STATE OF MICHIGAN
DEPARTMENT OF ENVIRONMENTAL QUALITY
LANSING

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The Michigan Department of Environmental Quality (MDEQ) strives to ensure that the inclusion of differing perspectives are at the forefront of every policy decision we consider. Because Part 201 Cleanup Criteria Rules have not been comprehensively updated since 2002, the MDEQ embarked on a plan to determine the extent to which the rules should be updated.

In 2014, the MDEQ commissioned Public Sector Consultants (PSC) to facilitate a multi-stakeholder review of the Part 201 Cleanup Criteria Rules and to make recommendations for updates to those Rules. That process produced the Criteria Stakeholders Advisory Group (CSA) Final Report that was published in 2014. Since that time, the MDEQ has had further extensive stakeholder engagement. In December 2017, the MDEQ published its third version of the proposed amendments to the Part 201 Cleanup Criteria Rules. At the same time, the MDEQ requested PSC to re-engage the stakeholders from the 2014 CSA Final Report, to give us a further report on the extent to which the proposed Part 201 amendments are consistent with the recommendations contained in the 2014 CSA Final Report.

The enclosed PSC Report, "Michigan's Part 201 Cleanup Criteria Rules: Assessing the Road to Success," is a presentation of opinions from some stakeholders and provides their perspectives on the process. It is not an analysis of the merits of any positions put forth by stakeholders for the proposed Rules.

While the MDEQ sought feedback, which is depicted in this work, we respectfully disagree with some of the conclusions reached in this Report. The MDEQ solicited input related only to the process by which the Rules have been developed and, therefore, the Report does not present any new technical information regarding the development of the proposed Part 201 Cleanup Criteria presented in the Rules. Furthermore, many of the non-technical opinions echoed in this Report have been provided to the MDEQ previously through public meetings and public comment opportunities that are already under review and consideration by the MDEQ.

We look forward to issuing our responsiveness summary to comments provided as well as the resulting Rules package we submit for consideration. In the meantime, we continue to review the extensive public comment on the proposed amendments.

Sincerely,

Joshua Mosher, Assistant Director
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Enclosure

Michigan's Part 201 Cleanup Criteria Rules

Assessing the Road to Success

03.14.18

PSC

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EXECUTIVE SUMMARY

The Michigan Department of Environmental Quality (MDEQ) recently proposed rules that would rewrite the standards used to determine if a property is contaminated, and to what extent it must be cleaned up. The MDEQ hired Public Sector Consultants (PSC) in January 2018 to conduct an expedited review of the proposed rules and assess the assumptions and decision frameworks that create the basis for proposed regulatory standards.

The MDEQ asked PSC to determine whether the proposed rules followed the recommendations in the November 2014 report, *Part 201: Stakeholder Recommendations for Updating Michigan's Generic Cleanup Criteria,* developed through a nine-month process facilitated by PSC. The process also included recommendations from a Criteria Stakeholder Advisory Group (CSA).

Today, in some cases, stakeholders have questioned whether the proposed criteria are consistent with the CSA's final report and best practices and science, and ultimately, whether criteria will lead to the cleanup and redevelopment of contaminated sites.

For this process, PSC was tasked with:

- Assessing the background and recommendations of the CSA report and how they compare to the current proposed rules
- Better understanding the concerns raised by stakeholders through research and analysis and compiling the major concerns into a document accessible to a general audience
- Benchmarking U.S. Environmental Protection Agency (EPA) and other states' best practices
- Developing a set of recommendations for the continuous engagement and improvement of the rules

While a significant amount of work has been completed by MDEQ staff, and consensus has been reached among various stakeholder groups and the MDEQ for many of the current provisions of the proposed cleanup rules, several significant elements of the rules remain under debate, including:

- Stakeholder engagement, or lack thereof, used to develop the proposed rules
- How and when the MDEQ diverts from using the EPA's Integrated Risk Information System (IRIS)
- The process for establishing whether a chemical is a mutagenic carcinogen or a developmental toxicant
- Modeling chronic exposure assumptions to arrive at single-event exposure levels for developmental and reproductive toxicity endpoints
- Vapor intrusion modeling assumptions

A key component of PSC's work was a series of structured interviews, meetings, and discussions with 23 CSA participants and stakeholders (industry representatives, environmental organizations, consultants, and MDEQ staff) to gain a better understanding of their key issues and perspectives to assess the alignment between the proposed rules and the CSA report.

PURPOSE OF GENERIC CLEANUP CRITERIA

Generic cleanup criteria serve a variety of purposes under Part 201, but most importantly, they are designed to provide protection for public health and the environment. Generic cleanup criteria also remain a valuable tool for the property transaction process to assess liability risk related to the potential presence of hazardous substances. Generic criteria, when used alone or in combination with engineering controls, provide an important level of certainty and simplification to the regulatory process for those seeking to return brownfield property to productive use.

The challenge is balancing public health and environmental concerns with the public interest in cost and time-efficient resolution of potential contamination issues at thousands of former commercial and industrial properties in Michigan. If cleanup requirements are unnecessarily restrictive, then the time delays and related investigative costs increase for both the private and public sector. If, on the other hand, criteria for site cleanups are not stringent enough, then residual contaminants left onsite could pose a threat of future injury to public health or natural resources.

It is critical that the generic cleanup criteria be appropriately calibrated to ensure that sites of real concern are identified and addressed, and that sites with minimal potential for public health or environmental harm are not inadvertently brought into the Part 201 process. Incorporating sites into Part 201 with very low or no risk to public health and the environment reduces the public resources needed to address those sites that pose a significant threat, and places Michigan at an economic disadvantage compared to other states using private sector investments for brownfield property redevelopment.

The 2014 CSA recommendations attempted to establish scientifically appropriate protocols and a transparent and robust process to establish the most appropriate chemical/physical and toxicity values, routes of exposure, and exposure assumptions when rules are updated.

BENCHMARKING

Michigan is unique in its approach to managing contaminated properties. Due to differing purposes and regulatory processes, it is difficult to compare Michigan's cleanup standards to those of other states or the EPA. However, this assessment of the processes and resources used by Michigan, the EPA, and other states can provide insight into Michigan's proposed cleanup rules.

Currently, the EPA and other states use conservative standards as an initial screening tool to determine if a site requires additional action. If further actions are necessary, they use site-specific assessments to define the measures needed to ensure protection of public health and the environment. These site-specific cleanup measures may not be as restrictive as the initial screening criteria based on the potential for exposure, but the process can be time intensive and costly for both the regulated industries and government agencies responsible for reviewing site-specific information and developing site-specific cleanup standards. Michigan sought to reduce these costs and accelerate the cleanup process by developing generic cleanup standards that are appropriately protective of human health and the environment without being overly restrictive.

SUMMARY FINDINGS

In preparing this report over a six-week period, PSC staff interviewed and met with nearly two dozen individuals, including MDEQ staff, who participated as members of the CSA and/or the various technical advisory groups (TAGs). PSC received wide-ranging views regarding the MDEQ's proposed rules and how they conform to or are at odds with the 2014 CSA report. In its review, PSC has avoided exchanges with MDEQ staff or stakeholders on what the specific criteria values should be. The firm has, however, requested and reviewed specific examples from the MDEQ and stakeholders that, in their view, demonstrate how the proposed rules have or have not conformed to CSA-recommended processes.

Each of the CSA recommendations are listed and numbered beginning on page 22. When possible, PSC provides assessment of the extent to which the recommendation was implemented or not. This was a challenging task, striving to filter and reconcile differing interpretations of the CSA recommendations from both the stakeholders and the MDEQ in their understanding of the CSA recommendations and how they were implemented. For many of the CSA recommendations, the MDEQ's actions did result in at least partial implementation. In other cases, "full implementation" or "not implemented" are recorded. What is not captured in simply applying an implemented/not implemented approach to this evaluation is the collaborative spirit that the CSA was created to foster, which appears to be missing from the proposed rules. The following summary findings related to collaboration and technical issues are offered:

- It is not clear why a narrow involvement through required public hearings was implemented instead of a more robust stakeholder and collaborative process, recommended to the MDEQ by the CSA. While PSC acknowledges that a small subset of CSA participants was engaged on a limited basis over the last two years, the process did not embrace the collaborative spirit of future updates as contemplated by the CSA members. This may have been due to time and resource constraints placed upon the agency given the significant task at hand. It may also be due to the differing expectations and interpretations of the decision-making frameworks and hierarchies recommended by the CSA. Regardless, the general lack of engagement has resulted in a divisive rule package.
- A close reading of the CSA report does not offer concise directions for the MDEQ to follow in determining toxicity values. The report endorses a tiered decision framework from the chemical-specific toxicity and chemical/physical data (TAG 1) report that also requires the MDEQ to evaluate if the toxicity value provided in a tier is the best available value. During this current assessment, the MDEQ provided a document outlining the process they used to evaluate best available science, but while this document outlines the criteria, it does not provide a hierarchical decision-making or scoring system that gives PSC confidence that it produced the same result for each of the evaluations the department conducted. Without a documented tiered system used for decisions, it is not clear if the value chosen is the best available, or just the most recent study.
- The MDEQ and CSA stakeholders agreed to a modified approach after the CSA report to the physical and chemical toxicity value decision framework, allowing for equal consideration of EPI Suite values against Soil Screening Guidance (SSG). However, PSC's review of the rules demonstrates a preference for the EPI Suite, with very few values coming from the SSG. The MDEQ indicated that this was due to time constraints and the fact that the EPI Suite generally has more robust and updated values. This decision was not communicated before the release of the rule, and subsequent discussions on this issue have not resolved concerns with the deviation from the agreement between the MDEQ and many stakeholders.

- The CSA recommended that age-dependent adjustment factors (ADAFs) should be used with toxicity values for those carcinogens identified as mutagenic by the EPA or any agency/scientific body, as long as they are in accordance with EPA guidelines on identifying mutagenic mode and evaluated by the MDEQ. The MDEQ did implement this recommendation using ADAFs for carcinogens identified as mutagenic by the EPA; however, some stakeholders assert that the MDEQ went beyond the discussions of the CSA and created scenarios for single-event exposures and full-term exposures for noncarcinogenic mutagenic or developmental toxicants. While this topic was discussed at the TAG level, a consensus did not emerge and CSA discussion did not identify a recommended approach. Several stakeholders assert that the MDEQ has proposed cleanup criteria that assume a single-event exposure for all developmental toxicants regardless of whether there are studies available that assess impacts from acute exposure to develop a meaningful risk assessment. These stakeholders believe, as the EPA notes in its guidance, use of chronic-exposure studies to model and develop single-event exposure assumptions is not appropriate.
- The MDEQ provided the Data Quality Objectives (DQO) to Syracuse Research Corporation to use as the basis for updating the data sources to develop exposure assumptions. It is unclear how the DQOs were applied to derive the generic exposure assumptions. The MDEQ did attempt to use Michigan-specific data, but the resulting generic exposure values are not always realistic to specific Michigan conditions.
- The area where the MDEQ appears to have diverged most from the CSA recommendations regarding vapor intrusion is providing opportunities for meaningful stakeholder engagement while the proposed rules were under development. For example, the consensus reached by TAG 3 assumed that vapor intrusion models would assume a depth to groundwater of more than ten feet. The TAG discussed the best approach for assessing risk when depth to groundwater is less than ten feet but could not reach consensus. The TAG then recommended that an additional advisory group be formed to address this scenario (Appendix A of the TAG 3 report). After the CSA issued its report in 2014, the MDEQ developed a tiered approach that followed the spirit of the CSA recommendation but changed the depth to groundwater assumption because new Michigan-specific data embraced by the MDEQ indicates that depth to groundwater in a majority of the state is ten feet or less. Despite the significance of this assumption, an understanding that the Johnson and Ettinger (J&E) model would be the basis of the MDEQ's vapor intrusion model, and acknowledgement from TAG 3 that further stakeholder engagement was warranted for shallow groundwater sites, the MDEQ did not follow this recommendation from the CSA process as the proposed vapor intrusion rules were developed.
- If the MDEQ is to rely upon the most conservative assumptions, the Part 201 generic criteria essentially become the same as screening criteria used by the EPA and most other states, shifting from the original intent of developing generic cleanup criteria.

PROJECT PURPOSE

In January of 2018, the Michigan Department of Environmental Quality contracted with Public Sector Consultants Inc. of Lansing, Michigan to review stakeholder comments and the MDEQ's responses to the November 2017 proposed *Part 201 Generic Cleanup Criteria Rules* as part of the process and within the time frame for public comment.

PSC conducted the following tasks:

Task One: Review of proposed rules compared to CSA recommendations and decision frameworks

PSC first reviewed unresolved issues identified by the MDEQ and gleaned information from the public comment period and stakeholder discussions following release of the proposed rules. PSC then reassessed the processes outlined in the CSA report from 2014 to determine if conformity with the agreed-upon frameworks for setting standards was achieved between the 2017 rules and the 2014 recommendations. Some stakeholders expressed that many of the changes in the proposed rule package were outside of the scope of discussions and agreements that occurred during the CSA process. PSC's current review occurred against the backdrop of the 2014 CSA report to ensure that the decision frameworks outlined therein were followed to the extent practicable.

The review also included structured interviews and discussions with subsets of CSA participants and stakeholders (industry representatives, environmental organizations, consultants, and the MDEQ) to gain a better understanding of their key issues and perspectives with a goal of ensuring alignment between the proposed rules and the CSA report.

Task Two: IRIS process review

PSC also conducted an examination of the Integrated Risk Information System updated and maintained by the EPA. IRIS is an electronic database containing information on human health effects that may result from exposure to various chemicals in the environment. It is a primary platform recommended by the CSA for the MDEQ to use for generating toxicological values in the proposed rules.

Task Three: Benchmarking

PSC compiled relevant information from the EPA and other states to support the recommendations for modifications to the final rules and for future criteria updates.

Task Four: Process development and recommendations comparison

PSC examined the MDEQ's processes used and conducted a comparison summary between the proposed rules and the CSA recommendations, a summary of the IRIS process and its decision-making framework, benchmarking of EPA and other states, and recommendations for resolving key issues in the final rules package.

BACKGROUND

Michigan's industrial history has left a legacy of contamination in soils, groundwater, and river and lake sediments. This heritage affects Michigan's quality of life through impacts on human health, safety, and welfare; property values and redevelopment potential; and impairment of public trust resources, including drinking water and productive land.

Michigan's environmental remediation program[1] (Part 201) regulates most sites of environmental contamination in Michigan. Part 201 is currently administered by the Remediation and Redevelopment Division of the MDEQ, and affects many segments of Michigan's environment and economy, including land use, surface water and groundwater use, fishery health, business, banking, development, and real estate.

Michigan was one of the first states to recognize and address the need for state-funded response to contamination and has realized many successes. The state has provided public funding to address immediate public health, safety, and environmental threats at thousands of sites. State funding has also readied hundreds of sites for redevelopment through grants and loans to local government, and in addition, projects undertaken directly by the MDEQ and the remediation program have been nationally recognized for their innovative features.

Private interests have invested aggressively in redevelopment in Michigan, aided by causation-based liability provisions that are unique among the states as well as by land use-based cleanup options that match cleanup objectives to planned development. Liable parties can avail themselves of a broad range of options to establish compliance with cleanup requirements. The current statutory framework for Part 201 was established in 1995, and the most unique feature of the program at that time was a shift from a strict liability standard to a causation-based liability standard. Under strict liability, there is no requirement to prove fault, negligence, or intention of new site owners—they remain liable for any historical contamination. The causation-based liability scheme and land use-based cleanup requirements are supposed to encourage solutions to historical contamination while protecting human health and natural resources with several incentives for redevelopment and liability protection for new owners from legacy contamination.

Despite those successes, the MDEQ estimates that there are still thousands of contaminated sites in Michigan that have not been adequately addressed. The causation liability scheme for owners and operators has done much to facilitate redevelopment, but it has also complicated efforts to secure prompt and appropriate response actions from liable parties. For example, some properties change hands many times while hazardous substance use continues, making it difficult to establish proofs required to support action against liable owner/operators. Specific affirmative obligations and broad freedom for liable owners/operators to conduct cleanups without state involvement or approval were intended to maximize the rate of cleanups achieved as part of the 1995 amendments to Part 201. The reporting provisions of Part 201 give the MDEQ extremely limited information on which to judge compliance rates for liable parties and their remedial obligations as well as for all owners and operators of contaminated property (for their due care obligations). However, anecdotal observations led the MDEQ to conclude that parties are not addressing conditions for which they are liable in a timely manner. Further, the level of knowledge

[1] Natural Resources and Environmental Protection Act Part 201 Environmental Remediation. (1994). P.A. 451.

about and compliance with the more limited due care obligations, which apply to any person who knows their property is contaminated, also appears to be inadequate.

Part 201 implementation also faces a declining program budget as well as new scientific evidence that supports changes in the consideration of exposure pathways. These changes exacerbate challenges to ensuring timely site cleanup and adequate management of health, safety, and environmental risks. In addition, the flexibility provided by land use-based cleanup categories, including numerous options to control exposures to remaining contamination, has resulted in liable parties pursuing remedial strategies that do not remove contamination sources. It appears that liable parties do not recognize (or are not motivated to consider) that the costs of continued monitoring and maintenance of such controls often exceed the costs of more active contaminant removal in the long term. In addition, leaving contamination onsite undermines the ability of liable parties to achieve closure. The tension between regulatory finality and ongoing risk management obligations is a major issue that delays liable party actions.

OVERVIEW

Over many years, the MDEQ has been in the process of updating Michigan's Part 201 rules for contaminated sites. During this time, the MDEQ has engaged the regulated community in a variety of ways, from the CSA in 2014 to small group and individual stakeholder settings for the past 18 months.

For the 2014 project, the CSA reviewed the existing rules to determine if they should be updated. Several TAGs were also convened to assess and digest the most technical issues for consideration by the CSA. The CSA concluded the criteria should be updated and (1) developed guiding principles to base future criteria updates on; (2) applied those guiding principles in the selection of exposure assumptions used to update the criteria; and (3) provided recommendations for future updates of the toxicological and chemical/physical aspects of the cleanup criteria in Part 201 rules, including decision-making hierarchies to be embraced by the MDEQ. Recognizing that additional work would be necessary, the CSA achieved broad consensus in many areas (e.g., updating toxicity and chemical/physical values, exposure assumptions, and vapor intrusion assumptions).

In addition, the MDEQ director at the time charged the CSA with proposing how and at what frequency the generic cleanup criteria should be updated in the future. He emphasized that the recommendations would only be those of the CSA members, and while the director acknowledged he possessed ultimate responsibility to initiate changes to the cleanup criteria, great weight would be placed on consensus recommendations of the CSA.

Efforts to update the cleanup criteria under Part 201 began in 2010, involving numerous public meetings and stakeholder interactions with the MDEQ. While consensus has been reached among various stakeholder groups and the MDEQ for some of the current provisions of the proposed Part 201 cleanup rules, many significant elements remain under debate, including:

- Stakeholder engagement, or lack thereof, used to develop the current rules package
- How and when the MDEQ diverts from using IRIS
- Establishing what chemicals are mutagenic carcinogens or developmental toxicants
- Modeling chronic exposure assumptions to arrive at acute exposure-level assumptions
- Vapor intrusion modeling assumptions

Understanding the unique approach and background in Michigan's efforts to develop generic cleanup criteria helps to frame the issues.

GENERIC CLEANUP CRITERIA

Generic cleanup criteria were thought to be an answer to delays and high costs incurred by the state and the private sector through the standard site-specific cleanup reviews of potentially contaminated properties. Considerable state resources are needed to review test results and to evaluate proposed remedies at former commercial and industrial properties to prevent injuries to natural resources or threats to public health. The costs are also high for the regulated community to provide site-specific information and to propose actions for state review and approval on a site-by-site basis. All parties agreed that if a set of generic standards could be established for sites across Michigan, then fewer costly site-specific reviews would be needed, and public and private resources could focus on achieving more cleanups and increasing the number of productive reuses of former commercial and industrial sites at an expedited pace and lower cost.

The challenge is balancing public health and environmental concerns with the public interest in cost and time-efficient resolution of potential contamination issues at thousands of former commercial and industrial properties. If cleanup requirements are unnecessarily restrictive, then the time delays and related investigative costs increase for both the private and public sectors. If, on the other hand, criteria for site cleanups are not stringent enough, then residual contaminants left onsite could pose a future threat. One of the guiding principles of the 2014 report unanimously adopted by the CSA highlighted the importance of a balanced approach:

> "The generic cleanup criteria need to be protective of public health and natural resources such that there are no unacceptable exposures to hazardous substances. Generic criteria are to be protective of the most sensitive toxic effect in a given exposure pathway for the hazardous substance in question. It is important to recognize the relative risk of the specific hazardous substance compared to those risks routinely encountered by people."

Assessing technical information on physical and chemical properties, toxicity, and routes of potential exposure, and incorporating the information into models that include various exposure assumptions, is a very complex process. Even a seemingly modest change in any one of these factors can significantly alter the final cleanup criteria number. Unfortunately, the science that provides the foundation for establishing the standards is not perfect and often produces a range of values requiring interpretation. Additionally, research produces new and better scientific information for some chemicals on a frequent basis.

The 2014 CSA report attempted to recommend scientifically defensible protocols and a transparent and robust process to establish the most appropriate chemical/physical and toxicity values, routes of exposure, and exposure assumptions to consider when rules are updated.

FINDINGS

Several events have occurred since the 2014 report's release that have likely contributed to the substantial differences between the MDEQ's proposed rules and what the regulated community and property owner consultants believe was previously agreed upon:

1. - There was a widely held belief by participants at the conclusion of the CSA and TAGs' 2014 processes that the collaborative scientific exchange of ideas would continue prior to preparation of the current rules package. However, following 18 months of no or minimal contact with stakeholders following the 2014 recommendations, the MDEQ proposed the new cleanup rules in fall of 2016. The familiar process of the agency proposing rules, stakeholders commenting, and the agency responding by defending its proposed rules began. It is not clear why a narrow involvement through required public hearings and comment was implemented instead of a more robust stakeholder and collaborative process recommended to the MDEQ by the CSA. While PSC acknowledges that a small subset of CSA participants was engaged on a limited basis over the last two years, the process did not embrace the spirit of future updates as envisioned by CSA members. This limited stakeholder process failed to resolve major concerns and, in some cases, created unintentional misunderstandings between the agency and stakeholders.
2. - The City of Flint's contaminated water supply issues and the subsequent criminal charges against state employees, including individuals in the MDEQ, has influenced how state employees respond to risks associated with their regulatory responsibilities. Some state employees might be expected to become more risk adverse and make more conservative, protective decisions. Others will feel that they need to be more aggressive in protecting public health and the environment since the State, in the view of some, failed to do so during the Flint crisis. Both reactions were noted in discussions with stakeholders and regulators.
3. - Based upon its recommendation that IRIS should be the primary standard, the CSA report envisioned very infrequent use of other sources of information to determine toxicity, carcinogenicity, mutagenicity, or developmental levels of concern. However, the MDEQ's written response to stakeholders on the proposed rules indicates: *"*We cannot simply rely on IRIS, especially when the funding for IRIS evaluations may be limited and reduce the EPA's level of effort on these evaluations.*"* Thus, many chemicals in the proposed cleanup rules have levels not derived using IRIS, some because IRIS numbers had not been determined but many because the IRIS numbers were deemed inadequate by the MDEQ. The methods used to select alternative sources and cleanup criteria as substitutes for IRIS are a major point of dispute under the proposed rules.
4. - MDEQ leadership has gone through a series of changes since 2014. Conversations between the director, deputy directors, and division chiefs with stakeholders have changed in the last four years as new individuals filled these positions, and so have directives, guidance, priorities, and deadlines given to staff responsible for drafting the new rules. These changes exacerbate the very complex task of preparing a comprehensive set of cleanup rules the CSA envisioned in its recommendations, which assumed that many of the revisions would occur in distinct segments over several years rather than all at once in the same rules package.

In preparing this report, PSC staff interviewed 14 members of the CSA and/or the various TAGs over a six-week period. On two occasions, PSC staff also met with nine different MDEQ staff who prepared the proposed rules. Stakeholders aware of PSC's report also offered unsolicited comments and information. PSC has received wide-ranging views of the proposed rules and how the rules conform to or are at odds

with the 2014 CSA recommendations. The firm has avoided exchanges with MDEQ staff or stakeholders on what the criteria numbers should be; however, it has requested from those interviewed specific examples demonstrating how the proposed rules have or have not conformed to the processes adopted by the CSA.

RISK ASSESSMENT AND RISK MANAGEMENT

PSC found in exchanges with some stakeholders that the criteria updating process is further complicated due often to an apparent lack of understanding between risk assessment and risk management. The EPA defines the two as follows: **"**Risk assessments provide information on potential health or ecological risks, and risk management is the action taken based on consideration of that and other information."[2] Risk assessment is a technical/scientific analysis of reasonable bounds for the range of values protecting public health and the environment against harmful future exposures. Risk management is using professional judgement to serve public interest by selecting cleanup values within these bounds to adequately protect public health and the environment and allow cost-effective, timely cleanup and reuse of former commercial and industrial sites.

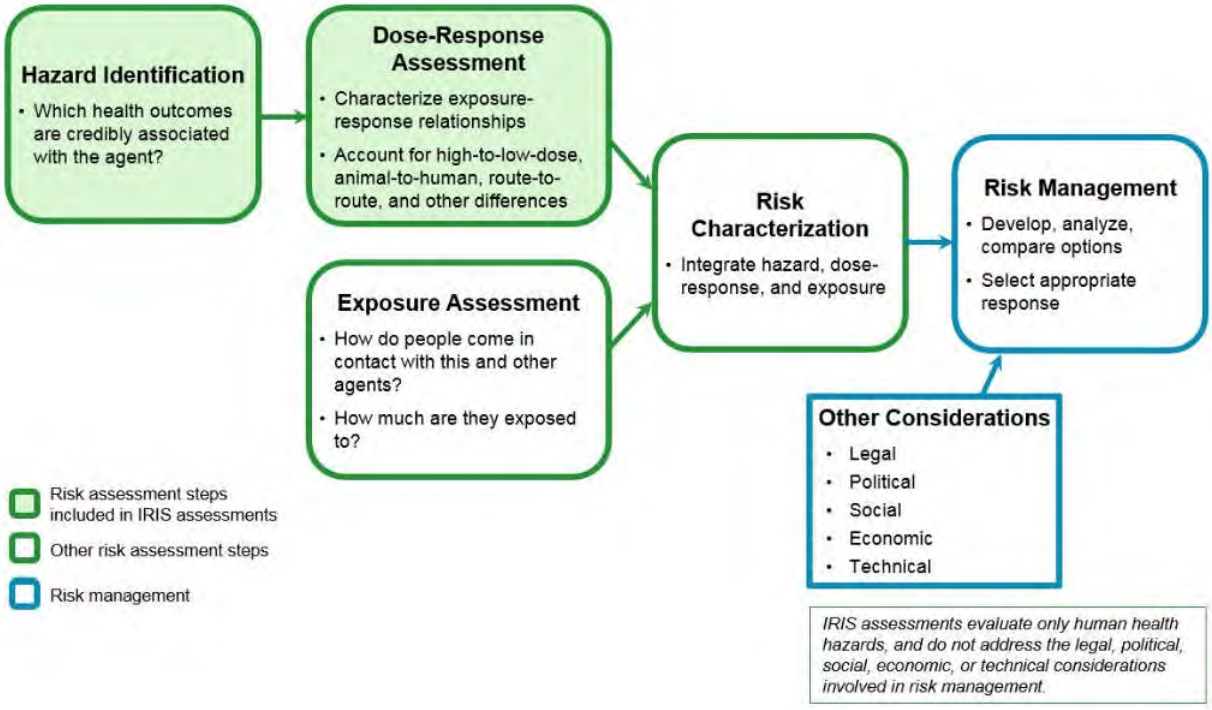
Risk management is not simply the application of site controls to minimize exposures. It includes determination of appropriate cleanup levels while considering other legitimate public values and avoiding unacceptable health and environmental risks by recognizing relative risks of specific chemical exposures compared to those risks routinely encountered in a person's normal activity. The CSA attempted to set guidelines for preparing science-based risk assessments that generate a range of cleanup numbers to help manage risks and avoid unacceptable exposures while still achieving other recognized public values.

The IRIS program and the MDEQ's cleanup criteria identify the expected health hazards associated with exposure to a chemical and at what dose (frequency) they pose a credible health threat. The quantitative relationship between the hazard identification and the dose response determine the toxicity value and the risk assessment. The exposure (identified through an assessment that looks at different pathways and the amount of exposure for each unique scenario) combined with the risk assessment outline the risk management.

The following connections between IRIS assessments, risk assessments, and risk management are important in helping regulators determine how to manage risk. Many times, regulators stop at the risk assessment, not taking other factors into account that lead to successful risk management.

[2] U.S. EPA. May 1, 2017. "Risk Management." *Risk Assessment.* Accessed January 29, 2018. https://www.epa.gov/risk/risk-management

EXHIBIT 1. Connections between IRIS Assessments, Risk Assessment, and Risk Management



THE IRIS PROGRAM

The MDEQ asked PSC to evaluate whether the proposed rules follow the recommendations and spirit of the 2014 CSA report. As part of that review, PSC evaluated EPA's IRIS program to understand the federal government's approach to developing toxicity values and compared that approach to the MDEQ's process for evaluating toxicity.

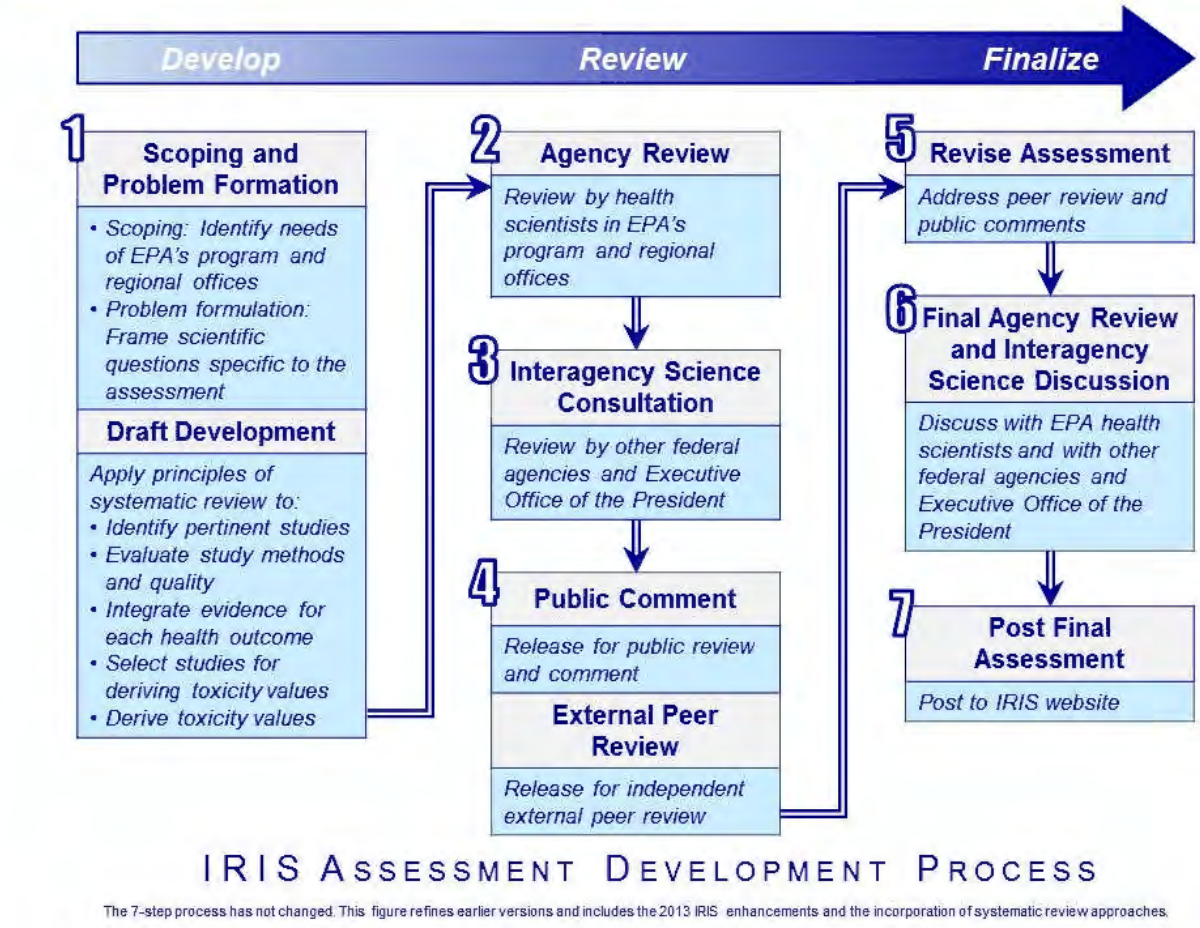
IRIS is a program responsible for developing toxicologic assessments of environmental contaminants. An IRIS assessment identifies health hazards associated with exposure to chemicals and the quantitative risk assessment that involves dose-response assessments of chemicals related to cancer and noncancer outcomes. Assessments are added to IRIS only after a comprehensive review of toxicity data from multiple peer reviewed studies. The IRIS database is the main toxicity database used by the EPA and many other state, local, and tribal governments to determine the toxicity of a broad range of chemicals that may pose health hazards when found in the environment.

An IRIS assessment provides toxicity values for health effects resulting from chronic exposure to chemicals, including a reference concentration[3] and oral noncancer toxicity value, or reference dose. It also includes cancer descriptors that characterize how likely the chemical is to be carcinogenic. The cancer risk from oral exposure and inhalation exposure is also provided from over a lifetime.

[3] U.S. EPA. May 24, 2017. "Basic Information About the Integrated Risk Information System." *IRIS.* Accessed February 14, 2018. https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system

DEVELOPING AN IRIS ASSESSMENT

EXHIBIT 2. IRIS Process Flow Chart



Source: U.S. EPA. September 28, 2016. *IRIS Process Flow Chart.* Accessed February 6, 2018. https://www.epa.gov/sites/production/files/2014-03/documents/iris_process_flow_chart.pdf

The IRIS process consists of seven stages of review.

Stage 1. Scoping, Problem Formation, and Draft Development

In the first stage, the EPA works with their regional offices to identify chemicals that need an updated or new toxicity assessment as well as to define the scope of the assessment, including identifying the most important exposure pathways. In defining the scope, the EPA identifies the scientific and human health issues to be addressed in the problem formulation materials. At this stage, the EPA holds a public meeting and shares scoping materials with the public and scientific community.

For example, in January 2018, the EPA announced new protocols for IRIS chemical reviews, beginning with the Systematic Review Protocol for the IRIS Chloroform Assessment (Inhalation) and the IRIS Assessment Plan (IAP) for uranium. The IAP communicates to the public the plan for assessing each individual chemical and includes summary information on the IRIS program's scoping and initial

problem formulation, objectives and specific aims for the assessment, and the PECO (populations, exposures, comparators, and outcomes) criteria that outline the evidence considered most pertinent to the assessment. The plan also identifies key areas of scientific complexity. The PECO provides the framework for developing literature search strategies and inclusion/exclusion criteria, particularly with respect to available evidence (i.e., human, animal, mechanistic); exposure measures; and outcome measures.[4]

Stage 2. Agency Review

Scientists in the EPA's other offices review the draft assessment. The draft assessment is revised based on the comments the IRIS program receives from other program offices within the EPA.

Stage 3. Interagency Science Consultation

Other federal agencies, including the Executive Office of the President, review the revised draft assessment. The draft assessment is revised again based on comments received.

Stage 4. Public Comment and External Peer Review

The draft assessment is released for review and comments, including proposed peer review questions, and a public meeting is held to collect more input.

Following revisions based on public comment, the draft assessment and peer review charge questions are released for external peer review by the EPA's Scientific Advisory Board Chemical Assessment Advisory Committee (CAAC). The public is invited to the CAAC meeting to hear discussion and provide comments.

Stage 5. Revise Assessment

The draft assessment is revised based on the comments received during the peer review.

Stage 6. Final Agency Review and Interagency Science Discussion

The revised assessment is reviewed by the EPA's regional and program offices, other federal agencies, and the Executive Office of the President.

Stage 7. Post Final Assessment

The final IRIS assessment is posted to the IRIS program's website.

IRIS Database

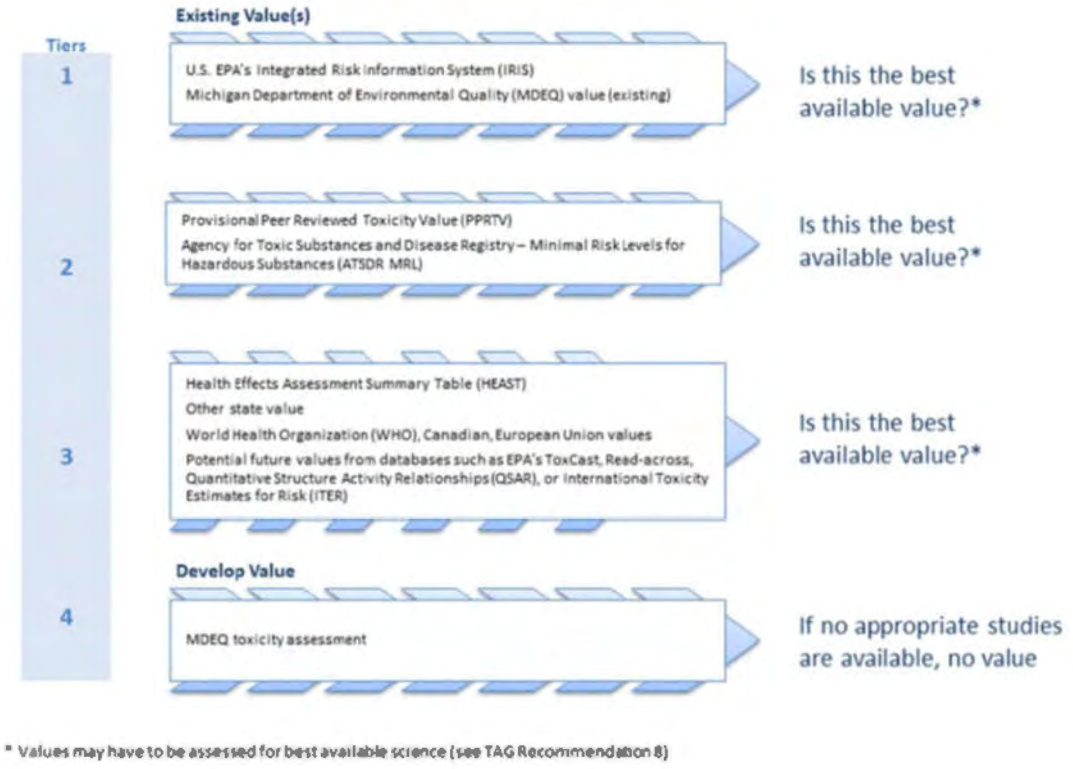
The IRIS database contains 511 chemical human health assessments, not all of which include a full assessment of the different health hazard and/or carcinogenicity assessments for lifetime exposure. Since 2002 (the last update to Part 201 rules), the EPA has updated 78 of these chemical assessments. In July 2016, they also archived 51 pesticide assessments more recently evaluated by the EPA's pesticide program. For these 51 pesticides, the IRIS program now relies on the Office of Pesticide Programs and the Human Health Benchmarks for Pesticides system.

[4] U.S. EPA. February 12, 2018. "Uranium, Natural." *IRIS.* Accessed February 12, 2018. https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=338655

At this time, of the 511 IRIS assessments, there are 22 chemical assessments at different stages of development by the EPA, including six chemicals for which the MDEQ has chosen an alternative reference dose source from a toxicity database.

The CSA, specifically TAG 1, spent considerable time researching and discussing how the MDEQ should update the toxicity values in the criteria. The CSA directed the MDEQ to use the best available science through a hierarchical decision-making tree shown below. The decision tree was adopted but moved the MDEQ value (existing) from the first tier to the fourth to better represent that, as the CSA recommended, there should be "very rare instances that an IRIS toxicity value would need to be independently evaluated and changed by the MDEQ."

EXHIBIT 3. Toxicity Value Decision Framework



Source: Final Report *Part 201: Stakeholder Recommendations for Updating Michigan's Generic Cleanup Criteria, November 2014, prepared by Public Sector Consultants.*

Best available value was not specifically defined by the CSA, but instead, a list of criteria was developed to evaluate data sources. These criteria include studies and data that are:

- Peer reviewed
- Subject to notice and comment
- Derived through relevant and accepted methods
- Consistent
- Credible
- Regularly maintained
- Based on experimental data

BENCHMARKING

Public Sector Consultants also reviewed how Michigan's proposed cleanup criteria compare to other states and the EPA. The review focuses on the approach of Michigan's cleanup program compared to other states and the processes used to develop the cleanup criteria. Specifically, the assessment focused on a limited range of issues that were identified by the MDEQ that were of particular concern to the regulated community, including the process to model and establish toxicity values, vapor intrusion, and single-event exposures.

MICHIGAN'S UNIQUE APPROACH TO CLEANUP CRITERIA

Michigan is unique in its approach to managing contaminated properties. Most states and the federal government utilize a process to screen potentially contaminated properties using a series of conservative assumptions. When a property is found to have contaminant levels higher than the conservative screening levels, additional analysis is performed to develop site-specific cleanup standards.

Michigan's unique approach to developing generic cleanup standards can create challenges when comparing Michigan's requirements to those of other states and the federal government. It is not appropriate to compare Michigan's generic cleanup standards to screening levels used by the EPA or other states because the programs function differently. However, an assessment of the processes and resources used by Michigan, other states, and the EPA can provide insight into Michigan's proposed rule package.

ESTABLISHING TOXICITY VALUES

Toxicity values are developed to calculate risks and hazards or derive dose estimates for potential contaminants. These values are inputs to complex algorithms that determine acceptable exposure levels based on exposure assumptions and pathways. To establish toxicity values, the EPA and most states have developed processes establishing a hierarchy of data sources that guides which information and studies will be used to set toxicity values. These hierarchies give substantial preference to data sources that include robust analysis of the best available science and include substantial opportunities for peer review and stakeholder engagement. As new studies are completed, the scientific understanding of individual chemicals and their potential health impacts continues to evolve. In some instances, multiple studies reach different conclusions that must be thoroughly evaluated before selecting the results of one study over another. The hierarchies used by the EPA and other states prioritize this review process over a singular study that may present newer science.

For example, the EPA Superfund program utilizes a hierarchy for application of toxicity values. Based on a 2003 guidance memo, the program uses defined sources to establish toxicity values (see Appendix). IRIS is the first tier, and when an IRIS assessment is unavailable, lower tiers are utilized. When an IRIS toxicity assessment is released, the next tier, provisional peer reviewed toxicity value (PPRTV) is removed and the IRIS value is used instead, even if the IRIS profile indicates a toxicity value could not be derived. Exhibit 4 shows the hierarchy used by the Superfund program.

EXHIBIT 4. EPA Superfund Program Hierarchy for Establishing Toxicity Values

	EPA Superfund Program Hierarchy
1	Integrated Risk Information System
2	Provisional Peer Reviewed Toxicity Values
3	Human Health Benchmarks for Pesticides, derived by Office of Pesticide Programs
4	Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Levels
5	California EPA Chronic Reference Exposure Levels
6	Health Effects Summary Tables (HEAST)

Source: U.S. EPA. December 5, 2003. *Health Human Toxicity Values in Superfund Risk Assessments.* Accessed February 15, 2018. https://www.epa.gov/sites/production/files/2015-11/documents/hhmemo.pdf

Similarly, the Ohio EPA (OEPA) utilizes IRIS as its primary source of toxicity information and only uses other sources when an IRIS value is not available. In these instances, OEPA has adopted a similar hierarchy as the EPA's Superfund program.[5]

The CSA recommended using a similar approach that places the EPA's IRIS database as the first tier of information and outlined data sources that would follow in other tiers. The CSA recognized that, in some instances, better science may become available; however, the agency concluded that it should be "a very rare instance when a toxicity value would need to be independently evaluated and changed by the MDEQ. There are other established peer reviewed sources for toxicity values, and an independent MDEQ evaluation would only be appropriate in those situations where other toxicity sources had not had the opportunity to complete a timely update based upon widely recognized, new scientific information."

VAPOR INTRUSION

The intrusion of hazardous vapors from contaminated soils or groundwater into buildings is an area of emerging science evolving relatively rapidly. The federal government and most states are establishing standards that address the health risks posed by vapor intrusion.

The federal government and many Great Lakes states have implemented a tiered approach to assessing risk associated with vapor intrusion that adopts a risk-screening process beginning with highly conservative assumptions. These groups then use gradually increasing detail to determine response actions. The CSA recommended that Michigan adopt a similar approach to address vapor intrusion.

The MDEQ's proposed vapor intrusion rules follow the spirit of this recommendation by using a hierarchical approach. The MDEQ developed a screening tool that begins with conservative assumptions

[5] Ohio Environmental Protection Agency. April 2, 2010. *Technical Decision Compendium: Remedial Response Program.* Accessed February 9, 2018. http://www.epa.ohio.gov/portals/30/rules/Assessing%20Compounds%20without%20Formal%20Toxicity%20Values.pdf

based on a worst-case scenario, as directed by the CSA. The second tier incorporates geologic-based information from the contaminated property. The third and final tier incorporates land use and building-specific information. As an individual property moves through the tiered process, facility-specific generic criteria are provided. This attempts to strike a middle ground of Michigan's approach to developing cleanup criteria by providing a generic standard while also allowing facility-specific information to be considered without going through an MDEQ-reviewed site-specific process.

Interviews conducted with stakeholders suggested that there is a perception that Michigan's proposed vapor intrusion rules diverged from the CSA-recommended approach because of underlying assumptions within the state's vapor intrusion model.

VAPOR INTRUSION ASSUMPTIONS

The CSA-recommended approach to address vapor intrusion utilized the Johnson and Ettinger model that assumes the depth of surface to groundwater is greater than ten feet. This model assumes that there is at least five feet of soil present between the building (e.g., the floor of a basement) and the upper extent of groundwater. According to the EPA and other states surrounding the Great Lakes, the J&E model is not appropriate in instances where the depth from surface to groundwater is less than ten feet or there is less than five feet between the building and groundwater. Note that this approach is used by other Great Lakes states and the EPA, but that Michigan has higher groundwater than most other states.

When developing the proposed vapor intrusion rules, the MDEQ diverged from the CSA approach to use the J&E model because Michigan-specific data became available after the CSA process. This data embraced by the MDEQ indicates that approximately 65 percent of the geographic area of the state has a depth to groundwater of less than ten feet. If this is an accurate assessment for Michigan, following EPA guidance and approaches used in other states would suggest that the MDEQ made a reasonable deviation from the CSA recommendations. However, TAG 3 discussed how to address sites with shallow groundwater (less than ten feet) and could not reach consensus on an approach. Appendix A of the TAG 3 report states, "The TAG could not resolve how to address potential volatilization of [contaminants of concern] from groundwater that intrudes into basement construction. The group agreed that it is essentially a separate pathway [from vapor intrusion], and that the MDEQ may need to have another advisory group evaluate this pathway and recommend an approach for evaluating the potential risks from volatilization from the water to the indoor air." Changing the underlying assumption regarding depth from surface to groundwater has significant implications and could result in a greater number of properties qualifying as facilities that may require response actions unnecessarily depending upon the veracity of those assumptions.

Other assumptions in the MDEQ's vapor intrusion model have been called into question as being overly restrictive compared to other states. For example, the EPA and Indiana each recognize a greater rate of vapor intrusion when there are cracks in concrete (e.g., foundations and floors). In Michigan, it appears that the proposed vapor intrusion rules assume a greater rate of intrusion through intact concrete than other states. Stakeholders have also expressed concern over assumptions, such as the size of a sump pump used in new construction. While these concerns may have merit, the MDEQ was tasked with assuming a worst-case scenario to screen for properties that may be affected by vapor intrusion and then using gradually more detailed information to revise risk assessments based on facility-specific conditions.

The area where the MDEQ diverged most from the CSA recommendations regarding vapor intrusion is providing opportunities for meaningful stakeholder engagement while the proposed rules were under development. Despite the significance of the depth to groundwater assumptions, an understanding that the J&E model would be the basis of the MDEQ's vapor intrusion model and acknowledgement from TAG 3 that further stakeholder engagement was warranted for shallow groundwater sites, it appears that the MDEQ did not follow this recommendation from the CSA process while the proposed vapor intrusion rules were developed. The MDEQ may have had a more productive response if affected stakeholders were engaged at the time the MDEQ decided to change course rather than waiting until proposed rules were released.

SINGLE-EVENT EXPOSURE

Interviews revealed concerns over the MDEQ's proposed approach to developing single-event exposure criteria. While the topic was discussed at the TAG level, a consensus did not emerge and the CSA discussion did not identify a recommended approach.

Since the CSA did not recommend an approach regarding single-event exposures, PSC cannot provide an assessment of the fidelity to the CSA process on this topic. However, given the significance of the topic to both the MDEQ and the regulated community, as well as human health, PSC has assessed the issues related to single-event exposures to support further conversations about how they should be managed in Michigan.

The EPA recognizes that chemicals that have a developmental or reproductive impact may have adverse impacts from a single or acute exposure event in addition to chronic exposures over a longer period of time. It appears that the MDEQ has drawn from the EPA's understanding to develop cleanup standards that assume a single-event exposure for chemicals that are developmental toxicants. While the EPA assumes that developmental toxicants may cause adverse impacts, it has not integrated this approach into its screening criteria because there is insufficient data for many chemicals. In the EPA Risk Assessment Guidance for Superfund (RAGS), the EPA states that "short-term exposures should be quantitatively assessed; however, there is no simple or widely accepted method for estimating such risks."[6]

Many of the scientific studies available to assess health impacts of chemicals assess chronic exposure (repeated exposure over a long period of time), and subchronic, rather than an acute (single) exposure. The EPA states that using chronic exposure studies to assess acute exposure risks may not be appropriate. Specifically, the EPA's guidance provided to PSC by the MDEQ to support its approach notes, "For developmental effects, for example, lifetime time-weighted averages have little relevance, so different types of data must be collected, in this case usually shorter-term exposure profile data during a particular time window. Consequently, the exposure assessors and scientists who conduct monitoring studies need to collaborate with those scientists who evaluate a chemical's hazard potential to assure the development of a meaningful risk assessment"[7]

Some stakeholders interviewed assert that the MDEQ has proposed cleanup standards based on a single-event exposure for all developmental toxicants regardless of whether there are studies available that

[6] U.S. EPA. April 19, 2016. "Appendix C: Short Term Toxicity Values." *Risk Assessment Guidance for Superfund: Part C*. Accessed February 15, 2018. https://www.epa.gov/sites/production/files/2015-09/documents/appc.pdf

[7] U.S. EPA. August 17, 2010. "Guidelines for Exposure Assessment." *U.S. Environmental Protection Agency*. Accessed February 15, 2018. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=15263

assess impacts from acute exposure that are necessary to develop a meaningful risk assessment. These stakeholders hold the view that, as the EPA notes in its guidance, use of chronic exposure studies is not appropriate to develop an acute standard.

Primarily, the tension between the MDEQ's proposed rules and many stakeholders lies with the agency's ability to develop meaningful risk assessments. While the EPA assumes that developmental toxicants may have adverse impacts after a single exposure, the available science may not support a given standard without specifically assessing impacts from a single exposure.

COMPARISON TO CSA RECOMMENDATIONS

PSC attempted to assess whether the MDEQ followed the recommendations of the CSA, as outlined in the 2014 report. Each of the CSA recommendations are listed and numbered below as they appear in the 2014 report. When possible, PSC provides its assessment of the extent to which the recommendation was implemented or not. This was a challenging task, striving to reconcile differing interpretations both from the stakeholders and the MDEQ in their understanding of the recommendations and how they were implemented.

For many of the CSA recommendations, the MDEQ's actions did result in at least partial implementation as written. In other cases, "fully implemented" or "not implemented" is recorded. What is not captured in simply applying an implemented/not implemented approach to this evaluation is the collaborative spirit the CSA workgroup should foster, which appears to be missing from the proposed rules package. While MDEQ staff believes that they followed the written CSA recommendations based upon their interpretation, the agency did not embrace the collaborative spirit that underpinned the CSA process in drafting the current rules. This may have been due partially to time and resource constraints placed upon the agency given the significant task at hand. It may also be due to the differing expectations and interpretations of the decision-making frameworks recommended by the CSA. Regardless, the general lack of engagement has resulted in a divisive rule package.

The PSC analysis that follows only points out the general lack of inclusiveness when the recommendation specifically suggested meaningful stakeholder participation and input. Even with the full cooperation and input from MDEQ staff, PSC still found it difficult to follow the MDEQ's decision-making processes for the implementation of several CSA recommendations.

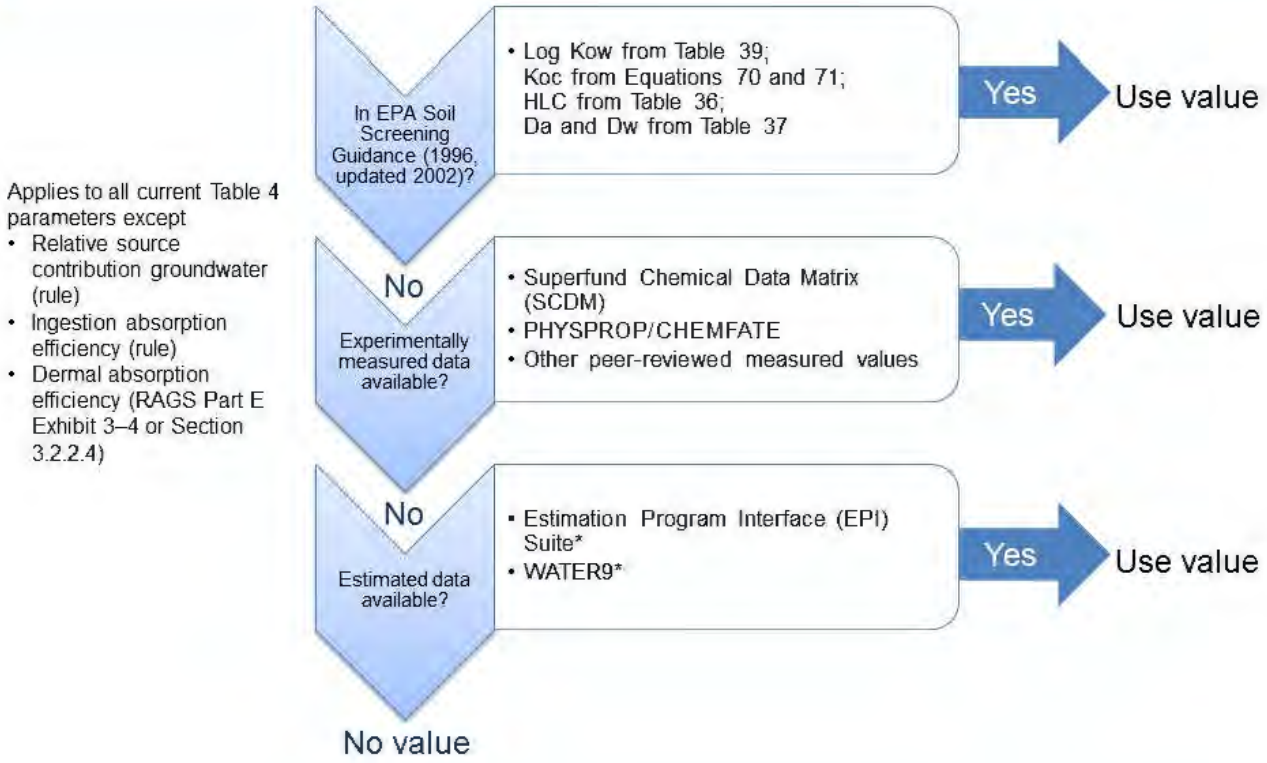
CHEMICAL-SPECIFIC TOXICITY AND CHEMICAL/PHYSICAL DATA (TAG 1)

Recommendation 1.1

The CSA has reviewed the proposed TAG 1 decision frameworks with respect to toxicity and chemical/physical parameters (TAG 1 Appendices A and B) and recommends that the framework proposed for toxicity values (TAG 1 Appendix B) be adopted by the MDEQ with the following exception: the "MDEQ value (existing)" be removed from Tier 1 (TAG 1 Appendix B) and maintained in Tier 4 to better reflect the CSA's opinion that it is a very rare instance when a toxicity value would need to be independently evaluated and changed by the MDEQ. There are other established peer reviewed sources for toxicity values, and an independent MDEQ evaluation would only be appropriate in those situations where other toxicity sources had not had the opportunity to complete a timely update based upon widely recognized, new scientific information.

After review of the changes proposed by TAG 1 to the current method for determining chemical/physical parameters, the CSA recommends continued use of the current method (existing data sources) for these parameters as shown in Exhibit 5.

EXHIBIT 5. CSA Alternative: Chemical/Physical Value Decision Framework



*Estimated values should be derived using the above estimation program(s), or programs that supersede these programs, e.g., WATER9 replaced WATER8 subsequent to the publication of the SSG.

PSC Analysis

The CSA report offered conflicting directions for the MDEQ to follow in determining toxicity values. The report endorses a decision framework from the TAG 1 report that lists tiers but also has the MDEQ evaluate if the toxicity value provided in that tier is the best available value. In addition, the report stated that it should be a "very rare instance that an IRIS toxicity value would need to be independently evaluated and changed by the MDEQ. Since there is an established EPA process for updating IRIS toxicity values, it would only be under those conditions where the EPA did not have the resources to complete a timely revision that was supported by widely recognized, new scientific information." The MDEQ, however, assessed each value produced through the different toxicity inventories to determine which was the best available, regardless of the tier.

The exhibit below identifies 83 toxicity values where an IRIS value was available, for which the MDEQ chose a different toxicity source.

EXHIBIT 6. Alternative Toxicity Values Used When IRIS Value is Available

Source	Number
P/Michigan Department of Environmental Quality	16
Office of Pesticide Programs	28
Agency for Toxic Substances and Disease Registry	26
Provisional Peer Reviewed Toxicity Values	11
MDEQ, Air Quality Division	1
California EPA	1

Source: PSC compiled information using data provided by the MDEQ.

While this may follow the instructions of the TAG 1 report, it does not follow the CSA recommendations. While the MDEQ did provide a document outlining the criteria they use to evaluate best available science, it does not provide a hierarchical decision-making or scoring system that offers PSC confidence that it produced the same result for each of the evaluations that the MDEQ undertook. Without that, it is not clear to PSC if the value chosen is the best available, or just the most recent study.

Without this information, this recommendation was only **partially implemented**.

Recommendation 1.2

The MDEQ should include a short reference for each value and chemical/physical parameter in Table 4 of the generic criteria rules that identifies the source of the values and that also indicates, when relevant, whether physical parameters are measured or modeled. A more detailed explanation of the reference could be stored in a separate table or other resource, as this would give each value greater transparency. The Ministry of the Environment and Climate Change in Ontario, Canada uses a similar model and the MDEQ should consider this format while designing its updated tables.

PSC Analysis

This recommendation was **fully implemented.**

Recommendation 1.3

The MDEQ should 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.

PSC Analysis

While the MDEQ provided opportunities for feedback after it had proposed its rules, there seemed to be a lack of meaningful collaboration and instead seemed to devolve into a back and forth dispute.

The spirit of this recommendation was for the MDEQ to engage stakeholders outside of/prior to the proposed rule issuance so that staff would be engaged in an open scientific/risk management discussion instead of the more contentious posture of simply defending the proposed rules. This recommendation was not intended to reference the existing process of obtaining public input during rule making.

The recommendation was **not implemented** within the spirit of the CSA report.

Recommendation 1.4

When administrative rules are updated, the inhalation toxicity terms in the VSIC, PSIC, GVIIC, and SVIIC equations and relevant rule language should be changed to allow the MDEQ the flexibility to select inhalation toxicity values that differ from those developed by the MDEQ's Air Quality Division (AQD), considering best available science and practices. The MDEQ's Remediation and Redevelopment Division staff should not have to evaluate all inhalation toxicity values, though some attention should be given to those based upon the AQD's most minimal data requirements at the time they are evaluated. Inhalation toxicity value reference sources should be included in Table 4 in the rules.

PSC Analysis

The regulated community asserts that AQD values were given preference over other values, including when an IRIS assessment recently determined there was insufficient information available to derive a value.

The recommendation was **partially implemented**.

Recommendation 1.5

The MDEQ should adopt the CSA-modified decision framework previously identified in Exhibit 5.

PSC Analysis

The MDEQ and stakeholders agreed to a modified approach to this recommendation, allowing for EPI Suite values to be considered equally to the SSLG. PSC's review of the values shows a preference given to the EPI Suite, with very few values coming from the SSLG. During PSC meetings with MDEQ, staff indicated that this was due to time constraints and EPI Suite generally having more robust and updated values.

The modified recommendation was **partially implemented**.

Recommendation 1.6

The MDEQ should utilize the chemical update worksheet (Appendix D in the appended TAG 1 Report) to collect information and as a communication tool. A Web-friendly version (e.g., a PDF) should be placed on the MDEQ website.

PSC Analysis

This recommendation was **fully implemented**.

Recommendation 1.7

The CSA believes 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.

PSC Analysis

This recommendation was **fully implemented**.

Recommendation 1.8

The CSA concurs with data sources supported by TAG 1 for chemical/physical parameters and toxicity values consistent with the fundamental data source characteristics presented below, with one exception noted (these characteristics are consistent with, and in many cases more detailed than, the guiding principles adopted by the CSA cited earlier in this report). Note that the CSA changed the TAG 1 report subheading to "Consistency" rather than "Comprehensive" and modified the description that follows that subheading to reflect its belief that it is more important that data sources be consistent rather than just more comprehensive. The characteristics below should accurately describe data sources that are utilized:

Peer reviewed—Every effort should be made to identify and use peer reviewed data sources populated with information developed using the best available science and practices. Scholarly review by experts in the field ensures data meet necessary quality standards prior to publication.

Subject to notice and comment—Toxicity values developed by non-MDEQ sources through a process that allows public review and comment are preferred. (Note: It is desirable to allow affected stakeholders [and affected Michigan citizens and regulated community members] input when changing Table 4 of values.) In general, chemical/physical data do not undergo public review and comment procedures.

Derived through relevant and accepted methods—Priority should be given to sources that provide chemical/physical and toxicity data based on similar methods as those used for Tier 1 and Tier 2 of the decision-making hierarchy, and that contain values which are peer reviewed, available to the public, and transparent about the methods and processes used to develop the values.

Consistency—To help ensure greater consistency of the data used in developing the risk-based values for chemical/physical or toxicity data, the MDEQ should utilize sources that use consistent methods for development of the data. This helps to assure greater consistency of the data used in developing the risk-based values.

Credible data—Sources that are respected and trusted by the international scientific community are preferred.

Regularly maintained—Science evolves. Regular review and updating of the chemical toxicity information will ensure that it represents the best available science and practices in that field. For example, two recent guidance documents are good resources to consider in selection or development of toxicity values: *EPA Framework for Human Health Risk Assessment to Inform Decision Making* and the National Research Council's *Review of EPA's Integrated Risk Information System*.

Based on experimental data—Chemical data presented in scientific literature and the many compiled documents and database resources can vary in method of derivation. Experimental chemical/physical data, where relevant to applied environmental conditions, are preferred over extrapolated, modeled, or estimated data. Similarly, experimental toxicity data are preferred, with the understanding that the scientific field is moving away from traditional, whole-animal experimental studies to higher throughput and less resource-intensive in vitro, array, and computer-based toxicity data.

PSC Analysis

It appears that the MDEQ used all the parameters to evaluate both chemical/physical parameters and toxicity values. However, it is unclear to PSC in which circumstances which of the parameters were

applied. In discussions and in documents produced by the MDEQ the use of these parameters is referenced, but PSC cannot discern any sort of hierarchy or documentation that shows the parameters were consistently used in the same method across all toxicity values and chemical/physical values.

PSC concludes that this recommendation was only **partially implemented** according to the CSA recommendations.

Recommendation 1.9

Age-dependent adjustment factors should be used with toxicity values for those carcinogens identified as mutagenic by the EPA or any agency/scientific body, as long as it is conducted in accordance with EPA guidelines on identifying mutagenic mode and evaluated by the MDEQ.

PSC Analysis

The MDEQ did implement this recommendation using ADAFs for carcinogens identified as mutagenic by the EPA. However, some stakeholders assert that the MDEQ went beyond the discussions of the CSA and created scenarios for single-event exposures and full-term exposures for developmental toxicants. While the topic was discussed at the TAG level, a consensus did not emerge, and CSA discussion did not identify a recommended approach.

This recommendation was **partially implemented**.

Recommendation 1.10

The MDEQ should first determine whether a chemical is considered carcinogenic to humans by the EPA and the International Agency for Research on Cancer (IARC). If it is to be regulated as a carcinogen, then potential route-specific differences in carcinogenicity should be considered and evaluated. If it is noncarcinogenic, then only the reference dose (RfD) and reference concentration (RfC) candidate values would be assembled to select an RfD and an RfC.

PSC Analysis

In determining if the chemical is considered carcinogenic to humans, the MDEQ did not always rely on both the EPA and IARC to identify the chemical. In some cases, if just one of the agencies listed it, the MDEQ regulated it as a carcinogen, though it is difficult to ascertain if the CSA's intent was limited to have a chemical appear on both sources before it is to be classified as a carcinogen. Furthermore, it is difficult to ascertain if the CSA's recommendation was limited to an IRIS identification of a substance as being carcinogenic.

This recommendation was **partially implemented.**

Recommendation 1.11

The criteria should be footnoted to denote whether the carcinogenic or noncarcinogenic algorithms were used to calculate the final criteria for a chemical.

PSC Analysis

This recommendation was **fully implemented**.

Recommendation 1.12

Deviation from EPA methodology should be allowed where there is good information to suggest that the EPA's methodology or data are not consistent with current best science. When these modifications are made by the MDEQ, there should be an opportunity for public input and comment.

Note: TAG 1 did not prepare a recommendation to question eight (presented to the TAG by the CSA), which asked, "Should an independent evaluation (by the MDEQ) of the chemical-specific data be conducted even if a value is published in the primary database of the hierarchy?" In the written response to the question, however, TAG 1 indicated that the MDEQ should be able to perform independent evaluations of a value published in the primary database of the hierarchy. While the CSA agrees, it wants to point out that it is a very rare instance that an IRIS toxicity value would need to be independently evaluated and changed by the MDEQ. Since there is an established EPA process for updating IRIS toxicity values, it would only happen under those conditions where the EPA did not have the resources to complete a timely revision that was supported by widely recognized, new scientific information.

PSC Analysis

The intent of this recommendation is that IRIS would be a primary data source, recognizing that better science may emerge that is not always reflected in IRIS or that Michigan-specific information may be available. The CSA noted that this should occur in rare instances and, furthermore, that it would be rare that MDEQ independently develop a toxicity value. Under both circumstances, the CSA recommended proactive stakeholder engagement prior to publishing proposed rules. While the MDEQ did not independently develop toxicity values, there are numerous instances where an IRIS determination was available and MDEQ selected alternative values without stakeholder engagement. The MDEQ did not allow for public comment or input prior to publishing the proposed rules that included numerous deviations from IRIS.

This recommendation was **not implemented**.

GENERIC EXPOSURE ASSUMPTIONS (TAG 2)

Recommendations 2.1, 2.2, and 2.3

The CSA recommends the following as the appropriate receptors, guidance, and descriptive language to use for residential land use generic criteria:

- **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.
- **Guidance:** Use EPA information to develop a process to account for those chemicals, or classes of chemicals, that have documented developmental or reproductive effects.
- **Descriptive language:** 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.

PSC Analysis

The MDEQ followed the recommendation for using child plus adult for the age-adjusted receptor. In addition, the MDEQ did use EPA information to evaluate chemicals that have developmental or reproductive effects. However, it appears that the MDEQ expanded this recommendation to include nonresidential exposure sites and use EPA guidance related to adopted screening levels not relevant to remediation, neither of which were included in the recommendation and may be distinct from clean up standards.

This recommendation was **fully implemented**.

Recommendation 2.4

ADAFs for the chemicals recommended by the EPA's *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* in March 2005 (and updates) should be used to address early-life exposure from mutagenic carcinogens.

PSC Analysis

This recommendation was **fully implemented**.

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 that includes additional mutagenic carcinogens as they are identified by EPA.

PSC Analysis

This recommendation has been **partially implemented**. The MDEQ has developed a document to outline the process to evaluate best available science, but it remains unclear how the document is being applied.

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 drinking water standards. A chemical-specific drinking water standard, currently established by the SDWA, applies to water for both residential and nonresidential use.

PSC Analysis

PSC is unable to discern to what extent the MDEQ considered impacts of Part 201 generic criteria on other programs.

Recommendation 2.7

For all updated values, TAG 2 recommends a process and decision framework for selection of the generic exposure assumptions that is transparent and provides opportunities for meaningful public input.

PSC Analysis

The MDEQ hired an outside contractor to select the generic exposure assumptions. The information that was provided to Syracuse Research Corporation was based upon Part 201 and the CSA report. However, there appears to have been no opportunity for the CSA workgroup or other stakeholders to review the documents or the exposure assumptions provided by the corporation before they were included in the draft rule.

This recommendation was **not implemented**.

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 comment. The specific alternative processes for updating are outlined in the CSA Legal TAG 4 Report.

PSC Analysis

This recommendation was **not implemented**.

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, also called Data Quality Objectives, described below.

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 is 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.

PSC Analysis

The MDEQ provided these DQO to Syracuse Research Corporation to use as the basis for the update to the data sources for exposure assumptions. It is unclear how the DQO's were applied in order to derive the generic exposure assumptions.

This recommendation was **partially implemented**.

Recommendation 2.10

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

PSC Analysis

The MDEQ did attempt to use Michigan-specific data, but in some instances the resulting generic exposure values do not appear to be realistic to specific Michigan conditions.

This recommendation was **partially implemented**.

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.

PSC Analysis

The MDEQ did attempt to use Michigan-specific data, but the resulting generic exposure values do not appear to be realistic to specific Michigan conditions.

This recommendation was **partially implemented**.

Recommendation 2.12

As a starting point, the CSA recommends the use of the identified values TAG 2 presents in Table A (Appendix B) of its report, and the use of the decision framework proposed by TAG 2 to establish and confirm values for all exposure factors, including those recommended by TAG 2.

PSC Analysis

See Recommendation 2.7.

Recommendation 2.13

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.

In addition, 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. Specifically, the CSA recommends that prior to seeking public input on any generic residential or nonresidential exposure scenario and its corresponding exposure factors, a probabilistic analysis should be used to assess the validity of the final combination of selected point-estimate exposure factors, where feasible.

PSC Analysis

The MDEQ did include the basis for each value presented in Tables A and B of the TAG 2 report. It is not clear to PSC if the MDEQ used probabilistic approaches to ensure the exposure factors represent a reasonable maximum exposure, resulting in **partial implementation**.

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.

PSC Analysis

This recommendation was **fully implemented**.

VAPOR INTRUSION CRITERIA (TAG 3)

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.

PSC Analysis

The MDEQ appears to have developed a screening tool that begins with conservative assumptions that are based on a worst-case scenario, which was the direction provided by the CSA. The structure of the proposed tiers used by the MDEQ is appropriate.

This recommendation was **fully implemented**.

Recommendation 3.2

The CSA accepts and encourages the MDEQ to adopt the investigative approach detailed in the series of exhibits provided in the TAG 3 report endorsed by all TAG 3 members.

PSC Analysis

The area where the MDEQ appears to have diverged most from the CSA recommendations regarding vapor intrusion is providing opportunities for meaningful stakeholder engagement while the proposed rules were under development. The consensus reached by TAG 3 estimated that vapor intrusion models would assume a depth from surface to groundwater of more than ten feet. The TAG discussed the best approach for assessing risk when depth to groundwater is less than ten feet but could not reach consensus. The TAG then recommended that an additional advisory group be formed to address this scenario (Appendix A of the TAG 3 report). After the CSA issued its report, the MDEQ developed a tiered approach that followed the spirit of the CSA recommendation but changed an underlying assumption because new Michigan-specific data embraced by the MDEQ indicates that depth from surface to groundwater in the majority of the state is less than ten feet. Given the significance of the depth to groundwater assumptions, an understanding that the J&E model would be the basis of the MDEQ's vapor intrusion model, and acknowledgement from TAG 3 that further stakeholder engagement was warranted for shallow groundwater sites, it appears that this recommendation was **not implemented**.

A PATH FORWARD

Based upon our analysis, PSC offers the following recommendations for consideration by MDEQ:

- Rather than delaying the entire rules package resulting from eight years of complex and challenging work, the MDEQ should consider implementing a rules package that covers topics upon which there appears to be general consensus and postpone adopting rules for topics where significant debate remains, including:

  1. - Using non-IRIS values when IRIS has evaluated a chemical
  2. - New categorizations that establish chemicals as mutagenic carcinogens
  3. - Developing single-event exposure criteria that draw on chronic or subchronic exposure assumptions
  4. - Vapor intrusion model assumptions

  A central tenet of the CSA recommendations was that stakeholders represented would engage in a collaborative scientific exchange of ideas as the rules were developed, rather than through the public comment process after the rules were proposed. The MDEQ should engage a neutral facilitator to evaluate these topics with stakeholders with a goal of reaching a consensus-based approach using sound science and generally accepted practices. While delaying promulgation of a complete rules package may not be ideal, it is critical that the generic cleanup criteria be appropriately calibrated to ensure that sites of real concern are identified and addressed, and that sites with minimal potential for public health or environmental harm are not inadvertently brought into the Part 201 process. The current rules on these topics could remain in place while further evaluation occurs in the near term.

- Pursuant to the 2014 CSA report, the MDEQ should follow the EPA and most other states in using an IRIS determination for chemicals that IRIS has evaluated (including instances where the IRIS process has reviewed a substance and determined that no value should be established). If a chemical does not have an IRIS assessment, the MDEQ should use CSA-recommended hierarchy for determining alternative values, unless they can provide clear rationale for using a different source from a lower tier of the hierarchy. While imperfect, the robust stakeholder and peer review of the IRIS program makes it superior to other data sources.
- In instances where the MDEQ is inclined to diverge from IRIS, at a minimum, the MDEQ should continue to document the criteria they used to determine if and why they deviated from IRIS and engage stakeholders in a collaborative scientific exchange. These determinations should be made using the data quality objectives established by the CSA and follow the recommendation that an IRIS toxicity value should only need independent evaluation and updating by the MDEQ in rare instances.
- The MDEQ should consider commissioning an independent peer review process to assess depth from surface to groundwater assumptions used within the vapor intrusion model due to the significance that this assumption has to both public health and the potential number of properties that could be brought into the Part 201 process. One approach could be structured like the C8 Science Panel convened to review the health effects of perfluorooctanoic acid (PFOA) on residents of the mid-Ohio Valley. To insure public health during the interim, the MDEQ can regulate vapor intrusion as it has while the proposed rules are developed.
- Interviews with MDEQ staff and other stakeholders confirm that a strained relationship exists between some stakeholders involved in updating the rules package. Meaningful collaborative dialogue may be difficult to achieve without a neutral party guiding the discussion. The MDEQ should engage a

neutral facilitator to lead any process reconciling differing points of view on topics where significant debate remains.

- In the coming years, further updates to Michigan's cleanup criteria will become necessary as science evolves. The current updates to Michigan's cleanup criteria effectively cover the entire program. In the future, the MDEQ should consider conducting more frequent updates that are narrower in scope, as agreed to by the CSA.

SUMMARY AND CONCLUSION

The Michigan Department of Environmental Quality has been engaged in updating Michigan's Part 201 cleanup rules for contaminated sites for many years. During this time, the MDEQ has engaged the regulated community in a variety of ways, from the Criteria Stakeholder Advisory workgroup in 2014 to small group and individual stakeholder settings for the past 18 months. Efforts to update the cleanup criteria under Part 201 began in 2010. Since that year, numerous public meetings and stakeholder interactions with the MDEQ have occurred both before and after the 2014 CSA report recommendations. While a consensus has been reached among various stakeholder groups and the MDEQ for some of the current provisions of the proposed Part 201 cleanup rules, many significant elements of the proposed rules package remain under debate.

A key observation offered is that risk assessment and risk management are two sides of the same coin. Risk assessment is designed to develop a range of toxicological values according to the best available science that remain protective of public health and the environment. Risk management includes the determination of appropriate cleanup levels while still considering other legitimate public values and avoiding unacceptable health and environmental risks by recognizing relative risks of specific chemical exposures compared to those routinely encountered by people in the course of normal activity. In the context of the proposed generic cleanup rules, the CSA attempted to set guidelines for preparing science-based risk assessments that would allow promulgation of cleanup numbers for risk management that avoid unacceptable exposures while still achieving other recognized public values.

While it is uncertain where the process goes from here, one observation has become abundantly clear: The City of Flint-contaminated water supply issues and the subsequent criminal charges against state employees, including individuals in the MDEQ, can influence how state employees respond to judging risks associated with their regulatory decisions. Some state employees might be expected to become more risk averse and make more conservative, more protective decisions. Others will feel that they need to be more aggressive in protecting public health and the environment since the state, in the view of some, failed to do so in the case of Flint.

While significant strides have been made and a tremendous amount of work carried out by MDEQ staff, since the CSA process, the agency should consider reexamining the full spirit and intent of the CSA report and its recommendations and consider investing additional resources into stakeholder engagement processes.

APPENDIX -

TOXICITY SOURCES COMPARISON

The table below discusses choosing among toxicity values from multiple sources and references.

EXHIBIT A1. Interstate Technology and Regulatory Council Source of Toxicity Values[8]

Name	Regulatory Agency	Review Process	Additional Notes
Integrated Risk Information System	EPA	Internal agency review, interagency science consultation, independent external review, public comment, interagency science discussion, and final approval by the Office of Research and Development	Intended for use by all EPA programs
Provisional Peer Reviewed Toxicity Values	EPA (Superfund Health Risk Technical Support Center for the EPA Superfund program)	Internal review by EPA scientists followed by external peer review from independent scientific experts	Revised Health Effects Assessment Summary Table values have been derived per the request of regional Superfund offices for chemicals not covered under IRIS. In 2009, screening toxicity values were added to certain PPRTV assessments. While these values have utility for screening purposes, caution should be taken when using screening toxicity values to support final remedial action decisions. PPRTVs are similar to IRIS assessments but not as rigorously reviewed.
Agency for Toxic Substances and Disease Registry	U.S. Department of Health and Human Services	Reviewed by the Division of Toxicology and Environmental Medicine's Human Health Effects/Maximum Residue Level (MRL) Workgroup, expert panel of peer reviewers, agency-wide MRL Workgroup (participation from other federal agencies)	MRLs are set below levels that may cause adverse human health effects in sensitive subpopulations. Not intended to define cleanup or action levels. Serve as screening values. Do not provide cancer toxicity values.
Health Effects Assessment Summary Tables	EPA (Superfund and Resource Conservation and Recovery Act hazardous waste programs)	Updated regularly from early to mid-1990s Last updated in 1998	Historical database of human health toxicity values

[8] Interstate Technology and Regulatory Council. 2015. *Decision Making at Contaminated Sites: Issues and Options in Human Health Risk Assessment.* Accessed January 29, 2018. www.itrcweb.org/risk-3

Name	Regulatory Agency	Review Process	Additional Notes
Toxicity Criteria Database	California EPA	Submitted for public comment and external peer review	Developed by the Office of Environmental Health Hazard Assessment under Senate Bill 32, the California Land Environmental Restoration and Reuse Act
Energy and Environmental Affairs Risk Assessment Website	Massachusetts Department of Environmental Protection	Peer reviewed within the Office of Research and Standards	
Health Risk Values and Health Risk Limits	Minnesota Pollution Control Agency	EPA guidelines for derivation and review	For air and water Derived with stakeholder involvement
Toxicity Values (used to develop soil cleanup objectives)	New York State Department of Environmental Conservation	Selected from values published by established regulatory agencies, internal and external review of acute exposures	
Toxicity Factors	Texas Commission on Environmental Quality (TCEQ)	Developed and reviewed by TCEQ toxicologists, posted for public review and comment, and internally revised prior to finalizing toxicity factors	
World Health Organization/ International Programme on Chemical Safety (IPCS) Concise International Chemical Assessment Documents	World Health Organization (WHO)	Reviewed by IPCS, peer reviewed internationally, then final review by the review board	Can be used in conjunction with Environmental Health Criteria documents
National Institute of Public Health and the Environment (RIVM), Netherlands provides maximum permissible risk (MPR)	RIVM	International committee of experts examines existing toxicological reviews for substances for which an MPR is to be developed	Provisional and temporary values presented
Toxicological Reference Values (TRVs)	Health Canada	Sources of TRVs include Health Canada Water Quality, Health Canada Priority Assessments Program, IRIS, California EPA, WHO, ATSDR	

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