the rule reference. R299.34(3) is the rule that gives the department authority to protect for developmental or reproductive effects when they represent the most sensitive endpoint. Implementation of this recommendation assures that the department is developing cleanup criteria that are protective of the most sensitive adverse effects.

(Details: "R299.34(3) The department may calculate generic cleanup criteria for certain hazardous substances using exposure assumptions other than those shown in the algorithms in these rules if either of the following conditions is satisfied:

- (a) A hazardous substance causes an adverse effect in a sensitive subpopulation that is not adequately protected or represented by the generic exposure assumptions.*
- (b) The toxicokinetics of a hazardous substance are not best represented by the average daily dose, when accounting for the most sensitive effect."*

The R299.49(DD) Footnote reads: "Hazardous substance causes developmental effects. Residential direct contact criteria are protective of both prenatal and postnatal exposure. Nonresidential direct contact criteria are protective for a pregnant adult receptor." This is not the rule language that gives the department the authority to protect for developmental or reproductive effects when they represent the most sensitive endpoint.)

CSA Recommendation 2.4

Age-dependent adjustment factors for the chemicals recommended by the USEPA's Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens, March 2005 (and most recent updates) should be used to address early-life exposure from mutagenic carcinogens.

RRD Response: The RRD notes that this recommendation addresses the same concern addressed by CSA recommendation 1.9 above. The RRD supports both recommendations.

CSA Recommendation 2.5

A periodic review of the list of mutagenic chemicals should be included in the criteria update process to ensure that the MDEQ uses updated information, reflecting the best available science and includes additional mutagenic carcinogens as they are identified by the USEPA.

RRD Response: The RRD supports this recommendation, consistent with its responses to CSA Recommendations 1.9 and 2.4.

CSA Recommendation 2.6

The MDEQ should consider the impact of Part 201 generic criteria on other programs such as drinking water programs. For example, the Michigan Safe Drinking Water Act or SDWA (1976 PA 399) does not recognize a distinction between residential and other (i.e., non-residential) drinking water standards. A chemical-specific drinking water standard currently established by the SDWA applies to water for both residential and non-residential use.

RRD Response: The RRD supports this recommendation. The RRD has considered this matter and notes that state and federal drinking water statutes and regulations do not make a distinction between residential/non-residential drinking water standards – drinking water is provided uniform protections regardless of land use. Accordingly, the RRD will monitor the impacts, if any, of parties' use of the non-residential drinking water criteria on public health and environment to determine if further revisions to those criteria are necessary.

CSA Recommendation 2.7

For all updated values, the TAG recommends a process and decision framework for selection of the generic exposure assumptions that is transparent and provides opportunities for meaningful public input.

RRD Response: The RRD supports this recommendation.

CSA Recommendation 2.8

The CSA recommends a process for publicly reviewing and updating the algorithms and exposure parameters for generic cleanup criteria once every three years or less, consistent with the legal requirements for the promulgation of administrative rules and adequate opportunity for public review and Part 201: Updating Michigan's Part 201 Generic Cleanup Criteria 12 comment. The specific alternative processes for updating are outlined in the appended Legal TAG 4 Report.

RRD Response: Since a schedule was contemplated by TAGs 1, 2, and 4, this recommendation is addressed in the RRD's response to the TAG 4 report.

CSA Recommendation 2.9

The CSA supports the use of data sources for the generic exposure assumptions for reasonable and relevant scenarios that best meet the fundamental data source characteristics as follows, herein referred to as Data Quality Objectives (DQOs).

- Relevant and Applicable to Michigan: The extent to which the information is relevant and applicable to Michigan generic criteria development (e.g., representative of Michigan population and conditions, currency of the information, adequacy of the data collection period).
- Clear and Comprehensive: The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations, and analyses employed to generate the information are documented.
- Sound and Credible: The extent to which the scientific and technical procedures, measures, methods, or models employed to generate the information are reasonable for, and consistent with, the intended application, and are regularly maintained, subject to peer review, and the best available science.
- Transparent and Objective: The data are published or publicly available and free from conflicts of interest.
- Certainty: The extent to which the variability and uncertainty (quantitative and qualitative) in the information or the procedures, measures, methods, or models are evaluated and characterized, including peer review and agreement of studies.

RRD Response: The RRD supports this recommendation.

CSA Recommendation 2.10

The CSA recommends evaluating Michigan-specific data, USEPA sources, and other sources against current generic exposure values to select values that best meet the DQOs and are consistent with the decision framework.

RRD Response: The RRD supports this recommendation.

CSA Recommendation 2.11

The CSA recommends using Michigan-specific data to generate values for the exposure parameters when it is available and best meets the DQOs.

RRD Response: The RRD supports this recommendation.

CSA Recommendation 2.12

As a starting point, the CSA recommends the use of the nonresidential exposure values TAG 2 presents in Table A (Appendix B of the TAG 2 report) and the TAG 2 decision framework to select the nonresidential exposure values.

RRD Alternative Recommendation:

The RRD proposes the selection of the outdoor worker as a generic non-residential receptor for the soil direct contact exposure pathway.

Outcome:

The RRD alternative recommendation was discussed with the CSA members during the April 20, 2015, meeting convened by Director Wyant. Consensus was reached that the RRD alternative recommendation is acceptable and the RRD is proceeding accordingly.

CSA Recommendation 2.13 (First Part)

The CSA recommends that the MDEQ include the basis and percentile for each value presented in Tables A and B of the TAG 2 report.

RRD Response: The RRD supports this part of this recommendation.

CSA Recommendation 2.13 (Second Part)

The CSA recommends that the MDEQ continue to evaluate and actively pursue the use of probabilistic approaches to ensure that the combination of exposure factors eventually selected for an exposure scenario represents a reasonable maximum exposure (RME). Specifically, the CSA recommends that prior to seeking public input on any generic residential or non-residential exposure scenario and its corresponding exposure factors, a probabilistic analysis be used to assess the validity of the final combination of selected point-estimate exposure factors, where feasible.

RRD Alternative Recommendation:

While there are potentially significant questions regarding the approach, the RRD supports the performance of a probabilistic risk analysis of the Part 201 generic cleanup criteria, but lacks the resources to undertake that analysis at this time.

Outcome:

The RRD alternative recommendation was discussed with the CSA members during the April 20, 2015, meeting convened by Director Wyant. The CSA members recognized the RRD's resource limitations. The performance of a PRA analysis may be discussed further as part of future criteria update efforts.

CSA Recommendation 2.14

To the extent possible, the CSA recommends that the MDEQ provide a detailed description of each value in a technical support document that includes DQOs, citations, and calculations.

RRD Recommendation: The RRD supports this recommendation.

Updating Part 201 Vapor Intrusion Criteria
Technical Assistance Group (TAG) 3

CSA Recommendation 3.1

The CSA recommends that the MDEQ use a tiered approach as the most appropriate process to investigate whether or not there is a vapor intrusion pathway that poses an unacceptable risk.

RRD Response: The RRD supports the TAG 3 recommendation.

CSA Recommendation 3.2

The CSA accepts and encourages the M

DEQ to adopt the investigative approach detailed in the series of exhibits provided in the TAG 3 report endorsed by all TAG 3 members.

RRD Response: The RRD supports this recommendation. The RRD notes that the third tier of the TAG 3 approach can also provide for site-specific strategies that minimize the need for RRD review and approval.

Part 201 Key Legal Issues for Updating Michigan's Generic Cleanup Criteria
Technical Assistance Group 4

CSA Recommendation 4.1

After CSA review of the TAG 4 Report and considerable discussion by the CSA of the two alternatives outlined, the CSA reached a consensus recommendation that the DEQ should proceed with the update of the Generic Cleanup Criteria under Part 201 following Option 1 by placing the algorithms, inputs, and resulting tables into the rules (including future updates to inputs) pursuant to Part 201 and the Administrative Procedures Act. In addition, the CSA supports the consensus recommendations of TAG 4 with respect to the general principles that should be followed during adoption of the updated cleanup criteria.

The Michigan Environmental Council's (MEC's) representative on the CSA does not support this consensus recommendation and objects to its fairness. At least two other divisions of the DEQ make decisions regarding the "inputs" as they pertain to health impacts outside the rule process. Parties responsible for the cleanup of a contaminated parcel pursuant to MCLA 324.21020b are allowed within a site-specific cleanup to advocate for the change to health impact inputs outside the rule process, but members of the public do not have the ability to do so.

RRD Response: The RRD supports this recommendation.

MDEQ Response to CSA Workgroup Final Report and Recommendations

Exhibit 1 – Alternative Decision Framework – CSA Recommendation 1.1

Alternative Version:

Toxicity Value Decision Framework



* Values may have to be assessed for best available science (see TAG Recommendation 8)

[Discussed during the April 20, 2015 CSA meeting.]

Alternative Approach: Physical-Chemical Value Decision Framework

