TCEQ REGULATORY GUIDANCE
Remediation Division
RG-366/TRRP-19 ● Revised March 2009

Toxicity Factors and Chemical/Physical Parameters

Overview of This Publication

Objectives: This guidance document addresses how changes in human toxicity factors will be handled, establishes a schedule for updating the human toxicity factors table, and describes the procedure for requesting toxicity factors and chemical/physical parameters for chemicals of concern not listed on the Tier 1 Protective Concentration Limit tables.

Audience: Regulated Community and Environmental Professionals

References: The Texas Risk Reduction Program (TRRP) rule, together with conforming changes to related rules, is contained in 30 TAC Chapter 350. The TRRP rule was initially published in the September 17, 1999 Texas Register (24 TexReg 7413-7944) and was amended in 2007 (effective March 19, 2007; 32 TexReg 1526-1579).

Find links for the TRRP rule and preamble, Tier 1 PCL tables, and other TRRP information at: <www.tceq.state.tx.us/remediation/trrp/>

TRRP guidance documents undergo periodic revision and are subject to change. Referenced TRRP guidance documents may be in development. Links to current versions are at: <www.tceq.state.tx.us/remediation/trrp/guidance.html>.

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Introduction

Human toxicity factors (e.g., oral (SFo) and dermal (SFd) slope factors, inhalation unit risk factors (URF), oral (RfDo) and dermal (RfDd) reference doses, and reference concentrations (RfC)) are used in the equations outlined in Figure: 30 TAC §350.74(a) to calculate exposure pathway-specific risk-based exposure limits (RBELs) for both residents and commercial/industrial workers. RBELs are an integral component of protective concentration level (PCL) equations (i.e., cleanup level equations) as discussed in the TCEQ guidance document Tiered Development of Human Health PCLs (RG-366/TRRP-22). Unless otherwise specified in §350.76 or directed under §350.73(b), TRRP requires that the human toxicity factors be obtained from the following hierarchy of sources: EPA Integrated Risk Information System (IRIS; <www.epa.gov/iris/>); EPA Provisional Peer Reviewed Toxicity Values (i.e., Superfund Health Risk Technical Support Center); EPA Health Effects Assessment Summary Tables; EPA National Center for Environmental Assessment (i.e., Superfund Technical Support Center); TCEQ Chronic Remediation-Specific Effects Screening Levels; Agency for

Toxic Substances and Disease Registry; and other scientifically valid sources as approved by the TCEQ (§350.73(a)). For convenience, the TCEQ has developed a table containing the most current human toxicity factors from the specified hierarchy of sources. The human toxicity factors table can be obtained from the TRRP web page at <www.tceq.state.tx.us/remediation/trrp/>. This table, as well as the corresponding Tier 1 PCL tables, will be updated in accordance with the schedule outlined below.

It is important to note that §350.73(a) requires persons to use the most current toxicity factors as of the date of submittal of the Self-Implementation Notice (SIN) or the Response Action Plan (RAP). The toxicity factors and corresponding PCLs provided on the TRRP web page are provided solely as a convenience. If a newer toxicity factor is provided in the original source, or in a source higher up in the hierarchy, persons will be required to use the newer toxicity value at the time of submittal of the SIN or RAP. It should also be noted that the absence of a chemical of concern (COC) from the Tier 1 PCL tables does not imply that the COC can be disregarded (see §350.73(c)). Persons may need to evaluate COCs not currently listed on the Tier 1 PCL tables. Although the focus of this guidance document is specifically on toxicity factors and chemical/physical parameters, persons will most likely be scanning the Tier 1 PCL tables to find COCs and, therefore, reference made here is to the Tier 1 PCL tables. If there is a Tier 1 PCL for a COC then this means that there are already toxicity factors and chemical/physical parameters for the COC. In cases where the TCEQ determines that it is necessary to evaluate COCs not currently listed, the TCEQ will develop appropriate human toxicity factors. As human toxicity factors are developed for new COCs (i.e., those COCs not listed on the most current version of the toxicity factors table), those values will be provided in a separate file entitled “Tables for Additional COCs” on the TRRP web page. The procedure for requesting toxicity factors for new COCs is described in detail below. Additionally, in some cases, a specific COC may have a toxicity factor for one route of exposure but not for another (e.g., a COC may have an inhalation unit risk factor but neither an oral slope factor or oral RfD). In such cases, persons are not required to develop toxicity factors for the other route of exposure unless the TCEQ specifically directs such action and provides the toxicity factor. In general, a determination to proceed with developing toxicity factors for the other route of exposure will be based upon the release of new toxicity information. Furthermore, as indicated in the preamble to the final rule, the TCEQ does not support an across the board use of route-to-route extrapolation techniques. The appropriateness of carrying out route-to-route extrapolation should only be considered on a case-by-case basis and should account for the relationship between physicochemical properties, absorption, and distribution of toxicants, the significance of portal-of-entry effects, and the potential differences in metabolic pathways associated with the intensity and duration of exposure.

Once RBELs have been calculated using appropriate human toxicity factors in accordance with §350.73(a)-(e), the RBEL is then used in conjunction with applicable chemical/physical parameters provided in Figure: 30 TAC §350.73(f) to calculate PCLs. In all cases, persons must use the chemical/physical parameters provided in Figure: 30 TAC §350.73(f) to calculate PCLs, unless the TCEQ approves the use of more representative alternative values in accordance with §350.73(f)(1) and (2). Specifically, under Tier 2 or 3, the rule allows the person to determine the property-specific pH and accordingly establish the soil-water distribution coefficient (Kd) for inorganic COCs and organic-water partition coefficient (Koc) for ionizing organic COCs using the values provided in Figures: 30 TAC §350.73(f)(1)(A), (B), and (C). Additionally, persons may develop site-specific Kd and Koc values if prior approval is given by the TCEQ. In developing such values, it should be noted that both organic and inorganic COCs (metals) require test methods specifically developed for the purpose of determining partition coefficients. Table 1 provides a partial list of suggested resources and methods appropriate for determining site-specific Kd and Koc values. In selecting a method, it is critical that the method be appropriate for the COC.

For those COCs not currently listed on Figure: 30 TAC §350.73(f), if the TCEQ determines that it is necessary to evaluate such COCs, the TCEQ will develop appropriate chemical/physical parameter values. As chemical/physical parameters are developed for new COCs (i.e., those COCs not listed on the most current version of the Tier 1 PCL tables), those values will be provided in a separate file entitled “Tables for Additional COCs” on the TRRP web page.

Finally, it is important to note that the chemical/physical parameters for each specific COC are also used to determine when specific exposure pathways must be evaluated. For example, vapor pressure is used to determine if the dermal pathway is relevant for a specific COC. In accordance with §350.74(c), if the vapor pressure of a specific COC is less than 1 mm of mercury (Hg), then the dermal pathway should be evaluated. Once it has been determined that it is necessary to evaluate the dermal pathway, the vapor pressure is then used to determine the appropriate ABSGI and ABS.d value in cases where it is necessary to use a default value. Finally, the Henry’s Law constant and Log Kow value are used to determine if it is necessary to establish a RBEL for below-ground vegetables. In accordance with §350.74(e), if the Henry’s Law constant is less than 0.03 and the COC is a metal or has a Log Kow greater than 4, then a RBEL should be calculated for below-ground vegetables.

Table 1. Methods for Kd Determination

COC	Method
Organics	ASTM D5285 - *Standard Test Method for 24-h Batch-Type Measurement of Volatile Organic Sorption by Soils and Sediments*
	ASTM E1195 - *Standard Test Method for Determining a Sorption Constant (Koc) for an Organic Chemical in Soil and Sediments*
Organic and Inorganic	ASTM D4646 - *Standard Test Method for 24-h Batch-Type Measurement of Contaminant Sorption by Soils and Sediments*
Inorganics	ASTM D4319 - *Standard Test Method for Distribution Ratios by the Short-Term Batch Method*
	EPA 402-R-004A (1999) *Understanding Variation in Partition Coefficient, K_d, Values; Volume 1: The K_d Model of Measurement, and Application of Chemical Reaction Codes.* (Contains a summary of five Kd test methods.)

Policy for Handling Changes in Toxicity Factors

Recognizing that toxicity factors may change during the course of a response action, the TCEQ addressed the issue of changes in toxicity factors that occur after submittal of the SIN or RAP in the TRRP rule. Specifically, §350.73(a) states that "the executive director may determine during the review of the Response Action Completion Report (RACR) that a change in a toxicity factor since the submittal of the SIN or RAP has been of such a magnitude that the PCLs previously developed for a COC would clearly not be protective of human health and the environment, then the adequacy of the response action must be reevaluated. Likewise, if the executive director determines at any time that a subsequent change in a toxicity factor is of such a magnitude such that the proposed response action is no longer warranted to protect human health and the environment, then a response action based on that previous chronic toxicity factor consideration shall no longer be required." An order of magnitude or greater change in the final PCL will be used as a general rule of thumb in determining whether or not a change is of sufficient magnitude to warrant further action. However, changes in a final PCL of less than an order of magnitude may be considered sufficient to warrant further action based upon, but not limited to, consideration of the following: the target organ(s) affected, the type of toxic effect(s), relevant toxicokinetic and mechanistic information, relevance of the route of exposure to humans, degrees of conservatism inherent in the calculation, impact on the final PCL, etc.

Following a determination from the TCEQ that the change in the PCL is of sufficient magnitude to warrant further action, the PCLs will have to be revised unless the person can demonstrate to the satisfaction of the TCEQ that there is no longer any exposure to the COCs based on field evidence. For example, if the COCs are completely capped with an impervious barrier under Remedy Standard B, and a change in the PCL would have not changed the remedial endpoint, then there is no need to adjust the PCLs. If it is determined that PCLs for an affected property must be

modified as a result of a changed toxicity factor, then the timeframe and manner in which those adjustments must be made and reported to the TCEQ will be established on a case-specific basis.

Schedule for Updating Toxicity Factor and Chemical/Physical Parameter Tables

The human toxicity factors table, chemical/physical parameters table, and the corresponding Tier 1 PCL tables, will be updated annually in March of each year unless a more frequent update is deemed necessary in cases where a change in a toxicity factor is of sufficient magnitude to warrant such action. Further, as already discussed, the TCEQ will maintain a list of toxicity factors and chemical/physical parameters developed to address additional COCs in a separate file entitled "Tables for Additional COCs" on the TRRP web page. The March update to the human toxicity factors table will incorporate the toxicity factors developed for the additional COCs during that prior year.

As already discussed, current toxicity factors must be used. This means that the toxicity factors need to be current during the March to February time period for the year in which the SIN or RAP is submitted to TCEQ. For example, if an Affected Property Assessment Report is submitted in June 2002 based on the toxicity factors current as of March 2002, and then a RAP is submitted August 2003, the RAP must address any PCLs that have been modified as a result of changes to the toxicity factors posted in the March 2003 update. If the toxicity factors change subsequent to the submittal of the SIN or RAP, then that situation will be addressed as discussed in the previous section of this guidance document.

Procedure for Requesting Toxicity Factors and Chemical/Physical Parameters

As already discussed, the absence of a COC from the toxicity factors and chemical/physical parameters tables or Tier 1 PCL tables does not imply that the COC can be disregarded (see §350.73(c)). Therefore, persons may need to evaluate COCs not currently listed on the tables. TCEQ project managers will make a determination regarding the need to address specific COCs that are not listed on the tables. In addition, in making determinations regarding the specific COCs to be analyzed for, persons should consult the TCEQ guidance document entitled *Selecting Target Chemicals of Concern* (RG-366/TRRP-10) before sample data are collected. When it is determined that a COC not listed in the tables must be addressed, persons should take the following steps:

Step 1:

Download the file containing the Tier 1 PCL tables, as well as the file entitled "Tables for Additional COCs" from the TRRP web page. Again, as already discussed, although the focus of this guidance document is specifically on toxicity factors and chemical/physical parameters, persons will most likely be scanning the Tier 1 PCL tables to find COCs. If there is a Tier 1 PCL for a COC then this means that there are already toxicity factors and chemical/physical parameters for the COC.

Step 2:

Search all applicable Tier 1 PCL Tables on the TRRP web page by synonym and by the Chemical Abstract System Registry Number (CASRN or CAS number) to determine if the COC is listed on the tables. Also, search the tables entitled "Tables for Additional COCs". It should be noted that in developing the Tier 1 PCL tables, attempts were made to list all COCs based on their most commonly used synonym as determined by the TCEQ. However, many COCs have numerous synonyms and different analytical laboratories may use any of the applicable synonyms when reporting results. For example, cymene is also commonly referred to as isopropyltoluene, methylcumene, methylisopropylbenzene and cymol.

Step 3:

Evaluate the data under §350.71(k)(2) to determine if any of the COCs will be eliminated from further consideration. Note, if your investigation is not yet complete, this step is not applicable.

Step 4:

Contact the TCEQ and provide the following information:

1. Each COC' name and list of common synonyms;
2. Each COC's CAS registry number;
3. The melting point (range) of each COC, including the literature/internet reference used (note, if you cannot find any melting point (range) information, please include a list of literature and internet references exhausted by your research);
4. The name, address, and if known, the regulatory ID number of the facility; and
5. The TCEQ project manager to whom, or the TCEQ program under which, the data will be/have been submitted.

In cases where persons desire to submit toxicity information for consideration in developing toxicity factors, it should be noted that acute lethality (LC50 or LD50) data will not be accepted. In cases where persons are submitting PCLs, toxicity factors, or chemical/physical parameters to the TCEQ for consideration and approval, supporting documentation used in the derivation process must be included for the review.

The above-referenced information can be e-mailed to <tox@tceq.state.tx.us>; faxed to 512/239-1794; or mailed to: TCEQ, Toxicology Section, PCL/MSC Development Team (MC-168), P.O. Box 13087, Austin, TX 78711-3087.

Step 5:

Persons will receive an e-mail, fax, or letter in reply with the information requested. Persons should be sure to keep a copy of the reply for their records and for later inclusion in reports submitted to the agency. As stated earlier, the toxicity factors and chemical/physical parameters will also be incorporated into the file entitled "Tables for Additional COCs" on the TRRP web page.

Toxicity Factors and Chemical/Physical Parameters for Ecological Matters

It is important to note that human toxicity factors should not be used to determine ecological PCLs. Rather, the TCEQ guidance document entitled Guidance for Conducting Ecological Risk Assessments at Remediation Sites in Texas should be consulted to determine appropriate toxicity values.

With regard to COC chemical/physical parameters, the same COC chemical/physical properties used to develop human health PCLs should also be used in deriving ecological PCLs except in instances where a specific chemical/physical parameter value was determined based upon an exposure assumption that is specific to human exposures. For example, TRRP specifies that certain above (Brabg) and below-ground (Brbg) soil-to-plant biotransfer factors be used to evaluate the uptake of certain COCs into vegetables grown for human consumption. Soil-to-plant transfer varies across different vegetable types. Accordingly, the soil-to-plant biotransfer factors provided in TRRP are ratioed to reflect the types of vegetables that a typical resident gardener may grow and consume. Given that these biotransfer factors are weighted for a particular human health exposure scenario, they are not generally appropriate for the types of vegetation that may be relevant to ecological receptors. Vegetation types that are relevant to the ecological receptor of interest should be determined. Biotransfer factors that are specific to these vegetation types should then be utilized. When there is concern that a specific

chemical/physical parameter may not be appropriate in calculating ecological PCLs, persons should provide specific justification for why the standard COC chemical/physical parameter value is not appropriate, as well as provide justification for the proposed chemical/physical parameter value.