MDHSS Evaluation of Toxicity Values for Use in Tier 3 MRBCA Risk Assessments

The hierarchy of toxicity data sources as per EPA's Human Health Toxicity Values in Superfund Risk Assessments, OSWER Directive 9285.7-53, 2003 is as follows:

- Tier 1: U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS). In the development of IRIS toxicity values, EPA undergoes a rigorous scientific process and includes both internal and external peer review by scientific experts and agency consensus review.
- Tier 2: EPA Provisional Peer Reviewed Toxicity Values (PPRTVs). PPRTVs are derived using the same methodology as IRIS values and receive internal and external review, but differ from IRIS values in that PPRTVs do not receive the agency consensus review provided for IRIS values.
- Tier 3: Other Toxicity Values - Tier 3 includes additional EPA and non-EPA sources of toxicity information and the hierarchy states that priority should be given to those sources of information that are the most current, the basis for which is transparent and publicly available, and which have been peer reviewed.

To further improve the transparency and consistency of identifying, evaluating, selecting, and documenting Tier 3 toxicity values, EPA issued the Tier 3 Toxicity Value White Paper, OSWER Directive 9285.7-86, 2013.

In recommending and selecting toxicity values for use in human health risk assessments, MDHSS also follows this recommended hierarchy in order to ensure values used are scientifically defensible and applied consistently across sites. Furthermore, in reviewing sources for Tier 3 values, MDHSS follows EPA's recommendations outlined in the Tier 3 Toxicity Value White Paper.

The 2006 MRBCA and the proposed update both follow EPA's hierarchy for Tier 1 and 2 toxicity values. For Tier 3 toxicity values, differences are discussed below.

MRBCA's 2006 Tier 3 toxicity values were selected from the following sources:

- National Center for Environmental Assessment (NCEA) as listed in USEPA's Region IX Preliminary Remediation Goal (PRG) Table,
- California Office of Environmental Health Hazard Assessments (OEHHAs) chemical database,
- Health Effects Assessment Summary Tables (HEAST) as listed in USEPA's Region IX PRG tables, and
- Table for Texas Risk Reduction Program.

MDHSS proposed revising this for the MRBCA update effort to follow the general hierarchy of sources for Tier 3 toxicity values used in developing the EPA Regional Screening Levels (RSLs) as follows:

- Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk levels (MRLs)

- California Environmental Protection Agency (OEHHA) Office of Environmental Health Hazard Assessment's Chronic Reference Exposure Levels (RELS) and Cancer Potency Values
- Screening toxicity values provided in the appendix to certain PPRTV assessments (for the EPA RSLs these were put ahead of HEAST toxicity values because these appendix screening toxicity values are more recent and use current EPA methodologies in the derivation, and because the PPRTV appendix screening toxicity values also receive external peer review)
- EPA's Health Effects Assessment Summary Tables (HEAST)

MRBCA's Tier 1 and Tier 2 risk assessments use the toxicity values published in MRBCA. For Tier 3 MRBCA risk assessments, the MRBCA guidance states that the most current toxicity values may be used and also states that the use of toxicity values different than those listed in Appendix E may be used.

Given this, it is MDHSS' interpretation that at a Tier 3 MRBCA evaluation, current toxicity values from the approved hierarchy of sources should be used. If no toxicity value is available from the specified hierarchy of sources or if an alternate Tier 3 source of toxicity values is identified, a technical justification for the proposed alternative toxicity values should be submitted to MDHSS for review. In such reviews, MDHSS follows EPA's recommendations to use sources that provide toxicity information based on similar methods and procedures used by EPA, contain values which are peer reviewed, are available to the public, and are transparent about the methods and processes used to develop the values.