Volume 1: Final-ARAMS Terrestrial Toxicity Database

ARAMS Terrestrial Toxicity Database Background and Description

Prepared for

USACHPPM
ATTN: MCHB-TS-THE
5158 Blackhawk Road
Aberdeen Proving Ground, MD 21010-5403
(410) 436-3969

Prepared by

Parametrix, Inc.
1600 SW Western Blvd., Suite 165
Corvallis, OR 97333
(541) 758-2103
www.parametrix.com

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ACRONYMS

ARAMS	Army Risk Assessment Modeling System
BCMELP	British Columbia Ministry of Environment, Lands and Parks
BTAG	United States Environmental Protection Agency Region IX Biological Technical Advisory Group
CAS Number	Chemical Abstracts Service Registration Number
CCME	Canadian Council of Ministers of the Environment
COPC	Compound of Potential Concern
DOTN	Department of the Navy
EC_{50}	Effects Concentration for 50% of the test organisms
$EC_{50\text{-}NL}$	Effects Concentration (non-lethal) for 50% of the test organisms
EC_X	Effects Concentration
ECL	Effects Concentration Low
ED_{10}	Effective Dose for 10% of the test organisms
ER-L	Effects Range Low
Eco-SSL	Ecological Soil Screening Level
EPA	Environmental Protection Agency
LC_{20}	Lethal Concentration for 20% of test organisms
LC_{50}	Lethal Concentration for 50% of the test organisms
LD_{50}	Lethal Dose for 50% of the test organisms
LED_{10}	Lower bound of an ED_{10} (based on the 95% confidence limit)
LOAEC	Lowest Observable Adverse Effects Concentration
LOAEL	Lowest Observable Adverse Effects Levels
LOEC	Lowest Observable Effects Concentration
MATC	Maximum Acceptable Threshold Concentration
MHSPE	Dutch Ministry of Housing, Spatial Planning and Environment

ACRONYMS (Continued)

MOEE	Ontario Ministry of Environment and Energy
NOAEC	No Observable Adverse Effects Concentration
NOAEL	No Observable Adverse Effects Level
NPCA	Norwegian Pollution Control Agency
ORNL	Oak Ridge National Laboratories
$PNEC_{soil}$	Predicted No Effect Concentrations for Soil
QSARs	Quantitative Structure Activity Relationships
SQG_{SC}	Soil Quality Guidelines for Soil Contact
TEC	Threshold Effect Concentration
TRVs	Toxicity Reference Values
USACHPPM	United States Army Center for Health Promotion and Preventative Medicine
USEPA	United States Environmental Protection Agency

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The following professionals participated in developing this database:

Key Technical Authors:	Anne Fairbrother	Parametrix, Inc.
	Jeffrey R. Wirtz	Parametrix, Inc.
	Lisa Allen	Parametrix, Inc.
Outside Reviewers:	Mark S. Johnson	USACHPPM
	Matthew McAtee	USACHPPM
	Lia Gaizick	USACHPPM
	Melanie Hawkins	USACHPPM
	Matthew Bazar	USACHPPM

POINTS OF CONTACT

For further information or assistance, contact USACHPPM at the following offices.

Mr. Matthew McAtee
United States Army Center for Health Promotion and Preventative Medicine
ATTN: MCHB-TS-EHR, Bldg. E1675
Aberdeen Proving Ground, MD 21010-5403
(410) 436-2953 / DSN 584-2953

Dr. Mark S. Johnson
United States Army Center for Health Promotion and Preventative Medicine
ATTN: MCHB-TS-THE, Bldg. E2100
Aberdeen Proving Ground, MD 21010-5403
(410) 436-3980 / DSN 584-3980

This background and description report and a user's guide for the database are available at the following website:

1. GOAL OF ARAMS TERRESTRIAL TOXICITY DATABASE

This Microsoft Access® 2000 database provides a selection of ecologically relevant Toxicity Reference Values (TRVs) for wildlife and soil benchmarks for plants and soil invertebrates. The database was developed by reviewing values derived by various jurisdictions and ranking them according to quality and relevance. The ranked values are supplied in a Microsoft Access® 2000 database that is searchable by genus, family, order, class, general data groupings (*e.g.*, all soil benchmark values), and chemical name, Chemical Abstracts Service Registration Number (CAS Number) or synonym. The default value is the most conservative TRV or benchmark value with the highest quality ranking and thus, total score; however, a user may select another value deemed of lesser quality if desired.

It is important to note that more than one definition of TRV exists. For example, some jurisdictions define TRVs as doses below which it is believed that no adverse effects would occur to individual wild animals, and above which there is a possibility that such effects might occur (*i.e.,* a toxicity threshold). The United States Army Center for Health Promotion and Preventative Medicine Technical Guide 254 (USACHPPM TG 254, 2000) defines a TRV as a chemical concentration expressed as an administered dose (*e.g.*, oral, inhalation or dermal dose), or as a media concentration that is used in conjunction with an exposure prediction to estimate health hazard or ecological risk. As a final example, some jurisdictions provide both a low and a high TRV for the chemical. The low TRVs often correspond to a value with a chronic No Observable Adverse Effects Level (NOAEL) and the high TRVs correspond to a Lowest Observable Adverse Effects Level (LOAEL), or some other effects level (*e.g.*, Effects Concentration (EC_x)). For the purposes of this database, the use of the term TRV incorporates all of the different definitions of a TRV. The particular definition of TRV that a given jurisdiction uses can be found in Section 3 of this report in the subsection that describes each jurisdiction, and also in the TRV/benchmark Derivation Method column of the TRV/benchmark electronic database.

Soil benchmarks are soil concentrations that have the same properties in regard to soil infauna (*i.e.*, invertebrates and plants) as TRVs do for individual wild animals. However, not all soil benchmarks are defined exactly the same way. For example, a Predicted No Effect Concentration for Soil ($PNEC_{soil}$) developed by Norway provides the concentration of a substance where no harmful effects to the environment are expected (NPCA, 1999), while a Dutch Intervention Value is a concentration of a contaminant in soil above which the functionality of the soil for human, plant and animal life is seriously impaired or threatened (MHSPE, 1994). For the purposes of this database, the use of the term benchmark incorporates all of these different definitions of a soil benchmark. As for the TRVs, the particular definition of soil benchmark that a given jurisdiction uses can be found in Section 3 of this report in the subsection that describes each jurisdiction, and also in the TRV/benchmark Derivation Method column of the TRV/benchmark electronic database.

2. SELECTION OF JURISDICTIONS

To determine which jurisdictions should have data included in the database, background documents on derivation methods of TRVs and soil benchmarks were read. Jurisdictions that have published such values were identified. Information from each jurisdiction that was applicable to this project was obtained by downloading from each jurisdiction's Internet website, by ordering it from their publications department, or by directly contacting someone at the jurisdiction. To have their values included in this database, a jurisdiction had to provide appropriate TRVs/benchmark values (*i.e.*, ecotoxicity-based values), along with a minimal explanation of how the values were derived, what the values meant in terms of what they were protecting, and the degree of that protection.

The following jurisdictions were evaluated, but were not included in the database as they did not provide enough of the information described above to evaluate the adequacy or applicability of TRVs or soil protection values. The following jurisdictions provided no explanations of how their values were derived: German Federal Environmental Agency; Danish Ministry of Environment and Energy; Finnish Environment Institute; Swedish Environmental Protection Agency; and the Swiss Agency for the Environment, Forests and Landscape. It was not possible to determine if the soil values provided were for protection of human health or included any ecological receptors. The United Kingdom Environment Agency and Environment Australia specified that their soil values were human health based, and so were not included. Environment Australia has proposed methods for developing ecological soil protection values, but has not yet generated any numbers. The Savannah River Site and the United States Fish and Wildlife Service values were excluded because they were compilations of values from a variety of jurisdictions and lacked sufficient explanations of how the particular values were selected. Furthermore, the Savannah River Site specifically prohibits use of their values without direct permission and purchase. All United States Environmental Protection Agency Regions, except Region VI, lacked ecological soil protection values. A selected search of state agencies (*e.g.,* Florida, Massachusetts, Michigan, Washington, and Wisconsin) returned no TRVs or soil benchmarks. The California Environmental Protection Agency (EPA) has compiled data from wildlife toxicity tests that could be used to derive TRVs, but has not developed their own set of TRVs.

A total of 10 jurisdictions were identified that met the data requirements discussed above and therefore had their values included in the database. The 10 jurisdictions included in this database are the following: Norwegian Pollution Control Authority; Dutch Ministry of Housing, Spatial Planning and Environment; British Columbia Ministry of Environment, Lands and Parks; Canadian Council of Ministers of the Environment; Ontario Ministry of Environment and Energy; Oak Ridge National Laboratories; United States Environmental Protection Agency Region VI; United States Navy in consultation with United States Environmental Protection Agency Region IX Biological Technical Advisory Group, the United States Environmental Protection Agency's Superfund Ecological Soil Screening Levels and the United States Army Center for Health Promotion and Preventative Medicine. The data provided by these jurisdictions are described further in the next section of this report.

3. DESCRIPTION OF DATA PROVIDED BY SELECTED JURISDICTIONS

3.1 NORWEGIAN POLLUTION CONTROL AUTHORITY (NPCA)

The values provided by Norway that are included in the database are soil screening guidelines called Predicted No Effect Concentrations for Soil ($PNEC_{soil}$) (NPCA, 1999). By definition, a $PNEC_{soil}$ value is the concentration of a substance where no harmful effects to the environment are expected (NPCA, 1999). These values were derived by examining available toxicity data and selecting the single best study. The toxicity data from the selected study were then used directly as the $PNEC_{soil}$, or after an uncertainty factor was applied if a chronic NOAEL was not available. As such, these data are soil screening values that are protective of both plants and invertebrates. They are not directly applicable to birds, mammals, or herpetofauna, as they do not include consideration of toxicity to these organisms.

3.2 DUTCH MINISTRY OF HOUSING, SPATIAL PLANNING AND ENVIRONMENT (MHSPE)

All chemicals evaluated by the Dutch that were included in the database have a Target Value, and some also have an Intervention Value, both of which are guidelines for soil evaluation and clean-up. They were derived to be applicable to standard soil (10% organic matter and 25% clay) (MHSPE, 1994; MHSPE, 1999). A Target Value is the soil quality required for sustainability and is a concentration at which the chemical's environmental impact is expected to be negligible (MHSPE, 1999). The Intervention Value is a concentration of a contaminant in soil above which the functionality of the soil for human, plant and animal life is seriously impaired or threatened (MHSPE, 1994). Concentrations in excess of an Intervention Value correspond to serious contamination and require remedial action. In order to derive these values, a refined effect assessment can be used when ecotoxicity data from four or more taxonomic groups are available. If less information is available, a preliminary effect assessment is used, and if lab data are insufficient or lacking, toxicity data can be obtained using Quantitative Structure Activity Relationships (QSARs). These data are soil screening values that are protective of both plants and invertebrates, but are not directly applicable to birds, mammals, or herpetofauna.

3.3 BRITISH COLUMBIA MINISTRY OF ENVIRONMENT, LANDS AND PARKS (BCMELP)

BCMELP provides two types of soil quality standards that are land use specific and also legally enforceable (BCMELP, 1996a; Fox, pers. comm.). Both types of standards are designed to be concentrations that protect key ecological receptors. Generic Numerical Soil Standards were taken from the Canadian Council of Ministers of the Environment (CCME) Interim Soil Quality Criteria (1991) and are used for substances with a limited toxicity database (Fox, pers. comm.). Matrix Standards have been developed for 20 or so substances with a larger amount of data that are of a higher priority and that are most commonly found in British Columbia (Fox, pers. comm.). Generic Numerical Standards are intended to be protective of both human health and environmental receptors (Fox, pers. comm.). Matrix Standards provide separate numbers for human health and ecological receptors, and are more flexible as a result (Fox, pers. comm.). In order to derive a Matrix Standard, a Lethal Concentration for 20% of test organisms (LC_{20}) and an Effects Concentration (non-lethal) for 50% of the test organisms ($EC_{50\text{-}NL}$) for each chemical evaluated were determined (BCMELP, 1996b). For Agricultural, Urban Park and Residential land uses, the concentration corresponding to the more stringent of the LC_{20} and the $EC_{50\text{-}NL}$

values was chosen as the appropriate "Toxicity to Soil Invertebrates and Plants" soil quality Matrix Standard. For Commercial and Industrial land uses, the less stringent is chosen (BCMELP, 1996b). When available, "Toxicity to Soil Invertebrates and Plants" soil quality Matrix Standards were entered into the database, but if such values were not available, Generic Numerical Soil Standards were entered instead. Again, these standards are soil screening values that are protective of both plants and invertebrates.

3.4 CANADIAN COUNCIL OF MINISTERS OF THE ENVIRONMENT (CCME)

CCME also provides soil quality guidelines that are land use specific (CCME, 1997). For Agricultural and Residential/Parkland land uses, the concentration provided is a Threshold Effect Concentration (TEC) (CCME, 1996). A TEC is the concentration of a chemical below which no adverse effects are expected to occur. If sufficient toxicity data are available, the TEC is estimated using a weight of evidence approach. If there are not enough data to do that, the TEC is estimated by extrapolating from the lowest Lowest Observable Adverse Effects Concentration (LOAEC), or Effect Concentration for 50% of the test organisms (EC_{50}) or Lethal Concentration for 50% of the test organisms (LC_{50}). Each subsequent method for TEC derivation incorporates a larger uncertainty factor to account for a less preferable data set. For Commercial and Industrial land uses, the soil quality guideline provided is an Effects Concentration Low (ECL). The ECL is the 25^{th} percentile of the effects data distribution only and at that level, some effects will be incurred by soil-dependent biota. For the purposes of the database, only Soil Quality Guidelines for Soil Contact (SQG_{SC}) values based exclusively on data from toxicity studies on plants and invertebrates were entered (CCME, 1997). For six of the 21 chemicals evaluated, a soil and food ingestion guideline for mammalian and avian species on agricultural lands is listed, but insufficient data are provided to derive a TRV from the soil benchmark value provided. In instances were SQG_{SC} values were not provided due to a lack of toxicity data, CCME Interim Soil Quality Criteria were used instead (CCME, 1991). However, CCME Interim Soil Quality Criteria (1991) that had already been entered into this database as BCMELP Generic Numerical Soil Standards were not entered again under CCME. Again, these guidelines are soil screening values that are protective of both plants and invertebrates.

3.5 ONTARIO MINISTRY OF ENVIRONMENT AND ENERGY (MOEE)

MOEE provides ecotoxicity-based soil criteria for 14 different contaminants that are both land use and soil type specific, all of which were entered into the database (MOEE, 1995). These criteria are an approximation of a NOAEL, although exactly how these criteria were derived is not clear. This jurisdiction has developed criteria for more than 14 contaminants, but the additional criteria are not exclusively ecotoxicity-based, and thus were not included in the database (*i.e.*, they included human health info). For the 14 different contaminants examined by MOEE, different criteria values are provided for Residential/Parkland/Agricultural land uses versus Industrial/Commercial land uses. In most cases, different criteria values also are provided depending upon whether the soil being considered is medium and fine textured or coarse textured. However, while there is always a different criteria value for a given contaminant based upon the land use being considered, different soil types do not always result in a different criteria value. Unlike the other jurisdictions discussed so far that have provided soil screening values protective of both plants and invertebrates, MOEE criteria are only phytotoxicity-based and are not necessarily protective of invertebrates as a result.

3.6 OAK RIDGE NATIONAL LABORATORIES (ORNL)

Oak Ridge National Laboratories (ORNL) provides a wide range of TRV/benchmark values for chemicals commonly found at United States Department of Energy sites, all of which were included in the database. Ecotoxicological screening benchmarks that are believed to represent acceptable concentrations with respect to selected ecological receptors are provided for both plants and earthworms (ORNL, 1997a, 1997b). For both sample types, if more than 10 toxicity studies were available, these screening benchmarks were derived by determining the Effects Range Low (ER-L) for a given contaminant. This was accomplished by rank ordering the Lowest Observable Effects Concentration (LOEC) values from toxicity studies and then picking a number that approximated the 10^{th} percentile (*i.e.*, a concentration at which 10% of species will be affected). If 10 or fewer studies were available, the lowest LOEC was used as the ER-L instead.

Both NOAELs and LOAELs TRVs for 9 representative mammal species and 11 representative bird species also are provided (ORNL, 1996). The NOAEL-based TRVs represent values believed to be non-hazardous to the listed wildlife species. In contrast, the LOAEL-based TRVs represent threshold values at which adverse effects are likely to become evident. In most cases, these TRVs were estimated from toxicity studies on a different species of wildlife or on domestic or lab animals, and sometimes on less than ideal data (*e.g.*, Lethal Dose for 50% of the test organisms [LD_{50}]). The single best study was selected and the experimentally-derived TRV was used to estimate the TRVs for the representative mammal or bird species by adjusting the dose according to differences in body size. Appropriate uncertainty factors, if necessary, also were applied to derive a given TRV. For the purposes of this database, only the TRVs that are provided for the test species in the single best study, and not the allometrically-derived TRVs for the representative species, were included.

3.7 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION VI (USEPA REGION VI)

USEPA Region VI provides TRVs for birds, mammals, plants, earthworms and other soil invertebrates (USEPA, 1999). These TRVs are defined as a representation of a Compound of Potential Concern (COPC) concentration or dose that causes no observed adverse effects to an ecologically relevant endpoint of a receptor exposed for a chronic duration (*e.g.*, the most conservative chronic NOAEL for a class (Aves or Mammalia)). The single best study was selected and the appropriate uncertainty factors, if necessary, were applied to derive a given TRV. It is worth noting that this is the only instance, with the exception of the USACHPPM TRVs for terrestrial amphibians, in which a jurisdiction refers to a soil concentration as a TRV rather than a benchmark. Again, all this information was entered into the database under the appropriate receptor type (*e.g.*, Birds, Mammals, etc.).

3.8 UNITED STATES NAVY IN CONSULTATION WITH USEPA REGION IX BIOLOGICAL TECHNICAL ADVISORY GROUP (NAVY BTAG)

The United States Navy, in consultation with United States Environmental Protection Agency Region IX Biological Technical Advisory Group (BTAG), developed Draft low and high TRVs for birds and mammals for chemicals routinely found at Naval installations in the San Francisco Bay Area (DOTN, 1997). It is important to note that these values were arrived at via consensus, and that the United States Navy Engineering Facility Activity West was the author/publisher/sponsor (M. Johnson, USACHPPM, pers. comm.). Their low TRV is defined as a conservative value consistent with a chronic no effect level, while the high TRV is a value at which adverse effects have been demonstrated (*i.e.*, represents a level at

which ecologically significant adverse effects are likely to occur). Chronic exposures and responses and NOAEL and LOAEL data were preferred for low TRV derivation. Toxicity data on mortality and other acute effects were considered inappropriate for deriving low TRVs, although mortality occasionally was considered for high TRV derivation. Dose versus Effect scatterplots were made for each chemical that was evaluated in order to reflect the range of adverse effects potentially caused by the chemical. The TRVs derived for each chemical captured the variability between the no effects level consistent with the low TRV and the effect levels indicated by a high TRV. After review of the data, doses on which to base low and high TRVs were selected *(Note: Region 9 BTAG made the recommendation to withdraw the 0.0015 mg/kg/d value for the low mammalian TRV for lead and replace it with 1.0 mg/kg/day. This change is reflected in the latest version of the TTD database.)* All the TRV information provided by Navy BTAG was entered into the database, but no soil benchmarks for protection of soil infauna were provided by this jurisdiction.

3.9 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY SUPERFUND ECOLOGICAL SOIL SCREENING LEVELS (ECO-SSL)

Eco-SSL Draft TRVs are provided for birds and mammals, and Draft soil benchmarks are provided for plants and invertebrates for chemicals commonly found at Superfund sites. These TRVs are defined as doses above which ecologically relevant effects might occur to wildlife species following chronic dietary exposures and below which it is reasonably expected that such effects will not occur (Eco-SSL, 2000a). The Eco-SSL soil benchmarks are concentrations of contaminants in soil that are protective of ecological receptors that commonly come into contact with soil or ingest biota that live in or on the soil (Eco-SSL, 2000b). Both types of values were derived using chronic exposure data when available and the results of the toxicological data extracted were evaluated using a weight of evidence approach. With this approach, all toxicological data (NOAELs and LOAELs) extracted from the studies identified in the literature review and determined to be appropriate in establishing a TRV/benchmark are plotted, and the relative magnitude of the results examined to identify a suitably protective threshold. In most cases, the TRV is equal to the weighted geometric mean of adjusted NOAELs for growth and reproduction effects and the soil benchmark is equal to the weighted geometric mean of the Maximum Acceptable Threshold Concentrations (MATCs). A MATC is defined as the geometric mean of the No Observable Adverse Effects Concentration (NOAEC) and LOAEC values. The result is the best estimate of a chronic NOAEL for each chemical and ecological receptor. All such data were entered into the database under the appropriate receptor type (*e.g.*, Birds, Mammals, Plants, etc.).

3.10 UNITED STATES ARMY CENTER FOR HEALTH PROMOTION AND PREVENTATIVE MEDICINE (USACHPPM)

USACHPPM provides both low and high TRVs for mammals and birds for a range of chemicals (Johnson and McAtee, 2000; USACHPPM, 2000a-b, 2001a-d). Low TRVs for terrestrial amphibians also are provided for some chemicals, and it is worth noting that this is the only jurisdiction that has any type of value derived specifically for herpetofauna. USACHPPM also is the only jurisdiction that provides a TRV specifically for a guild (mammalian omnivores). Depending upon the quantity and quality of data available for a given chemical of interest, different methods are used to derive the high and low TRV (USACHPPM TG 254, 2000). If the data show a clear dose/response relationship in a unimodal design, the benchmark dose approach is used. The benchmark dose approach uses the dose response curve to select the dose that corresponds to a 10% response (Effective Dose for 10% of the test organisms; the ED_{10}) and the lower bound of that ED_{10} (the LED_{10}; based on the 95% confidence limit). The ED_{10} is then selected as the high TRV and the LED_{10} is selected as the low TRV. If an insufficient amount of

data is available to use the benchmark dose approach, but the minimum data requirements are still met, the NOAEL/LOAEL approach is used instead. The high TRV is chosen then by selecting the lowest documented LOAEL that either is suggestive of a population-relevant endpoint or, when that is not known, the LOAEL that is protective of other endpoints. The low TRV is determined by selecting the highest NOAEL (that is lower than the LOAEL that was selected for the high TRV) within the same endpoint as the selected high TRV. If a NOAEL from the same endpoint is unavailable, then the highest NOAEL (that is less than the LOAEL that was selected for the high TRV) within all relevant endpoints should be selected. Finally, if the minimum data requirements are not met, an approximation approach is used. In this approach, the most relevant study identified in the toxicity profile that is most reliable in terms of quality and applicability should be used to develop TRVs that approximate the low and high TRVs described previously. These TRVs are developed by dividing the effect level of interest by appropriate uncertainty factors (*e.g.*, an uncertainty factor of 10 for interspecies differences), where multiple uncertainty factors are multiplied before dividing. Regardless of the derivation method used, the bracketed range represented by the low and high TRVs provides the risk assessor with a level of confidence between which no observed adverse effects may occur and where low adverse effects may occur. The TRVs provided by USACHPPM were entered into the database, but no soil benchmarks for protection of soil infauna were provided by this jurisdiction.

4. CRITERIA SELECTION

Before deciding upon criteria to use to rank the quality of the TRVs/benchmarks from the various jurisdictions, all of the necessary background information relating to the derivation of the values from each jurisdiction was obtained and read. As this background information was being evaluated, thorough notes were taken on how each set of values was derived by its respective jurisdiction. At the end of this process, a list of all possible criteria that could potentially be used to rank the quality of the different values from each jurisdiction was made based upon all the factors that each jurisdiction had considered important in deriving their TRV/benchmark values, as well as best professional judgement. From this list, the criteria considered key to the derivation of scientifically-defensible values were selected based upon best professional judgement (25 in all). Once selected, each criterion had at least two, and sometimes more, possible categories assigned to it in order to represent what the different jurisdictions had used in their derivation processes. For example, for the criterion regarding the use of uncertainty factors, the possible categories were: None Used, 2 to 10, 11 to 100, >100, or Not Clear. After all the different categories from each jurisdiction had been represented, point values for each possible answer were given based upon the quality of each possible category and best professional judgement. The last task in this process was to assign a weighting factor (ranging from 1 to 10) to each criterion based upon its relative importance to the other 24 criteria, again based upon best professional judgement (see Table 1 below for the breakdown of weighting factors and their corresponding importance). After all the above tasks were completed, each TRV/benchmark from the 10 jurisdictions was evaluated using the 25 criteria. Finally, each TRV/benchmark value was entered into the database along with a corresponding criteria sheet representing that TRV/benchmark's score in the ranking process. The total score that a given TRV/benchmark received was the sum of the points received for each criterion times the weighting factors. These criteria are described in the following section.

Table 1: Weighting Factors and their corresponding Importance

Very Low	Low	Low	Moderate	Moderate	Moderate	Moderate	High	High	Very High
1	2	3	4	5	6	7	8	9	10

5. CRITERIA SELECTED FOR EVALUATION OF TRVS/BENCHMARKS

5.1 CONSERVATISM

This criterion reflects the varying degrees of conservatism that were found to exist for the different types of TRVs/benchmarks included in the database. Since this database was designed to help identify TRVs/benchmarks that can be used in an initial site assessment, the very conservative TRVs/benchmarks (*e.g.*, lowest reported NOAEL when available) received the highest possible points (10 points). The moderately conservative values (*e.g.*, ER-L or lowest reported LOAEL available) received five points, and the unconservative ones (*e.g.*, dose at which adverse effects have been demonstrated) received one point. Due to its very high importance, this criterion received the maximum weighting factor of 10. The user should note that on the TRV/benchmark ranking sheet, the program is designed to group all TRVs/benchmarks by the degree of their conservatism first (*i.e.*, very conservative, moderately conservative or unconservative). Then, the TRVs/benchmarks are listed from highest to lowest based on the total points. The data presentation allows the user to determine the best very conservative, moderately conservative and/or unconservative TRV(s)/benchmark(s) for a given endpoint.

5.2 ENDPOINT USED FOR TRV/BENCHMARK DERIVATION

Due to the paucity of toxicity data that existed for certain chemicals, jurisdictions could not always use the most appropriate data to derive their TRVs/benchmarks. For example, sometimes an LD_{50} was used to derive very conservative TRVs/benchmarks. If a TRV/benchmark was NOAEL or benchmark dose-based, it received 10 points. If it was LOAEL or MATC-based, it received five points, while an Effects Concentration (EC_X) derived value received two points. If an LD_{50} was used to derive a TRV/benchmark, no points were awarded, as was the case if it was not clear as to how a value was derived. Since this criterion was determined to have very high importance, it received the maximum weighting factor of 10. Additionally, the user of this database can sort by this criterion in order to more easily identify which TRVs/benchmarks are NOAEL or benchmark dose, LOAEL or MATC, EC_X, or LD_{50}-based by clicking on the "Endpoint" button(s) on the far right of the TRV/benchmark ranking sheet.

5.3 UNCERTAINTY FACTORS

When less than ideal data were used for a particular TRV/benchmark derivation, some jurisdictions used uncertainty factors to accommodate for this. The best case scenario of no uncertainty factors being used was awarded 10 points, while an uncertainty factor of two to 10 was awarded five points. Previous reviews of interspecific variables in sensitivity indicated there generally was no more than a 10-fold difference. Therefore, if an uncertainty factor of 11 to 100 was used, only one point was awarded. In instances when an uncertainty factor of greater than 100 was used, or when it was not clear whether or not an uncertainty factor was used, no points were awarded. This criterion received a weighting factor of five due to its moderate importance.

5.4 TRV/BENCHMARK DERIVATION METHOD BY DEFINITION

Each jurisdiction had an ideal method to derive TRVs/benchmarks by definition (*i.e.*, clearly explained in a jurisdiction's background materials). Sometimes this method was used for every TRV/benchmark the jurisdiction derived (*e.g.*, the lowest NOAEL or LOAEL was always chosen), and other times the method

depended upon how much data were available (*e.g.*, if more than 10 studies were available, a scatterplot was made to establish an ER-L; otherwise, the lowest LOAEL was chosen). The most appropriate methods for TRV/benchmark derivation were determined to be the distribution plot (Eco-SSL method) and the benchmark dose approaches (USACHPPM method). Both methods received 10 points. These methods were awarded the most points since they incorporated more types of species, more endpoints, and therefore, more tests in their derivation processes than any other method.. The use of a scatterplot was awarded eight points and the use of the lowest NOAEL or LOAEL was awarded five points. This criterion also received a weighting factor of five due to its moderate importance.

5.5 EXTRAPOLATION USE

Sometimes a jurisdiction used extrapolations from related chemicals or aquatic toxicity data to derive a particular TRV/benchmark for a chemical that did not have enough toxicity data of its own available. This is a less than ideal situation and the most points were awarded by this criterion to the TRVs/benchmarks that had no extrapolations used in their derivation process (10 points awarded). If a QSAR extrapolation was used, five points were awarded, while only one point was awarded if an aquatic to terrestrial extrapolation was made. If it was not clear whether an extrapolation was made or not, no points were awarded. Since this criterion was considered to have very high importance, it received the maximum weighting factor of 10.

5.6 PEER REVIEW OF TRV/BENCHMARK DERIVATION PROCESS

Certain jurisdictions had their TRV/benchmark derivation process peer reviewed to ensure its integrity, while others did not. If a jurisdiction had their process peer reviewed, each one of their TRVs/benchmarks received 10 points, while if they did not, five points were awarded. This criterion is only of low importance, so its weighting factor is a two.

5.7 CONFIDENCE RANKING RECEIVED BY TRV/BENCHMARK VALUE BY THE JURISDICTION THAT GENERATED THAT VALUE

In some instances, the TRVs/benchmarks derived by a jurisdiction also were rated by that jurisdiction to reflect the confidence that the jurisdiction had in its own values. If a TRV/benchmark received a high confidence rating from its jurisdiction, 10 points were awarded, while eight points were awarded to TRVs/benchmarks that received medium confidence ratings. If low or no confidence ratings were received, three points were awarded. This criterion is also only of low importance, so its weighting factor is a two.

5.8 QUALITY OF LITERATURE EVALUATION CRITERIA

How a jurisdiction went about collecting its toxicity data literature was key in determining the quality of the values that ultimately were produced. As such, jurisdictions that provided explicit criteria about how their literature was obtained received 10 points for each of their TRVs/benchmarks, while only five points were awarded in instances when only general criteria were given. If no criteria were given, one point was awarded. Since this criterion has high importance, it received a weighting factor of eight.

5.9 ENDPOINTS ALLOWED FOR TRV/BENCHMARK DERIVATION

Most jurisdictions only allowed the use of the ecologically relevant endpoints of growth, mortality and reproduction to derive a given TRV/benchmark, while others allowed a wider range of less ecologically relevant endpoints. If only growth, mortality and reproduction were allowed as endpoints, 10 points were awarded to that TRV/benchmark. If behavioral studies were also allowed, six points were awarded. If biomarker or other types of studies were allowed, or if it was not clear what types of studies were allowed, three points were awarded. This criterion also received a weighting factor of five due to its moderate importance.

5.10 SPECIES APPLICABILITY OF TRV/BENCHMARK

Some TRVs/benchmarks were designed by their jurisdictions to be applicable to species in a geographically limited situation only (*e.g.*, Navy BTAG values for San Francisco Bay Area species), while others were designed to be generally applicable to a wide range of situations. If a jurisdiction's TRVs/benchmarks were designed to be generally applicable, 10 points were awarded to each TRV/benchmark. In contrast, only five points were awarded for geographically limited ones. This criterion received a weighting factor of six due to its moderate importance.

5.11 BACKGROUND CONCENTRATIONS INCORPORATED INTO DERIVATION FOR PLANT AND SOIL INVERTEBRATE BENCHMARK VALUES

Some jurisdictions considered the naturally occurring background levels of the elements (*e.g.*, metals) when deriving their benchmark values for plants and soil invertebrates. This was done by various jurisdictions in order to ensure that the benchmark values were not below the naturally occurring levels of those elements. If the compound was not naturally occurring, this criterion was marked "Not applicable" when that benchmark was being rated. Also, this criterion was applied only to benchmarks (*i.e.*, soil concentrations), not TRVs (*i.e.*, doses). If a jurisdiction incorporated background values into its derivation process, 10 points were awarded to each benchmark. If such values were not incorporated, one point was awarded. This criterion received a weighting factor of four due to its moderate importance.

5.12 ESSENTIALITY INCORPORATED INTO DERIVATION OF ALL TRV/BENCHMARK VALUES

Some jurisdictions also considered the essentiality of some of the elements (*e.g.*, Cobalt, Molybdenum) when deriving their TRVs/benchmarks. Again, this was done in order to ensure that the TRVs/benchmarks that were derived were not below the concentrations or doses that are required by some organisms for proper nutrition. Essentiality of all elements for plants and animals was reviewed and summarized by Fairbrother and Kapustka (1997). If a jurisdiction incorporated background values into its derivation process, 10 points were awarded to each TRV/benchmark. If such values were not incorporated, one point was awarded. This criterion received a weighting factor of four due to its moderate importance.

5.13 SENSITIVE LIFE STAGES CONSIDERED

Particularly sensitive life stages of ecological receptors were considered by some jurisdictions when deriving their TRVs/benchmarks. Certain jurisdictions made sure to consider this type of data so that all

TRVs/benchmarks that they developed were applicable to all life stages of the organisms considered, not just fully mature ones. If a jurisdiction considered sensitive life stages, 10 points were awarded to each TRV/benchmark, while only one point was awarded if they did not. This criterion received a weighting factor of five due to its moderate importance.

5.14 TYPE OF LITERATURE USED

Certain jurisdictions used only primary, peer-reviewed literature for toxicity data. Other jurisdictions used a wider range of available literature, including secondary, in order to increase the amount of available data for TRV/benchmark derivation, even though the quality of data in such literature could not be evaluated. If a jurisdiction used only primary literature, 10 points were awarded to each TRV/benchmark. If mostly primary literature was used, eight points were awarded, while if any literature (including secondary) was used, three points were awarded. If it was not clear what type of literature was used, only one point was awarded. This criterion received a weighting factor of six due to its moderate importance.

5.15 STUDY DESIGNS ALLOWED

Standard study designs were used exclusively by some jurisdictions when developing their TRVs/benchmarks, while a larger variety of study designs were allowed by other jurisdictions. If only standard designs were allowed, 10 points were awarded to each TRV/benchmark. If a jurisdiction increased the amount of data it could find on a given chemical by allowing any study approach, even questionable ones, three points were awarded. If it was not clear what types of study designs were allowed by a jurisdiction, three points were also awarded. This criterion received a weighting factor of four due to its moderate importance.

5.16 TIME SCALE OF LITERATURE REVIEW

How far back in time a jurisdiction went in its literature review of applicable data affected the amount of data available for TRVs/benchmarks derivation. If an examination of all available literature without constraint by year was made by a jurisdiction, 10 points were awarded to each TRV/benchmark. If only the last 20 years of literature were considered, six points were awarded, while four points were awarded if only the last 10 years of literature were considered. If the time scale of the literature review was unknown, only one point was awarded. This criterion received a weighting factor of four due to its moderate importance.

5.17 TOXICITY TEST DURATION CONSIDERED

Some jurisdictions considered the duration of the toxicity tests used to derive the TRVs/benchmarks in order to ensure that the duration of the tests was comparable to what might actually be seen in the field. If this was done, 10 points were awarded to each TRV/benchmark. If the duration was not considered, only one point was awarded. This criterion received a weighting factor of six due to its moderate importance.

5.18 MINIMUM NUMBER OF TOXICITY TESTS REQUIRED TO GENERATE A PARTICULAR TRV/BENCHMARK VALUE

In order to derive a more accurate TRV/benchmark, multiple toxicity tests should be considered so that differences due to inherent biological variability, interlaboratory differences, and specific methodology are taken into account. For TRVs/benchmarks that were derived using 10 or more toxicity tests, 10 points were awarded. If five to nine tests were required, seven points were awarded, while two points were awarded when less than five tests were used. Since this criterion has high importance, it received a weighting factor of eight.

5.19 MINIMUM NUMBER OF SPECIES REQUIRED TO GENERATE TRV/BENCHMARK

To help account for interspecies variability, and to derive the most accurate TRV/benchmark value, some jurisdictions evaluated data from more than one species in order to generate a particular TRV/benchmark, while others did not. If data from more than one species were evaluated to generate a TRV/benchmark, 10 points were awarded. If data from only one species were considered, or it was not clear how many were used, three points were awarded. This criterion received a weighting factor of eight due to its high importance.

5.20 USE OF FIELD DATA

Some jurisdictions incorporated toxicity data from field tests into their TRVs/benchmarks to help make their values as representative of real world conditions as possible. If field data were used to derive a TRV/benchmark, eight points were awarded. If field data were not used, or it was unclear whether field data were used, three points were awarded. No category was awarded 10 points for this criterion due to its very low importance and the desire to give it less than a 10 point total value even after being multiplied by its weighting factor. This criterion received a weighting factor of one due to its very low importance.

5.21 ROUTES OF EXPOSURE CONSIDERED IN TRV DERIVATION FOR MAMMALS AND BIRDS

Routes of exposure considered by a jurisdiction while deriving its TRVs affected not only how many data were available for the derivations, but also how relevant the TRVs would be. If exposure through both food and water was considered, 10 points were awarded to that TRV. If exposure from water only or food only was considered, nine points were awarded. If other routes of exposure (*e.g.*, injection) were considered, three points were awarded. This criterion did not apply to soil benchmarks and when such values were being rated, "Not applicable" was marked. This criterion received a weighting factor of eight due to its high importance.

5.22 ROUTES OF EXPOSURE CONSIDERED IN SOIL BENCHMARK DERIVATION FOR PLANTS AND INVERTEBRATES

Like the previous criterion, which routes of exposure were considered by a jurisdiction while deriving its soil benchmarks affected not only how much data were available, but also how relevant the benchmarks would be. If soil exposure only was considered, 10 points were awarded to that benchmark. If hydroponic exposure was considered, five points were awarded. The consideration of exposure from filter paper received three points, while the consideration of other types of exposure was awarded two

points. This criterion did not apply to TRVs and when such values were being rated, "Not applicable" was marked. Since this criterion has very high importance, it received a weighting factor of 10.

5.23 SOIL CHARACTERISTICS CONSIDERED IN SOIL BENCHMARK DERIVATION FOR PLANTS AND INVERTEBRATES

Some jurisdictions acknowledged that characteristics of the soil (*e.g.*, percent organic matter and clay) affect the bioavailability of certain contaminants. If soil characteristics were considered in the derivation process, 10 points were awarded each benchmark. If not, only one point was awarded. This criterion did not apply to TRVs and when such values were being rated, "Not applicable" was marked. Since this criterion has high importance, it received a weighting factor of eight.

5.24 CLEAR STATEMENT OF ASSUMPTIONS INCORPORATED INTO THE TRV/BENCHMARK DERIVATION PROCESS

A clear statement of the assumptions that a given jurisdiction incorporated into its TRV/benchmark derivation process is necessary to understand the validity of the values produced. If the assumptions were clearly stated, 10 points were awarded to each TRV/benchmark. If not, only one point was awarded. This criterion received a weighting factor of 10 due to its very high importance.

5.25 COMPARISON OF TRV/BENCHMARK VALUE TO ANALYTICAL CAPABILITIES TO CONFIRM ITS REASONABLENESS

After the derivation of a TRV/benchmark value, some jurisdictions compared the value to analytical capabilities available to see if such a value could be detected. If a jurisdiction made such a comparison, 10 points were awarded to each TRV/benchmark. If a comparison was not made, only one point was awarded. This criterion received a weighting factor of two due to its low importance.

6. QUALITY ASSURANCE

As the data were being entered into the Microsoft Excel® spreadsheets, but before their entry into the Microsoft Access® 2000 database, quality assurance methods were performed. At least 10% of the data on the spreadsheets were checked with the original documentation to make sure that the data were entered correctly. If greater than 10% of the data that were checked were found to have been entered incorrectly, an additional amount of data would have been selected and quality assured. However, that was not necessary since much less than 10% of the data were found to be entered incorrectly. Quality assurance records are available upon request.

7. DATABASE MAINTENANCE

To add new information to the database as it becomes available, an Edit option has been included. Upon opening the database, the user is presented with two different options. The first option is to enter a password and select the "…Then click to edit data" button to edit the data. This option was installed for database maintenance exclusively. Those persons attempting to select the edit function will be asked for a password to limit access and the potential for unrestricted edits. The password has been provided to USACHPPM since they will be responsible for database maintenance.

8. GENERAL DATABASE DESCRIPTION

After a thorough evaluation of applicable data from a wide range of jurisdictions, a total of 1156 TRVs/benchmarks from 10 different jurisdictions were included in the database. The TRVs/benchmarks represent data on 315 chemicals. TRVs are available for the classes of Amphibia, Aves, and Mammalia. If Reptilia is selected as a selection criterion, "No Data Available" appears on the screen. Benchmarks are available for the five general data groupings of Soil, Soil/Earthworms, Soil/Invertebrates, Soil/Plants, and Soil/Plants/Invertebrates.

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