Toxicity Criteria Rule Updated Informative Digest

The discussion below provides a summary of substantive regulatory changes made to the proposed rule, which was publicly noticed by DTSC on August 4, 2017 (August Proposed Rule). These changes were publicly noticed by DTSC on April 6, 2018 (April Proposed Rule). Additional changes to the August Proposed Rule that have no regulatory affect (are non-substantive under the Administrative Procedure Act) are discussed in the Final Statement of Reasons.

Revised Definition of IRIS Toxicity Criteria Database (Date Restriction Removed)

The August Proposed Rule had defined the IRIS toxicity criteria database in section (§) 69021(c)(4) as being limited to the version or values available as of September 30, 2017. However, federal guidance, on both risk assessment and on toxicity criteria, and Health and Safety Code (HSC) §25356.1.5, anticipate that scientific information will be developed over time that may apply to cleanup actions and therefore require application of best available science to protect public health. Accordingly, DTSC is required by HSC §25356.1.5 to use U.S. EPA's IRIS values if DTSC determines those values represent better science than corresponding values found in Appendix I. DTSC would need to make this determination to meet the requirements of HSC §25356.1.5, including, but not limited to, ensuring the science shows the values protect California's sensitive subpopulations.

Limiting use of IRIS database values to a specific on-line publication date is not feasible for most risk assessors due to limited availability of outdated versions and, more importantly, because this limitation may prevent use of toxicity criteria representing newer and better science as required by HSC §25356.1.5. The only reliable and consistent way to both address this potential conflict and protect public health, as intended under the HSC and federal guidance, is to use the IRIS database in its "live" form. DTSC believes this rule's processes provide both transparency and consistency with state and federal requirements. The rule's mandated values come from U.S. EPA and California Office of Environmental Health Hazard Assessment (OEHHA) processes that use scientific rigor, and incorporate peer review and public input. To the extent that §69021(c) values are used to calculate screening levels and remediation goals, DTSC is following federal guidance and HSC §25356.1.5 requirements to use the best available science because those may be the only values available for the specific contaminant present at a cleanup site.

Updated/New IRIS Toxicity Criteria

After issuing the August Proposed Rule, DTSC determined that the rule would conflict with HSC §25356.1.5 whenever EPA issues new IRIS toxicity criteria that are more stringent than a corresponding value in Appendix I. HSC §25356.1.5, in addition to requiring the use of best available science for selecting toxicity criteria, also specifies that California's cleanup actions must be no less stringent than federal standards and remain consistent with federal guidance on toxicity criteria and risk assessment.

Commenters on the August Proposed Rule also identified this concern. To prevent a conflict, DTSC revised the August Proposed Rule to include language in §69021(a) and §69021(b) to allow new EPA toxicity criteria will supersede any less stringent corresponding toxicity criteria in Appendix I. This revision ensures that the rule will align better and not conflict with HSC §25356.1.5 and that the appropriate scientifically sound toxicity criteria are used for preparing human health risk assessments and in setting risk-based screening levels and remediation goals. Revisions eliminate the potential conflict and were included in the April Proposed Rule.

Should EPA's IRIS issue a new toxicity criteria value that is less stringent than a corresponding Appendix I value, DTSC (in consultation with OEHHA) will evaluate the scientific basis for the new IRIS value to ensure consistency with HSC §§25356.1.5 and 57004. DTSC will then determine if changes are needed to Appendix I to ensure it reflects the best available science for that contaminant. DTSC will pursue any appropriate rule changes to protect public health consistent with HSC §25356.1.5.

Change to Appendix I to List the Lead Toxicity Criteria Separately and Add an Explanation

Lead is not evaluated in human health risk assessments using the traditional approach for evaluating a noncancer hazard. Placing the toxicity criteria for lead and lead compounds under the reference dose column in Appendix I, as was done for the August Proposed Rule, could lead to confusion or misuse despite the annotations previously included. For clarity, as presented in the April Proposed Rule, Appendix I is now split into "Appendix I, Table A" and "Appendix I, Table B," where Table B provides the lead criterion and notes that it is a benchmark incremental change in blood lead concentration with units of micrograms per deciliter (µg/dL).

Table A provides the toxicity criteria for the remaining 56 contaminants listing the required oral cancer slope factors, inhalation unit risk factors, oral reference doses and chronic reference exposure levels. The word "chronic" was added to the heading for the non-cancer RELs in Table A to clarify that these are chronic values. This clarifying edit does not change the values within the Table and should avoid the possible implication that the listed values could replace any available OEHHA acute RELs, as OEHHA has both chronic and acute RELs for some analytes in the table. A corresponding text revision was also made in the April Proposed Rule as noted under editorial changes below.

Editorial Changes

To improve clarity, and in response to comments questioning potentially confusing statements, DTSC made several editorial changes to the August Proposed Rule. For example, to more accurately reflect the subject content, the titles in Articles 1 and 2, and §§68400.5 and 69020 have been revised. The text in §§68400.5 and 69022 has been changed to clarify the narrative standard. The word "chronic" was added to

§69021(a) to match the clarifying change that acute RELs are not the subject of this proposed rule. Acronyms are now defined and used only for certain terms stated more than once in the rule. An exception to this is for the screening level ("SL") acronym, which was removed since this is an uncommon acronym. The purpose of the rule is now explicitly stated in §69020. Section 69020(b) now explicitly references HSC §25356.1.5, which directs DTSC to consider sensitive sub-populations in risk assessments. This reference allowed for a large segment of text referring to children's health and environmental justice laws used by various agencies to be deleted. Furthermore, the reference to HSC §25356.1.5 ties the rule and its basis more clearly to the statute that it implements and clarifies. Minor punctuation corrections were also made to the proposed rule.

Finally, some commenters were concerned that the language "excluding TPH [total petroleum hydrocarbons] PPRTVs [provisional peer-reviewed toxicity values]" implied that DTSC believed TPH is not toxic and excludes TPH toxicity criteria from being used for human health risk assessments. Based on the discussion presented below under "Application of TPH by the Rule," DTSC replaced "excluding TPH PPRTVs" with the following sentence in the April Proposed Rule: "However, use of TPH PPRTVs is not required, but may be determined to be appropriate based on site-specific circumstances." This more precisely reflects the intent of the rule with respect to TPH PPRTVs.