

Evaluation of Toxicity Values Used to Calculate MSCs

BACKGROUND – Toxicity values are used by the Land Recycling Program (LRP) to calculate the numeric values used to establish the medium-specific concentrations (MSCs) for soil and groundwater. Toxicity values are also used by remediators to characterize risks in risk assessments performed under the site-specific standard. These toxicity values are provided in Tables 5A and 5B in Appendix A of the Chapter 250 regulations.

The LRP selects the toxicity values to be listed in Tables 5A and 5B using the list of sources in § 250.605(a). This list is used as a hierarchy for selecting toxicity values with EPA's Integrated Risk Information System (IRIS) at the top of the list, followed by EPA's Provisional Peer-Reviewed Toxicity Values (PPRTV) database, followed by third-tier sources which are weighted evenly. Each of the values in these databases goes through an extensive peer-review process by EPA with IRIS having the most rigorous peer-review process. The LRP's sole determination of how to select a value is based on where the value falls in this hierarchy of sources. For example, a toxicity value for a chemical that is listed in the PPRTV database is always selected over a toxicity value for the same chemical listed in a third-tier source. Thus, the LRP's level of confidence in the value is based on where the source falls in the hierarchy of sources.

PROBLEM – EPA reports various levels of confidence in the toxicity values it selects to be listed in its databases. Their confidence level is relative to the availability of human studies or how much animal studies can directly relate to toxicity effects in humans. This information can be found in the supporting documentation that describes the peer-review process. When EPA reports a low level of confidence in a toxicity value, it puts into question the appropriateness of using the toxicity value to calculate an MSC or to use it in a risk assessments under Act 2.

EXAMPLE – Vanadium does not have any IRIS values but it does have a PPRTV provisional oral reference dose (p-RfD) value of $7E-5$ mg/kg-day. The support document reports that the key study (Boscolo et al., 1994) calculated a p-RfD of 0.22 mg/kg-day. However, EPA has a low level of confidence in this value due to uncertainties such as interspecies extrapolation, the absence of information on the variability of toxicity in potentially susceptible humans, and the lack of a reproductive toxicity study. Due to EPA's low confidence in this value, they applied an uncertainty factor of 3000 which caused the p-RfD value to drop to $7E-5$ mg/kg-day. EPA posts toxicity values low confidence in its databases because after an extensive peer-review process, it is simply the best information available.

QUESTION – Should the LRP be evaluating toxicity values beyond just looking at their source? If so that change should apply to all contaminants evaluated under Act 2 and it will be a significant change in the time and effort required to update the Chapter 250 tables and the toxicity value database posted on the LRP website.

Note: A PPRTV is defined as a toxicity value derived for use in the Superfund Program when such a value is not available in U.S. EPA's IRIS. PPRTVs are developed according to a standard operating procedure and are derived after a review of the relevant scientific literature using the same methods, sources of data, and Agency guidance for value derivation generally used by the U.S. EPA IRIS Program. All provisional toxicity values receive internal review by two U.S. EPA scientists and external peer review by three independently selected scientific experts. PPRTVs differ from IRIS values in that PPRTVs do not receive the multiprogram consensus review provided for IRIS values. This is because IRIS values are generally intended to be used in all U.S. EPA programs, while PPRTVs are developed specifically for the Superfund Program.