DEPARTMENT OF
ECOLOGY
State of Washington

Early-Life Exposure to Chemical Carcinogens: Looking at Benzo[a]Pyrene as an Example for updates to the Model Toxics Control Act Cleanup Regulation

MTCA/SMS Advisory Group
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Considerations Regarding Early-Life Exposure to Chemical Carcinogens

As part of updating the Model Toxics Control Act (MTCA) Cleanup Regulation, Ecology is evaluating the risk-based equations used to establish cleanup levels. This includes examining the methods and policies used to establish risk-based cleanup levels and standards protective of human health.

Over the past year, Ecology has engaged in discussions with the MTCA Science Panel regarding the scientific principles and methodologies related to the effects of early-life exposure to chemical carcinogens. The Science Panel provided to Ecology answers to the following questions:

- What changes, if any, should be made to the MTCA Cleanup regulation to account for early-life exposures to carcinogens?
- Should early-life age-dependent adjustment factors for carcinogens be used only for those carcinogens that act via a mutagenic mode of action or be applied for all carcinogens?

The information in this paper reflects those discussions.

Ecology is also asking a series of policy questions related to updates to the MTCA Cleanup Regulation and following from the scientific discussions. Policy Advisory Group Question: What information do Ecology's risk managers require to make informed decisions to update the MTCA Cleanup Regulation to account for early-life exposures to carcinogens?

Introduction

The MTCA Cleanup Regulation risk-based equations and cleanup levels represent a convergence of science and policy risk management decisions. A variety of different but related elements and factors get considered during the rule update process. This ensures cleanup standards are based on the best available science, are reasonable, and are protective of the environment and public health.

Ecology is evaluating information needed to make risk management decisions related to updating and changing the MTCA Cleanup Regulation. Factors being considered include:

- Informed Science
- State Regulatory Policies and Procedures
- Federal Regulatory Policies and Procedures
- Comparing of Risk-Based Concentrations with Background Concentrations and Analytical Limits
- Other?

About this document

This document provides a summary of the factors that led to Ecology's proposal. Benzo[a]pyrene (B[a]P) is used to illustrate the implications of potential changes to the MTCA Cleanup Regulation. This chemical was chosen because both the U.S. EPA and Cal-EPA recognize the potential for early-in-life susceptibility from exposures to B[a]P.

A separate report, "Considerations of Early Life Exposure to Chemical Carcinogens" provides a more comprehensive review of information on early life stage susceptibility and exposure to carcinogens.[1]

Question for discussion

Are there other factors that Ecology should consider when deliberating about if and how to incorporate early-in-life age adjustment factors for carcinogens? (As required by the Administrative Procedures Act, Ecology will be conducting a cost-benefit analysis as part of this rule making.)

MTCA Rulemaking Options

Ecology has examined the issues relevant to the increased susceptibility of children from environmental exposures to carcinogens. This includes current scientific information, federal and state regulatory policies and procedures, and scientific opinions and recommendations by technical expert panels.[2]

Based on an examination of the current scientific information, regulatory policies and procedures, and the conclusion of expert panels, the MTCA Science Panel supports Ecology's proposal to revise the MTCA Cleanup Regulation to account for early-life exposure to carcinogens.

Ecology is considering two options for revising and updating the MTCA Cleanup Regulation to account for early-life exposures to carcinogens:

- Option 1: revisions to account for early-life exposure only for those carcinogens that act via a mutagenic mode of action.
- Option 2: revisions to account for early-life exposure from all carcinogens: carcinogens that act via a mutagenic and carcinogens that act via a non-mutagenic mode of action.

Ecology's Proposal: Age Dependant Adjustment Factors for Early Life

Ecology believes there is a strong scientific basis that supports revisions to the MTCA Cleanup Regulation to account for early-life exposures to chemical carcinogens.

[1] Considerations of Early-Life Exposure to Chemical Carcinogens, Dept. of Ecology. MTCA Science Panel. November 12, 2009.

[2] Expert Panels: NRC, 1993. Natinal Research Council, Pesticides in the Diets of Infants and Children. Natinal Academy Press. Washington, DC. 1993.

To account for early-life susceptibility to carcinogens, an age-dependant adjustment factor for early life exposures is applied to carcinogenic toxicity values (also called cancer potency values).

Ecology is evaluating whether age dependant adjustment factors for early-life exposures should be applied to all carcinogens. Part of this evaluation is to ask what other factors, if any, should be considered in this determination and to look at the implications of lower cleanup levels.

Rationale

Ecology's rationale is based on evaluations of current scientific information, and is supported by conclusions and recommendations from the MTCA Science Panel.

EPA and Cal-EPA Conclude Increased Sensitivity in Children

Working independently, the U.S. Environmental Protection Agency (EPA) and the California Environmental Protection Agency's (Cal-EPA) Office of Environmental Health Hazard Assessment have assessed and developed age groupings to help evaluate childhood exposures to environmental contaminants.

- The analyses of both agencies support the application of weighting factors to address potential increased susceptibility to carcinogen exposures occurring prenatally and during postnatal and juvenile life-stages. Both agencies apply age related factors to adjust the cancer potencies to consider early life susceptibility for infants and children.
- Although the age groupings between the agencies vary slightly, the adjustment factors are the same. For the U.S. EPA, the age adjustment factors are termed: Age Dependent Adjustment Factors (ADAFs);[3] for Cal-EPA, the age adjustment factors are termed Age Sensitivity Factors (ASFs).[4]

Using different methodologies to evaluate cancer potency, the U.S. EPA and the Cal-EPA independently concluded that risks of cancer from exposures to carcinogens occurring from conception through puberty can be different than those cancer risks from exposures occurring in adulthood. Both agencies have determined that there is sufficient evidence that exposures to carcinogens during early-life may result in a carcinogenic response late in life. The identical default age adjustment factors used by both agencies are based on informed science that shows the potential for early-in-life susceptibility from exposures to carcinogens.

A Strong Biological Basis for Early-Life Susceptibility

Both EPA and Cal-EPA have drawn on a variety of information that points to a strong biological basis for concluding that exposure early in life can result in a greater lifetime risk of cancer.

[3] Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. U.S. Environmental Protection Agency, Risk Assessment Forum, March 2005. EPA/630/R-03/003F.

[4] Air Toxics Hot Spots Program Risk Assessment Guidelines, Part II, Technical Support Document for Cancer Potency Factors, June 2008, Public Review Draft, California Environmental Protection Agency, Office of Environmental Health Hazard Assessment.

There are multiple reasons that exposure to a carcinogen early in life may result in greater lifetime risk of cancer:

- Cancer is a multi-stage process and the occurrence of the first stages of the carcinogenic process in childhood increases the chance that the entire carcinogenic process will be completed, and a cancer produced, within an individual's lifetime.
- Tissues undergoing rapid growth and development may be especially vulnerable to carcinogenic agents. During periods of increased cell proliferation there is rapid turnover of DNA, and more opportunity for miss-repair of damage (that is, DNA breaks, crosslinks, adducts) or alterations resulting permanent changes to the DNA (such as mutations, altered DNA methylation) that may ultimately lead to cancer.
- During early life stages or development, a greater proportion of the body's cells are undifferentiated stem cells, and undifferentiated stem cells represent a large target population of somatic cells capable of passing along permanent changes to the DNA during future cell divisions.
- There may be greater sensitivity to hormonal (that is., endocrine disrupting) carcinogens early in life since the development of many organ system is under hormonal control (that is, male and female reproductive systems, thyroid control of central nervous system development).
- Anatomical, physiological, and behavioral characteristics may influence or play a role in increased cancer risk from exposures during critical development periods such as differences in immunological activity, intestinal absorption, biliary and kidney excretion, blood and fat distribution, and expression of enzyme systems that activate or detoxify carcinogens.

Other Lines of Evidence Point to Biological Effects from Early-In-Life Exposures

Table 1 below provides selected examples of human cases that reflect early-in-life cancer susceptibility. These selected examples of human evidence of early-in-life susceptibility to carcinogens serve to reinforce the importance of consideration of early-life exposures to carcinogens in the regulatory framework.

Table 1: Examples of Early-Life Cancer Susceptibility in Humans		
Agent	**Susceptible Group**	**Biological Response**
Diethylstilbestrol (DES)[5]	Fetus	*In utero* exposure arising from administration of DES during pregnancy resulted in an increased risk of adenocarcinoma of the vagina and cervix in the daughters, but not in mothers taking the drug.
X-Irradiation treatment for Hodgkins Lymphoma[6]	Girls with developing breast tissue (10-16 years old)	10-16 year old girls considerably much more likely to develop breast cancer than those under age 10 similarly treated. 35% increased risk of cancer by age 40.
Radioactive iodine fallout from 1986 Chernobyl accident[7]	Fetus/Children	An increased risk of thyroid carcinoma was observed in children from Ukraine and Belarus exposed to radioactive iodine fallout. The greatest risk of thyroid carcinoma was observed in children aged five and under at the time of the accident.
Immunosuppresive drug treatment associated with organ allograft[8]	Children ages 18 years or less	Children are more prone to develop post-transplant lymphomas and lymphoproliferative disorders than adults (53% Vs 15%).
Adapted from Cal-EPA, 2009. Appendix J: In Utero and Early life Susceptibility to Carcinogens: the Derivation of Age-at-Exposure Sensitivity Measures. May 2009. Table 2, page 11		

Regulatory Policies and Procedures

A number of factors go into risk management decisions. Ecology has evaluated Washington regulatory policies and procedures, looked at what other states are doing, and is following federal regulatory developments.

Washington State

The MTCA Cleanup Regulation includes policies and procedures for identifying and characterizing carcinogens. Ecology initially published these provisions in 1991. Although Ecology modified selected provisions in 2001, the current regulation largely reflects policies and procedures in the 1986 EPA cancer risk guidelines. Key features of the current MTCA Cleanup Regulation include:

- The definition of "carcinogen" reflects the terminology and policies in the 1986 EPA guidelines.

[5] Herbst AL, Ulfelder H, Poskanzer DC (1971) Adenocarcinoma of the vagina. Association of maternal stilbestrol therapy with tumor appearance in young women. N Engl J Med 284 (15): 878-81; Preston-Martin S (1989). Epidemiological studies of perinatal carcinogenesis. IARC Sci Publ. 96: 289-314, International Agency for Research on Cancer, Lyon France.

[6] Bhatia S, Robison LL, Oberlin O, Greenberg M, Bunin G, Fossati-Bellani F, et. al., (1996) Breast cancer and other second neoplasm after childhood Hodgkins disease. N Eng J Med 334 (12): 745-51.

[7] Moysich KB, Menezes RJ, Michalek AM (2002). Chernobyl-related ionizing radiation exposure and cancer risk: an epidemiological review. Lancet Oncol 3(5): 269-79.

[8] Penn I (2000). Post-transplant malignancy: the role of immunosuppression. Drug 23 (2): 101-13.

- Cleanup levels are calculated using carcinogenic potency factors (cancer slope factors) published by EPA in the Integrated Risk Information System (IRIS) database.
- The MTCA Cleanup Regulation defines procedures for selecting cancer slope factors when values are not available in the IRIS database. This includes a hierarchy of information sources for cancer slope factors (such as the National Center for Environmental Assessment) that was added in 2001. The regulation also defines procedures for calculating cancer slope factors using the linearized multi-stage low dose extrapolation model and an animal to human scaling factor.

The MTCA Cleanup Regulation does not reflect recent advances in technical information and regulatory guidance. In particular, the risk-based policies and procedures in the MTCA Cleanup Regulation do not explicitly account for early life exposures to carcinogens with the carcinogenic response expressed later in life.

Other States

Many states are grappling with how to address children's exposure to chemical contaminants. Table 2 below summarizes information regarding states that have implemented or are considering implementation of guidance and risk-based cleanup levels for early-life exposures (ELE).

- Of the ten selected states surveyed by Ecology, five states (California, Colorado, Maine, New York, and Oregon) have explicit guidance or risk-based cleanup levels that recognize early-life exposures to carcinogens.
- Massachusetts and Minnesota are in the process of implementing early-in-life exposures guidance and regulations for soil risk-based cleanup levels.
- Texas will consider early-in-life exposure age adjustments during the next rule revision for the Texas Risk Reduction Program.

According to the National Conference of State Legislators (a bipartisan organization that serves the legislators and staffs of the nation's 50 states, its commonwealths, and territories) between 1998 and 2008, there were 771 bills in 49 different states that considered children's environmental health. In 2009, there were 124 bills pending in 10 different states and 32 bills enacted in 18 different states related to children's environmental health.[9]

[9] The National Conference of State Legislators, Environmental Health Legislation Database Archive and Environmental Health Legislation Database. http://www.ncsl.org/Home/tabid/118/Default.aspx

Table 2: State Risk-Based Cleanup Levels for PAH Contaminated Soils Using Benzo[a]pyrene (B[a]P) As An Indicator							
State	**Exposure Pathways & Risk-Based B[a]P Cleanup Level**				**Target Risk Level**	**Consideration of Early-Life Exp.**	**Comment**
	Ingestion	Derm.	Inh.	Cleanup Level (mg/kg)			
California	X	X	X	3.8E-02	10^{-6}	yes	OEHHA Soil Screening T. 1 [http://oehha.ca.gov/risk/chhsltbl091709.html]
Colorado	X	X	X	2.2E-02	10^{-6}	yes	http://www.cdphe.state.co.us/hm/csev/pdf
Maine	X	X	X	2.6E-01	10^{-6}	yes	Maine Remedial Action Guidelines, Appendix 1 includes BaP soil level of 0.26 mg/kg (10^{-5} risk); Appendices 2 & 3 list screening level of 0.026 mg/kg (10^{-6} risk)
MA	X	X		2.0E+00	10^{-6}	no	Risk-based CUL = 7.5E-01 mg/kg adjusted to background 2 mg/kg; in the process of considering ELE
Michigan	X	X		2.0E+00	10^{-5}	no	April 2005, Remediation and Redevelopment Division Operations Memo. No.1,Technical Support Document, Attachment No. 6
Minnesota	X	X	X	2.0E+00	10^{-5}	no	Minnesota is in the process of incorporating age dependent adjustment factors for ELE for different media, still work in progress
New York	X	X	X	1.1E-01	10^{-6}	yes	Subpart 375-6: Remedial Program Soil Cleanup Objective for B[a]P is 1 mg/kg from Table 375-6.8 (a) based on soil background concentration from rural areas
New Mexico	X	X	X	6.21E-01	10^{-5}	no	ftp://ftp.nmenv.state.nm.us/hwbdocs/HWB/guidance_docs/NMED_June_2006_SSG.pdf (see Page 10, Age adjustments done to account for differences in exposures between children and adults but no indication of adjustments to account for ELE)
Oregon	X	X	X	1.5E-02	10^{-6}	yes	Technical Memorandum, March 14, 2007. From DEQ Toxicology Workgroup. Incorporation of Early-Life Exposure in Human Health Risk Assessments
Texas	X	X	X	5.6E-01	10^{-5}	no	ELE under consideration for future rule making

Federal Regulatory Policies and Procedures

Following updated federal regulatory guidance from EPA headquarters, U.S. EPA Regions 3, 6, and 9 have introduced regulatory policies and procedures to account for early-in-life exposures to carcinogens that operate via a mutagenic mode of action. Tables and risk-based cleanup levels were developed through an Interagency Agreement with the Oak Ridge National Laboratory that also employ the same equations to calculate risk-based cleanup levels.[10]

The National Toxicology Program is considering revising the standard animal bioassay protocols used to assess chemical carcinogenicity to better account for age dependent sensitivity and susceptibility to carcinogens.[11]

Significantly, the U.S. EPA is reconsidering the policy decision to limit early-life Age Dependent Adjustment Factors to those carcinogens that operate via a mutagenic mode of action.

Uncertainty and Variability

A variety of factors complicate the selection of appropriate default Age Dependent Adjustment Factors, ADAFs (or, as they are called by Cal-EPA, Age-Sensitivity Factors, ASFs). These factors are used to weight exposures that occur early- in-life for prenatal, postnatal, and juvenile exposures. Some of these complications include:

- Limited database of chemicals and studies available for analysis and broad distribution of results for different chemicals to evaluate the susceptibility of prenatal and postnatal life stages to developing cancer than developing cancer in the adult life stage.
- Large variability in age-at-exposure related susceptibility across different carcinogens and susceptibility among studies of the same carcinogen due to timing of exposure within a given age window, and gender, strain, and species differences in tumor response.
- In recognition of the uncertainties in applying conclusions from a relatively small set of chemicals to a much larger number of chemicals of concern the default age adjustments specify greater than half-log precision (i.e., value of 1, 3, 10).
- Rodents are born at a stage of maturity that approximates a third-trimester human.

Cal-EPA recognized and noted the limitations of the database and analysis for the development of default age adjustment factors for early-life exposures to carcinogens.

[10] Risk-Based equations, levels and background information found at the following Link: http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/index.htm

[11] MTCA Science Panel Communication, Dr. Elaine Faustman. November 2009

In addressing in-utero exposures, Cal-EPA noted the following regarding the limitations of the analysis:[12]

> "OEHHA recognizes the limitations in the data and analyses presented, as discussed above. However, the analyses do provide some guidance on the extent to which risk may be over or underestimated by current approaches. While there is a great deal of variability across chemicals in the prenatal ASFs, the data indicate that the potency associated with prenatal carcinogen exposure is not zero. A factor of 3 is close to the median ASF, while a factor of 10 falls roughly at the 70th percentile of the prenatal ASF estimate. An ASF could be applied as a default when calculating lifetime cancer risk in humans arising from carcinogen exposures that occur in utero. In view of the considerable variability in the data for different carcinogens and the limited database available for analysis, OEHHA is not proposing the application of a specific factor to cancer potency estimates for prenatal exposures in the first and second trimesters as a default position in these Guidelines. However, given that the rodent is born at a stage of maturation similar to a third trimester fetus, it is reasonable to include the third trimester in the 10X potency weighting proposed up to age 2 years. The applicability of a cancer potency adjustment factor for first and second trimester prenatal exposure will be evaluated on a case-by-case basis, and may be used as evidence develops that supports such use. The consideration of prenatal exposures, including application of an appropriate susceptibility factor, would not make a large difference for risk estimates based on continuous lifetime exposures due to the relatively short duration of gestations. However, risk estimates for short-term or intermittent exposures would be slightly increased by inclusion of the risks to the fetus during the prenatal period. Thus, risk may be underestimated when the first and second trimesters are excluded from the analysis."[13]

[12] Cal-EPA, 2009. Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures. California Environmental Protection Agency, Office of Environmental Health Hazard Assessment. May 2009. Page 52. [Web location: http://www/oehha.ca.gov/air/hot_spots/2009/TSDCancerPotency.pdf]; ASF, Age Sensitivity Factors are the same as Age Dependent Adjustment Factors, ADAFs, used by the U.S. EPA

[13] ASFs is a Cal-EPA acronym for Age Sensitivity Factors which is the same as U.S. EPA's Age Dependent Adjustment Factors (ADAFs)

Example: Affects on Benzo[a]Pyrene Cleanup Levels

In the following sections, Benzo[a]pyrene (B[a]P) is used to illustrate the implications of potential changes to the MTCA Cleanup Regulation. Ecology believes that scientific evidence supports including adjustments for early life exposure in calculating cleanup levels. Benzo[a]pyrene, a carcinogenic polycyclic aromatic hydrocarbon (PAH) was chosen for this example because both the U.S. EPA and Cal-EPA recognize the potential for early-in-life susceptibility from exposures to B[a]P.

Ecology is questioning whether to apply early life adjustments only to chemicals acting through a mutagenic mode of action. The practical implication of choosing this option is that only B[a]P would be affected. Should Ecology choose to apply early life adjustments to all carcinogens, a much larger set of chemicals would be affected. To illustrate the policy choices that arise when early life adjustments result in lowering cleanup levels, this paper looks at B[a]P concentrations measured in Washington, and at two data sets for background concentrations.

Data Analysis: B[a]P Contamination in Washington

Polycyclic aromatic hydrocarbons (PAHs) are formed during the incomplete combustion of organic matter, such as, the burning of coal, oil, gas, wood, garbage, or other organic substances, such as tobacco and charbroiled meat. PAHs enter the environment mostly as releases to air from volcanoes, forest fires, residential wood burning, and exhaust from automobiles and trucks. Surface runoff from asphalt roads is another common contributor to PAHs in the environment. As a result, PAHs are considered ubiquitous in soil and throughout the environment due mostly to the anthropogenic (resulting from the influence of human beings) combustion processes discussed above.[14]

Ecology maintains a database that collects environmental data from throughout the state. This database, the Environmental Information Management System (EIM) contains physical, chemical, and biological data and measurements for different media.

Data on B[a]P in Washington was pulled from EIM to provide an estimate of the magnitude of the proposed changes. That is, to give some idea of locations potentially fall above the risk based concentrations.

For this analysis, MyEIM was used to retrieve and evaluate benzo[a]pyrene (B[a]P) soil and groundwater (GW) data in Washington. MyEIM is an advanced toolset for searching and analyzing data from the EIM database. It allows customized searches that facilitate the retrieval and analysis of data. The purpose of this evaluation was to provide a general idea of the geographic distribution of elevated B[a]P concentrations across the state.

Retrieved soil and groundwater data was statistically evaluated using MTCASTAT available in the MyEIM web application. To determine where B[a]P concentrations are most prevalent, MTCA Method A soil and groundwater cleanup levels were used to assess where media

[14] DHHS (U.S. Department Of Health And Human Services), 1995. *Toxicological Profile For Polycyclic Aromatic Hydrocarbons*. Agency for Toxic Substances and Disease Registry. August 1995.

concentrations are above risk based cleanup levels.[15] This information was used by MyEIM to generate maps displaying location in WA where EIM data shows B[a]P concentrations above current risk-based cleanup levels..

Soil

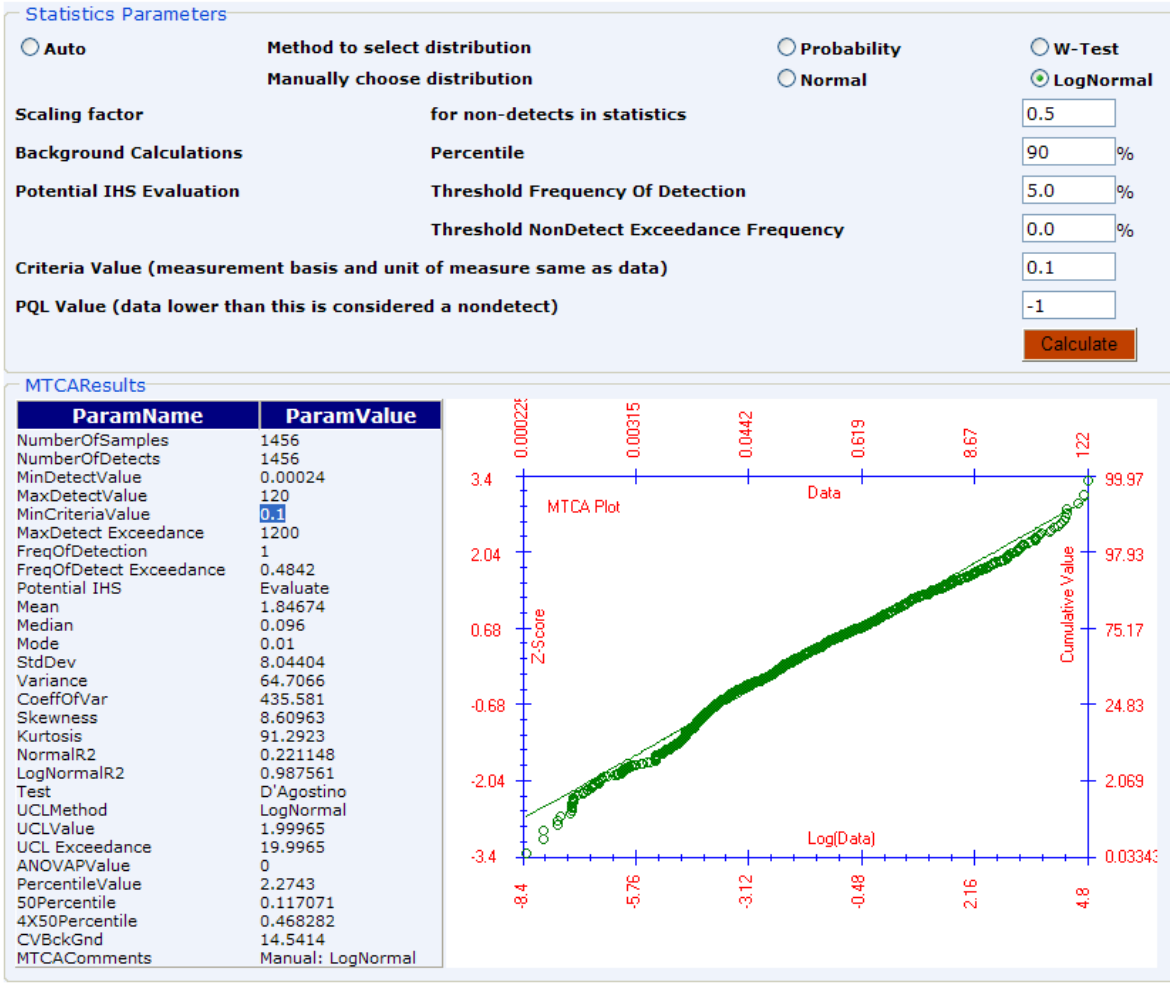
Descriptive statistics for soil data was based on detected soil concentrations for Washington State from EIM monitoring stations. Non-detects and two soil sample statistical outliers were rejected for this analysis because incorporation of this data would not fit any described distribution and would skew the results towards the outliers. Table 3 below provides the descriptive statistics for the soil data retrieved from EIM for benzo[a]pyrene.

Table 3: Descriptive Statistics for Soil MyEIM Data

Descriptive Statistics	Value (mg/kg)
Number Of Samples	1456
Minimum Detect Value	0.00024
Maximum Detect Value	120
Mean	1.84674
Median	0.096
Standard Deviation	8.04
UCL	1.99
UCL Exceedances	19.9
Data Distribution: LogNormal	

The image below provides further descriptive statistics for the soil data retrieved from EIM and the graphical analysis that describes lognormality for the soil dataset.

[15] MTCA Table 740-1, Method A Soil Cleanup Levels for Unrestricted Land Uses for Benzo[a]pyrene is 0.1 mg/kg based on the direct contact equation 740-2. MTCA Table 720-1 Method A Cleanup Levels for Groundwater for Benzo[a]pyrene is 0.1 µg/liter based on applicable state and federal law adjusted to a 10^{-5} risk level.

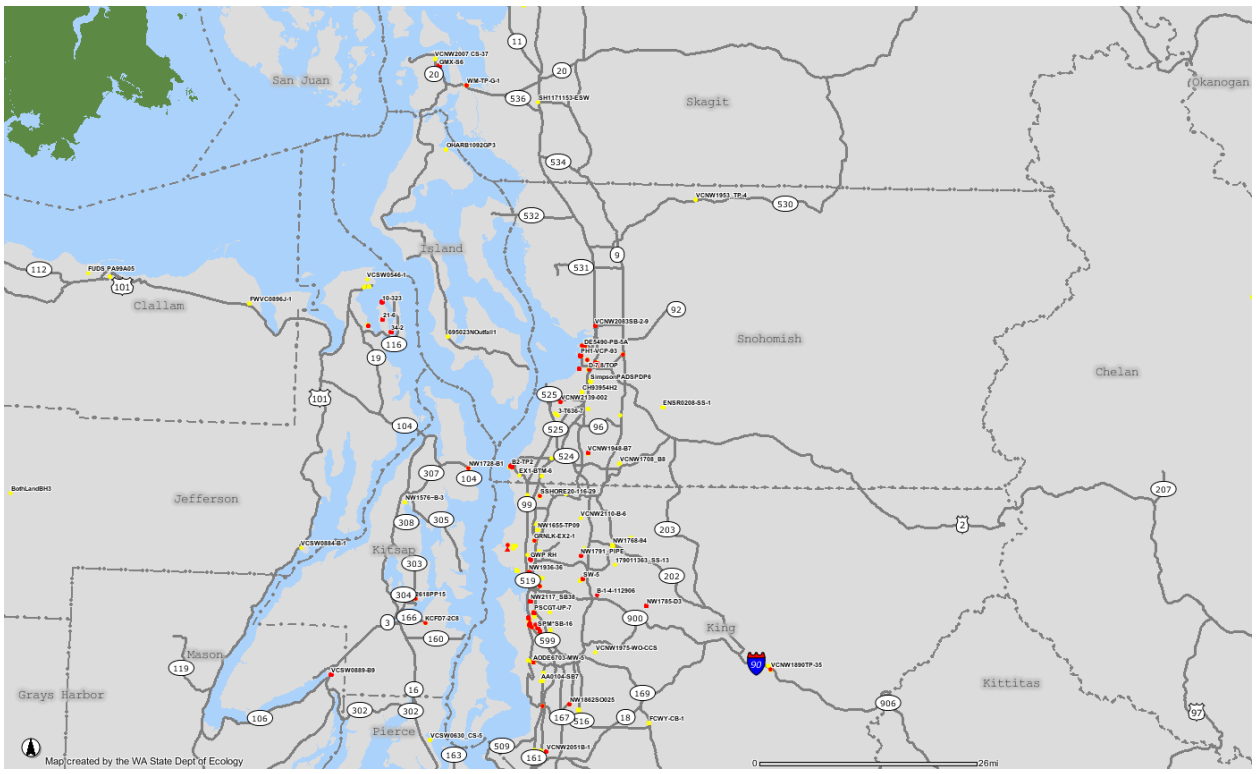


ParamName	ParamValue
NumberOfSamples	1456
NumberOfDetects	1456
MinDetectValue	0.00024
MaxDetectValue	120
MinCriteriaValue	0.1
MaxDetect Exceedance	1200
FreqOfDetection	1
FreqOfDetect Exceedance	0.4842
Potential IHS	Evaluate
Mean	1.84674
Median	0.096
Mode	0.01
StdDev	8.04404
Variance	64.7066
CoeffOfVar	435.581
Skewness	8.60963
Kurtosis	91.2923
NormalR2	0.221148
LogNormalR2	0.987561
Test	D'Agostino
UCLMethod	LogNormal
UCLValue	1.99965
UCL Exceedance	19.9965
ANOVAPValue	0
PercentileValue	2.2743
50Percentile	0.117071
4X50Percentile	0.468282
CVBckGnd	14.5414
MTCAComments	Manual: LogNormal

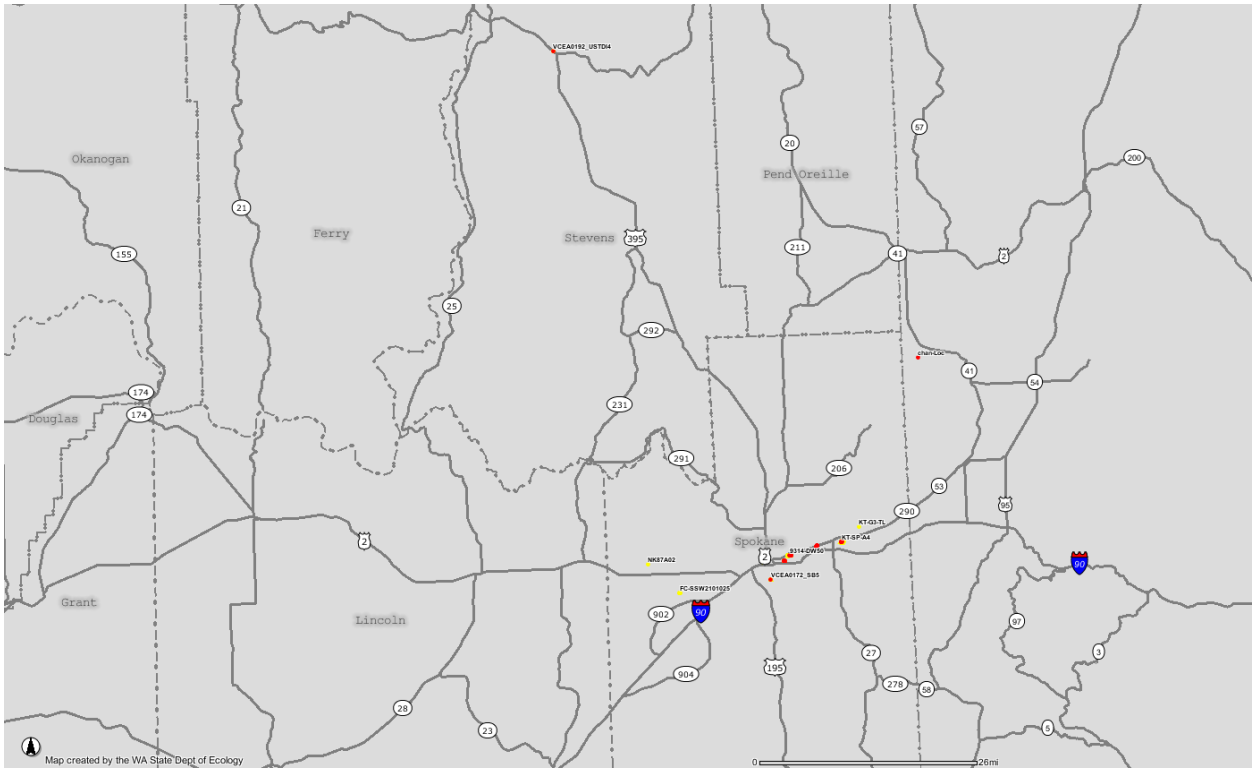
Selected maps are provided below that visually display soil EIM B[a]P data for Washington State.

The red dots show where soil concentrations are greater than the Method A soil cleanup level of 0.1 mg/kg.

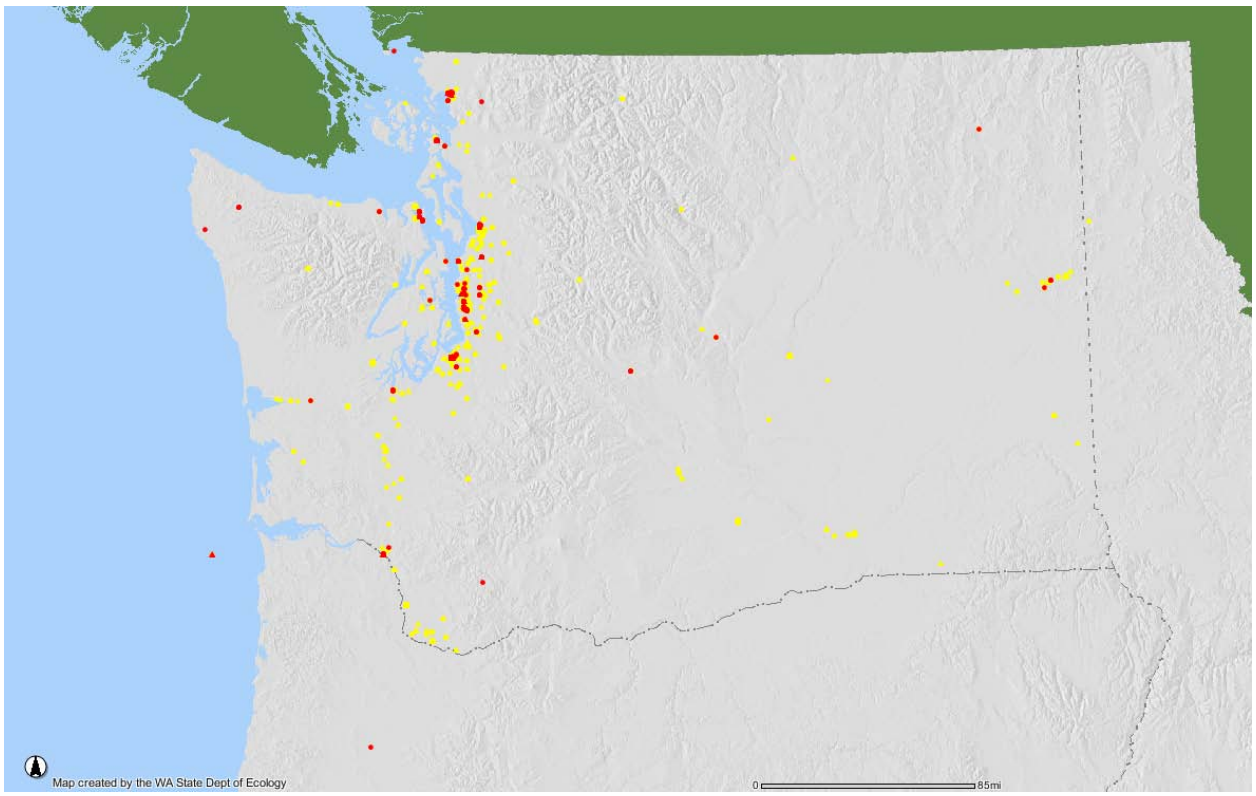
Soil data for B[a]P for the Puget Sound/Seattle I-5 corridor.



Soil data for B[a]P for the Spokane area.



Soil data for B[a]P for Washington State.



Groundwater

Descriptive statistics for groundwater data was based on detected groundwater concentrations for Washington State from EIM monitoring stations. Non-detects were rejected for this analysis.

Table 4 below provides the descriptive statistics for the groundwater data retrieved from the EIM database for benzo[a]pyrene.

Table 4: Descriptive Statistics for GW MyEIM Data	
Descriptive Statistics	**Value (µg/Liter)**
Number Of Samples	675
Minimum Detect Value	0.0016
Maximum Detect Value	7500
Mean	35.1721
Median	0.122
Standard Deviation	325.04
UCL	17.2173
UCL Exceedances	172.173
Data Distribution: LogNormal	

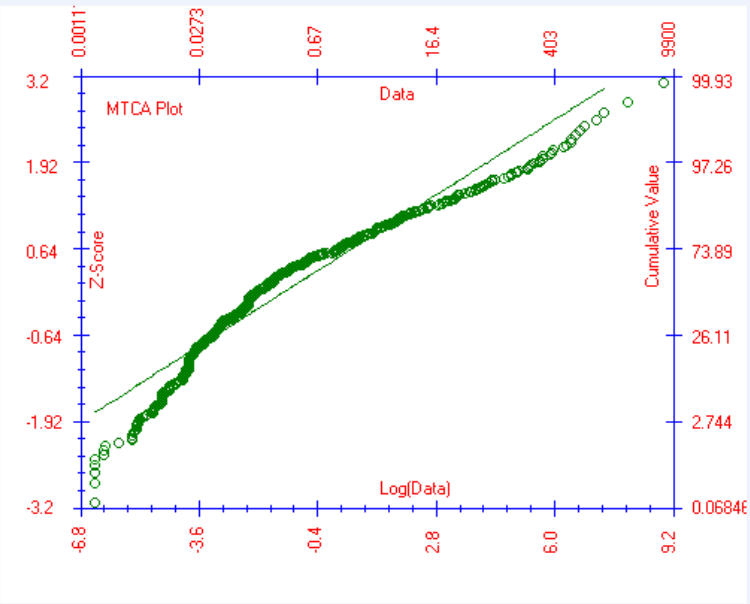
Statistics Parameters

(•) Auto	Method to select distribution	( ) Probability	( ) W-Test
	Manually choose distribution	( ) Normal	( ) LogNormal
Scaling factor	for non-detects in statistics		0.5
Background Calculations	Percentile		90 %
Potential IHS Evaluation	Threshold Frequency Of Detection		5.0 %
	Threshold NonDetect Exceedance Frequency		0.0 %
Criteria Value (measurement basis and unit of measure same as data)			0.1
PQL Value (data lower than this is considered a nondetect)			-1

Calculate

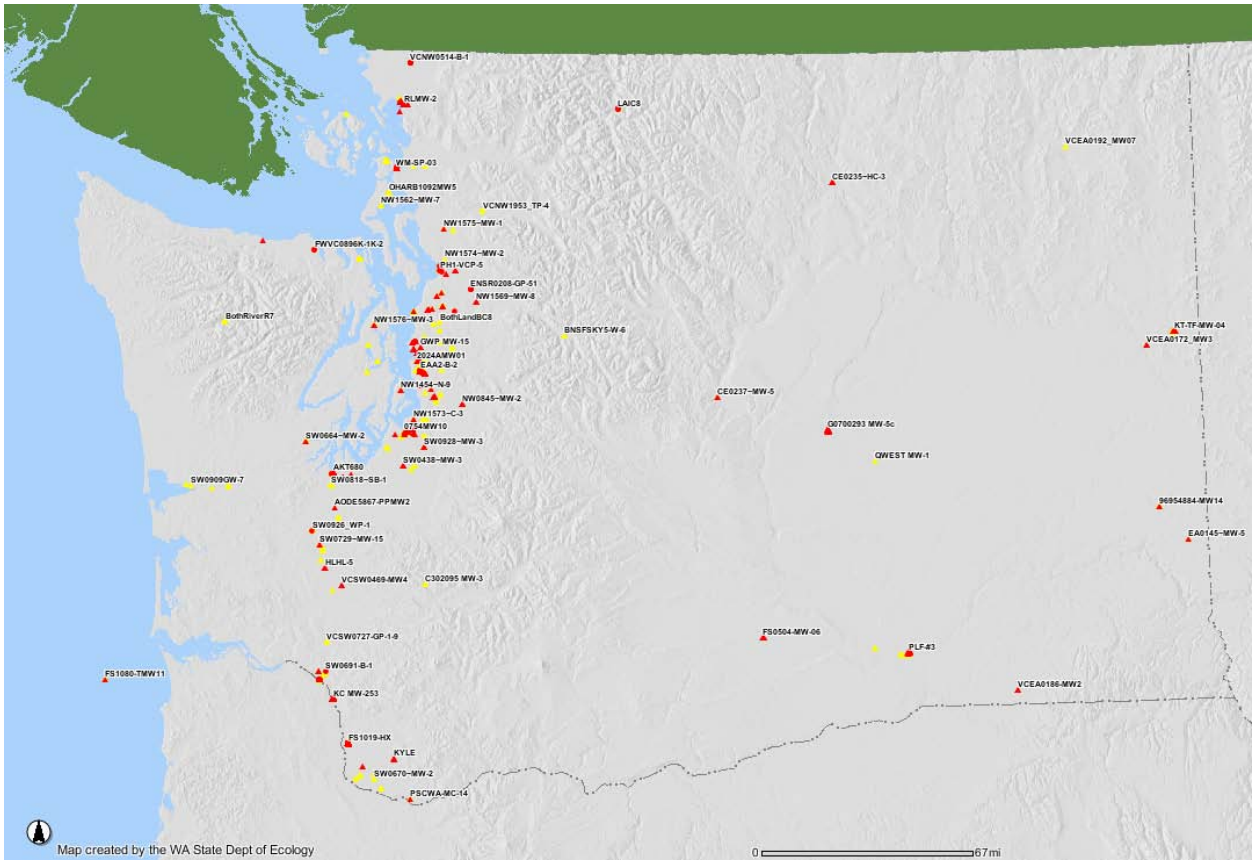
MTCAResults

ParamName	ParamValue
NumberOfSamples	675
NumberOfDetects	675
MinDetectValue	0.0016
MaxDetectValue	7500
MinCriteriaValue	0.1
MaxDetect Exceedance	75000
FreqOfDetection	1
FreqOfDetect Exceedance	0.5289
Potential IHS	Evaluate
Mean	35.1721
Median	0.122
Mode	0.1
StdDev	325.04
Variance	105651
CoeffOfVar	924.14
Skewness	19.2358
Kurtosis	422.301
NormalR2	0.074596
LogNormalR2	0.932917
Test	D'Agostino
UCLMethod	LogNormal
UCLValue	17.2173
UCL Exceedance	172.173
ANOVAPValue	0
PercentileValue	9.9891
50Percentile	0.254802
4X50Percentile	1.01921
CVBckGnd	60.1919
MTCAComments	Probability: LogNormal



The following map visually displays groundwater EIM B[a]P data for Washington State. The red dots note where concentrations are greater than the Method A groundwater cleanup level, 0.1 µg/liter.

Groundwater data for B[a]P for Washington State.



Background Concentrations of PAHs

To estimate background concentrations Ecology reviewed two reports on PAH background concentrations.

The Agency for Toxic Substances and Disease Registry reviewed background soil PAH concentrations for rural, agricultural, and urban soils. Background soil concentrations for selected PAHs are provided in Table 5 below:

Table 5: Background Soil Concentrations (mg/kg) of Selected Polycyclic Aromatic Hydrocarbons (PAHs)

Selected PAHs	Rural Soils	Agricultural Soil	Urban Soils
Benzo[a]anthracene	0.005-0.02	0.056-0.11	0.169-59
Benzo[a]pyrene	0.002-1.3	0.0046-0.9	0.165-0.22
Benzo[b]fluoranthene	0.02-0.03	0.058-0.22	15-62
Benzo[e]pyrene		0.053-0.13	0.06-14
Benzo[g,h,i]perylene	0.01-0.07	0.066	0.9-47
Benzo[k]fluoranethen	0.01-0.11	0.058-0.25	0.3-26
Chrysene	0.038	0.078-0.12	0.251-0.64
Fluoranthene	0.0003-0.04	0.12-0.21	0.2-166
Phenanthrene	0.03	0.048-0.14	
Pyrene	0.001-0.0197	0.099-0.15	0.145-147

Adapted from Table 5-3, page 262, *Toxicological Profile For Polycyclic Aromatic Hydrocarbons*, 1995.

PAH concentrations at selected wood preserving sites are provided in Table 6, below. Studies indicate significantly elevated concentrations of PAHs at various types of contaminated sites. Because of different sampling protocols, sampling designs, analytical methods, and site sampling locations the comparison of PAH concentrations across different contaminated sites does not provide a reliable comparison. However, the scale of differences between areas of soil contamination for wood preserving sites compared with background concentrations can be several orders of magnitude.

Table 6: Selected Polycyclic Aromatic Hydrocarbons (PAHs) Soil Concentrations (mg/kg) From Contaminated Wood Preserving Sites

Selected PAHs	Wood Preserving Sites	
	Surface Soils	Sub-Surface Soils
Benzo[a]anthracene	12	171
Benzo[a]pyrene	28	82
Benzo[b]fluoranthene	38	140
Chrysene	38	481
Fluoranthene	35	1629
Phenanthrene	11	4434
Pyrene	49	1016

Adapted from Table 5-4, page 263, *Toxicological Profile For Polycyclic Aromatic Hydrocarbons*, 1995.

A second set of data is provided by a 1994 study that collected 20 surface soil samples from three New England cities and analyzed for PAHs.[16] The results of the PAH datasets across the three different cities are not statistically different and can be considered one dataset representative of urban environments. The samples were taken in typical urban areas not located near known industrial sites or activities. Hence, this dataset may be considered to be representative of the generalized effects of urban activities.

Summary statistics for this data set are provided in Tables 7 through 10 below, by city, with the arithmetic mean and upper 95% confidence level concentrations.

Table 7: Background PAH Concentrations in Urban Soils for Boston (n=20)

Compound	Arithmetic Mean (mg/kg)	Upper 95% Confidence Level (mg/kg
Total B[a]P-TEF	2.4	4.6
Total CPAHs	8.4	16.0
Total PAHs	18.7	35.9

Table 8: Background PAH Concentrations in Urban Soils for Providence (n=20)

Compound	Arithmetic Mean (mg/kg)	Upper 95% Confidence Level (mg/kg
Total B[a]P-TEF	2.1	2.9
Total CPAHs	7.8	11.0
Total PAHs	16.8	23.5

Table 9: Background PAH Concentrations in Urban Soils for Springfield (n=20)

Compound	Arithmetic Mean (mg/kg)	Upper 95% Confidence Level (mg/kg
Total B[a]P-TEF	2.8	4.5
Total CPAHs	10.6	18.3
Total PAHs	19.1	29.9

▪

Table 10: Background PAH Concentrations in Urban Soils for All 3 Cities (n=60)

Compound	Arithmetic Mean (mg/kg)	Upper 95% Confidence Level (mg/kg
Total B[a]P-TEF	2.4	3.3
Total CPAHs	9.0	12.4
Total PAHs	18.4	24.8

[16] L.J.N Bradley, B.H. Magee, and S.L. Allen Background Level of Polycyclic Aromatic Hydrocarbons (PAH) and Selected Metals in New England Urban Soils. Journal of Soil Contamination, 3(4): 1-13. 1994.

Summary statistics for selected PAHs for all sampling areas combined across the three cities sampled are provided in the Table 11 below.

Table 11: Summary Statistics of Selected PAH Background Concentrations For All 3 Cities

Selected PAH	Minimum Detect mg/kg	Maximum Detect mg/kg	Arithmetic Mean	Upper 95% Confidence Limit mg/kg
Benzo[a]anthracene	0.48	15	1.319	1.858
Benzo[a]pyrene	0.040	13.0	1.323	1.816
Benzo[b]fluoranthene	0.049	12.0	1.435	1.973
Benzo[g,h,i]perylene	0.200	5.90	0.891	1.195
Benzo[k]fluoranthene	0.043	25.0	1.681	2.522
Chrysene	0.038	21.0	1.841	2.693
Fluoranthene	0.110	39.0	3.047	4.444
Phenanthrene	0.071	36.0	1.838	2.982
Pyrene	0.082	11.0	2.398	2.945
Total B[a]P-TEF	0.257	21.31	2.437	3.324
Total c-PAHs	0.680	77.70	8.973	12.423
Total PAHs	2.292	166.65	18.361	24.819

Observations, Conclusions & Implications

Data from EIM show that areas west of the Cascades have significantly greater B[a]P contamination in both soil and groundwater. This analysis provides an indicator of the extent of the affected area.

- For soils, using the EIM dataset for Washington, the 95% upper confidence limit for B[a]P concentration is 20 times greater than the current MTCA risk-based cleanup level of 0.1 mg/kg. Concentrations over the cleanup levels are most pronounced west of the Cascades, particularly along the I-5 corridor in the Puget Sound region.
- For groundwater, using the EIM dataset for Washington, the 95% upper confidence limit for B[a]P concentration is about 170 times greater than the current MTCA risk-based cleanup level of 17.2 µg/liter.

As reported by Bradley *et al* (1994) target risk-based cleanup levels for carcinogenic PAHs, (based on B[a]P toxicity equivalency factors) range from 0.1 to 0.7 mg/kg). These values are considerably below urban background surface soil concentrations. For all cities combined, the urban background concentration of B[a]P-TEF at the 95% upper confidence level (3.3 mg/kg) is approximately 30 times higher than the MTCA risk-based cleanup level of 0.1 mg/kg.

The total c-PAHs (12 mg/kg) and total PAHs (25 mg/kg) background concentrations at the 95% upper confidence level is approximately 40 to 100 times the target risk-based cleanup levels.[17]

Accounting for Early-Life Exposure to B[a]P

Risk management decisions attempt to balance competing and, sometimes, divergent factors. The data for B[a]P in Washington and the fact that risk based concentrations may fall below background levels illustrates the complexity involved. Decisions to adjust MTCA risk-based cleanup equations consistent with new technical information and regulatory policies immediately encounter these questions.

What is the effect of lowering cleanup levels when those risk-based cleanup levels fall considerably below background concentrations? This is the policy question Ecology is addressing regarding updates to the MTCA rule.

There are implications for the cleanup of hazardous waste sites where risk-based cleanup levels are below background concentrations. Under the MTCA Cleanup Regulation, cleanup requirements are adjusted to background concentrations. The regulatory framework provides that cleanup of contaminants at hazardous waste sites is not required to below background concentrations.

Affect on Soil Cleanup Levels

Table 12 shows the effect of adding Age Dependant Adjustment Factors (ADAFs) that take into account exposures in early life. The current Method B and modified Method B cleanup levels (one exposure pathway and two exposure pathways, columns i and ii) are compared to two exposure pathway and three exposure pathways cleanup levels calculated with ADAFs (column iii and iv). The ADAF calculations were done two ways, as detailed in Appendix A. The second "alternative" calculation reflects corrections to the exposure parameters and age groupings recommended by the MTCA Science Panel.

Note that in the current regulation, the B[a]P Method A soil cleanup level for unrestricted land use, calculated using the Method B Equation 740-2, is 0.1 mg/kg.

Table 12: Comparison of Soil Cleanup Levels for Carcinogens With & Without ELE Age Adjustments

	i	ii	iii		iv	
Chemical	Soil Cleanup Level Carcinogen Method B, Eqn.740-2 mg/kg	Soil Cleanup Level Carcinogen Method B, Eqn.740-5 mg/kg	Soil Cleanup Level Carcinogen ELE Dermal + Ingest. mg/kg		Soil Cleanup Level Carcinogen ELE Dermal + Ing + Inh mg/kg	
			Current	Alternative	Current	Alternative
Benzo[a]pyrene	1.37E-01	1.04E-01	1.70E-02	1.10E-02	1.70E-02	1.1E-02
Other States B[a]P Risk-Based Cleanup Level Range for ELE: ≈ 1.5E-02 to 2.6E-01 mg/kg EPA Region 3, 6, & 9 Residential Soil Screening Level for B[a]P = 1.5E-02 mg/kg						

[17] L.J.N Bradley, B.H. Magee, and S.L. Allen Background Level of Polycyclic Aromatic Hydrocarbons (PAH) and Selected Metals in New England Urban Soils. Journal of Soil Contamination, 3(4): 1-13. 1994, page 12

It's illustrative also to compare effects of accounting for exposures with other decision parameters used to establish cleanup levels. Table 13 compares, for B[a]P:

- Cleanup levels calculated using two exposure pathways (ingestion + dermal) without age dependent adjustment factors (i)
- Cleanup levels calculated using two exposure pathways (ingestion + dermal) with age dependent adjustment factors (ii)
- Soil concentrations that protect drinking water against contaminants leaching from soil into groundwater (iii)
- Soil background concentrations (iv)

Table 13: Comparison of ELE Cleanup Levels With Other Soil Values for B[a]P

i	ii	iii	iv	
Carc. Soil Cleanup Level Dermal + Ingestion Method B, Eqn.740-5 mg/kg	Soil Cleanup Level Carcinogen ELE Dermal + Ingestion mg/kg	Soil Concentration Protective of GW 3-Phase Model mg/kg	Soil Background Concentrations mg/kg	
			3.3	Upper 95 %ile B[a]P-TEF
1.04E-01	1.70E-02	4.3E-01	12.4	Total c-PAHs
			24	Total PAHs
0.104	0.017	0.43	≈ 2.0	MyEIM 95% UCL
			1.8	Mean MyEIM

Regardless of whether early-life exposures are factored in, the risk-based soil cleanup levels and soil concentrations protective of groundwater are consistently below some measure of B[a]P soil background concentrations.

As risk based concentrations become lower, for example when the effects of exposure during early life is factored in, cleanup decisions will increasingly be based on background concentrations. This has implications for potential updates to the MTCA cleanup regulation and for decision making at future cleanup sites. It brings up, for example, questions about how to define and determine contaminant background concentrations.

Ecology is aware that determining background is already a significant cleanup consideration, and is evaluating the implications of adding age dependant adjustments factors. Ecology considers the change from risk-based decisions to a regulatory decision making framework based on background concentrations to be a significant risk management consideration in evaluating whether age dependant adjustment factors for early-life exposures should be applied to all carcinogens.

The goal for Ecology's MTCA Cleanup Regulation update, when considering early-life exposure, continues to be for cleanup standards and requirements that are based on the best available science, are reasonable, and are protective of the environment and public health.

Appendix A: Age Groupings and Age Adjustment Factors

Early life adjustments to the soil ingestion factor (IFS) are made as follows. Exposure parameters are organized into four groups. Multipliers of 10, 3, 3, and 1 reflect the greater susceptibility of infants and children.

Early-Life Exposure (ELE) Age Adjustment For Soil Ingestion From Exposure To Carcinogens, mg-year/kg-day

$$IFS_{ele\text{-}adj} = \frac{ED_{0\text{-}2} * SIRc * 10}{BWc} + \frac{ED_{2\text{-}6} * SIRc * 3}{BWc} + \frac{ED_{6\text{-}16} * SIRa * 3}{BWa} + \frac{ED_{16\text{-}30} * SIRa * 1}{BWa}$$

Early life adjustments to the soil dermal factor (DFS) are made as follows. Exposure parameters are organized into four groups. Multipliers of 10, 3, 3, and 1 reflect the greater susceptibility of infants and children.

Early-Life Exposure (ELE) Age Adjustment For Dermal Contact From Exposure To Carcinogens, mg-year/kg-day

$$DFS_{ele\text{-}adj} = \frac{ED_{0\text{-}2} * AFc * SAc * 10}{BWc} + \frac{ED_{2\text{-}6} * AFc * SAc * 3}{BWc} + \frac{ED_{6\text{-}16} * AFa * SAa * 3}{BWa} + \frac{ED_{16\text{-}30} * AFa * SAa * 1}{BWa}$$

The "alternative" exposure parameters are based on recommended by the MTCA Science Panel.

Table 14: Early-Life Exposure (ELE) Age Adjustment Factors For Carcinogens, Soil Ingestion Pathway

Parameter	Definition	Default Exposure Parameters For Early-Life Exposure							
		← Age Groupings →							
		< 2 years		2 to < 6 Years		6 to < 16 Years		Adult	
		Default	Alternative	Default	Alternative	Default	Alternative	Default	Alternative
ADAF	Age-Dependent Adjustment Factor, Unitless	10	----	3	----	3	----	1	----
ED	Exposure Duration, Years	2	----	4	----	10	----	14	----
BW	Body Weight, kg	16	10	16		70	45	70	----
SIR	Soil Ingestion Rate, mg/day	200	----	200	----	50	100	50	100
AF	Soil Adherence Factor, mg/cm^2-event	0.2	----	0.2	----	0.2	----	0.2	0.07
SA	Body Surface Area Exposed, cm^2	2200	2000	2200	3100	2500	5400	2500	5700