

FINAL STATEMENT OF REASONS

TOXICITY CRITERIA FOR HUMAN HEALTH RISK ASSESSMENTS, SCREENING LEVELS, AND REMEDIATION GOALS

Department of Toxic Substances Control Reference Number: R-2016-08
Office of Administrative Law Notice File Number: Z-2017-0725-08

UPDATE OF INITIAL STATEMENT OF REASONS

As authorized by Government Code section (§)11346.9 (d), the Department of Toxic Substances Control (DTSC) incorporates by reference the Initial Statement of Reasons (ISOR) prepared for this rulemaking and provides further clarification in this Final Statement of Reasons (FSOR).

Based on further technical and legal review, as well as comments received in the 45-day public comment period on the August 4, 2017 publicly noticed proposed rule (August Proposed Rule), substantive and non-substantive sufficiently-related changes were made to the August Proposed Rule. The revisions were publicly noticed for an additional 15-day public comment period on April 6, 2018 as a revised proposed rule (April Proposed Rule). The 15-day public comment period closed on April 21, 2018. This FSOR provides responses to public comments on both versions of the proposed rule and a summary of the changes that were made to the August Proposed Rule and minor clarifications and editorial changes made to the April Proposed Rule.

The final rule requires risk assessments prepared pursuant to the Hazardous Substances Account Act (HSC §25300 et seq., “Chapter 6.8”) to be based on specified toxicity criteria, and provides three ranks of toxicity criteria for use in this order:

- For a given contaminant, users first consult Appendix I and use those values so long as they are no less stringent than current U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS) toxicity values — in other words, more stringent IRIS database values must be used instead of less stringent values in Appendix I;
- If no toxicity criteria for that contaminant are in Appendix I, the IRIS database values must be used;
- If neither of those two sources contains an appropriate toxicity criteria value, then users must turn to the sources listed in §69021(c), and typically will only find one value among those sources.

Additional Supporting Information for the Rule

DTSC intends to provide additional guidance and outreach to further address any frequently asked questions related to the rule and its implementation. Among other things, DTSC will confirm that a) the NCP risk management range still applies to contaminated site cleanups; b) the rule does not define remediation goals to be equal to the screening levels; and c) the rule neither sets the remediation goal at screening

levels (e.g., 1×10^{-6}), nor prohibits remediation goals from being set at the screening level.

Below DTSC provides additional supporting information for the proposed rule.

Revision to the Economic and Fiscal Impact Statement (Form 399) and Analysis (Attachment to Form 399)

DTSC has revised the Economic and Fiscal Impact Statement (Form 399) and the Form 399 Attachment after consultation with the California Department of Finance (DOF) to ensure these documents accurately reflect economic and fiscal impacts to businesses and government and are consistent with statements made in the ISOR and responses to comments on the August Proposed Rule. Below DTSC provides an explanation of changes to the Form 399 from the April 2018 version.

Because the proposed rule is adding rather than amending regulatory language, in Section A of the Economic Impact Statement of Form 399, DTSC has checked Boxes “a”, “b” and “g,” rather than Box “h,” and completed the remaining portions of the Economic Impact Statement. As discussed in the August Proposed Rule and April Proposed Rule public notices, DTSC continues to believe that this rule has very limited economic and fiscal impact because the proposed rule does not change existing policy and practice and the vast majority of values in Appendix I are already in use. This rule merely formalizes existing practice with some toxicity criteria updates as required to comply with existing statutes, federal law and guidance. Accordingly, DTSC has determined there will be a “net zero” cost to businesses in implementing the rule as stated in the Economic Impact Statement.

In both the August Proposed Rule and April Proposed Rule, Box “4” was checked in the Fiscal Effect on Local Government” section of the Fiscal Impact Statement. DOF has instructed DTSC to check only Box “5” as the proposed rule promulgates a process already utilized by local government in accordance with state and federal guidance.

In the April Proposed Rule, Box “4” was checked in the “Fiscal Effect on State Government” section of the Fiscal Impact Statement to reflect costs for future rule amendments as discussed in Attachment 2 (to this FSOR). In fact, the need for future rule amendments to keep Appendix I of the rule updated and consistent with requirement in Health and Safety Code section 25356.1.5 is a function of the Legislative directive to use best science, and not a requirement of the rule itself. Therefore, since the rule does not specifically require or cause future rulemaking updates, no cost estimate is included at this time for future rule amendments and Box “3” (“no fiscal impact exists”) is now checked instead of Box “4.” Note that Box “3” had also been checked in the August Proposed Rule. The Form 399 Attachment now reflects the above discussion.

Additional Information on Impact to Businesses

DTSC concludes that there will be no increased economic costs from this action, including any impact on the ability of California businesses to compete with businesses in other states, because the rule formally adopts an existing practice that conforms to federal guidance and California per Health and Safety Code (HSC) §25356.1.5. DTSC anticipates that the public, including employees, residents, and commercial tenants will

benefit from the continued, enhanced, and consistent human health protection that use of specified toxicity criteria will afford at cleanup sites statewide through this action.

Formal adoption of the rule will also clarify and facilitate responsible parties' determination of the correct toxicity criteria to use when conducting human health risk assessments and cleanup, possibly resulting in an unquantifiable net cost reduction for responsible parties. Under the rule, for a given contaminant and given exposure pathway, risk assessors will simply check Appendix I first for toxicity criteria and use listed values if the IRIS values are not more stringent. If no values are provided in Appendix I, then IRIS values apply. If no values are provided in either Appendix I or IRIS, then risk assessors must use sources discussed in §69021(c). This approach for identifying appropriate values is substantively the same as the current (and historical) practice. In addition, DTSC's Human Health Risk Assessment Note 3, which includes the toxicity criteria used for screening levels, will still be regularly updated and available online for ease of reference.

Additional Information on Impact to Local Government Entities

DTSC concludes there will be no fiscal impacts to local government because the rule formally adopts existing practice. Because it clarifies an existing mandate regarding human health risk assessments and calculating risk-based screening levels and remediation goals pursuant to HSC §25356.1.5, the proposed rule may reduce costs and simplify compliance by government entities.

Consistency of Toxicity Criteria Used Across State Programs

DTSC collaborates with and relies on the California Office of Environmental Health Hazard Assessment (OEHHA) because of OEHHA's long-standing and well-established expertise in conducting risk assessments and developing toxicity criteria. While the two agencies have different sets of expertise, they have complementary roles in protecting public health. OEHHA develops toxicity criteria that DTSC and other state agencies, boards, and departments use as regulators to assess human health risks and determine safe exposure to known and potential contaminants. DTSC uses the toxicity criteria to calculate screening levels and to set human health risk-based remediation goals for contaminants that may remain in the environment after remedial action is completed.

Different state environmental programs use OEHHA's scientific expertise based on laws and policies that apply to those programs. For example, the California Air Resources Board (ARB) uses OEHHA toxicity criteria for stationary source risk assessments. These risk assessments are generally used for industrial or commercial facilities that release air emissions that may be subject to the California State Air Toxics Hot Spots Information and Assessment Act; which requires reporting of air toxics emissions, risk assessment of these emissions, public notification of the health risks, and risk reductions as appropriate. By comparison, DTSC uses the toxicity criteria to calculate screening levels and to set human health risk-based remediation goals for contaminants that may remain in the environment after remedial action is completed.

The proposed rule is also consistent with how the San Francisco Regional Water Quality Control Board (SFRWQCB) and State Water Resources Control Board (Water Board) use OEHHA toxicity criteria. The SFRWQCB publishes environmental screening

levels (ESLs) for various media (e.g., soil, groundwater, soil vapor), and uses OEHHA toxicity criteria where they are more stringent than the U.S. EPA IRIS, U.S. EPA Provisional Peer Reviewed Toxicity Values (PPRTVs), and Agency for Toxic Substances and Disease Registry (“ATSDR”) minimal risk levels. Additionally, priority is given to toxicity values “from publications that are peer-reviewed, readily available to the public, and are transparent about the methods and assumptions used to develop the values.” (Users Guide: Derivation and Application of Environmental Screening Levels (“ESLs”) Interim Final 2016). In addition, the State Water Resources Control Board uses OEHHA toxicity criteria in their technical document, “Technical Justification for Soil Screening Levels for Direct Contact and Outdoor Air Exposure Pathways (Final 03-15-2012)” which supports their Low-Threat Underground Storage Case Closure Policy.

DTSC and other state agencies are work together on shared issues, including the use of toxicity criteria for environmental cleanup work. For instance, DTSC routinely consults with the Water Board and regional water boards on shared topics, including guidance development, toxicology, site evaluation, and site oversight. While the Water Boards have toxicologists for assessing risk at environmental sites under their purview, DTSC also provides toxicological services for some sites under Water Board oversight, and will collaborate directly with Water Board staff on human health risk-based screening levels and remediation goals to assure that all site cleanups based on human health risk use the rule’s toxicity criteria as appropriate. Also, under California Land Reuse and Revitalization Act (“CLRRA,” or “Chapter 6.82”), both DTSC and the Water Boards have oversight authority for cleanup of hazardous material releases, so DTSC anticipates further collaboration with the Water Board to facilitate their independent understanding and use of the rule. To the same end, DTSC anticipates outreach to local agencies that oversee human health risk-based cleanups under the Hazardous Waste Control Law (“Chapter 6.5”).

Application of Total Petroleum Hydrocarbon by the Rule

Some commenters were concerned that the phrase “excluding TPH PPRTVs” in the August Proposed Rule implied that TPH is not toxic and prohibits TPH toxicity criteria from being used for human health risk assessments. This was not DTSC’s intention, so DTSC has revised §69021(c) to allow, but not require the use of the PPRTV TPH values when appropriate.

The rule defines TPH as “... a term to describe a large family of several hundred chemical compounds derived from crude oil,” and DTSC has maintained this definition in the final rule. For further context, however, DTSC does note TPH is a term used in environmental investigations as a parameter representing the mass of hydrocarbons in an environmental (soil or water) sample. TPH is comprised of thousands of related organic hydrocarbons. Environmental scientists quantify specific petroleum hydrocarbon mixtures (e.g., diesel, gasoline, motor oil) to assess environmental impact. Specific hydrocarbons known to be toxic to human health may be present within a quantified TPH mixture, and toxicity criteria may or may not be available for these mixtures. Use of TPH in assessing site risk and for risk-based decision making requires a contaminant-specific application of correct analytical method(s), fraction definition, and toxicity criteria for those fractions.

Because of the complex nature of TPH in any given sample, quantifying the risk for TPH is not feasible at this time. TPH toxicity criteria may be available from other sources as defined in the proposed rule under §69021(c). Section 69021(c) of the proposed rule neither provides a comprehensive list of alternate sources nor does it establish a hierarchy for sources within the subdivision. Until OEHHA or U.S. EPA IRIS issues final toxicity criteria for TPH mixtures, DTSC will continue its long-standing practice of using toxicity criteria for TPH fractions that are consistent with HSC §25356.1.5(c). For each site, DTSC will continue to use its best scientific judgement in selecting the appropriate source for TPH toxicity criteria.

Peer Review Definition

One commenter recommended that DTSC add a definition for peer review, and recommended language that is consistent with 3 CCR 1301(r). DTSC notes that HSC §57004 describes processes and defines terms applicable to “peer review.” Therefore, DTSC does not need to revise the rule to include a new description of “peer review,” given HSC §57004.

DTSC also notes that OEHHA typically develops toxicity criteria using scientific research that is published “in a peer-reviewed publication and not refuted by subsequent experiment or evidence” as recommended by 3 CCR 1301(r). Additionally, DTSC and OEHHA have verified that the Appendix I values went through a transparent and well-established peer review process.

Removal of Toxicity Criteria from Appendix I

HSC §57004 and HSC §25356.1.5 require that promulgated numbers, such as the OEHHA toxicity criteria values in the rule’s Appendix I, be peer-reviewed and represent best available science, respectively. After publicly noticing the August Proposed Rule, DTSC obtained OEHHA’s confirmation that some of the OEHHA toxicity criteria provided in Appendix I in the August Proposed Rule did not meet HSC §57004 and HSC §25356.1.5 requirements, and therefore are non-compliant and would not be enforceable. DTSC finds these changes non-substantive under the Administrative Procedure Act. Accordingly, the following toxicity criteria were removed from Appendix I:

- Inhalation unit risk (IUR) for arsenic;
- Oral cancer slope factor (CSFo) for bromoform;
- IUR for 1,3-dichlorobenzidine;
- CSFo and IUR for chlordane;
- CSFo and IUR for mirex;
- CSFo for 1-naphthylamine;
- CSFo for o-toluidine;
- CSFo for 1,3-dichloropropene;
- CSFo and IUR for epichlorohydrin;

- REL for manganese (non-diet);
- CSFo for vinyl chloride;
- IUR for carbon tetrachloride;
- CSFo and IUR for both cis-1,3-dichloropropene and trans-1,3-dichloropropene; and
- IUR 1,4 for dioxane; and
- Chronic reference exposure level (REL) for 2-butoxyethanol. Note that OEHHA officially adopted the REL on May 4, 2018. This REL will be adopted in a future rule amendment.

The revisions listed above ensure that the toxicity criteria in Appendix I are no less stringent than federal standards and represent best available science in accordance with HSC §25356.1.5, and have undergone a scientific peer review and subject to public review and comment in accordance with HSC §57004. Specific reasons for each contaminant are provided in Supplement 1 of Attachment 2.

Consistency with Applicable U.S. EPA Guidance

Several commenters claimed that the proposed rule is inconsistent with federal guidance, specifically U.S. EPA Risk Assessment Guidance for Superfund (RAGS), U.S. EPA Office of Solid Waste and Emergency Response (OSWER) Directives 9285-7.16 and 9285.7-53. The commenters claim that at least for U.S. EPA-lead Superfund sites, toxicity criteria published in the U.S. EPA IRIS database must be used for human health-based risk assessments, and values from other sources (including OEHHA) may only be used if IRIS does not have a corresponding value. DTSC disagrees with these claims and explains below how the proposed rule is consistent with these guidance documents.

U.S. EPA RAGS Part A

It is true that U.S. EPA RAGS Part A mentions that “IRIS supersedes all other sources” and that the list of additional sources should be consulted only “if information is not available in IRIS for the chemical being evaluated...” However, that Part A also refers the reader to the U.S. EPA OSWER Directive 9285.7-53, discussed in more detail below. Briefly, this latter directive explicitly allows for flexibility in selecting toxicity criteria and for U.S. EPA and state staff to use and accept other technically sound approaches.

U.S. EPA OSWER Directive 9285.7-16

OSWER Directive 9285.7-16 clarifies the U.S. EPA RAGS policy for sources of toxicity criteria for U.S. EPA Superfund sites and notes that U.S. EPA generally recommends use of IRIS criteria but that this is not the sole source and that toxicity criteria from other sources might be more credible and appropriate for use. In particular, the directive states (emphasis in bold added):

...**IRIS is not the only source of toxicological information**, and in some cases more recent, credible and relevant data may come to the Agency's attention. In

particular, toxicological information other than that in IRIS may be brought to the Agency by outside parties. Such information should be considered along with the data in IRIS in selecting toxicological values; **ultimately, the Agency should evaluate risk based upon its best scientific judgment and consider all credible and relevant information available to it.**

And the final section entitled Implementation further supports the need for case-by-case analysis and judgment as follows (emphasis in bold added):

The weight to be given information from sources other than IRIS will necessarily have to be determined on a case-by-case basis. ... The evaluation of credible and relevant information should consider a variety of factors in evaluating the hazards associated with chemical exposure including: whether the study was designed using approved protocols and whether it was conducted observing good laboratory practices. ...

Specifically, OSWER Directive 9285.7-16 follows the same path as U.S. EPA RAGS, and does not mandate use of IRIS values in all cases. It requires consideration of all credible and relevant information available, and reminds users that the uncertainties inherent in the toxicological criteria values need to be evaluated for site specific application.

U.S. EPA OSWER Directive 9285.7-53

U.S. EPA OSWER Directive 9285.7-53 builds on U.S. EPA RAGS and OSWER Directive 9285.7-16 by describing the process for selecting toxicity criteria for use in human health risk assessments for U.S. EPA Superfund sites. U.S. EPA's OSWER Directive 9285.7-53 revised the hierarchy of human health and toxicity values generally recommended for use in risk assessments contained in the December 1989 version of RAGS Part A, and set forth a recommended approach to identify and select toxicity criteria. However, the directive starts with significant admonitions about evaluating and determining the appropriateness of applying the hierarchy. It states on page 1 (emphasis in bold added):

EPA and state personnel **may use and accept other** technically sound approaches, either on their own initiative, or at the suggestion of potentially responsible parties, or other interested parties. Therefore, interested parties are free to raise questions and objections about the substance of this memorandum and the appropriateness of the application of this document to a particular situation. **EPA will, and States should, consider whether the recommendations or interpretations in this memorandum are appropriate in that situation. This memorandum does not impose any requirements or obligations on EPA, States, or other federal agencies, or the regulated community.**

The directive goes on to establish three tiers of toxicity criteria with U.S. EPA's IRIS values labeled as the Tier I source and starting point when gathering toxicity criteria for possible use at cleanup sites. Absent an IRIS value, the U.S. EPA PPRTVs are labeled as the Tier II source. Tier III values include other U.S. EPA and non-U.S. EPA sources, and notes on page 3 (emphasis in bold added):

Priority should be given to sources that provide toxicity information based on similar

methods and procedures as those used for Tier I and Tier II, contain values which **are peer reviewed, are available to the public, and are transparent about the methods and processes used to develop the values.**

As discussed in the ISOR, the Appendix I toxicity criteria values meet the scientific quality and transparent development standards for priority given above.

In addition, under Implementation on page 4, the directive states explicitly that (emphasis in bold added) “[a]dditional sources of toxicity values, which are not specifically referenced in this recommended hierarchy, can be considered.” This makes clear that once IRIS toxicity criteria have been identified, it is not the only choice available.

The directive clearly indicates that the IRIS is a starting point, and should not be the first and only stop if an IRIS value exists, and that the hierarchy was not intended to avoid or preempt further analysis. OSWER Directive 9285.7-53 explicitly allows U.S EPA and state staff to use and accept other technically sound approaches. It cautions users to consider whether the recommendations or interpretations in the directive are appropriate for each site, and proposes the IRIS toxicity criteria values and the tiered hierarchy as a point for initial consideration.

Application of Rule to Background Levels

A commenter requested that the proposed rule include a provision for excluding background levels in the selection of toxicity criteria. This is unnecessary for two reasons. First toxicity criteria are contaminant-specific values of the inherent potency of the contaminant, so site conditions are irrelevant. In the human health risk assessment, background levels are discussed and factored into the site-specific assessment. Similarly, consistent with Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), background levels are considered in assessing the need for a remedy, and if appropriate, in selecting remediation goals. Depending upon site-specific considerations and issues, remediation goals may or may not be set to background levels. This rule does not pertain to how background levels are considered. Thus, a detailed discussion of how background levels are addressed for individual sites is beyond the scope of the proposed rule and this FSOR, and remains excluded from both documents.

Selection of Toxicity Criteria in Appendix I

Commenters asked for greater detail on how DTSC selected the toxicity criteria listed in Appendix I. As described in the Initial Statement of Reasons, in HERO Note 3, DTSC provides recommended toxicity criteria for use in human health risk assessments, human health risk-based screening levels and human health risk-based remediation goals. These criteria are derived from multiple sources, the primary being values published by OEHHA and U.S. EPA on their websites. Note 3 identifies and provides links to these sources. DTSC relies on OEHHA’s expertise in developing the toxicity criteria used and included in Appendix I.

In developing Appendix I, DTSC used HERO Note 3 to generate a table listing the OEHHA toxicity criteria that are more stringent than the corresponding U.S. EPA IRIS value. From that list, DTSC evaluated whether the toxicity criteria met the requirements

of HSC §25356.1.5(c) and whether the toxicity criteria went through a public peer review process for purposes of HSC §57004. DTSC searched the OEHHA website for the technical document that discusses the derivation of the toxicity criteria and for the peer review and public comments received for that toxicity criteria. Where the documentation could not be located, DTSC worked with OEHHA staff to gather the technical, peer review, and public comment documentation.

DTSC reviewed the technical documentation, and generated a table listing the scientific basis for the OEHHA value if: 1) DTSC was uncertain whether the toxicity criteria were based on best available science; 2) the value was a route-to-route extrapolated toxicity criteria value. The IRIS value and its scientific basis were also included in the table, if available. The scientific justification for removing or including toxicity criteria in Appendix I was provided to DTSC's Human and Ecological Risk Office (HERO) Supervising Toxicologist for review. The scientific justification included but was not limited to, whether the toxicity criteria value a) was a route-to-route extrapolation, and b) met the peer review/public review requirement; or 3) it was based on best available science. The HERO Supervising Toxicologist reviewed and provided concurrence for removal or listing of the toxicity criteria from the then-draft Appendix I. DTSC collaborated with OEHHA staff to verify that the toxicity criteria listed in Appendix I are the correct values and meet both the HSC §25356.1.5 and §57004 requirements. Supplement 1 of Attachment 2 to the FSOR provides the result of the joint DTSC-OEHHA confirmation of peer review and numerical accuracy.

Selection of Toxicity Criteria under §69021(c)

Commenters asked for greater detail on how the HERO Supervising Toxicologist will approve toxicity criteria under §69021(c). In general, when identifying toxicity criteria, DTSC is statutorily required to comply with HSC §25356.1.5, and with the applicable requirements of HSC §57004. Therefore, DTSC has determined that it is not necessary to revise the rule.

When evaluating toxicity criteria pursuant to §69021(c) for contaminants without toxicity criteria listed in Appendix I or IRIS, DTSC will continue its current practice, as outlined below.

- DTSC will maintain and semiannually update an informational list of toxicity criteria values that qualify for use under §69021(c), and their sources. The list will be incorporated into a forthcoming Human Health Risk Assessment (HHRA) Note and will be made available to the public on DTSC's website. When evaluating toxicity criteria for inclusion in this HHRA Note, the HERO Supervising Toxicologist or designee will review the available toxicity criteria for a given contaminant from credible and authoritative sources and, in consultation with OEHHA, select the toxicity criteria that best meet the requirements of HSC §25356.1.5 and as much as possible, the conditions of §57004. The toxicity criteria that best meet these statutory requirements will be included in the new HHRA Note.
- When DTSC receives a draft site-specific risk assessment where any toxicity criteria were selected pursuant to §69021(c), the HERO toxicologist will first screen the toxicity criteria used in the risk assessment to determine whether

preferred toxicity criteria are available for those contaminants under subdivision (a) or (b) in §69021, that is, in Appendix I or IRIS. DTSC will require the use of toxicity criteria from Appendix I or IRIS, consistent with this rule, for any contaminant where such toxicity criteria are available.

- Where no toxicity criteria are available in Appendix I or IRIS, the toxicity criteria used in the risk assessment will be compared to the most recent HHRA Note. Risk assessments using toxicity criteria listed in the HHRA Note will then proceed for evaluation of other aspects of the assessment; the evaluation is summarized in a formal memorandum. If the risk assessment uses toxicity criteria that are not listed in the HHRA Note, the HERO toxicologist will evaluate those criteria and make a recommendation regarding their use (see below). This recommendation is included in the evaluation memorandum for the risk assessment.
- To ensure the correct toxicity criteria are consistently applied to all cleanup sites, HERO memoranda undergo a two-stage internal review: 1) review by a HERO toxicologist in the unit familiar with the site/facility and/or issues; and 2) concurrence review for the policy and program issues by the HERO unit supervisor, a Senior Toxicologist.
- Additionally, for a given site, use of any value not listed in the forthcoming HHRA Note will require approval by the second level supervisor or branch chief, the HERO Supervising Toxicologist or his or her designee who will consult with OEHHA before approving use of toxicity criteria that best meet the conditions of HSC §25356.1.5, and as closely as possible, the conditions of §57004. The decision will be documented in a memorandum.

The toxicity criteria selected under §69021(c) will not necessarily meet all of the conditions under HSC §57004, but represent the best available toxicity criteria until OEHHA or U.S. EPA IRIS develops and adopts or issues a new toxicity criteria. Typically, when toxicity criteria are selected from a §69021(c) source, there is only one available value from established sources.

Clarifications to the Initial Statement of Reasons

A commenter pointed out that the ISOR noted that “OEHHA had previously developed screening levels pursuant to HSC §57008, but did not promulgate them.” The ISOR discussion related to HSC §57008 has no specific bearing on the rule and was provided in the ISOR to show that while OEHHA had developed human health risk-based screening levels pursuant to HSC §57008, none were promulgated.

Commenters expressed concerns regarding how toxicity criteria will be updated. As discussed in the rulemaking public workshops and the ISOR, DTSC will periodically amend the rule to ensure the most current appropriate OEHHA toxicity criteria are listed consistent with HSC §25356.1.5 pursuant to existing law, the California’s Administrative Procedure Act (APA). To incorporate future new or updated OEHHA values or delete an OEHHA value because new or revised IRIS toxicity criteria represent the best available science, DTSC will amend the rule as needed, probably on an annual basis, and possibly through an emergency rulemaking to achieve compliance with HSC

§25356.1.5 as soon as feasible. Rule amendments are promulgated in accordance with the APA, an open and transparent process that includes public input.

DTSC expects to coordinate its rulemaking timelines with OEHHA to adopt new values that are consistent with DTSC's statutory requirements as soon as feasible. DTSC routinely monitors OEHHA and U.S. EPA toxicity criteria developments and will identify any criteria that may require a rule amendment. DTSC will take steps to identify toxicity criteria that are likely to change and through careful planning will work with responsible parties to minimize impacts to cleanup decision time-frames.

Discrepancies between the ISOR and the August Proposed Rule

The ISOR provided detailed explanations of the individual sections of the August Proposed Rule, however there remain some minor discrepancies between the ISOR and the August Proposed Rule which are clarified below.

The ISOR stated that in §69020 "Subdivision (a) explains that differences in culture, genetics and age can contribute to different exposures and sensitivities to contaminants." DTSC did not include this explanation in the rule and instead references HSC §25356.1.5, which allows these to be factored into risk assessments through consideration of sensitive subpopulations.

The ISOR stated that in §69020 "Subdivision (b) states the regulation's scope and identifies its applicability to all hazardous substance release sites." This text was not included in the noticed August Proposed Rule as DTSC found it unnecessary.

The ISOR summarized language that did not actually appear in §69020(b). The incorrect summary stated "...notes that this rule is not retroactive and does not change any prior determination upon its effective date by operation of law." This language was not included in the August Proposed Rule to avoid confusion about applicability to the Five-Year Review required under CERCLA. While the text of the August Proposed Rule specifically states that it applies to risk assessments submitted after the effective date of the rule, any Five Year Review performed after the effective date will be completed in compliance with this rule. For more detailed explanation, please see the Comment Category "Five-Year Reviews and Changes to Existing Documents" in the Responses to Comments in Attachment 1 and the response to Latham & Watkins, LLP in Attachment 2 to this FSOR.

The ISOR identified the presence of a §69020(d), which was not included in the August Proposed Rule (and is not in the final rule). This subdivision was not included, and the references to Chapters 6.5 and 6.8 were moved to §69020(b). Please note that in the final rule, the reference to Chapter 6.5 has been removed from §69020(b) because corrective action is addressed in §68400.5.

The ISOR, referring to §69020, stated, "For clarity and to ensure consistency with federal law, subdivision (c) specifies that remediation goals developed under this rule will be consistent with the National Oil and Hazardous Substances Pollution Contingency Plan, also known as the National Contingency Plan (NCP), and in particular with CFR Title 40, §300.430." DTSC did not include this text in the rule because it is duplicative of the HSC §25356.1.5 requirement to be based on and not inconsistent with the NCP.

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 have also been made to the proposed rule.

Several commenters expressed concern that risk managers might interpret the rule in a manner that conflicts with the NCP. In particular, they requested that the NCP’s risk management range be expressly included in the rule to avoid the misimpression that the rule requires remediation goals to be set at 1×10^{-6} risk levels. As explained above, the rule neither sets nor prohibits the remediation goals from being set at screening levels, and does not define remediation goal as equal to the screening level. DTSC intends to provide additional guidance and outreach to further address any frequently asked questions related to the rule and its implementation.

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 in the rulemaking Updated Informative Digest 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.

Finally, non-substantive editorial changes without regulatory affect have been made to the April Proposed rule. DTSC removed certain informative language that did not change or alter existing statutory or rule requirements. These changes include the following:

- Section 69020(b), first sentence: Deleting “The purpose of” and replacing “is to adopt” with “is to establish.”
- Section 69020(b), first sentence: Deleting “where those levels are memorialized in documents” from the latter part of this sentence.
- Section 69020(b), second sentence: Deleting the sentence, “This Chapter clarifies, without changing, the Department’s existing practices for screening

levels and human health risk-based remediation goals.” This information was provided in the Initial Statement of Reasons.

- Section 69020(c)(3): Deleting “. This Chapter incorporates by this reference” and replacing it with “, for” to reflect that the IRIS standard is the national floor of protection and would apply under both federal law and guidance as the federal “floor of protection” required under HSC §25356.1.5.
- Appendix I: Deleting “Confidential draft” and “Draft” wherever they appear because this is the final version of the rule.

LOCAL MANDATE DETERMINATION

The proposed rule codifies and clarifies existing practice and imposes no new mandate on local agencies or school districts, there are no financial costs for these entities in applying the rule.

ALTERNATIVES DETERMINATION

DTSC has determined that no alternative would be equally or more effective in carrying out the purpose of the proposed rule, or would be less burdensome to affected private persons than the proposed rule. The proposed rule will adopt specified California toxicity criteria for use in human health risk assessments to set risk-based screening levels and remediation goals for both corrective action under the Chapter 6.5 and response actions under, Chapter 6.8. Also, because Chapter 6.82 specifically refers to Chapter 6.8, risk assessments, screening levels, and remediation goals prepared pursuant to Chapter 6.82 will also be governed by this rule.

The current practice of applying federal and state guidance to toxicity criteria has in recent years become the subject of differing interpretations and disputes at hazardous waste and substance release sites in California. The proposed rule codifies DTSC’s established practice to require the use of California’s OEHHA toxicity criteria for specified contaminants at hazardous substance release sites in accordance with existing law, including statutory requirements.

By adopting the proposed rule, DTSC will ensure consistent application of the appropriate toxicity criteria statewide for all cleanup sites, regardless of which statute authorizes the cleanup or which party is responsible for carrying it out. Adopting the proposed rule will also ensure that toxicity criteria used to protect California’s residents appropriately account for population-specific variations in health endpoints and other responses to exposures to contaminants. This is consistent with California’s statutory requirements, as well as with its overall environmental justice objectives and DTSC’s obligations under state law to ensure protection across age, racial, ethnic, cultural and income groups.

BUSINESS REPORT

DTSC has determined that this rulemaking will not require businesses to write a new

report, as defined by Government Code §11346.3(c).

ADVERSE ECONOMIC IMPACT ON SMALL BUSINESSES

Neither the proposed rule, nor any of the alternatives considered, is anticipated to result in an adverse economic impact on small businesses. To the contrary, cost savings may be achieved because the proposed rule provides clarity which simplifies the process for identifying the appropriate toxicity criteria for use in risk assessments, human health risk-based screening levels, and determining human health risk-based remediation goals.

SUMMARY OF COMMENTS AND AGENCY RESPONSES

Comments were received on the August Proposed Rule. On April 6, 2018 DTSC publicly noticed (with a 15-day comment period) a revised version as the April Proposed Rule and preliminary responses to the comments on the August Proposed Rule. Additional comments were received as part of this more recent 15-day comment period. Comments and responses to comments on the August Proposed Rule are provided in Attachment 1. Comments and responses to comments on the April Proposed Rule are provided as Attachment 2 to this FSOR.

Attachment 1: Final Responses to Comments on the Draft Proposed Rule

Attachment 2: Final Response to Comments on the Revised Draft Proposed Rule