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April 30, 2020

VIA ELECTRONIC MAIL
The Honorable Patrick McDonnell
Secretary, Pennsylvania Department of Environmental Protection
Chair, Pennsylvania Environmental Quality Board
Rachel Carson State Office Building,
16th Floor
400 Market Street, Harrisburg, Pennsylvania 17101-2301

Re: **Proposed Amendments to 25 Pa. Code Chapter 250**
Administration of Land Recycling Program

Dear Secretary McDonnell:

On February 15, 2020, the Pennsylvania Environmental Quality Board ("EQB") published a notice in the Pennsylvania Bulletin soliciting public comments regarding proposed substantive revisions to the current version of 25 Pa. Code Chapter 250: Administration of the Land Recycling Program ("Chapter 250"). 50 Pa. Bull. 1011 (Feb. 15, 2020). Chapter 250 implements requirements under the Pennsylvania Land Recycling and Environmental Remediation Standards Act ("Act 2"). The notice in the Pennsylvania Bulletin invited submission of comments regarding the proposed changes to Chapter 250 and established a public comment period through April 14, 2020. Due to the COVID-19 pandemic, the public comment period was subsequently extended until April 30, 2020. The purpose of this submission is to provide comments on behalf of the Pennsylvania Chamber of Business and Industry ("PA Chamber") regarding the proposed changes to Chapter 250.

The PA Chamber is the largest, broad-based business advocacy group in the Commonwealth. Our nearly 10,000 member companies are involved in all industrial categories and are of all sizes. In drafting these comments, the PA Chamber has drawn from a variety of views, interests and resources from its diverse membership, which consists of a broad spectrum of Pennsylvania industrial entities, businesses, and commercial enterprises, many of which will be affected by the proposed revisions to Chapter 250. The PA Chamber has also utilized the resources and experience of Manko, Gold, Katcher & Fox, LLP in helping to prepare the comments.

The PA Chamber has worked closely with the Pennsylvania Department of Environmental Protection ("PADEP") over many years in an effort to craft policies that allow for economic development and environmental protection to occur together. In that regard, the PA Chamber has been a staunch supporter of Pennsylvania's Land Recycling Program. The Land Recycling Program has brought tremendous benefits to Pennsylvania by helping facilitate remediation and reuse of thousands of contaminated sites across the Commonwealth while protecting public health and the environment. It is critically important that the Land Recycling Program continue to be implemented in a manner that fosters the key objectives that led to the adoption of Act 2 in 1995. It is in this context that we offer the comments set forth below. The PA Chamber appreciates the time and efforts of PADEP staff in reviewing these comments and considering our suggestions and recommendations.

BACKGROUND

The proposed changes to Chapter 250 are the product of extensive efforts by PADEP to prepare revisions to Chapter 250 that clarify how certain elements of the Pennsylvania Land Recycling Program are being implemented. In addition, proposed changes to numeric cleanup standards set forth in Chapter 250 incorporate updated toxicological information and exposure assumptions that serve as the basis for the medium specific concentrations ("MSCs") that PADEP has developed to implement the statewide health standard under Act 2. Indeed, under 25 Pa. Code § 250.11, PADEP is required to "review new scientific information that relates to the basis of the MSCs as it becomes available." PADEP is also required to propose appropriate changes to the MSCs for consideration by the EQB as necessary, "but in no case more than 36 months after the effective date of the most recently promulgated MSCs." *Id*. We note that the most recently promulgated version of the MSCs took effect on August 27, 2016. 46 Pa. Bull. 5655 (Aug. 27, 2016).

In the course of its efforts to prepare revisions to Chapter 250, PADEP worked with the Cleanup Standards Scientific Advisory Board ("CSSAB"). This coordination resulted in significant improvements to the proposed regulations and eliminated a number of issues that might otherwise have been appropriate focal points for public comment. For example, the proposed version of Chapter 250 preserves Aroclor-specific cleanup standards for polychlorinated biphenyls ("PCBs") which have been part of the framework under Act 2 since the inception of the Land Recycling Program. The proposed version of Chapter 250 also includes a very reasonable and sensible approach to dealing with sulfate and chloride in soils so that those two substances can be addressed using the statewide health standard.

However, there are certain issues that have not been addressed in this process. These issues involve the methodology that PADEP is utilizing in developing MSCs to implement the statewide health standard under Act 2 as a general proposition and the specific MSCs that PADEP has developed for certain regulated substances as set forth in the proposed version of Chapter 250. It is critical to the vitality of Pennsylvania's Land Recycling Program and other programs that rest on Chapter 250 that these issues be resolved. One such program that relies heavily on the MSCs pursuant to Act 2 is the fill management program. On January 1, 2020, the new Management of Fill Policy (Document No. 258-2182-773) issued by PADEP took effect. Under the new Management of Fill Policy, the numeric values on which cleanup standards for soils are based in Chapter 250 are incorporated by reference for purposes of determining the clean fill concentration limits and the regulated fill concentration limits. These concentration limits in turn affect virtually every project in Pennsylvania where fill materials are being imported or exported.

We are taking this opportunity to provide comments for consideration by the EQB and PADEP with the belief that further changes can and should be made to the proposed version of Chapter 250 before the regulations are finalized. These comments are set forth below.

DISCUSSION

1. Methodology for Developing MSCs

Act 2 was adopted 25 years ago to establish a fresh and innovative approach for investigating and remediating properties in Pennsylvania impacted by releases of regulated substances. Section 102 of Act 2 sets forth key objectives that the General Assembly had in mind in passing Act 2. It is useful to revisit several of these goals as guiding principles when reviewing PADEP's proposed revisions to the regulations implementing Act 2. The goals as set forth in Act 2 include the following:

- The elimination of public health and environmental hazards on existing commercial and industrial land across this Commonwealth is vital to their use and reuse as sources of employment, housing, recreation and open-space areas. The reuse of industrial land is an important component of a sound land-use policy that will help prevent the needless development of prime farmland, open-space areas and natural areas and reduce public costs for installing new water, sewer and highway infrastructure.

- Incentives should be put in place to encourage responsible persons to voluntarily develop and implement cleanup plans without the use of taxpayer funds or the need for adversarial enforcement actions by the Department of Environmental Resources [now PADEP] which frequently only serve to delay cleanups and increase their cost.

- Public health and environmental hazards cannot be eliminated without clear, predictable environmental remediation standards and a process for developing those standards. Any remediation standards adopted by this Commonwealth must provide for the protection of public health and the environment.

- Cleanup plans should be based on the actual risk that contamination on the site may pose to public health and the environment, taking into account its current and future use and the degree to which contamination can spread offsite and expose the public or the environment to risk, not on cleanup policies requiring every site in this Commonwealth to be returned to a pristine condition.

- The public is entitled to understand how remediation standards are applied to a site through a plain language description of contamination present on a site, the risk it poses to public health and the environment and any proposed cleanup measure.

35 P.S. § 6026.102.

Clearly, the General Assembly was intending for PADEP to develop remediation standards based on actual risk to human health and the environment, and not based on returning a site to a "pristine" or completely unimpacted condition. Act 2 also requires PADEP to develop remediation standards according to a uniform framework that is transparent, predictable, and understandable to the public and responsible parties. The statutory language is clear that key goals of Act 2 are to encourage and incentivize the voluntary remediation and reuse of impacted sites, to provide important economic and public welfare benefits to the Commonwealth, and to prevent the unnecessary development of unimpacted sites.

The development of remediation standards is an intensive and constantly-evolving process, as new and often conflicting toxicological and other scientific information becomes available across multiple sources. Such information must be routinely reviewed, evaluated, and incorporated (if appropriate) into equations defining the remediation standards. Recognizing the difficulty of this task and the need for independent technical assistance for PADEP, the General Assembly established the CSSAB pursuant to Section 104(a) of Act 2 for the purpose of: (i) assisting PADEP and the EQB in developing the MSCs under the statewide health standard; (ii) determining the appropriate statistically and scientifically valid procedures to be used; (iii) determining the appropriate risk factors, and (iv) providing other technical and scientific advice as needed to implement the provisions of Act 2. Clearly, the CSSAB was established to play an active role in determining the procedures and risk factors to be used by PADEP in developing remediation standards to be promulgated by the EQB. *See* 35 P.S. § 6026.104(a).

Section 303 of Act 2 describes the requirements for developing the MSCs under the statewide health standard. Specifically, under Section 303(a) of Act 2, the MSCs must include any existing residential and non-residential health-based standards adopted by the Federal Government by regulation or statute. However, the MSCs cannot be more stringent than those standards. Section 303(b) of Act 2 defines additional requirements for the MSCs, including compliance with applicable laws governing discharges to air and surface waters, and compliance with maximum contaminant levels ("MCLs") and health advisory levels ("HALs") established by the United States Environmental Protection Agency ("EPA") under the Safe Drinking Water Act for groundwater that may be used for drinking water or agricultural purposes. Section 303(c) of Act 2 goes on to state that, outside of these applicable federal standards, the MSCs "shall be calculated by the department using valid scientific methods, reasonable exposure pathway assumptions and exposure factors for residential and nonresidential land use which are no more stringent than the standard default exposure factors established by EPA" based on the cancer risk range and noncarcinogenic effects specified in Act 2. 35 P.S. § 6026.303(c).

The foregoing reflects a framework for responsible parties to remediate and reuse impacted sites using risk-based remediation standards as developed by PADEP with assistance from the CSSAB, based on valid scientific procedures and risk factors, but not any more stringent than those used by EPA for similar purposes. Act 2 directs PADEP in concert with the CSSAB to develop for promulgation by the EQB clear, scientifically-valid and transparently-developed remediation targets that facilitate returning impacted sites to productive use as quickly as possible while still being protective of human health and the environment to the specified level of risk set forth in Act 2.

In recent discussions with the CSSAB, PADEP has expressed its desire to follow a transparent and objective process for developing the MSCs in order to justify its assumptions and methods to the public. PADEP has also expressed a desire to utilize well defined protocols in selecting toxicological endpoints from the scientific literature that serve as the critical inputs for calculation of the MSCs, because it does not have the staff or resources available to competently evaluate and make professional judgements regarding the appropriateness of such toxicological and epidemiological studies for hundreds of chemicals. These desires are fully consistent with the stated goals of Act 2 and mesh well with the fact that the General Assembly mandated the creation of the CSSAB to supplement PADEP's technical expertise. However, in developing the MSCs now proposed for adoption, it is apparent that PADEP has not followed a transparent and objective process. Moreover, as described in more detail below, PADEP has ignored the valid scientific procedures and risk factors presented to it by the CSSAB in promulgating MSCs for vanadium.

Sources of toxicity information are presented in 25 Pa. Code § 250.605 and referenced in the Pennsylvania Land Recycling Technical Guidance Manual (the "TGM") for purposes of calculating a

site-specific standard under Act 2. PADEP typically uses these same sources of toxicity information in developing MSCs. While there is no prescribed hierarchy of sources of toxicity information presented in the regulations, PADEP has indicated that it follows a hierarchy with the Integrated Risk Information System ("IRIS") serving as the "gold standard" followed by EPA's Provisional Peer-Reviewed Toxicity Values ("PPRTVs") followed by a collection of "other sources" listed in 25 Pa. Code 250.605(a)(3). The regulations do not differentiate among such "other sources" for purposes of calculating the MSCs pursuant to the statewide health standard (some of which are many years out of date and no longer updated), requiring PADEP to pick and choose among such sources in developing MSCs. If PADEP wishes to follow a transparent and objective process that limits subjective decision-making, it would be helpful for the "other sources" to be appropriately weighted and the hierarchy to be disclosed to the regulated community and the public within the regulations implementing Act 2.

We note that the foregoing issues will multiply in complexity. The EQB is proposing to add two new sources to the list of equally-weighted "other sources" of toxicity information in 25 Pa. Code § 250.605(a)(3): the EPA Human Health Benchmarks for Pesticides ("HHBP") and EPA PPRTV Appendix Values. PADEP has previously relied on PPRTV Appendix Values to calculate many of the current MSCs, and while listing this source in the regulations may provide some additional transparency in that regard, it should be appropriately weighted among the unranked "other sources."

The PPRTV Appendix Values are more appropriately called screening values by EPA because they have been determined to be of very limited utility in calculating risk-based standards, for one or more of the following reasons: (i) the data are published in non-peer-reviewed sources, (ii) the underlying study has unacceptably high uncertainty, which drives the resulting toxicological value outside the range of usefulness for actual risk-based decision-making, and/or (iii) the value is not chemical-specific and is based on a surrogate when no useful human or animal toxicity data are available for the chemical of interest.[1] (The appropriateness of the use of surrogate toxicity information for calculating specified MSCs is discussed in more detail below.) The use of PPRTV Screening Values to calculate risk-based remediation targets is not generally appropriate or scientifically justified, and, for that reason, this source should be ranked at or near the bottom of the hierarchy, only to be used in the absence of any other chemical-specific information. As an example, the supporting document for the derivation of the PPRTV Screening Value that PADEP is using for the oral slope factor for benzo[a]anthracene explicitly states that the value should only be used for screening purposes. (The value itself is also based on the relative carcinogenicity of benzo[a]pyrene, which has recently been updated as discussed hereinafter.) Because of the significant uncertainty and limited utility of PPRTV Screening Values, the use of PPRTV Screening Values should also require increased review and input from the CSSAB.

Similarly, the use of EPA's Human Health Benchmarks for Pesticides may be an additional source of toxicity values for certain pesticides in limited circumstances, but the use of this source should be considered and appropriately weighted among the unranked "other sources" in the 25 Pa. Code § 250.605(a)(3) or should otherwise be described. Based on the proposed revisions to 25 Pa. Code Chapter 250, Appendix, Table 5a (listing toxicological information for organic regulated substances), the use of this source to supplant previously-used toxicity values sourced from the IRIS database appears to violate the hierarchy that PADEP is purporting to follow. The use of HHBPs over IRIS values or PPRTVs is likely only appropriate where EPA has archived the IRIS value or PPRTV and specifically referenced the HHBP as the replacement value.

[1] Basic Information About Provisional Peer-Reviewed Toxicity Values (PPRTVs). EPA September 2019. Available at https://www.epa.gov/pprtv/basic-information-about-provisional-peer-reviewed-toxicity-values-pprtvs

In discussions with the CSSAB regarding the MSCs for vanadium (as discussed in more detail below), PADEP has advanced the position that in the absence of toxicity values for a particular regulated substance, it is inappropriate to use toxicity values from a surrogate regulated substance. The regulations implementing Act 2 place great emphasis on using toxicity values as inputs to the equations utilized to calculate MSCs that are chemical-specific. Surrogate values do not meet this test. Nevertheless, it is clear from a review of the toxicity values listed in both the current and proposed versions of 25 Pa. Code Chapter 250, Appendix, Table 5a that PADEP is relying widely on toxicity information from surrogate regulated substances. No footnotes or other information are provided to identify the regulated substance that is being used as a surrogate for a particular regulated substance where toxicity values are not available or to justify PADEP's decision to use such a surrogate. Moreover, no information is provided to describe why the toxicity of the surrogate regulated substance is indicative of the toxicity of the primary regulated substance.

Instead of the transparent and objective process that PADEP desires, the use of surrogate values is an ambiguous process that requires PADEP to assume the toxicity of a chemical in the absence of valid scientific data. It appears that surrogate values have been used when none of the other listed sources of toxicity data are able to provide chemical-specific information. Typically, this is because those sources have evaluated the available scientific literature and have determined that there is not enough available data to quantify the dose-response relationship, or that the amount of inherent uncertainty would make any such quantification meaningless for practical risk-based decisions (as is the case for certain PPRTV Screening Values). PADEP's use of surrogate values in these situations, sourced from unidentified chemicals and used for unspecified reasons, is not scientifically valid, predictable, or understandable to the regulated community, as Section 303(c) of Act 2 requires.[2]

As the comments set forth below illustrate, the process that PADEP is using to develop MSCs is not a mechanical exercise. PADEP is picking and choosing sources of toxicity information and other physical and chemical-specific information without being transparent as to bases for its decisions. Where PADEP is selecting toxicity information that result in MSCs that are overly conservative or are not based on sound science, the underpinnings of the Land Recycling Program are eroded. There are very real consequences to the decisions PADEP is making that are detrimental to the ability to transact business in Pennsylvania and return environmentally-impacted properties to productive use.

[2] We do not suggest that all uses of surrogate toxicity information is inappropriate. However, such a step necessarily involves multiple layers of technical judgment and decision-making that should be transparent. In such circumstances, input from the CSSAB is critical to ensuring that the use of surrogate toxicity information is warranted and justified.

2. Medium Specific Concentrations for Vanadium

a. Background Information Concerning Vanadium

Vanadium is a naturally occurring metal that is found in soils across Pennsylvania. The naturally-occurring background levels of vanadium in soils in Pennsylvania have been assessed as part of two separate national soil surveys conducted by the United States Geologic Survey ("USGS") in 2007 and 1981. The 2007 soil survey is more comprehensive than the 1981 soil survey and included 76 sampling locations across the Commonwealth. Three soil samples were collected from each location - one from the ground surface and one each from the tops of the first two soil horizons, but with all of the soil samples being collected within the first meter of the soil column. Vanadium was detected in all 227 soil samples that were collected.[3] The concentrations of vanadium that were detected ranged between 12 milligrams per kilogram ("mg/kg") and 162 mg/kg, with an average concentration of 66 mg/kg.

The 1981 soil survey contains fewer samples than the 2007 soil survey. However, the results are consistent. A single surface soil sample was collected from each of 16 locations across the Commonwealth. Vanadium was detected in all 16 samples that were collected. The concentrations of vanadium that were detected ranged between 15 mg/kg and 150 mg/kg, with an average concentration of 80 mg/kg.

b. Prior Cleanup Standards for Vanadium

Until revisions to Chapter 250 were promulgated on August 27, 2016, vanadium was typically not a regulated substance that required action or posed concerns at sites being investigated or remediated in Pennsylvania, absent unique circumstances. However, the revisions to Chapter 250 that took place in 2016 changed that frame of reference entirely. Despite concerns raised by the CSSAB and the regulated community, PADEP decided to use different toxicological information in calculating the MSCs for vanadium that resulted in significant decreases in the MSCs for vanadium in soils and groundwater. The table set forth below shows the dramatic changes that occurred.

Source	**Surface Soils (mg/kg)**		**Groundwater – Used Aquifers (TDS ≤ 2,500 mg/L) (µg/L)**	
	Residential	**Non-Residential**	**Residential**	**Non-Residential**
2011 MSCs	1,500	20,000	260	720
2016 MSCs	15	220	2.9	8.2

mg/kg – milligrams per kilogram
mg/L – milligrams per liter
µg/L – micrograms per liter

Because vanadium is neither a volatile compound nor a carcinogenic compound, the reductions in the MSCs from 2011 to 2016 are solely due to a change in the Oral Reference Dose ("RfD_o") parameter used to calculate the soil and groundwater MSCs for the ingestion pathway. The RfD_o used by PADEP in 2011 was 0.007 mg/kg-day, which was sourced from the Health Effects Assessment Summary Table ("HEAST") issued by EPA. The RfD_o used by PADEP in 2016 was 0.00007 mg/kg-day, sourced from EPA's list of PPRTVs. It is obvious that the sourcing of this input parameter plays an extremely significant role in determining the MSCs for vanadium, and by extension, the cost and timeliness of cleanup activities under Act 2.

[3] We note that USGS analyzed only two samples rather than three sample from one soil sampling location.

c. Discussions with the CSSAB Regarding MSCs for Vanadium

On July 17, 2018, PADEP discussed with the CSSAB proposed revisions to the cleanup standards in Chapter 250. The proposed revisions did not include any changes at that time to the MSCs for vanadium that became effective in 2016. PADEP did, however, allow an additional opportunity for PADEP and the CSSAB to revisit this important issue. The CSSAB again expressed concerns regarding the underlying science on which PADEP had based the MSCs for vanadium (i.e., the toxicity value on which the MSCs are based is expressly described as a "low confidence" value). The CSSAB also raised the concern that the MSC for vanadium in soils at residential properties overlying used aquifers (the "residential soil MSC") is below background levels and would have a significant detrimental impact on the clean fill program once revisions to the Management of Fill Policy were finalized (as has subsequently occurred). The CSSAB recommended revision or removal of the MSCs for vanadium that had taken effect in 2016 and remained in the proposed regulations without modifications. In addition, the CSSAB provided several options for developing more appropriate MSCs for vanadium that are fully consistent with the hierarchy of toxicological sources and other required provisions of Act 2. However, PADEP rejected these recommendations, apparently resting on its belief that the toxicological information that it had selected for use was appropriate. PADEP ultimately proceeded with the proposed rulemaking unchanged notwithstanding the CSSAB's recommendations, prompting the CSSAB to take the important and unusual step of issuing a letter expressly withholding its endorsement of the proposed revisions to Chapter 250 insofar as they failed to revise the MSCs for vanadium. A copy of the CSSAB's letter dated December 4, 2020, is attached hereto and incorporated by reference.

d. Approaches by Other Regulatory Agencies to Cleanup or Screening Standards for Vanadium

As the CSSAB and others have explained in discussions with PADEP and in various submittals made to PADEP, the MSC for vanadium in soils at residential properties included in the proposed version of Chapter 250 is well below naturally occurring background levels of vanadium and is significantly out of step with screening values and cleanup standards for vanadium developed by EPA and other state regulatory agencies. In fact, it appears to be substantially lower than any published federal or state values.

For example, EPA has published Regional Screening Levels ("RSLs") that serve as screening values for use in making decisions as a threshold matter as to whether investigation and/or remediation might be necessary at Superfund sites being addressed pursuant to the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA") and corrective action sites pursuant to the Resource Conservation and Recovery Act ("RCRA"). The RSLs are used to determine whether or not the presence of particular substances requires further investigation or cleanup at such sites. Screening values based on the RSLs can serve a similar purpose in the context of sites being addressed under the site-specific standard of Act 2. RSLs are not cleanup standards that apply to determine whether remedial measures have reduced risks to acceptable levels. Instead, if a concentration of a regulated substance is below an RSL, it is indicative that no concerns are posed by that regulated substance and further actions are not necessary. The RSL for vanadium and compounds at residential properties based on a carcinogenic risk of $1x10^{-6}$ and a hazard quotient of 1 is 390 mg/kg, more than an order of magnitude higher than (i.e., 26x) the residential soil MSC for vanadium that PADEP has established.

Pennsylvania is similarly an outlier in comparison with other states. In comparison with the residential soil MSC for vanadium of 15 mg/kg, other states have much higher cleanup standards for vanadium in soils at residential properties based on direct contact exposure. Examples include the following:

- Massachusetts – 400 mg/kg
- Connecticut – 470 mg/kg
- New York – 10,000 mg/kg
- New Jersey – 78 mg/kg[4]
- Delaware – 134 mg/kg
- Ohio – 680 mg/kg
- California – 530 mg/kg

e. Toxicological Information Regarding Vanadium

As indicated above, PADEP chose to base the MSCs for vanadium on toxicological information from the PPRTV database. That database was developed by EPA to quantitatively evaluate the risk of chemicals before those chemicals have been evaluated in EPA's Integrated Risk Information System database, the database of toxicological information that is generally given the greatest weight in risk evaluations. The PPRTVs are developed specifically for use in site-specific risk assessments for EPA's Superfund Program. That process does not include interagency review or the external peer review with a public notice and comment period required for toxicity values to be placed in IRIS. For this reason, PPRTVs can be developed more expeditiously than toxicity information placed in IRIS, but they have not been promoted for use in other EPA or non-EPA programs.

The PPRTV for vanadium is based on studies using sodium metavanadate. EPA has applied an uncertainty factor of 3,000 to the PPRTV for vanadium and has assigned a "low confidence" rating to the PPRTV for vanadium. Notwithstanding these limitations, PADEP is using the PPRTV for vanadium even though information for another vanadium compound (vanadium pentoxide) is available in IRIS. While EPA has assigned a "low confidence" rating to the information in the IRIS database, it has applied a far lower uncertainty factor of 100. We note that both vanadium pentoxide and sodium metavanadate are vanadium compounds containing vanadium in an oxidation state of +5, and therefore are expected to have similar vanadium-induced toxicity. In fact, the vanadium toxicity evaluated in the IRIS and PPRTV studies is similar, and the dramatic difference in reference doses is almost entirely due to the dramatic difference in uncertainty factors that are applied.

In deciding how to calculate RSLs for vanadium, EPA faced the same choice that PADEP faced – whether to use the PPRTV for sodium metavanadate or to use the toxicity information for vanadium pentoxide from the IRIS database. EPA determined that using the information from IRIS database for vanadium pentoxide rather than the PPRTV for sodium metavanadate was appropriate in developing the

[4] The New Jersey Department of Environmental Protection has proposed to increase this standard to 390 mg/kg, following the methodology used by EPA and described below. *See* Proposed Soil Remediation Standards (April 6, 2020) at https://www.nj.gov/dep/rules/proposals/20200406a.pdf (See also 52 N.J.R. 566(a)).

RSLs for vanadium. As a result, the screening standard for vanadium in soils at residential properties is significantly higher than the cleanup standard that PADEP has developed for soils at such properties under Act 2.

EPA decided to use the IRIS reference dose for vanadium pentoxide to derive a reference dose for vanadium compounds - instead of using the PPRTV for vanadium - because of the significantly higher uncertainty adjustment applied in the PPRTV (3,000 vs. 100) and because IRIS is a higher-ranked source of information. This derivation was performed using the weight percentage of vanadium in vanadium pentoxide as is discussed in Section 5.4 of the RSL User's Guide. The main difference between the calculated PPRTV for vanadium and the calculated IRIS toxicity value for vanadium is the amount of uncertainty adjustment that is applied, not the toxicity measured in the underlying studies.

f. Revisions to the MSCs for Vanadium are Critically Important

Since 2016, the MSCs for vanadium have created significant implementation problems at sites being remediated in Pennsylvania under Act 2. Remediators have faced the challenge of dealing with naturally occurring levels of vanadium in soils that exceed the MSCs. Those issues will continue if no changes are made. Of key importance, PADEP has suggested that even when the site-specific standard is being used, the toxicological inputs to risk assessments must rely on the PPRTV values for vanadium rather than the toxicological information from the IRIS database. PADEP's proposed solution to this problem is to require pathway elimination (i.e., capping). Capping vast areas of soils because they have naturally occurring concentrations of vanadium that do not pose any material risks to human health is not an approach that is practicable, nor is it consistent with the legislative goals of Act 2 as discussed above.

The problems that have occurred in the Act 2 program have recently been magnified by the fact that PADEP has incorporated by reference the MSC for vanadium in soils at residential properties as the clean fill concentration limit in the new version of the Management of Fill Policy that went into effect on January 1, 2020. Moreover, PADEP is mandating that historic fill be analyzed for vanadium in order to qualify as clean fill thereby placing numerous members of the regulated community in a regulatory straight-jacket.[5] The impact of reducing the clean fill concentration limit to a level well below background concentrations for vanadium cannot be overestimated.

As discussed above, the combined USGS datasets obtained to evaluate naturally occurring background concentrations of vanadium in soils in Pennsylvania clearly demonstrate that the residential soil MSC and clean fill concentration limit for vanadium of 15 mg/kg is far below those naturally-occurring background levels. The USGS datasets indicate that the naturally-occurring vanadium content of soils in Pennsylvania is as high as 162 mg/kg. Of the 243 background samples in the combined USGS datasets, only two samples contained vanadium below the residential MSC of 15 mg/kg. Although the new Management of Fill Policy provides a process for developing alternative clean fill concentration limits based on background concentrations, the process is arduous, data-intensive, and imposes additional restrictions of

[5] The Management of Fill Policy requires as a first step that due diligence be performed to determine whether the fill material that is to be transferred has been impacted by a spill or release of regulated substances. If the fill material has not been impacted by a spill or release, then it can qualify as clean fill without being sampled. Historic fill stands on a different footing, however, and must be sampled in order to show that it meets the clean fill concentration limits. (Historic fill is a combination of soils and other materials such as brick, block, concrete, used asphalt and dredged material that was placed as fill material in the past.) Given the naturally occurring background levels of vanadium in soils, the requirement to sample historic fill for vanadium will be destined to failure in virtually all circumstances.

the movement of material that would otherwise be unregulated. With respect to vanadium, the process is also completely unnecessary when options to develop a more appropriate MSC for vanadium that are fully consistent with the risk-based provisions of Act 2 are available to PADEP.

g. Purported Barriers to Modifying the MSCs for Vanadium

PADEP has articulated various reasons for resisting modifying the MSCs for vanadium, notwithstanding the fact that those MSCs are clearly unworkable and unsupported by the CSSAB. None of those purported reasons withstand scrutiny.

First, PADEP has expressed its view that it should follow the hierarchy of sources of toxicity values that it typically uses. We understand PADEP's desire in this regard but not the outcome. In promulgating the MSCs to implement the statewide health standard under Act 2, PADEP generally follows an established hierarchy of sources of toxicity information. The hierarchy is substantially similar to the hierarchy established by EPA in 2003 and updated in 2013 by EPA's Office of Superfund Remediation and Technology Innovation. In each hierarchy, sources of toxicity information are "ranked" according to the relative certainty and appropriateness of the toxicity information they contain, as determined by the level of scientific and governmental peer review to which each source is subject. IRIS is at the top of the hierarchy, representing the highest ranked source of toxicity information over and above other sources of toxicity information. IRIS in fact contains toxicity information for vanadium that can readily be used and would result in significant increases in the MSCs for vanadium.

Second, PADEP has indicated that it does not wish to use the IRIS toxicity value for vanadium because it is based on toxicity studies using vanadium pentoxide rather than elemental vanadium. However, the PPRTV for vanadium that PADEP has used is also based on a vanadium compound – sodium metavanadate – rather than elemental vanadium.[6] If this is the source of PADEP's concern, the PPRTV stands on exactly the same footing as the IRIS toxicity value in that both are based on vanadium compounds. In fact, because vanadium pentoxide contains a greater mass fraction of vanadium than does sodium metavanadate, and does not contain any sodium, it is arguably more representative of the underlying vanadium toxicity.

Third, PADEP has suggested that there is uncertainty associated with the toxicity value for vanadium available from the IRIS database. We do not disagree. However, the uncertainty factors that EPA applied to the PPRTV are 30 times higher than the uncertainty factors presented in the IRIS database. This is due in part to the fact that the PPRTV for vanadium is based on a subchronic (short term) study using rats over a period of six months. By contrast, the IRIS toxicity value is based on a long-term study that lasted 2.5 years.

Fourth, PADEP has raised issues regarding transparency in how it establishes MSCs. Again, we agree with PADEP's objectives, but do not understand the concern. To remove any doubt as to the basis for the MSCs for vanadium, PADEP can easily add a footnote to the relevant tables in 25 Pa. Code Chapter 250, Appendix A to explain for all to see the source of the toxicity information it is using.

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[6] The PPRTV database lists toxicological information for "Vanadium and Its Soluble Inorganic Compounds Other Than Vanadium Pentoxide." Vanadium Pentoxide was specifically excluded from the PPRTV because of the more robust information already present in the IRIS database. Regardless of the label that is used, the reality is that the toxicological information supporting the PPRTV is for sodium metavanadate as is evident for the sources of the information used in the PPRTV development document.

Finally, PADEP has suggested that it may have difficulty converting toxicity information for vanadium pentoxide into toxicity information for vanadium itself. While noting that the same issue is present with respect to toxicity information for sodium metavanadate used in developing the PPRTV, the issue simply is not a real barrier. The derivation relies on using the weight percentage of vanadium in vanadium pentoxide. This is an elementary calculation and is discussed in Section 5.4 of the RSL User's Guide.

Recommended Modifications to the MSCs for Vanadium

Given the foregoing, we strongly urge PADEP to revise the MSCs for vanadium in Chapter 250 and base those MSCs on the IRIS toxicity value for vanadium rather than the PPRTV for vanadium. Factors supporting this outcome include the following:

- The IRIS toxicity value is based on long-term studies rather than short-term studies.
- The IRIS toxicity value has undergone a more rigorous peer review and comment process.
- The IRIS toxicity value comes from a higher-ranked source in the toxicity hierarchies.
- The IRIS toxicity value has significantly less uncertainty and requires fewer artificial adjustments as a result to account for such uncertainty.
- Use of the IRIS toxicity value is consistent with EPA's approach in developing the RSLs.

If PADEP uses the IRIS toxicity value for vanadium, the MSC for vanadium in soils at residential properties overlying used aquifers would be approximately 1,100 mg/kg. This MSC would be significantly lower than the 2011 HEAST-based MSC of 1,500 mg/kg, but still comfortably above the typical background concentrations of vanadium in soils in Pennsylvania, unlike the current MSC for vanadium in soils at residential properties overlying used aquifers of 15 mg/kg.

One of the principal goals underlying the enactment of Act 2 in 1995 was to set risk-based cleanup standards for soils instead of requiring use of cleanup standards based on achieving pre-anthropogenic background levels (i.e., pristine naturally-occurring background levels). Failure to adjust the MSCs for vanadium and leave them where they are in the face of the foregoing information would set cleanup standards for vanadium in soils to <u>less</u> than natural background levels and thus be inconsistent with this cornerstone of the Land Recycling Program under Act 2. Moreover, it would turn a blind eye to superior science and result in needless expenditures of resources (both within PADEP and by the regulated community) to achieve standards that are not necessary to protect public health and the environment. From an administrative perspective, cleanup activities for soils will continue to face needless complications by effectively eliminating the availability of the statewide health standard as an option for vanadium and requiring the use of the background standard even if all other regulated substances are being addressed using the statewide health standard. In addition, the clean fill concentration limit for vanadium under the new Management of Fill Policy which relies on the residential soil MSC in Chapter 250 will continue to wreak havoc with the ability of those in the regulated community to demonstrate that fill material meets the clean fill standards for vanadium. The impact of this outcome on PADEP's administrative resources and the regulated community, as a whole, cannot be overstated.

None of these outcomes are necessary. The current MSCs for vanadium are not necessary to protect public health and the environment. There is a sound basis for PADEP to revise the MSCs for vanadium.

Adjusting the MSCs for vanadium is a step that is critically important, both for the regulated community and to conserve PADEP's limited administrative resources. Refusing to act in the face the foregoing is wholly inappropriate.

3. Medium Specific Concentrations for Polycyclic Aromatic Hydrocarbons

The proposed version of Chapter 250 includes adjustments for the cleanup standards for certain polycyclic aromatic hydrocarbons ("PAHs"). For example, PADEP is proposing to raise the MSCs for benzo[a]pyrene based on new toxicity information. This modification will avoid the problems that have existed since 2011 when the residential soil MSC for benzo[a]pyrene was reduced to levels below anthropogenic background concentrations. We support this adjustment.

Beyond benzo[a]pyrene, there are MSCs for other PAHs that we believe merit comment. For example, Chapter 250 includes MSCs for acenaphthylene, benzo[g,h,i]perylene, 2-methylnaphthalene, and phenanthrene. It does not appear that toxicity values for these PAHs are included in the sources of toxicity information such as IRIS that PADEP has identified as acceptable. Likewise, EPA has not developed RSLs for these PAHs, presumably because of the absence of toxicity information. What is clear from 25 Pa. Code Chapter 250, Appendix A, Table 5a is that PADEP is using toxicity information associated with surrogate compounds as the basis for the MSCs for these PAHs. In the interests of transparency, it would be useful for PADEP to identify which surrogate compounds are being used and the rationale that PADEP is using to select those surrogate compounds.

With respect to certain other PAHs that are classified as carcinogenic compounds, we note that PADEP is using cancer slope factors (the basic toxicological input values) to calculate MSCs that are significantly at odds with the toxicity information that EPA is using to calculate RSLs for those same PAHs. Using higher cancer slope factors (i.e., greater cancer potency) drives the MSCs lower (there is an inverse correlation between cancer slope factors and MSCs). These differences are highlighted in the table below.

PAHs	PADEP		EPA		Potency Differential
	CSF_o	Source	CSF_o	Source	
Benzo[a]anthracene	0.7	PPRTV Appendix	0.1	Potency relative to B[a]P	7 times higher
Benzo[b]fluoranthene	1.2	CalEPA	0.1	Potency relative to B[a]P	12 times higher
Chrysene	0.12	CalEPA	0.001	Potency relative to B[a]P	120 times higher
Dibenzo[a,h]anthracene	4.1	CalEPA	1	Potency relative to B[a]P	4.1 times higher
Indeno[1,2,3-c,d]pyrene	1.2	CalEPA	0.1	Potency relative to B[a]P	12 times higher

CalEPA – California Environmental Protection Agency
B[a]P – Benzo[a]pyrene

In researching the source of these differences, it becomes apparent that the cancer slope factors used by EPA for calculating the RSLs as well as the cancer slope factors developed by the California Environmental Protection Agency ("CalEPA") for many PAH compounds are based on a relative potency to benzo[a]pyrene, because the toxicity of that compound has been studied much more extensively and is better understood than the toxicity of other PAHs. Both EPA[7] and CalEPA[8] have published technical guidance documents explaining the basis for the relative potency factors ascribed to each PAH compound as compared to benzo[a]pyrene, and this is further discussed in the referenced PPRTV Screening Value derivation for benzo[a]anthracene and the RSL user guide. Therefore, if an updated cancer slope factor becomes available for benzo[a]pyrene, as is now the case with the IRIS-sourced value that PADEP proposes to incorporate, the cancer slope factors for the other PAHs should be appropriately scaled to that new value since their carcinogenicity has only been quantified relative to that of benzo[a]pyrene. This has not been done by PADEP in the current revisions to the MSCs for these other PAHs. This is another example of a situation where simply looking up a toxicity value in a source database, without understanding the basis for that value, results in cleanup standards that are not scientifically valid, risk-based, or defensible.

The groundwater MSCs for a third group of PAHs are being driven by theoretical solubility limits which produce MSCs that are significantly lower than the corresponding risk-based MSCs:

PAHs	Risk-based MSC (µg/L)	Solubility-based MSC (µg/L)	Risk/Solubility Ratio
Benzo[g,h,i]perylene	2,000	0.26	7,700
Fluoranthene	1,300	260	5
Phenanthrene	10,000	1,100	9.1
Pyrene	1,000	130	7.7

µg/L – micrograms per liter

Note that the risk-based values presented in the above table were calculated based on the residential, used aquifer exposure assumptions and using the toxicity values listed in 25 Pa. Code Chapter 250, Appendix A, Table 5a.

There are several commonly-encountered factors that can increase the practical solubility of the foregoing compounds far beyond the theoretical solubility limits that form the basis of the current MSCs, including pH and temperature variations in groundwater as well as the presence of co-solvent and co-solute effects. Given the significant discrepancies between the risk-based standards and the MSCs based on theoretical solubility limits described above, we suggest that further evaluation is appropriate to determine how to appropriately address these discrepancies, particularly for benzo[g,h,i]perylene.

4. Medium Specific Concentrations Based Upon the New Definition of Volatile Compounds

We note that the proposed version of Chapter 250 includes modifications to the definition of a "volatile compound" to include criteria based on the Henry's law constant and molecular weight of particular regulated substances. The effect of this definitional change is that a wider range of regulated substances

[7] Provisional Guidance for Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons (EPA/600/R-93/089, July 1993).

[8] Technical Support Document for Cancer Potency Factors – Appendix B: Chemical-Specific Summaries of the Information Used to Derive Unit Risk and Cancer Potency Values (CalEPA OEHHA, January 2011)

qualify as volatile compounds. In determining MSCs for volatile compounds, PADEP evaluates both the ingestion and inhalation pathways. This does not mean that PADEP should calculate MSCs based on both pathways where toxicological information is missing. The issue is illustrated by the following example.

Under the proposed change in the definition of a volatile compound, both naphthalene and 2-methylnaphthalene qualify as volatile compounds. The residential soil MSCs for both regulated substances have dropped significantly because PADEP has included risk calculations based on the inhalation pathway. As indicated in the proposed version of 25 Pa. Code Chapter 250, Appendix A, Table 5a, toxicity information is available for naphthalene on which to base a risk calculation using the inhalation pathway. That is not true, however, for 2-methylnaphthalene. Instead, it appears that PADEP has used toxicity information from an unspecified surrogate regulated substance and assumed that it is representative of the inhalation toxicity for 2-methylnaphthalene. Moreover, PADEP has assumed that 2-methylnaphthalene is in fact toxic if inhaled rather than ingested. In turn, that daisy chain of assumptions leads to a reduction in the residential soil MSC for 2-methylnaphthalene from 680 mg/kg to 25 mg/kg. We note that when faced with the same sort of informational limitations in the scientific literature, EPA chose not to develop RSLs for 2-methylnaphthalene based on the inhalation pathway.

In addition, many of the other physical and chemical-specific inputs PADEP is using to calculate inhalation-based numeric values are not transparent to the regulated community. For example, PADEP is incorporating newly proposed transport factors ("TFs") which are calculated using formulas set forth at 25 Pa. Code § 250.307. The derivation of PADEP's newly proposed TFs is not readily transparent as the reference information is not provided for several chemical-specific inputs that are used to derive the TFs for each relevant regulated substance. These chemical-specific inputs are not identified in the existing or proposed version of 25 Pa. Code Chapter 250, Appendix A, Table 5a. Furthermore, the current regulations addressing the calculation of the inhalation pathway numeric values reference outdated EPA documents that have since been updated and other source information that is not readily accessible to the regulated community. Similar to the discussions above, the use of these outdated methodologies results in the adoption of MSCs that are more stringent than standards in other states and guidance values calculated by EPA.

In accordance with 25 Pa. Code § 250.11, PADEP should review the methodology for calculating numeric values based on the inhalation pathway of exposure to ensure the scientific validity of that methodology in light of the passage of time since the methodology was first proposed. PADEP should also identify the sources of information used to derive newly proposed TFs.

5. Medium Specific Concentrations for Certain Perfluoroalkyl and Polyfluoroalkyl Substances

As part of the proposed version of Chapter 250, PADEP is including for the first time MSCs for three perfluorinated compounds - perfluorooctane sulfonate ("PFOS"), perfluorooctanoic acid ("PFOA") and perfluorobutane sulfonate ("PFBS"). As required under Act 2, the groundwater MSCs for PFOS and PFOA are based on the HAL for those two substances issued by EPA in 2016. To date, EPA has not promulgated MCLs for any perfluoroalkyl and polyfluoroalkyl substances ("PFAS"). Should EPA promulgate MCLs for PFOA and PFOS, such MCLs will supplant the HAL that EPA has issued. We also understand that Pennsylvania is evaluating whether to establish state-specific MCLs for one or more PFAS. Should such a step occur, the state-specific MCLs will need to be addressed as part of any future revisions to Chapter 250. We note that there is significant information available indicating that the HAL established by EPA for PFOA and PFOS is conservative and protective for those two compounds.

Because toxicity information for PFBS exists in the PPRTV database, that information has been used as the basis for the proposed groundwater MSCs for that substance.

Consistent with procedures contained in Chapter 250, PADEP is also proposing to establish soil to groundwater numeric values for PFOS, PFOA and PFBS based on values that are 100 times the groundwater MSCs. PADEP has not proposed to develop generic soil to groundwater numeric values for these substances. This approach appears to be appropriate based on the difficulty in determining the potential leaching potential from soils to groundwater based on the variability of sources of PFAS to soils (including direct application such as fire fighting foams and biosolids versus atmospheric deposition), soil types and unique properties of the substances in applying common leaching models.

The widespread presence of PFOA and PFOS in soils as an anthropogenic background condition warrants further evaluation. Unlike many of the regulated substances covered by Act 2, studies are indicating that these compounds have a widespread, even global, background presence in soils. Sources of background concentrations of PFOA and PFOS include the land application of biosolids and atmospheric deposition. These background levels are an important consideration in any cleanup strategy.

Published studies indicate detectable concentrations of PFAS in surface soil samples collected from around the world, including the northeastern United States, which are indicative of atmospheric deposition. These studies include Strynar et al. 2012[9] and Rankin et al. 2016[10] which showed that almost every soil sample collected in these studies had quantifiable concentrations of PFAS, with PFOA and PFOS being the most prevalent. Results such as these indicate that there is a global background distribution of PFAS in soils, which needs to be considered when establishing soil standards for these compounds. In addition to the global studies, a study of PFAS concentrations in shallow soils in Vermont was recently published by the Vermont Department of Environmental Conservation ("VTDEC").[11] The study was conducted by the University of Vermont and Sanborn Head with partial funding and support provided by VTDEC. Because PFAS is anthropogenically sourced, it is reasonable to suspect that background data collected from largely-rural Vermont may be indicative of, or perhaps underpredict, background concentrations that may be detected in more urbanized areas such as Pennsylvania.

Based on the wide-spread evidence of atmospheric deposition of PFAS, it may be useful for PADEP to evaluate and publish anticipated background levels of PFAS due to atmospheric deposition that can be utilized during site investigations and remediations. Act 2 expressly provides for the use of a background standard in accordance with 25 Pa. Code § 250.201, including reliance on regional background conditions. Without the leadership of PADEP in establishing generalized background levels of PFAS based on atmospheric deposition, addressing PFAS in soils may become extremely challenging and result in a patchwork of individualized determinations that will sap the resources of both PADEP and regulated community and that may be difficult to explain to the public.

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[9] Mark J. Strynar, Andrew B. Lindstrom, Shoji F. Nakayama, Peter P. Egeghy, Laurence J. Helfant. (2012). Pilot scale application of a method for the analysis of perfluorinated compounds in surface soils. Chemosphere, 86, 252-257.

[10] Rankin, K., Mabury, S. A., Jenkins, T. M., & Washington, J. W. (2016). A North American and global survey of perfluoroalkyl substances in surface soils: Distribution patterns and mode of occurrence. Chemosphere, 161, 333–341.

[11] Badireddy, A.R, Zhu, W., Zemba, S. G., Roakes, H. (2019). PFAS Background in Vermont Shallow Soils. Available for download: https://anrweb.vt.gov/PubDocs/DEC/PFOA/Soil-Background/PFAS-Background-Vermont-Shallow-Soils-03-24-19.pdf

Given the technical complexity of the issues relating to PFAS, we encourage PADEP to use the resources available through the CSSAB in developing guidance and standards in connection with the rapidly evolving landscape regarding investigation and remediation of PFAS in soils and groundwater.

CONCLUSIONS

It is clearly evident that PADEP is making numerous individual decisions and assumptions that can have significant consequences on the MSCs themselves. These decisions and assumptions are not transparent, nor are they the result of a mechanical application of a set of operating rules. But they do have very significant ramifications for both cleanups in Pennsylvania and the myriad of projects where fill material is being imported or exported. We believe that in such circumstances, the transparency of the important information used to develop the MSCs is critical so that the regulated community can better understand and comment on the science behind the newly proposed MSCs. In addition, more effectively utilizing the resources of the CSSAB is critical.

In that context, revising the MSCs for vanadium is necessary, appropriate and overdue. Additional adjustments to the MSCs for certain PAHs are also warranted. We very much appreciate the opportunity to provide comments regarding the proposed changes to Chapter 250 and we would welcome the opportunity to further discuss these comments with PADEP.

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