RELATIVE POTENCY FACTORS FOR CARCINOGENIC POLYCYCLIC AROMATIC HYDROCARBONS

Discussion and Recommendations for Consideration by the Cleanup Standards Scientific Advisory Board

PAH Workgroup

June 2022

Introduction

During the meeting of the workgroup evaluating cleanup standards for polycyclic aromatic hydrocarbons ("PAHs") on October 7, 2021, the Pennsylvania Department of Environmental Protection ("PADEP") asked for justification for the use of Relative Potency Factors ("RPFs") to derive toxicity values for carcinogenic polycyclic aromatic hydrocarbons ("cPAHs") for use in calculating medium-specific concentrations ("MSCs") to implement the Statewide health standard ("SHS") under the Pennsylvania Land Recycling and Environmental Remediation Standards Act ("Act 2"). PADEP expressed concern with certain statements in guidance documents suggesting that the use of RPFs may be limited to cumulative risk assessments and may not be appropriate for the derivation of statewide cleanup standards for individual chemicals. To address this concern, the workgroup agreed that further research was needed regarding various guidance documents describing the derivation and use of RPFs.

Background

Development of the RPFs currently used by the United States Environmental Protection Agency ("EPA") for cPAH risk assessment is explained in an EPA guidance document from 1993.[1] In EPA's effort to develop drinking water criteria for PAHs, they developed weight-of-evidence judgements for seven PAHs ruled as "probable human carcinogens." EPA was able to calculate an IRIS oral cancer slope factor for benzo[a]pyrene ("BaP") but data were insufficient for the calculation of cancer slope factors for the other cPAHs. Previous quantitative risk assessments had assumed that all cPAHs are equipotent to BaP. However, available literature suggested that this was not the case, and risk assessment practices were being inconsistently applied. The need for a standard set of comparative risk estimates for assessment of cPAHs relative to the cancer potency of BaP was identified. Instead of potentially overestimating risk by applying the BaP cancer slope factor equally to these other seven PAH's, EPA determined RPFs to more accurately account for the toxicity of individual PAHs in mixtures.

The 1993 guidance document recommends the application of RPFs, using BaP as the index chemical, to assess the carcinogenic hazard from oral exposure to cPAHs. Additionally, the RPFs were developed as order of magnitude rankings of risks posed by cPAHs (i.e., factors of ten) because the quality of the available toxicological data did not support any greater precision. The guidance document does not discuss the use of RPFs in deriving chemical-specific cleanup standards or screening levels.

In 1994, the California Environmental Protection Agency ("CalEPA") expanded upon the EPA approach when it developed Potency Equivalency Factors ("PEFs") for use in evaluating PAH mixtures.[2] The approach CalEPA embraced in 1994 also uses BaP as the index chemical and includes PEFs for 22 cPAHs. The CalEPA approach also included the use of PEFs to address cPAH exposure via inhalation in addition to ingestion.

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[1] USEPA 1993. Provisional Guidance of Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons. EPA/600/R-93/089. Available at https://semspub.epa.gov/src/document/HQ/100000047

[2] CalEPA 1994. Benzo[a]pyrene as a Toxic Air Contaminant. Available at https://ww2.arb.ca.gov/sites/default/files/classic/toxics/id/summary/bap.pdf

The use of RPFs is further discussed in Section 4 of EPA's 2000 Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures.[3] The document acknowledges that the preferred approach for risk characterization of mixtures is a direct toxicological evaluation of the complete mixture, or toxicological evaluation of all of a mixture's individual component chemicals, but RPFs may be applied in the absence of such information when the component chemicals are expected to be toxicologically similar. The RPF approach is explained generally in Section 4.4 of the guidance document and the following example is given:

> *For example, if compound A is judged to be one-tenth as toxic as the index compound, i.e., it requires ten times the exposure to cause the same toxicity, then the RPF for compound A is 0.1.*

This is an example of applying an RPF in two directions: to the calculation of risk (one tenth as toxic) and to the calculation of exposures at a specified risk level (ten times the exposure to cause the same toxicity). The document describes three mixtures where EPA has employed the RPF approach with varying levels of certainty: dioxins, PCBs, and PAHs.

In 2001, EPA sponsored a two-day peer consultation workshop regarding approaches to PAH health assessment. As described in a report of the workshop,[4] the experts generally agreed that the RPF approach is not the preferred approach for health assessment of PAH mixtures but may be the only available approach in the absence of toxicological information on the mixture itself. Recommendations from the workshop included the following:

(1) EPA should convene a panel to re-evaluate the validity and usefulness of the RPF approach;

(2) the oral cancer slope factor of BaP should be updated, using the data from a recent chronic feeding study;

(3) EPA should develop an inhalation unit risk estimate for BaP;

(4) EPA should commission a new inhalation study, preferably with two species and two sexes per species, conducted by the National Toxicology Program;

(5) the validity of using BaP as the indicator compound should be re-evaluated;

(6) additional carcinogenic PAHs should be added to the current set of PAHs for which relative potency factors are derived (suggestions ranged from including all EPA "target" PAHs to adding only PAHs known to be potent and removing those known to be of low potency); and

(7) existing dermal carcinogenicity studies should be evaluated to obtain information on the absorption and distribution of PAHs and PAH-containing mixtures, and data on the systemic tumorigenicity of exposure via this route.

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[3] USEPA 2000. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. EPA/630/R-00/002. Available at https://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=4486

[4] USEPA 2001. Peer Consultation Workshop on Approaches to PAH Health Assessment. Available at https://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=36313

The use of RPFs is further discussed in EPA's 2005 Guidelines for Carcinogen Risk Assessment[5] as a dose-response assessment tool for well-defined classes of chemicals that operate through a common mode of action for the same toxic endpoint. Other members of the class are tied to the index chemical by RPFs that are based on characteristics such as relative toxicological outcomes, relative metabolic rates, relative absorption rates, quantitative structure/activity relationships, or receptor binding characteristics. The document lists dioxin-like compounds and cPAHs as examples of where EPA has employed this approach.

Also in 2005, CalEPA completed a review of its 1994 PEF values. The approach used by CalEPA in 2005 continues to use BaP as the index chemical and includes PEFs for 25 cPAHs, for both oral and inhalation risks. With the exception of a slight reduction in the PEF for dibenz(a,h)anthracene, none of the previous PEFs were modified following this review.[6]

The 2005 CalEPA technical support document was updated in 2009, and Appendix B to the technical support document containing chemical-specific information was updated in 2011.[7] The derivation of PEFs for cPAHs is discussed in the BaP section of Appendix B. Actual cancer potencies (not relative to BaP) were specified for five individual cPAHs and derivatives. The previous PEFs for the remaining 20 cPAHs were not adjusted.

In 2010, EPA released a draft document titled *Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures*[8] and sought external peer review[9] as well as public comment. The document acknowledges that the preferred "whole mixture" approach to PAH risk assessment may not be practicable for several reasons: (1) there are very few toxicity data available for whole PAH mixtures, (2) chemical analysis of the composition of mixtures is limited, (3) PAH-containing mixtures tend to be very complex, and (4) the composition of these mixtures tends to vary across sources and the various environmental media in which they are encountered. The document explains that there are two key assumptions underpinning the RPF approach: (1) a similar toxicological action of PAH components in the mixture, and (2) the absence of interactions among PAH mixture components at low levels of exposure typically encountered in the environment. The document concluded that these assumptions are reasonable and supported by the experimental data for PAHs.

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[5] USEPA 2005. Guidelines for Carcinogen Risk Assessment. EPA/630/P-03/001F. Available at https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

[6] CalEPA 2005. Air Toxics Hot Spots Program Risk Assessment Guidelines Part II: Technical Support Document for Describing Available Cancer Potency Factors. Available at https://oehha.ca.gov/air/crnr/adopted-air-toxics-hot-spots-program-risk-assessment-guidelines-part-ii-2005

[7] CalEPA 2009. Technical Support Document for Cancer Potency Factors. See also Appendix B. Available at https://oehha.ca.gov/media/downloads/crnr/tsdcancerpotency.pdf

[8] USEPA 2010. Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures (External Review Draft). Available at https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=494851&Lab=NCEA

[9] USEPA 2010. Draft Charge to External Reviewers. Available at https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=494850&Lab=NCEA

The bulk of the document is devoted to a review of available toxicological literature and the derivation of RPFs and the document represents a significant expansion and improvement upon the previous RPFs published by EPA in 1993. A comprehensive review of scientific literature dating from the 1950s through 2008 identified over 900 individual publications for a target list of 74 PAHs. More than 600 of these papers included cancer-related endpoint data on at least one PAH and BaP tested at the same time. RPFs from individual studies were calculated from over 300 data sets representing 51 individual PAHs, and adequate data were available for a weight of evidence evaluation of 35 compounds for inclusion in the RPF approach. Of these, final RPFs were derived for 27 PAHs, significantly increasing the number of PAHs that can be addressed through this approach.

Section 8 of the document discusses uncertainties inherent to the RPF approach, including extrapolation of cancer effects across exposure routes. Section 8.6 of the document finds that cross-route extrapolation is reasonable and supported by the toxicological data and recommends the use of these RPFs across all exposure routes, including both ingestion and inhalation.

The following table shows the RPFs and PEFs currently in use by EPA and CalEPA and the draft RPFs proposed by EPA in 2010 for the seven cPAHs listed in the tables included in 25 Pa. Code Chapter 250:

cPAH	EPA 1993	CalEPA 2011	EPA 2010 (draft)
Benzo[a]anthracene	0.1	0.1	0.2
Benzo[a]pyrene	1.0 (index)	1.0 (index)	1.0 (index)
Benzo[b]fluoranthene	0.1	0.1	0.8
Benzo[k]fluoranthene	0.01	0.1	0.03
Chrysene	0.001	0.01	0.1
Dibenz[a,h]anthracene	1.0		10
Indeno[1,2,3-c,d]pyrene	0.1	0.1	0.07

The 2010 draft document and the questions in the accompanying charge to peer reviewers were reviewed by EPA's Scientific Advisory Board ("SAB"), and the SAB's findings and recommendations are detailed in a 2011 report.[10] The SAB recognized the pragmatic need for the RPF approach, and based upon the currently available data, recommended that EPA continue to use the RPF approach for assessing cancer risk for PAH mixtures. The SAB found that the choice of BaP as the index chemical is well justified but urged EPA to quickly update the outdated BaP toxicity information in the Integrated Risk Information System ("IRIS") database.

The SAB agreed with EPA's application of the proposed RPFs across all routes of exposure. The SAB generally agreed with the RPFs derived by EPA with a few reservations. First, the SAB noted that the toxicological studies for certain PAHs (benzo[c]fluorene, dibenz[a,h]anthracene, and dibenzo[a,l]pyrene) resulted in highly divergent RPFs, and the use of the geometric mean may be more appropriate to calculate average RPFs for cPAHs with such outlier studies. Second, that SAB noted that the RPFs for certain PAHs (benzo[g,h,i]perylene, benzo[j]aceanthrylene, fluoranthene, and indeno[1,2,3-e]pyrene)

[10] USEPA 2011. SAB Review of EPA's "Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures (February 2010 Draft)". Available at http://yosemite.epa.gov/sab/sabproduct.nsf/36a1ca3f683ae57a85256ce9006a32d0/260CFBD4492CA1D785257798006E854B/$File/Draft+PAH+Mixtures+Report+09-08-10.pdf

were developed with data only from studies using non-physiological routes of exposure, and recommended against deriving RPFs for these compounds on the basis of such limited data.

EPA proceeded with updating the existing 1992 IRIS assessment for the indicator compound BaP, and the final toxicological review document was published to IRIS in January 2017.[11] The updated assessment was based on a comprehensive, systematic literature search through August 2016, and approximately 700 reference studies were included in the toxicological review. As stated in the document, both the oral slope factor and inhalation unit risk were derived with the intention that they will be paired with RPFs for the assessment of the carcinogenicity of PAH mixtures. A range of oral slope factors were considered and the highest (most conservative) value of 1 per mg/kg-day was selected for the IRIS value. Of the inhalation cancer studies, only a single study of lifetime exposure was located, and an inhalation unit risk of $6x10^{-4}$ per $\mu g/m^3$ from this study was selected as the IRIS value.

According to the April 2019 IRIS Program Outlook[12], during fiscal year 2018, EPA prioritized its IRIS assessments to meet the highest needs of EPA Programs and Regions and to bring greater focus to assessments actively under development. The 2010 draft assessment of PAH mixtures that was reviewed by the SAB was not identified as a priority for fiscal year 2019 and was suspended at that time. The program outlook says the draft assessment will remain available on the IRIS website and may be restarted as EPA priorities change.

In April 2022, the Agency for Toxic Substances and Disease Registry ("ATSDR") published its *Guidance for Calculating Benzo(a)pyrene Equivalents for Cancer Evaluations of Polycyclic Aromatic Hydrocarbons*[13]. The document is consistent with previous EPA and CalEPA guidance in that it recommends the use of PEFs for quantification of cPAH cancer risks relative to BaP. The ATSDR document recommends using the PEFs published by CalEPA in 2011 and the BaP slope factor developed by OEHHA over the RPFs developed by EPA and the current BaP slope factor published in the IRIS database.

We are therefore left with recent IRIS toxicity values for BaP that were intended to be paired with RPFs to assess the potency of other cPAHs. As the 2010 RPFs developed by EPA were never released from draft status, the choice of RPFs available to PADEP seems to be between the values derived by EPA in 1993 or CalEPA in 2011. The approach of using RPFs in lieu of chemical-specific risk factors was developed by EPA because sufficient toxicological data has not been developed to accurately quantify the cancer risk of individual cPAHs. Based on the scientific consensus that these cPAHs act similarly on the body, the use of RPFs is a pragmatic approach that allows accurate risk assessment over a wide range of possible PAH mixtures. It is the approach that EPA and other agencies have consistently found to be appropriate since 1993.

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[11] USEPA 2017. Toxicological Review of Benzo[a]pyrene. Available at https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0136tr.pdf

[12] USEPA 2019. A Message from the IRIS Program – April 2019. Available at https://www.epa.gov/sites/default/files/2019-04/documents/iris_program_outlook_apr2019.pdf

[13] ATSDR 2022. Guidance for Calculating Benzo(a)pyrene Equivalents for Cancer Evaluations of Polycyclic Aromatic Hydrocarbons. Available at https://www.atsdr.cdc.gov/pha-guidance/resources/ATSDR-PAH-Guidance-508.pdf

Use of RPFs in Calculating Cleanup Standards and Screening Levels

None of the guidance documents discussed above describe procedures for calculating risk-based cleanup standards or screening levels from RPFs. These documents either provide guidance for conducting risk assessments or provide the scientific basis for the relative potency of cPAHs – as such, these documents would not be expected to provide instructions for the calculation of risk-based standards. Those instructions are found in the Act 2 regulations, and while PADEP has some regulatory discretion in selecting appropriate toxicity values for input into the calculation of MSCs, PADEP wishes to follow a prescribed hierarchy of sources for simplicity and transparency. Because there are several other regulatory agencies which are tasked with calculating risk-based standards for PAHs in environmental media, it is helpful to review how other agencies have handled this issue.

California Department of Toxic Substances Control

The California Department of Toxic Substances Control ("DTSC") publishes screening levels (the "DTSC-SLs") for preliminary evaluation of contaminated sites for human health risks. The DTSC-SLs are calculated at the $1x10^{-6}$ cancer risk level and a hazard quotient ("HQ") of 1. The use and derivation of the current DTSC-SLs is described in the June 2020 version of HERO HHRA Note 3.[14] As explained in the guidance document, calculation of the DTSC -SLs follows the same equations and methods as EPA's Regional Screening Levels ("RSLs") but using promulgated toxicity criteria required by California's 2018 Toxicity Criteria Rule and using California-specific exposure factors. If a DTSC-SL was not calculated for a particular chemical, the user is directed to use the corresponding EPA RSL instead.

The toxicity criteria used to derive the DTSC-SLs are set forth in Table 1 of HERO HHRA Note 10,[15] last updated in February 2019. For BaP, DTSC is using the 2017 IRIS oral slope factor but is using an inhalation unit risk developed by CalEPA's Office of Environmental Health Hazard Assessment ("OEHHA") for use in a public health goal for drinking water. With the exception of dibenz[a,h]anthracene, for which OEHHA has developed specific toxicity values, the toxicities of the other five cPAHs listed in Chapter 250 are assessed relative to BaP. The RPFs published by EPA in 1993 and currently used to calculate the EPA RSLs were used to calculate the DTSC-SLs based on oral slope factors. The PEFs most recently published by CalEPA in 2011 were used to calculate the DTSC-SLs based on inhalation unit risks. It should be noted that the 1993 RPFs and 2011 PEFs for individual cPAHs are the same values with the exception of benzo[k]fluoranthene and chrysene, where the 2011 PEFs are more potent by a factor of 10.

In summary, DTSC has calculated screening levels for cPAHs in various environmental media by relating their toxicities to BaP through a combination of the 1993 EPA RPFs and the 2011 CalEPA PEFs. The RPFs are used to calculate screening levels based on oral slope factors and the PEFs are used to calculate screening levels based on inhalation unit risks. The use of PEFs in this application appears to be a statutory requirement of California's 2018 Toxicity Criteria Rule. As described above, with the exception

[14] DTSC 2020. HHRA Note 3, DTSC-modified Screening Levels. Available at https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/04/HHRA-Note-3-June-2020-A.pdf

[15] DTSC 2019. HHRA Note 10, Toxicity Criteria. Available at https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/02/HHRA-Note-10-2019-02-25.pdf

of the inhalation unit risk for BaP and the oral slope factor and inhalation unit risk for dibenz[a,h]anthracene, the toxicity values used to calculate the DTSC-SLs do not match those listed in the OEHHA database and currently listed in Table 5a.

New York State Department of Environmental Conservation

The New York State Department of Environmental Conservation ("NYSDEC"), in conjunction with the New York State Department of Health, calculated Soil Cleanup Objectives ("SCOs") for use in its Brownfield Cleanup Program. The development of the SCOs is described in a 2006 technical support document.[16] SCOs that are risk-based are calculated using the $1x10^{-6}$ cancer risk and HQ=1 hazard levels. The assessment of mixtures of PAHs is discussed in Section 5.1.5.1 of the document.
For the cPAHs, BaP is again used as the indicator chemical and the toxicities of the other six cPAHs listed in Chapter 250 are assessed relative to BaP using RPFs. RPFs are then used to convert the SCO for BaP into an SCO for each cPAH. In determining the appropriate RPF to use for each cPAH, NYSDEC performed a limited review of toxicological literature, including the EPA 1993 RPFs and the CalEPA 2011 PEFs among other sources. As shown in Table 5.1.5-2 of the document, NYSDEC selected the EPA 1993 RPF for all cPAHs except chrysene, for which it selected the CalEPA 2011 PEF which is more potent by a factor of 10.

New Jersey Department of Environmental Protection

The New Jersey Department of Environmental Protection ("NJDEP") recently updated its Soil Remediation Standards ("SRS") in a May 2021 rulemaking. As set forth in the rule adoption document,[17] and as required by statute, the SRS are calculated based on a cancer risk of $1x10^{-6}$ and an HQ of 1. Toxicity factors used in the development of the SRS are presented in Appendix 11 of the document. NJDEP is using the 2017 IRIS values for BaP and assessing the toxicity of the other six cPAHs relative to BaP. NJDEP is using the EPA 1993 RPFs to calculate remediation standards in various environmental media and exposure routes for the six cPAHs relative to the potency of BaP, consistent with the approach taken by EPA in calculating the RSLs.

US Environmental Protection Agency

EPA provides RSLs and a calculator to assist in screening-level decisions at CERCLA hazardous waste sites. Unlike the values published by NYSDEC and NJDEP, these are not regulatory cleanup standards, but like the DTSC-SLs, they are used in preliminary evaluations of contaminated sites. The RSLs are also used as the first step in a human health risk assessment under the Act 2 Site-Specific Standard. RSLs are calculated for a range of risk targets and hazard quotients, and across a variety of land use and exposure assumptions. The tables comprising the RSLs are updated semiannually by the RSL Workgroup as new toxicity values become available.

[16] NYSDEC and NYDOH 2006. Development of Soil Cleanup Objectives – Technical Support Document. Available at https://www.dec.ny.gov/docs/remediation_hudson_pdf/techsuppdoc.pdf
[17] NJDEP 2021. Courtesy copy of rule adoption. Available at https://www.nj.gov/dep/rules/adoptions/adopt_20210517a.pdf

The derivation of the RSLs is explained in a User's Guide,[18] with Section 2.3.6 describing the use of RPFs in assessing the potency of cPAHs. The guide cites the EPA 1993 guidance document as the source of RPFs used to calculate toxicity values and screening levels for cPAHs relative to BaP. The guide acknowledges that this application is not in complete agreement with the direction of the EPA 1993 guidance document, but the approach was used as a means to calculate toxicity values for each cPAH. The guide also notes that computationally it makes little difference whether the RPFs are applied to the concentrations of cPAHs found in environmental samples or to the toxicity values as long as the RPFs are not applied to both, and that if the adjusted toxicity values are used in a risk assessment, the user will need to sum the risks from all cPAHs to derive a total risk. This summation of risks from multiple chemicals and exposures is standard practice in any site-specific risk assessment and is required by the Act 2 regulations.

Discussion of Cumulative Risk under the Statewide Health Standard

Section 303 of Act 2 describes the procedures for establishing the MSCs implementing the Statewide health standard, and states that "for a regulated substance which is a carcinogen, the medium-specific concentration is the concentration which represents an excess upper bound lifetime cancer target risk of between 1 in 10,000 and 1 in 1,000,000." The regulations implementing Act 2 at 25 Pa Code Chapter 250 show that the MSCs are calculated based on a 1 in 100,000 excess cancer risk level. As has been discussed by members of the Cleanup Standards Scientific Advisory Board ("CSSAB"), the ten-fold reduction in allowable carcinogenic risk from 1 in 10,000 ($1x10^{-4}$) to 1 in 100,000 ($1x10^{-5}$) is an acknowledgement that multiple regulated substances may be detected at a site at concentrations at or near their MSCs (assuming those MSCs are based on direct contact numeric values rather than soil-to-groundwater numeric values), which could result in unacceptable cumulative cancer risks if the MSCs were calculated based on a $1x10^{-4}$ target risk. The MSCs are derived at a target cancer risk level that is ten times more conservative to safeguard against this possibility of adverse cumulative risk. By setting the MSCs at a risk level lower than the acceptable level, the Statewide health standard employs cumulative risk concepts, using default exposure factors and assumptions that can be safely applied across the state, including an inherent assumption that no more than ten carcinogens will be detected at a site at their maximum allowed direct contact concentration. This is currently the case with all carcinogens with MSCs listed in Chapter 250 and there is nothing about the application of RPFs to derive toxicity values and calculate MSCs that would necessitate a different approach for cPAHs.

The guidance documents described above suggest that RPFs should be used in a cumulative risk assessment of cPAH exposures, and the derivation of MSCs is consistent with that guidance. The regulatory procedures for calculating the MSCs do not discriminate between carcinogens – the maximum allowable risk from each carcinogen under the statewide health standard is established at the $1x10^{-5}$ level with the assumption that the cumulative risk at a site is unlikely to ever exceed a cumulative cancer risk of $1x10^{-4}$. Note also that additional conservatism is provided by the fact that the most sensitive oral slope factor was selected from a range of values in the IRIS assessment of BaP, which serves as the index chemical for the other cPAHs.

[18] USEPA 2021. Regional Screening Levels (RSLs) – User's Guide. Available at https://www.epa.gov/risk/regional-screening-levels-rsls-users-guide

Some of the toxicity values currently used by PADEP to calculate MSCs for cPAHs are sourced from CalEPA and were derived through the application of PEFs relative to BaP, as discussed previously. Therefore, the concept of RPFs is used in calculating the MSCs. Moreover, in the absence of specific toxicity values for certain non-carcinogenic PAHs, PADEP has defaulted to using surrogate toxicity values to calculate MSCs. The approach of using RPFs appears to be more thoroughly studied and vetted when compared to the uncertainty involved in selecting appropriate surrogates to use.

Recommendations for Implementation

The application of RPFs to derive relative toxicity values and cleanup standards is consistent with the supporting guidance documents given the assumption of cumulative excess risk inherent in the MSC calculations, as well as the precedence established by various regulatory agencies including EPA and CalEPA, the two agencies that have derived RPFs from the toxicological literature. Understanding that the 2017 IRIS toxicity values for BaP are of the highest available quality, PADEP is now faced with the choice of which RPFs to use and how to present them in a transparent way. The most recent and comprehensive development of RPFs appears to be the 2010 draft assessment developed by EPA. However, this document was never finalized and PADEP may not be able to use it as a reference. Therefore, the choice seems to be between the EPA 1993 RPFs and the CalEPA 2011 PEFs, or some combination of the two. If PADEP wishes to cite to a single guidance document as the basis for all RPFs, or does not wish to review the intricacies of the toxicological studies and apply its judgement in selecting individual RPFs for each cPAH, it may be preferable to pick one of these sets. Of these, selection of the 1993 RPFs developed by EPA would seem to be more consistent with the established hierarchy of sources and would be entirely consistent with the EPA RSLs used under the site-specific standard.

Application of the EPA 1993 RPFs will result in changes to some of the cPAH toxicity values currently listed in Table 5a and will result in increases to the corresponding MSCs. However, this is a direct result of the fact that the cancer potency of these chemicals has only ever been assessed relative to that of BaP, which itself was recently determined to be less potent though the 2017 IRIS assessment. Toxicity values sourced from IRIS are understood to be the highest available quality, and the IRIS values for BaP were developed with the intention that they would be paired with RPFs to allow carcinogenic risk assessment for the other cPAHs. While EPA has done some work to update and expand the available RPFs, that work has not been finalized and remains in draft status. Therefore, application of the existing 1993 EPA RPFs to derive toxicity values and calculate MSCs for the other cPAHs does represent the best available state of the science and is consistent with PADEP's established hierarchy of sources. A table is provided as an attachment to this document that compares the proposed toxicity values to the values currently listed in Table 5a, as well as the toxicity values and RPFs currently in use by the agencies described above. Applications of the proposed toxicity values will result in corresponding changes to the MSCs for the six cPAHs other than BaP. Those changes are shown in a separate table attached to end of this document.

Recommendations for Transparency

The CSSAB PAH Workgroup agrees that the use of RPFs to derive toxicity values needs to be clearly explained to the public and to users of the MSC tables. This can be accomplished using a footnote in Table 5a, in the appropriate section of the Chapter 250 regulations implementing Act 2, in the appropriate section of the Act 2 Technical Guidance Manual, or some combination of the three.

Footnote in Table 5a

Table 5a contains a series of footnotes explaining the source of the toxicity values listed. For the cancer slope factors and inhalation unit risks that are derived relative to those of BaP, it seems appropriate to add an additional footnote explaining the source of the RPFs used. A suggested footnote is as follows:

> *R = EPA 1993 Relative Potency Factors (relative to benzo[a]pyrene) per 250.605(a)(1)(i)*

Regulatory Language

25 Pa. Code 250.605 explains the hierarchy of sources of toxicity information that may be used in deriving site-specific standards, and PADEP wishes to follow this hierarchy in developing the Statewide Health Standards for purposes of consistency and transparency. The CSSAB PAH workgroup agreed that the use of RPFs should therefore be described in the section of the regulations. Because the 1993 RPFs were developed by EPA and are currently used by EPA and other agencies in conjunction with the IRIS values for BaP, the CSSAB PAH workgroup agreed that the derived toxicity values would be of higher quality and certainty than the sources listed in the hierarchy, with the exception of IRIS values developed specifically for the cPAHs (which do not currently exist). The following suggested language could be inserted under 250.605(a)(1):

> *250.605(a)(1)(i): Cancer slope factors and inhalation unit risk factors for carcinogenic PAHs are derived using Relative Potency Factors contained in United States Environmental Protection Agency July 1993 Provisional Guidance for Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons (EPA/600/R-93/089).*

Technical Guidance Manual

Similarly, Section III.H.3.c of the Act 2 Technical Guidance Manual presents the same hierarchy of sources of toxicity information that may be used in deriving site-specific standards, and the CSSAB PAH workgroup agreed that the use of RPFs should be explained here as well. For transparency and consistency with the regulatory language proposed above, the same suggested language could be inserted under III.H.3.c.i:

> *Section III.H.3.c.i.a: Cancer slope factors and inhalation unit risk factors for carcinogenic PAHs are derived using Relative Potency Factors contained in United States Environmental Protection Agency July 1993 Provisional Guidance for Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons (EPA/600/R-93/089).*

Attachment 1 – Comparison of PAH Workgroup-Proposed Toxicity Values to those Currently Used by PADEP and Other Agencies

		Benzo[a]pyrene	Benzo[a]anthracene	Benzo[b]fluoranthene	Benzo[k]fluoranthene	Chrysene	Dibenz[a,h]anthracene	Indeno[1,2,3-c,d]pyrene
PADEP Table 5a (current)	**CSF_o $(mg/kg\text{-}d)^{-1}$**	1 I	0.7 X	1.2 C	1.2 C	0.12 C	4.1 C	1.2 C
	IUR $(\mu g/m^3)^{-1}$	0.0006 I	0.00011 C	0.00011 C	0.00011 C	0.000011 C	0.0012 C	0.00011 C
PADEP Table 5a (proposed by PAH Workgroup)	**CSF_o $(mg/kg\text{-}d)^{-1}$**	1 I	0.1 R*	0.1 R*	0.01 R*	0.001 R*	1 R*	0.1 R*
	IUR $(\mu g/m^3)^{-1}$	0.0006 I	0.00006 R*	0.00006 R*	0.000006 R*	0.0000006 R*	0.0006 R*	0.00006 R*
	RPF used	none (index)	0.1	0.1	0.01	0.001	1.0	0.1
CA DTSC-SLs	**CSF_o $(mg/kg\text{-}d)^{-1}$**	1	0.1	0.1	0.01	0.001	4.1	0.1
	IUR $(\mu g/m^3)^{-1}$	0.0011	0.00011	0.00011	0.00011	0.000011	0.0012	0.00011
	RPF used	none (index)	0.1	0.1	varies by route	varies by route	none (CA-developed)	0.1
NYSDEC SCOs	**CSF_o $(mg/kg\text{-}d)^{-1}$**	9.03	0.903	0.903	0.0903	0.0903	9.03	0.903
	IUR $(\mu g/m^3)^{-1}$	0.0011	0.00011	0.00011	0.000011	0.000011	0.0011	0.00011
	RPF used	none (index)	0.1	0.1	0.01	0.01	1	0.1
NJDEP SRS	**CSF_o $(mg/kg\text{-}d)^{-1}$**	1	0.1	0.1	0.01	0.001	1	0.1
	IUR $(\mu g/m^3)^{-1}$	0.0006	0.00006	0.00006	0.000006	0.0000006	0.0006	0.00006
	RPF used	none (index)	0.1	0.1	0.01	0.001	1.0	0.1
USEPA RSLs	**CSF_o $(mg/kg\text{-}d)^{-1}$**	1	0.1	0.1	0.01	0.001	1	0.1
	IUR $(\mu g/m^3)^{-1}$	0.0006	0.00006	0.00006	0.000006	0.0000006	0.0006	0.00006
	RPF used	none (index)	0.1	0.1	0.01	0.001	1	0.1

*Although the toxicity values proposed for Table 5a are sourced from IRIS, the existing IRIS footnote in Table 5a does not describe the application of RPFs to the IRIS values for BaP. PADEP and CSSAB have discussed the need to add an additional footnote to Table 5a that explains this step in more detail for the six cPAHs other than BaP.

Attachment 2 – PAH Workgroup-Proposed MSCs Calculated Using Toxicity Values Derived Using EPA 1993 RPFs

		Table 1 - Groundwater						Table 3a - Soil Direct Contact			Table 3b - Soil to Groundwater												
		Used Aquifers				Nonuse Aquifers		Surface Soil		Subsurface Soil	Used Aquifers								Nonuse Aquifers				
		TDS ≤ 2500		TDS > 2500							TDS ≤ 2500				TDS > 2500								
		R		R		R		R		NR	R		NR		R		NR		R		NR		
											100xGW MSC	Generic Value	100xGW MSC	Generic Value	100xGW MSC	Generic Value	100xGW MSC	Generic Value	100xGW MSC	Generic Value	100xGW MSC	Generic Value	
		ug/L	ug/L	ug/L	ug/L	ug/L	ug/L	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	
Benzo[a]pyrene	**current**	0.2 M	0.2 M	3.8 S	3.8 S	3.8 S	3.8 S	4.2 G	91 G	190000 C	0.02	46 E	0.02	46 E	0.38	860 E	0.38	860 E	0.38	860 E	0.38	860 E	
	proposed*	0.2 M	0.2 M	3.8 S	3.8 S	3.8 S	3.8 S	4.2 G	91 G	190000 C	0.02	46 E	0.02	46 E	0.38	860 E	0.38	860 E	0.38	860 E	0.38	860 E	
Benzo[a]anthracene	**current**	0.3 G	3.9 G	11 S	11 S	11 S	11 S	6.1	130	190000 C	0.03	26 E	0.39	340 E	1.1	960 E	1.1	960 E	1.1	960 E	1.1	960 E	
	proposed*	2.1 G	11 S	11 S	11 S	11 S	11 S	42 G	910 G	190000 C	0.21	180 E	1.1	960 E	1.1	960 E	1.1	960 E	1.1	960 E	1.1	960 E	
Benzo[b]fluoranthene	**current**	0.18 G	1.2 S	1.2 S	1.2 S	1.2 S	1.2 S	3.5	76	190000 C	0.018	25 E	0.12	170 E	0.12	170 E	0.12	170 E	0.12	170 E	0.12	170 E	
	proposed*	1.2 S	1.2 S	1.2 S	1.2 S	1.2 S	1.2 S	42 G	910 G	190000 C	0.12	170 E	0.12	170 E	0.12	170 E	0.12	170 E	0.12	170 E	0.12	170 E	
Benzo[k]fluoranthene	**current**	0.18 G	0.55 S	0.55 S	0.55 S	0.55 S	0.55 S	3.5	76	190000 C	0.018	200 E	0.055	610 E	0.055	610 E	0.055	610 E	0.055	610 E	0.055	610 E	
	proposed*	0.55 S	0.55 S	0.55 S	0.55 S	0.55 S	0.55 S	420 G	9100 G	190000 C	0.055	610 E	0.055	610 E	0.055	610 E	0.055	610 E	0.055	610 E	0.055	610 E	
Chrysene	**current**	1.8 G	1.9 S	1.9 S	1.9 S	1.9 S	1.9 S	35	760	190000 C	0.18	220 E	0.19	230 E	0.19	230 E	0.19	230 E	0.19	230 E	0.19	230 E	
	proposed*	1.9 S	1.9 S	1.9 S	1.9 S	1.9 S	1.9 S	4200 G	91000 G	190000 C	0.19	230 E	0.19	230 E	0.19	230 E	0.19	230 E	0.19	230 E	0.19	230 E	
Dibenz[a,h]anthracene	**current**	0.052 G	0.6 S	0.6 S	0.6 S	0.6 S	0.6 S	1	22	190000 C	0.0052	23 E	0.06	270 E	0.06	270 E	0.06	270 E	0.06	270 E	0.06	270 E	
	proposed*	0.21 G	0.6 S	0.6 S	0.6 S	0.6 S	0.6 S	4.2 G	91 G	190000 C	0.021	95 E	0.06	270 E	0.06	270 E	0.06	270 E	0.06	270 E	0.06	270 E	
Indeno[1,2,3-c,d]pyrene	**current**	0.18 G	2.3 G	18 G	62 S	62 S	62 S	3.5	76	190000 C	0.018	1400 E	0.23	18000 E	1.8	140000 E	6.2	190000 C	6.2	190000 C	6.2	190000 C	
	proposed*	2.1 G	27 G	62 S	62 S	62 S	62 S	42 G	910 G	190000 C	0.21	16000 E	2.7	190000 C	6.2	190000 C	6.2	190000 C	6.2	190000 C	6.2	190000 C	

*Numeric values proposed by the PAH Workgroup