

Revised Economic and Fiscal Impact Analysis for Proposed Rule on Toxicity Criteria for Human Health Risk Assessments, Screening Levels, and Remediation Goals

Attachment to California Form STD 399

Department of Toxic Substances Control (DTSC) Reference Number R-2016-08

Introduction

The proposed regulation on Toxicity Criteria for Human Health Risk Assessments, Screening Levels, and Remediation Goals will formalize current practice dating back to 1994. Toxicity criteria are used for risk assessments and setting human health risk-based screening levels and remediation goals at hazardous waste and hazardous substance release sites. Toxicity criteria, developed from peer reviewed scientific literature, are disseminated by the California Office of Environmental Health Hazard Assessment (OEHHA), the United States Environmental Protection Agency's (U.S. EPA's) Office of Research and Development (ORD), and other sources. ORD publishes their criteria in the Integrated Risk Information System (IRIS) database. OEHHA and ORD use a similar scientifically rigorous process for developing toxicity criteria. However, ORD values set a nationwide floor of protection with their criteria, while OEHHA factors in age and California's genetically, ethnically, culturally, and economically diverse population. Toxicity criteria from both sources are respected and used nationwide for developing human health risk assessments. In the absence of both OEHHA and IRIS toxicity criteria, other sources of toxicity criteria may be used for risk assessments. Those other sources include, but are not limited to other OEHHA toxicity criteria, U.S. EPA's Provisional Peer Reviewed Toxicity Values (PPRTVs), Agency for Toxic Substances and Disease Registry Minimal Risk Levels, PPRTV Appendix Screening Toxicity Values, and U.S. EPA Superfund Health Effects Assessment Summary Table values.

The proposed rule specifies the toxicity criteria to be used in human health risk assessments and for setting human health risk-based screening levels and remediation goals (cleanup levels) for each contaminant of potential concern at hazardous waste and hazardous substance release sites in California. The Department of Toxic Substances Control (DTSC) is promulgating this regulation to establish specific OEHHA toxicity criteria as Applicable or Relevant and Appropriate Requirements (ARARs) pursuant to the Comprehensive Environmental, Response, Compensation, and Liability Act (CERCLA). In so doing it is DTSC's intent to prevent confusion, conflict, and inefficiency; as well as reduce opportunities for lengthy and costly disputes on which toxicity criteria are appropriate for use in California. The propose rule clarifies and simplifies the selection of toxicity criteria for human health risk assessments, screening levels, and remediation goals at hazardous waste release sites thereby potentially reducing costs for businesses and government.

Private Sector Costs and Benefits

DTSC concludes that there will be no or minimal increased economic costs from this action, including any impact on the ability of California businesses to compete with businesses in other states, because it formally adopts existing practice that conformed to federal guidance in California per Health and Safety Code section 25356.1.5. Certain values adopted in this rulemaking relative to present practice are still consistent with the statute referenced above and are in fact less stringent than previously used values.

DTSC anticipates that the public, including employees, residents, and commercial tenants of military bases, will benefit from the continued, enhanced, and consistent protection that use of OEHHA toxicity criteria will afford through this action.

Formal adoption of this rule also clarifies the appropriate toxicity criteria to use, which relative to present practice, should result in a net cost reduction for responsible parties conducting risk assessments and cleanups. The rule provides three ranks of toxicity criteria: The first rank are toxicity criteria provided in Appendix I of the rule, which is populated by peer reviewed OEHHA values more stringent than the IRIS counterpart values; the second rank are toxicity criteria provided by U.S. EPA's IRIS database; and the third and final rank are other specified sources relied on for toxicity criteria when contaminants are not found in either Appendix I or IRIS. Under the rule, risk assessors simply check Appendix I first for criteria; and if none is specified for that contaminant, then IRIS is consulted. This is more straightforward than the current practice which requires risk assessors to compare criteria found in DTSC's Human and Ecological Risk Office (HERO) guidance and IRIS and then follow specific instructions for determining which criteria to use if both sources contain a value for a given contaminant.

Fiscal Impacts to Government

DTSC concludes there will be limited fiscal impacts to government because this rule formally adopts existing practice. Because it clarifies an existing mandate on the selection of toxicity criteria for human health risk assessments and establishing risk-based screening levels and remediation goals for hazardous waste and substance release sites in California pursuant to California Health and Safety Code §25356.1.5, the proposed rule will potentially reduce costs and simplify compliance by government entities. DTSC has determined the proposed regulations will not impose new costs to local government.

As part of normal intra- and interagency communications (e.g., memoranda and meetings), staff will communicate the rule requirements internally and to the Water Boards, OEHHA, and any local agencies that oversee cleanup under Chapters 6.5, 6.8, and 6.82, at a minimum, to be sure that this rule is consistently applied, enforced, and timely proposed for use in federal cleanups. Additionally, as part of the current practice of regular updates, the Department's Human and Ecological Risk Office will review (and as needed update) its guidance, Human Health Risk Assessment (HHRA) Note 3, to be

sure it comports with the regulation. Additional future rulemaking activities will be necessary either to incorporate all new OEHHA peer-reviewed toxicity criteria that are more stringent than their IRIS counterpart, or to delete any values if a more stringent IRIS value becomes available.

With promulgation of the rule, there likely will be fiscal benefits to the government from reduced Department staff time and associated invoiced costs for debating applicable toxicity criteria with landowners and pursuing or defending disputes to protect employee and resident health at contaminated properties undergoing cleanup.

DTSC has further determined there will be costs associated with approximate annual rule amendments. DTSC estimates that there will be approximately two to four new or updated toxicity criteria published by OEHHA for inclusion in Appendix I or published by the U.S. EPA in the IRIS database per year. Because of this, the rule will be updated on annual basis to ensure the updates are incorporated into the rule. Rule amendments will be done in accordance with standard DTSC rulemaking procedures and as part of the general rulemaking activities routinely performed by DTSC. DTSC estimates the costs will be approximately \$35,000 per year. DTSC anticipates that no increase in DTSC's budget will be required and the costs will be borne by DTSC's Site Mitigation and Restoration Program and Hazardous Waste Management Program as the rule is applicable to both.