Recent Modifications to Part 201 Cleanup Criteria for Environmental Remediation in Michigan

Public Act 581 of 2018

February 13, 2019

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Define a Hierarchy for DEQ when selecting Toxicity Data

- **Section 20120a(3)**
  - (a) Use toxicity values (value) from final U.S. EPA (EPA) IRIS Toxicological Review documents; or if incorporated by IRIS, more recent EPA Office of Pesticide Program's toxicity values
  - If EPA has determined there is insufficient scientific data to derive a value for IRIS, the department shall not derive or adopt such a value for that hazardous substance.
  - If an IRIS value is not available, in conjunction with rigorous systematic review as discussed in subsection 20120a(3)(c),use the following in order of preference:
    - (i) Best final minimum risk level value from the U.S. ATSDR or the EPA's Provisional Peer-Reviewed Toxicity Values (PPRTV)
    - (ii) Best final value from EPA's health effects assessment summary table or final values adopted by other states, the World Health Organization or the European Union.
    - (iii) If a value as described above is not available, a value may be developed by the department, if there is sufficient supporting toxicity data and information available in the peer-reviewed published scientific literature as discussed in Section 20120a(3)(c).

Define a process for DEQ when selecting Toxicity Data Other than IRIS

- **Section 20120a(3)**

  (c) If the department desires to use a toxicity value or input different than is available in IRIS or as discussed Section 20120a(3)(a), the department shall provide public notice and a written explanation of intent and conduct a stakeholder process to obtain input. After obtaining stakeholder input, the department may promulgate a rule to use an alternate value in an order of precedence as discussed in Section 20120a(3)(a) if the department demonstrates all of the following:

  (*i*) The IRIS value is based on a determination that is at least 10 years old.

  (*ii*) There is more current data in peer reviewed scientific literature that is used on a general basis by the EPA or multiple other regulatory agencies nationally for the purpose of calculating cleanup criteria or standards.

  (*iii*) After assessing the body of evidence available using a rigorous systematic review methodology the weight of scientific evidence clearly supports the use of the proposed value as best available science for the purpose of calculating generic cleanup criteria.

Define a Hierarchy for DEQ when selecting Chemical & Physical Data

Section 20120(a)(3)(b) Apply the following order of precedence when selecting chemical or physical data for the development of Cleanup Criteria:

- The best relevant experimentally measured data.
- If data are not available as described above, the best relevant modeled or estimated data.

Address single event exposure when calculating cleanup criteria based on developmental effects

- Section 20120a(3)(e) . . . when addressing prenatal developmental effects, the DEQ may apply a single-event exposure scenario for a hazardous substance, pursuant to the notice process described in Section 20120a(3)(f), but only when either of the following occurred:

(i) The EPA applies a single-event exposure scenario to establish Regional Screening levels for that hazardous substance.

(*ii*) The department demonstrates, after conducting a comprehensive assessment of the hazardous substance, that a single exposure may result in an adverse effect and the weight of scientific evidence supports the application of a single-event exposure scenario.

The comprehensive assessment must, if appropriate, take into account all of the following:

(a) Whether there is data available involving single-day exposures to the hazardous substance during pregnancy.

(b) The differences in sensitivity, periods of development, and progression of different types of developmental effects in humans and animals.

(c) Differences in toxicokinetics between species

Establish Inhalation Exposure assumptions for Nonresidential cleanup criteria

Section 20120a(3)(d)

Use a daily exposure time for inhalation in the exposure intake for a nonresidential worker in an algorithm or equation used to calculate generic cleanup criteria under this part that is equal to the average number of hours, not to exceed 10 hours, that a nonresidential worker spends working in a 5-day work week according to the most appropriate governmental data or information.

Require that generic cleanup criteria and target detection limits be promulgated by Rule

Section 20120a(17) The department shall promulgate all generic cleanup criteria and target detection limits as rules.

- Except for generic cleanup criteria and target detection limits developed before January 18, 2018, and those generic cleanup criteria determined as set forth in subsections (5) and (23) and generic GSI criteria, generic cleanup criteria and target detection limits, and any modifications or revisions to generic cleanup criteria and target detection limits, are not legally enforceable until promulgated as rules.
- The generic cleanup criteria and target detection limits are subject to the following:
  - The department may periodically promulgate rules for any portion of the generic cleanup criteria to adopt and use new toxicity values or chemical or physical data selected pursuant to section 20120a(3)(a) and (b), or
  - To otherwise update the generic cleanup criteria in accordance with this part to incorporate, as appropriate, knowledge gained through research and studies in the areas of fate and transport and risk assessment taking into account best practices from other states, reasonable and realistic conditions, and sound science.
  - The department may also repromulgate rules that establish target detection limits to update those limits in accordance with this part.

Calculation of Toxic Equivalency Quotients

Section 20120a(20) Calculation and application of Toxic Equivalency Quotients are subject to the following:

- (A) The Toxic Equivalency Factors used must only be those adopted by the World Health Organization.
- (B) When compounds contributed by 2 or more persons acting independently are combined in a Toxic Equivalency Quotient to assess human health risks, harm is divisible and subject to apportionment of liability under subsections 20129(1) and (2).
- (C) To assess human health risks, the Toxic Equivalency Quotient must be compared to generic or site specific criteria for the reference hazardous substance.

Define applicable exposure pathways for dioxins and furans

Section 20120a

(21) Polychlorinated dibenzo dioxin (dioxin) and dibenzo furan (furan) congeners are not likely to leach from soil to groundwater. The Groundwater Surface Water Interface protection and the Residential Drinking Water Protection exposure pathways are not applicable or relevant when assessing dioxin and furan congeners unless the department demonstrates that those congeners are leaching at material concentrations through co-solvation.

(22) Dioxin and furan congeners are not likely to volatilize from soil or groundwater into the air. Vapor inhalation exposure pathways are not applicable or relevant when assessing dioxin and furan congeners.

Specifies a process for DEQ to update generic cleanup criteria ahead of rule making

Section 20120a(23) For a substance that does not have a generic cleanup criteria, if, based on the best available information, the department determines that the substance is a hazardous substance, the department may calculate generic cleanup criteria for that hazardous substance using toxicity values and chemical and physical data selected pursuant to subsections 20120a(3)(a) and (b) and in accordance with all other requirements of this part and publish the generic cleanup criteria on the departments website.

Within 30 days after publishing the new generic cleanup, the department shall initiate rule-making to promulgate rules for the new criteria by filing a rule-making request.

The new published generic cleanup criteria remain effective and legally enforceable until replaced by a final rule or, until the director directs the department to withdraw the rule request under the Administrative Procedures Act.

Clarify when vapor intrusion is a reasonable and relevant pathway

- Section 20120f(1) To satisfy the requirements of this part, a person may evaluate, address, and manage the vapor intrusion to the indoor air inhalation exposure pathway for a hazardous substance using any of the following methods:
  - The cleanup methods outlined in the MIOSHA provision [Section 20120a(18)] of NREPA.
  - To address vapor intrusion, in cases dealing with air pollution from petroleum, the process outlined in the Interstate Technology Regulatory Council Petroleum Vapor Intrusion Guidance Document.
  - An approach, using multiple lines of evidence, demonstrating that the potential contamination does not pose an unacceptable risk to the public health, safety, or welfare, or the environment as consistent with options specified in subsection 20120f(1)(c)(i-iii).

Clarify options for evaluating and addressing vapor intrusion as a relevant pathway (cont.)

- Indoor air sampling that accounts for actual conditions and demonstrates acceptable indoor air concentrations resulting from vapor intrusion compared to applicable indoor air criteria as specified in subsection 20120f(1)(d)(i-iii).
  - EPA's Regional screening levels
  - Generic indoor air inhalation cleanup criteria promulgated by the department
  - EPA's "Documentation for EPA's Implementation of the Johnson and Ettinger Model to Evaluate Site Specific Vapor Intrusion into Buildings Version 6.0"
- An alternative method or model that utilizes only site-specific variables or a combination of site-specific or building-specific variables, as long as the method or model is scientifically sound and supported by adequate site information. Alternative methods or models would have to be approved by the DEQ for contamination that has migrated beyond the boundaries of the property.

Clarify options for evaluating and addressing vapor intrusion as a relevant pathway (cont.)

- An indoor air inhalation pathway (a pathway through which air can enter an indoor space and thus be inhaled by an individual) would not be considered a reasonable and relevant pathway in need of remedial action if there were no occupied building or planned occupied building within the separation distances (vertical and lateral) 30 feet from petroleum contamination or 100 feet from any other volatile hazardous substance contamination.
- If there were an occupied building or planned occupied building within these distances of volatile hazards, further evaluation is needed to determine if the pathway is reasonable and relevant considering site-specific factors.

Clarifies aspects of Work Plans, Response Activity Plans, NFA process – with respect to changes of generic cleanup criteria

Section 20120a(17)(b) If generic cleanup criteria are included in or relied upon as a basis for decision… the criteria in effect at the time of the submittal continue to apply. . . unless:

(i) The person making the submittal voluntarily elects to apply the revised criteria

(ii) The director makes a site-specific demonstration the prior cleanup criteria are no longer protective... Except that this does not apply if, no later than 6 months after the promulgation of the rule revision changing the cleanup criteria, both of the following conditions are met:

(A) The person has substantially completed all active remediation as set forth in the approved plan, request, or similar document, and only monitoring, maintenance, or activities remain.
(B) The person submits a request for a no further action approval to the department.

(c) No further action reports that have been approved by the department and that rely on cleanup criteria that have been subsequently revised remain valid, subject to the liability provisions of section 20126(4)(e).

(d) If generic cleanup criteria are included in or relied upon as a basis for decision in a no further action report, other than a no further action report described in subdivision (b)(ii), that is submitted to the department but not yet approved by the department prior to the effective date of a rule revising those cleanup criteria, then the generic cleanup criteria effective at the time of submittal continue to apply

Broaden the kinds of disputes the Response Activity Review Panel may be requested to review

- Sec. 20114e. (1) The director shall establish a response activity review panel to advise him or her on disputes**.**
- (13) as used in this section:

  (a) “Dispute” means any disagreement over a technical, scientific, or administrative issue, including, but not limited to, disagreements over assessment of risk, response activity plans, remedial action plans, no further action reports, certificates of completion, documentation of due care compliance under this part, determinations of whether a person has submitted sufficient information for the department to make a decision regarding a submittal under this part of part 213, and initial assessment reports, final assessment reports, closure reports, postclosure plans, and documentations of due care compliance under part 213.

Thank You!

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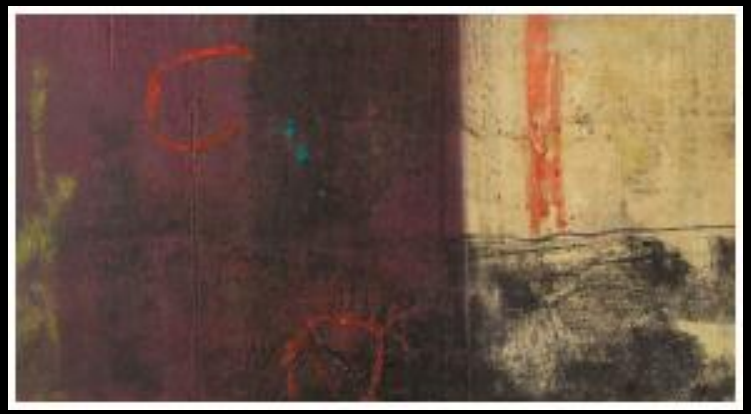

Act 581 Legal Analysis

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Act 581 Legal Issues and Analysis

The following slides contain a brief overview of many of the amendments to Part 201 effected by Public Act 581 of 2018. Any legal analysis is not intended to reflect the position of the MDEQ.

Act 581 – Toxicity Values

MCL 324.20120a(3) specifies a process for development of toxicity values that provides a preference (or hierarchy) in favor U.S. EPA (EPA) IRIS Toxicological Review (TR) toxicity values.

Act 581 – Toxicity Values

The process for developing toxicity values under MCL 324.20120a should provide for uniformity in the development of toxicity standards and cleanup criteria. This may allow for better coordination at sites where response activities are being conducted under potentially over-lapping state and federal statutes and regulations (Part 201, CERCLA, RCRA, TSCA).

Act 581 – Toxicity Values

The Section 324.20120a process for developing toxicity may require the MDEQ to utilize out-dated data. For example an IRIS toxicity value that is less than ten years old would be given a preference to more recent toxicity studies that are based on more recent studies or better science.

Act 581 – Toxicity Values

Although Act 581 was presumably passed to prevent the MDEQ from adopting cleanup criteria based on toxicity values that are more stringent than federally recognized toxicity values (e.g., IRIS), it is also possible that the Section 324.20120a process could prevent the MDEQ from lowering a cleanup criteria based on toxicity values that are less stringent than federally-recognized toxicity values.

Act 581 - Volatilization

MCL 324.20120f(1) codifies methods for evaluating the vapor intrusion to indoor air pathway, addressed in the following slides:

Act 581 - Volatilization

OSHA Method: Facilities can address the indoor air pathway by meeting conditions of MCL 324.20120a(18), which essentially allows a manufacturing facility (within certain NAICS codes) to demonstrate compliance with due care obligations by (1) complying with the occupational health standards for air contaminants; and (2) including the hazardous substance at issue in the facility's OSHA hazard communication program.

Act 581 - Volatilization

OSHA Method: The use of OSHA standards at manufacturing facilities seems appropriate as OSHA occupational health standards for air contaminants are intended to protective of worker exposure. This might also be helpful in scenarios where there is potential vapor intrusion of a hazardous substance that is also in use within a manufacturing facility (*e.g.,* acetone, benzene, etc.). In such instances it is very difficult if not impossible to determine the contribution of vapors vs. ambient sources (*e.g.,* evaporation) to the concentration of a chemical in indoor air.

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Act 581 - Volatilization

ITRC Method: Facilities can address the indoor air pathway by using the process outlined in the Interstate Technology Regulatory Council petroleum vapor intrusion guidance document (MCL 324.20120f(1)(b) for releases of petroleum described as regulated under MCL 324.21303(h)(ii) (which includes petroleum mixed with *de minimis* quantities of other hazardous substances).

- **The use of the ITRC guidance document allows for an alternative approach for petroleum releases.**

Act 581 - Volatilization

Facilities can address the indoor air pathway by using an approach, "using multiple lines of evidence, demonstrating that the vapor intrusion to the indoor air inhalation exposure pathway does not pose an unacceptable risk to the public health, safety, or welfare, or the environment, consistent with allow a combination of" one of more of the following: (1) OWSER Technical Guide; (2) the Interstate Technology Regulatory Council petroleum vapor intrusion guidance document; and/or (3) Documentation for EPA's Implementation of the Johnson and Ettinger Model.

Act 581 - Volatilization

The above-referenced option is very broadly worded and essential opens the door for regulated entities to make an argument that vapor intrusion has been adequately addressed under any of the referenced standards (or a combination thereof). This may allow for creative approaches to addressing volatilization.

Act 581 – NFA Process

Amendments to MCL 324.20114d allow for the submittal of a **no further action (NFA) report** before the completion of remedial actions that satisfied the requirements of Part 201. Furthermore, rather than documenting completion of all remedial actions (as was previously required) MCL 324.20114d provides that a no further action report must "document the basis for concluding that the remedial actions included in the no further action report are protective of the public health, safety, and welfare, and the environment with respect to the environmental contamination addressed by the remedial actions."

Act 581 – NFA Process

The amendments to MCL 324.20114d allow facilities conducting response activities more certainty by allowing for NFA approval before all response activities are completed. This mitigates the "moving target" concern raised by parties conducting remediation (often over extended periods of time).

Act 581- Response Activity Review Panel

Act 581 amendments to MCL 324.20114e(7) allow a person who submitted a response activity plan; **remedial action plan**; **postclosure plan**; a no further action report; a request for certificate of completion or documentation of due care compliance under this part; or an initial assessment report, final assessment report, closure report, or documentation of due care compliance under part 213 to appeal a decision made by the department to the Response Activity Review Panel regarding a **dispute** by submitting a petition to the director.

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Act 581- Response Activity Review Panel

The MCL 324.20114e(7) amendments included the addition of the terms "Remedial Action Plan" and "Postclosure Plan" that effectively broaden the issues that may be appealed. Likewise, the term "Dispute" was left in place while other terms suggesting that only dispute relating to technical or scientific disputes could be appealed under this MCL 324.20114e were removed, effectively broadening issues that could be appealed.

Act 581 – Other Considerations

As is the case with most environmental statutes, Part 201 authorizes the MDEQ to promulgate rules necessary to implement the statute. See MCL 324.20104(1). It remains to be seen whether the MDEQ will attempt to promulgate rules that attempt to implement to interpret the amendments contained in Act 581.

Act 581 – Other Considerations

The amendments contained in Act 581 have some obvious implications on the long-pending MDEQ effort to promulgate new MDEQ criteria. This begs the question – how long will the amendments delay promulgation efforts?

Act 581 – Other Considerations

In recent years the MDEQ has coordinated vapor intrusion regulation with the Michigan Department of Health and Human Services. Act 581 does not appear to limit the authority of MDHHS. What impact, if any, will Act 581 have on MDHHS evaluation of vapor intrusion risks?

Act 581 – Other Considerations

All Act 581 amendments concern provisions in Part 201. Furthermore, MCL 324.21301 provides that Part 213 "is intended to provide remedies using a process and procedures separate and distinct from the process, procedures, and criteria established under part 201 for sites posing a threat to the public health, safety, or welfare, or to the environment, as a result of releases from underground storage tank systems."

Based on the foregoing, many argue that Act 581 wasn't intended to affect Part 213. Nevertheless, many of the amendments in Act 581 have implications for Part 213 because Part 213 Risk-Based Screening Levels reference Generic cleanup criteria developed under Part 201. [*See e.g.,* MCL 324.21301(k)]. Furthermore, the provisions of Act 581 modifying MCL 324.20114e (Response Activity Review Panel) specifically discuss review for any "initial assessment report, final assessment report, closure report, or documentation of due care compliance under part 213."

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