

**Toxicity Criteria Rule
Proposed Regulations R-2016-08**

**Toxicity Criteria for Human Health Risk
Assessments, Screening Levels, and Remediation
Goals**

**Draft Responses to Comments
on the Draft Proposed Regulations**

Prepared by the Department of Toxic Substances Control (DTSC)

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OVERVIEW AND ORGANIZATION

This document summarizes, responds to, and addresses the public comments submitted to the Department of Toxic Substances Control (DTSC) on the proposed rulemaking titled *Toxicity Criteria for Human Health Risk Assessments, Screening Levels and Remediation Goals*, during the public comment period that began on August 4, 2017, and ended on September 20, 2017. An additional RTC document will address comments received during the 15-day comment period commencing in early 2018. The following summary provides an overview of DTSC's public outreach efforts and opportunities for public input in the development of this rulemaking package.

- A preliminary workshop version of the proposal was made available for public review and comment for 66 days from November 11, 2016 to January 16, 2017. DTSC informed the public that no formal responses to comments would be developed or distributed.
- A public workshop was held in Sacramento, California on December 12, 2016, for DTSC staff to explain the proposal and answer questions from the public on the workshop version of the proposed rule.
- Responding to public requests, DTSC extended the public comment period for the preliminary review draft version of the regulation for an additional 15 days. The public comment period then closed on January 31, 2017.
- Based on further evaluation of the proposal and consideration of the comments received, DTSC revised the proposed rule and began formal rulemaking by releasing the revised proposal on August 4, 2017 for a 45-day public review and comment period. This public comment period closed on September 20, 2017.
- Two public workshops were held in Sacramento, California on August 28, 2017 and in Cypress, California on August 31, 2017, for DTSC staff to present the regulation and answer questions from the public related to the August 4, 2017 version of the proposed rule.
- A public hearing was held in Sacramento, California on September 20, 2017.
- Based on further evaluation of the proposed rule and consideration of the latest public comments received in August and September 2017, DTSC further revised the proposed rule and released it to the public on February 14, 2018 for a 15-day public comment period. This second public comment period will close on March 1, 2018.

The proposed regulation adopts toxicity criteria for specific contaminants that were previously peer reviewed through the California Office of Environmental Health Hazard Assessment (OEHHA), consistent with DTSC's statutory directive at Health and Safety Code (HSC) section §25356.1.5. HSC §25356.1.5 also requires that response actions be no less stringent than federal law and be based on federal regulation and guidance, which in this case includes applicable federal toxicity criteria that have undergone peer

review. Given this legal constraint, this proposed rule was not submitted for further external scientific review under HSC §57004. Note, however, the promulgated toxicity criteria that are the scientific basis or scientific portion of the proposed rule (within the rule's Appendix I) were developed by the OEHHA through its peer review process.

Comment letters were received from the 15 organizations, companies or individuals identified in Table 1. For tracking purposes, also identified in the table is a unique acronym assigned to each commenter and the number of comments submitted by each commenter. For each commenter, comments are sequentially numbered, as shown in the attached compilation of comment letters. For example, CBG refers to the commenting group "Committee to Bridge the Gap" and the CBG comments are sequentially numbered (e.g., CBG-01, CBG-02, etc.). No comments were received at or during the September 20, 2017 public hearing. The hearing was recorded and the audio recording placed in the project docket. The docket number is R-2016-08.

For the purpose of orderly presentation, comments have been grouped by general category or "theme." Within some of the general categories, comments have been further grouped into sub-categories. For each group, using the commenter acronyms shown in Table 1 below, the comments are listed and then the comment group summarized. For some of the groupings, because of the large number of comments, following the summary, specific items in the comment group are listed. Finally, for each category or subcategory, responses are provided for each comment summary, and where the comment summary contains a numbered list, the corresponding responses are numbered in the same manner. Of the 15 commenters on the August 4, 2017 proposed rule, the Del Amo Action Committee and the Center for Public Environmental Oversight provided comments in general support of the proposed rule. In addition, in the interest of transparency, DTSC provides responses to the comments received from DTSC toxicologist Dr. Uta Hellmann-Blumberg, Ph.D.

Table 1. List of Commenters

Acronym	Name of Entity	Number of Comments
CBG	Committee to Bridge the Gap	9
CCEEB	California Council for Environmental and Economic Balance	11
CMTA	California Manufacturers and Technology Association	30
CPEO	Center for Public Environmental Oversight	3
DAAC	Del Amo Action Committee	4
DOD	U.S. Department of the Navy (Department of Defense)	19
HB	Dr. Uta Hellmann-Blumberg, Ph.D.	3
INTG	Integral Consultants	10
L&W	Latham & Watkins, LLP	5
LCC	League of California Cities	4
STO	Ms. Linda Stone, PG, CHg	2
MAT	Materion Corporation	1
SSIM	Mr. Scott Simpson	3
RWQCB	San Francisco Bay Regional Water Quality Control Board	4
TS	ToxStrategies	4

List of Acronyms/Abbreviations

§	Section
DTSC	Department of Toxic Substances Control
µg/dL	Microgram per deciliter
µg/m ³	Microgram per cubic meter
APA	Administrative Procedures Act
ARB	Air Resources Board
ACY3	Acylase
AGAT/AGXT2	Alanine-glyoxylate amino transferase
BACT	Best Available Control Technologies
BARCT	Best Available Retrofit Control Technologies
CCBL1	Cysteine conjugate β-lyase
CCNAT	Cysteine conjugate N-acetyltransferase
CEQA	California Environmental Quality Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
COPC	Contaminant of Potential Concern
CSFo	Oral Cancer Slope Factor
CSM	Conceptual Site Model
CYP	Cytochrome P450
DCA	Dichloroethane
DCP	Dichloropropene
DCTK	Dichlorothioketene
DOD	Department of Defense
ECOS	Environmental Council of States
EIR	Environmental Impact Report
FSOR	Final Statement of Reasons
FMO3	Flavin-containing monooxygenase
GSH	Glutathione
GST	Glutathione-S-transferase
HQ	Hazard Quotient
HERO	Human and Ecological Risk Office

HSC	Health and Safety Code
IRIS	Integrated Risk Information System
ISOR	Initial Statement of Reasons
IUR	Inhalation Unit Risk
MCL	Maximum Contaminant Level
NAcTCVC	N-acetyl-S-(1,2,2-trichlorovinyl)-L-cysteine
NAT8	N-acetyltransferase
NCP	National Contingency Plan
OEHHA	Office of Environmental Health Hazard Assessment
OSWER	Office of Solid Waste and Emergency Response
PHG	Public Health Goal
PPRTVs	Provisional Peer-Reviewed Toxicity Values
REL	Reference Exposure Level
RfC	Reference Concentration
RTCs	Response to Comments
TCE	Trichloroethylene
TCVC	Trichlorovinyl-L-cysteine
U.S. EPA	United States Environmental Protection Agency

EXECUTIVE SUMMARY

DTSC appreciates the comments provided by businesses, non-governmental organizations, agencies and individuals on the proposed regulation titled “*Toxicity Criteria for Human Health Risk Assessments, Screening Levels and Remediation Goals*” (Toxicity Criteria Regulation). The proposed regulation was released by DTSC to the public on August 4, 2017, and the comment period ended on September 20, 2017. This rulemaking would formally adopt specified California toxicity criteria for use in human health risk assessments to set risk-based screening levels and remediation goals, consistent with DTSC’s established practice for both corrective actions under the Hazardous Waste Control Law (Chapter 6.5), and response actions under the Hazardous Substances Account Act (Chapter 6.8) and the California Land Reuse and Revitalization Act of 2004 (Chapter 6.82).

The proposed Toxicity Criteria Regulation codifies DTSC’s established practice to require the use of California’s Office of Environmental Health Hazard Assessment (OEHHA) toxicity criteria for specified contaminants at hazardous substance release sites. Toxicity criteria are used for risk assessments, and setting risk-based screening levels and remediation goals for contaminants at hazardous substance release (e.g., cleanup) sites. It is important to point out that the proposed regulation does not change the risk management range allowed for establishing remediation goals, which remains consistent with the National Oil and Hazardous Substances Pollution Contingency Plan (NCP); the allowed risk management range remains 1×10^{-6} to 1×10^{-4} based on site specific and other factors.

By adopting the proposed Toxicity Criteria Regulation, DTSC will ensure consistent application of the appropriate toxicity criteria for all cleanup sites in California regardless of which statute authorizes the cleanup or which party is responsible for carrying it out. Adopting the proposed Toxicity Criteria Regulation 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 overall environmental justice objectives and DTSC’s obligations under state law to ensure protection across age, racial, ethnic, cultural and income groups.

In reviewing and responding to comments on the proposed Toxicity Criteria Regulation, DTSC recognizes the general concerns from stakeholders regarding possible unintended consequences that could arise from this rulemaking. It is important to point out that the proposed Toxicity Criteria Regulation is codifying DTSC’s long standing current practice dating back to 1994. In particular, commenters expressed concerns that the proposed Regulation would change existing practice, restrict the risk management range for remediation goals, and increase remediation costs; the proposed Toxicity Criteria Regulation does not change existing practice, retains consistency with the NCP, and should have no impact on the costs of compliance. It

does, however, provide greater clarity and consistency, which may reduce the number or length of delays or disputes, which could ultimately reduce compliance costs.

Some of the businesses and industries or their representative associations and federal agencies expressed concerns that the regulation will change existing practice, increases financial burden, or requires the use of most stringent, rather than best science, toxicity criteria or restricts the use of site specific factors, such as future land use. DTSC appreciates the comments provided and points out that the regulation is only codifying the existing and longstanding practice and does not increase remediation costs but provides greater clarity and consistency. However, in response to the comments, DTSC has made some changes to the text of the regulation to ensure that the best available science is used and has removed selected contaminant toxicity criteria which did not meet the rule requirements from Appendix I. DTSC has also clarified that site-specific criteria will continue to be used in risk assessments and to set remedial goals and has changed the regulation by adding language to the definition of remediation goal to clarify that certain site-specific factors, such as future land use, will continue to be used in setting the remediation goals.

Although many community advocates and organizations supported the proposed regulation, concerns were expressed by some that Appendix I inappropriately included toxicity criteria developed by OEHHA that were less stringent than the corresponding criteria in IRIS. DTSC agrees that the state may not use criteria that are less stringent than the federal government uses and has updated Appendix I accordingly; it is important to note, however, that DTSC does not include OEHHA criteria that lack peer review even if those criteria would otherwise be more stringent. Further, in some cases a commenter made incorrect comparisons of values in Appendix I and concluded values were less stringent when in fact they are more protective. Some community advocates and agencies also expressed concerns that the language “(excluding TPH PPRTVs)” could be interpreted to mean the total petroleum hydrocarbon (TPH) mixture is not toxic, or that its toxicity should not be considered. DTSC revised the language to no longer specifically exclude TPH toxicity criteria, leaving open the option for risk managers to select TPH criteria from a third Tier source. Additional discussion of TPH is included in the Final Statement of Reasons.

Finally, a number of commenters from different sectors and organizations raised questions regarding DTSC’s intentions to update the values in Appendix I to ensure they continue to reflect the best available science. DTSC will periodically update Appendix I through rulemaking with public notice and opportunity to comment. DTSC’s Human and Ecological Risk Office (HERO) reviews advances in toxicology and risk assessment to ensure DTSC’s practices are consistent with best available science. Hero toxicologists, in consultation with OEHHA, will review toxicity criteria to ensure new and updated values are incorporated in a timely manner.

Summary of Comments by Commenter Groups

The major comments and DTSC responses are summarized below.

Representatives for Business, Associations, Councils, Consulting, Industry, Manufacturing, and Federal and Local Agencies

The primary categories of comments are discussed below.

Best available science: The overarching concern expressed by commenters was to ensure that selected toxicity criteria are based on best available science. DTSC agrees with this comment and has specifically crafted the proposed rule to ensure that the toxicity criteria selected are based on best available science as required in Health and Safety Code (HSC) §25356.1.5 and are peer-reviewed as required under HSC §57004. The OEHHA toxicity criteria included in Appendix I were specifically selected because they meet these statutory requirements. To ensure that this comment is addressed and to provide greater clarity on this topic, DTSC has made editorial changes to the rule. Additionally, to further ensure the use of best available science, selected contaminant toxicity criteria in Appendix I that were in the publicly noticed draft have been removed after an additional DTSC review determined these toxicity criteria did not meet the rule requirements.

Site evaluation/flexibility in determining remediation goals: Some commenters were concerned that the rule may eliminate the use of site-specific considerations and the CERCLA risk range in developing risk-based remediation goals. DTSC agrees that site-specific considerations factor into risk assessments, and into the identification of remediation goals and selection of remedial measures consistent with the NCP. To clarify this DTSC has added language to the definition of “Remediation Goal” to specify that site-specific information, such as future land use, will be considered as one of the factors in selecting the final remediation goal.

Outdated criteria and updating the rule: Some commenters were concerned that toxicity criteria established by the rule may become outdated as new more appropriate values are released by OEHHA or U.S. EPA. DTSC concurs and identified this concern in an early stage of the rulemaking process. DTSC believes that specific toxicity criteria must be included in the rule pursuant to state requirements. To address this concern DTSC made changes to the rule specifying how new U.S. EPA criteria are incorporated. The rule will also be periodically amended to ensure new and updated values are incorporated in a timely manner.

Changing existing practice: Some commenters also suggested that DTSC was changing existing practice on how toxicity criteria were selected, potentially resulting in more stringent standards, which may result in other problems. DTSC respectfully disagrees and, accordingly, did not change the proposed rule with respect to this comment. DTSC believes the rule applies best available science in a manner consistent with current law and practice for selecting toxicity criteria.

Inconsistency with laws, other regulations, and guidance: Some commenters expressed concern that the rule was inconsistent with other state and federal laws,

regulations and guidance. DTSC respectfully disagrees and explains in the Initial Statement of Reasons (ISOR) and in these responses to comments how the proposed rule is consistent with federal guidance and applicable federal and state laws.

Financial burden: Some commenters were concerned that the rule would result in an increased financial burden on businesses and private parties. DTSC respectfully disagrees, and therefore did not make any further changes to the proposed rule. DTSC has explained that the proposed rule does not specify more stringent screening levels and remediation goals compared to existing practice, so application of the rule is consistent with existing practice, and would not result in increased financial burden to private and public entities.

Concerns Raised by Environmental Organizations

The major comments and DTSC responses are summarized below.

General support for the rule and a desire that the rule not be biased in favor of industry: DTSC very much appreciates the support for the proposed rule, and is making every effort to ensure that the proposed rule is not biased in favor of any particular stakeholder(s), ensures fairness, and applies the best science. The proposed rule has been crafted to ensure that all sites in California, including federal sites, are subject to the same risk-based screening levels and remediation goals, without changing the consideration of site-specific conditions.

Inclusion of OEHHA-derived values in Appendix I that are less stringent than corresponding IRIS values: DTSC agrees that the state may not require the use of toxicity criteria that are less stringent than otherwise required by the federal government and has updated Appendix I accordingly.

Addressing petroleum hydrocarbon contamination: DTSC agrees and did not intend for the parenthetical statement in regulation “(excluding TPH PPRTVs)” to be interpreted to mean that the TPH mixture is not toxic, or that its toxicity should not be considered. The statement “(excluding TPH PPRTVs)” has been removed from the regulation and additional discussion of the issue will be included in the Final Statement of Reasons (FSOR).

The proposed rule does not require cleanup of all contaminants to background levels, and therefore, does not provide adequate protection of human health: DTSC agrees that it is important to protect human health and the environment, and believes that existing practice, as codified in the proposed rule, provides the greatest level of protection possible, factoring in requirements specified in federal and state law. These laws require consideration of site-specific conditions and other factors, and do not necessarily require the cleanup of all hazardous substance releases to the environment, or establish cleanup levels to background.

Concerns Raised by State Entities and Interested State Employees

The major comments and DTSC responses are summarized below.

Values included in Appendix I, and Maximum Contaminant Levels (MCLs): DTSC agrees that further explanations would be helpful to clarify the exclusion of certain

OEHHA values from Appendix I under applicable law, and that the rule does not replace MCLs. More detailed explanations are provided in the detailed responses to these comments, and the FSOR will discuss key issues raised by the commenters to enhance clarity of the rule's application to environmental programs.

Addressing petroleum hydrocarbon contamination: DTSC agrees and did not intend for the parenthetical statement in regulation "(excluding TPH PPRTVs)" to be interpreted to mean that the TPH mixture is not toxic, or that its toxicity should not be considered. The statement "(excluding TPH PPRTVs)" has been removed from the regulation and additional discussion of the issue will be included in the FSOR.

GENERAL COMMENT CATEGORY: RULE SUPPORT

General Support for the Rule

Comments: CPEO-02, CPEO-03, and DAAC-01

Comment Summary: Comments in this category express general support for the rule. One commenter noted that rulemaking is often disproportionately influenced by the regulated community because unlike the average citizen, the “regulated community” has greater resources and motivation to develop, modify, or “kill” rules and that U.S. Environmental Protection Agency (U.S. EPA) Integrated Risk Information System (IRIS) values are often established based on a disproportionate amount of input by the regulated community. Another commenter noted, “The rule will enhance the clarity, predictability and enforceability of the process of conducting Human Health Risk Assessments and will also aid in achieving consistency and predictability in establishing site remediation goals.” A commenter also suggested that adoption of the rule will ensure consideration [of] California’s policies in the selection of toxicity criteria,” and “achieve consistency and predictability in establishing remediation goals at hazardous waste sites across the state.”

Response: DTSC appreciates the public support for this rulemaking effort. DTSC carefully considers and weighs all stakeholder and public input into rulemaking process including comments received during the comment period. DTSC agrees that the rule provides consistency and protectiveness for the California population in the selection of toxicity criteria used for the evaluation and cleanup of hazardous waste and hazardous substance release sites throughout the state.

GENERAL COMMENT CATEGORY: BEST AVAILABLE SCIENCE

Best Available Science - General

Comments: CBG-03, CCEEB-04, CCEEB-06, DOD-01, DOD-02, DOD-07, DOD-07.1, DOD-07.2, DOD-07.3, DOD-19, INTG-03, MAT-01, and TS-02

Comment Summary: The overarching concern in this category was to ensure that the toxicity criteria listed in the rule use the “best available” science and that selected toxicity criteria are based on best science of the highest quality. The specific concerns are identified below:

1. One commenter stated that human health risk assessments, human health screening levels, and corrective action objectives must use the most protective standards with the best available science.
2. Concern was expressed that DTSC has not made public the process by which DTSC identified the appropriate toxicity criteria for inclusion in Appendix I, such as which science or journal publications are reviewed and how DTSC ensures that the

“sound science” source is credible and sound, that the study is well designed, and the findings and conclusions are appropriate.

3. A commenter recommended that DTSC focus on using the most up-to-date peer reviewed science when developing human health-risk based action levels and remediation goals.
4. A commenter expressed concern that the rule arbitrarily elevates the OEHHA toxicity criteria above more recent and nationally established “best science” toxicity data.
5. A commenter expressed concern that the proposed rule arbitrarily ignores more recent and nationally established “best science” data and does not include a mechanism to update the toxicity values. Also, the commenter expressed that the rule is contrary to the U.S. EPA Office of Solid Waste and Emergency Response (OSWER) Directive 9285.7-53 on the selection of toxicity values for human health risk assessment and management, and methodology advocated in a white paper developed by the Environmental Council of States (ECOS). The commenter also expressed concern that the toxicity criteria listed in the Appendix are static and inflexible, and could result in the use of criteria that are not based on best available science, thus conflicting with U.S. EPA guidance. Additionally, the commenter stated that DTSC (as California’s representative) is a member of the ECOS, a national non-profit, non-partisan association of state and territorial environmental agency leaders. The commenter claims that the proposed rule disregards the nationally developed and accepted practice of best available science where “the States, EPA, DoD, and other risk assessors should not be seeking to identify higher or lower toxicity values. Rather, the effort should continue to be to identify the best, or most scientifically defensible, toxicity value.”
6. A commenter expressed concern that the proposed rule sets an inappropriate precedent with respect to independent science. The commenter stated that for the past decade, U.S. EPA has placed an emphasis on scientific integrity and that favoring “best science” promotes the continual evaluation of toxicity criteria to ensure the most scientifically defensible result. The commenter believes that the proposed rule will create “a disincentive for toxicologists to re-evaluate existing toxicity criteria if a new evaluation results in a less protective value.” Also, that “there might be an inclination when developing toxicity criteria to choose a less appropriate study that would require additional safety factor(s)” and thus produce a more stringent, protective, toxicity criteria that the commenter feels would not be based on best available science. The commenter stated that the “regulation could promote the development of less-scientifically based values. In fact, the latest and best science may be intentionally ignored.” Finally, the commenter expressed concern that the rule would create professional conflicts for those researching toxicity criteria in California and that “one” (presumably regulators) might feel pressure to override the best available science.
7. Multiple commenters recommended that the rule be revised to ensure that the highest-quality toxicity criteria will be used even if outdated values are available from OEHHA or IRIS. The concern is that the proposed rule precludes use or proposed

use of an alternative toxicity criterion without flexibility and without regard for whether the toxicity criteria represents the best available science. In addition, the proposed rule may conflict with existing statutory requirements; such as California HSC §116365(c)(1).

8. A commenter believes that OEHHA used overly conservative uncertainty factors for the oral reference dose for beryllium and beryllium compounds in the California public health goal (PHG). Referenced is the *California EPA Public Health Goals for Chemicals in Drinking Water, Beryllium and Beryllium Compounds* (California EPA OEHHA September 2003). The commenter calls into question the uncertainty factor of 1,000 used by OEHHA in derivation of the beryllium PHG for drinking water. The commenter was unclear on what basis OEHHA uses to justify a more than 3X increase in the uncertainty factor, when both the California standard and the U.S. EPA Maximum Contaminant Level (MCL) for beryllium used the same data.
9. Last, two commenters stated that the use of the premise of California's diversity as a basis for the rulemaking is inappropriate. Concern was expressed that while California's diversity is important factor in many respects, it is not with respect to toxicity criteria for human health effects as the science is currently practiced. While California is a more diverse than other places in the United States, it is not the only place with these specific subpopulations, and U.S. EPA is required to consider these subgroups in their development of toxicity criteria. One of the commenters recommended that the discussion of diversity in the rule be replaced with language similar to that in the Initial Statement of Reasons (ISOR): "They [California's toxicity criteria] afford a greater protection of human health, safety, and the environment than the nationwide minimum standard provided by analogous federal toxicity criteria." Another commenter believes that federal guidance and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) already require and account for potential exposed subpopulations when evaluating risk to human health.

Response: The toxicity criteria listed in the Appendix I to the rule represent "best available science" of highest quality and considers California specific policies, consistent with HSC §25356.1.5. DTSC's response to specific concerns of the commenters are enumerated below.

1. DTSC agrees that risk assessments, screening levels, and corrective action objectives should be based on the most current sound scientific methods, knowledge and practices (collectively "best available science"). The best available science often also provides the most protective standards, but not in every case. Sometimes, more recent and scientifically robust studies demonstrate that earlier assessments overestimated impacts. Consistent with HSC §25356.1.5, DTSC has crafted this rule based on use of the best available science. As discussed herein in comment categories "Consistency with State Laws and Guidance" and "Flexibility in Selecting Toxicity Criteria and Setting Site-Specific Remediation Goals," a variety of factors are taken into consideration in developing remediation goals. Also, it is important to note that, for certain contaminants, a more protective OEHHA value is not listed in Appendix I, because in those cases, either the IRIS value represents the

best available science or the OEHHA value does not meet the peer review requirement of HSC §57004.

2. In developing the rule and Appendix I, DTSC used the DTSC Human and Ecological Risk Office (HERO) Human Health Risk Assessment (HHRA) Note 3 as its first draft list of toxicity criteria for the Appendix. HERO HHRA Note 3 provides DTSC's recommended toxicity criteria for use in human health risk assessments and is updated approximately semi-annually as new criteria become available from US EPA and OEHHA. For each contaminant in HERO Note 3, DTSC determined if the recommended toxicity criteria represented best available science based on the requirements of HSC §25356.1.5(c). DTSC then consulted with OEHHA to ensure the toxicity criteria listed in Appendix I underwent a peer review in accordance with HSC §57004. Toxicity criteria that did not meet the requirements of HSC §25356.1.5 and §57004 were then excluded from Appendix I in deference to corresponding IRIS values.

DTSC does not develop toxicity criteria; instead OEHHA develops toxicity criteria for California. OEHHA's process for deriving cancer and noncancer toxicity criteria is discussed in detail in the following technical documents: *Technical Support Document For the Derivation of Noncancer Reference Exposure Levels* (OEHHA June 2008), and *Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures* (OEHHA May 2009). These documents were released for public comment and external peer review prior to final issuance. Both technical support documents discuss the process used by OEHHA to derive cancer and noncancer toxicity criteria, state laws that OEHHA must follow, and OEHHA's toxicity criteria development process that includes internal OEHHA review, consultation with other agencies, a public comment period, public workshops, and external peer view prior to final issuance of that toxicity criteria. Both technical support documents are also available online, are listed in our ISOR as a reference that DTSC relied upon, and have been downloaded for inclusion in our rulemaking record that we will submit to OAL.

OEHHA uses a transparent process and the methods used to derive toxicity criteria have been published and peer reviewed in numerous guidance documents. In California, other state agencies, such as California Air Resources Board (ARB) and local agencies, such as air pollution control districts (including the South Coast Air Quality Management District, the largest local air pollution control agency in California and the nation) also rely on and use OEHHA toxicity criteria. DTSC has full confidence in OEHHA's staff, their expertise, and their professional review of the peer-reviewed scientific literature used in developing the toxicity criteria, and that their work is consistent with the application of best available science as required by HSC §25356.1.5(c) and the peer review requirements of HSC §57004.

3. DTSC agrees with the commenter's recommendation to use the most up-to-date peer reviewed science when developing human health risk-based action levels and remediation goals. DTSC believes using the OEHHA toxicity criteria listed in Appendix I satisfies this recommendation.

4. DTSC is not elevating OEHHA toxicity criteria above more recent and nationally established “best science” toxicity criteria. As described in the Initial Statement of Reasons (ISOR), the proposed rule will not change DTSC’s process for selecting toxicity criteria. DTSC has always applied best available science techniques, including many IRIS values current at the time of the risk assessment, and will continue to do so in the future as required by HSC §25356.1.5. For further discussion, please also see the comment category “Changing Existing Practice” below.
5. The commenter argues that the proposed regulation is contrary to the ECOS white paper and to OSWER Directive 9285.7-53. However, the commenter misinterprets the OSEWER Directive, which states in several places that risk assessors have discretion to vary from the directive’s tiered approach to selecting toxicity criteria. The commenter also overlooks the ECOS white paper’s explicit endorsement of the directive’s flexibility. Last, the commenter’s argument fails to acknowledge U.S. EPA’s and DTSC’s decades of practice using OEHHA criteria in lieu of IRIS numbers and OEHHA’s recent issuance of a more current, scientifically defensible, and appropriate toxicity criteria for tetrachloroethylene (PCE).

The commenter also expressed concerns about several issues addressed elsewhere in these comments, as follows: the concern regarding “best science” is addressed under response items one through four above and six through nine below. The commenter’s concern about not having a mechanism to update the toxicity values in Appendix I is addressed under the comment category “Updating the Rule.” The commenter’s concern that the proposed rule is “contrary” to OSWER Directive 9285.7-53 and ECOS guidance is responded to under the comment category “Consistency with Federal/State Laws and Guidance.” The commenter’s concern that the values in Appendix I are “static and inflexible” is addressed under the comment categories “Updating the Rule” and “Flexibility in Selecting Toxicity Criteria and Setting Site-Specific Remediation Goals.”

6. Like U.S. EPA, OEHHA and DTSC apply “independent science” with an emphasis on science integrity, transparency, and using best available science practices. In fact, OEHHA’s mission is “to protect and enhance public health and the environment by scientific evaluation of risks posed by hazardous substances.”¹ This includes evaluating current and proposed toxicity criteria to ensure the use of the most scientifically defensible criteria in human health risk assessments. Furthermore, as noted above, in developing toxicity criteria, OEHHA complies with HSC §25356.1.5(c) which requires use of the best available science practices.

DTSC toxicologists evaluate new toxicity criteria to determine if they represent best available science and applicability for risk assessments and, contrary to the commenter’s concern, there is no arbitrary incentive to develop and apply toxicity criteria that are simply more stringent and more health protective. For example, even though it is less protective than the OEHHA value, DTSC recommends using the recently released IRIS oral cancer slope factor for benzo(a)pyrene because the

¹ <https://oehha.ca.gov/> on January 26, 2018.

IRIS value is based on best available science. Similarly, we have removed the OEHHA 1,4-dioxane inhalation unit risk factor from Appendix I because DTSC has determined that the IRIS inhalation unit risk factor for 1,4-dioxane represents more recent and better science. For further discussion, please also see the comment category “Basis for Toxicity Criteria” below.

7. As discussed in the ISOR, the proposed rule promulgates past and current DTSC practice on selecting toxicity criteria; that practice is based on requirements of the applicable statute (HSC §25356.1.5) and federal guidance. Accordingly, DTSC will not revise the rule to allow use of an alternative toxicity criterion beyond that already specified in the rule because that would change DTSC’s practice of using the best available science. The toxicity criteria selected in the Appendix represent “best available science” and are peer reviewed. For further discussion on how the proposed rule will not be changing past or current practice, please also see the comment category “Changing Existing Practice” herein.

The commenter did not specify the reason for claiming the proposed rule could conflict with HSC §116365(c)(1), which applies to the Water Board and not to DTSC. However, DTSC notes that §116365(c)(1) requires use of the most current principles, practices and methods used by experts and shares similar language with HSC §25356.1.5; and §116365(c)(1) also emphasizes the protection of public health such that further revision of the rule is not necessary. As discussed in the ISOR, DTSC believes the rule is consistent with HSC §25356.1.5 and other existing statutory requirements. For further discussion on how the proposed rule is consistent with federal and state statutes, please see the comment category “Consistency with Federal/State Laws and Guidance” herein.

8. OEHHA is the expert agency that develops toxicity criteria for the State of California. DTSC is proposing to use only the OEHHA toxicity criteria that have undergone peer review. OEHHA may use a number of considerations in developing toxicity criteria for each compound and in determining the appropriate uncertainty factors to apply when developing an oral reference dose. We recommend the commenter contact OEHHA for further information on how they derived the toxicity criteria for beryllium in their public health goal document.
9. HSC §25356.1.5, subdivisions (b)(4) and (5) specifically require risk assessments to consider sensitive subpopulations, which would include infants and fetuses, and exposure and body burden that alter physiological function, among other things. Sensitive subpopulations would include those with high susceptibility to certain contaminants from genetic variations in metabolism or those facing higher contamination exposures through cultural (e.g., dietary) practices or geographic location, such as lower socio-economic or environmental justice communities who often face disproportionate environmental burdens. Therefore, the State Legislature has already required consideration of sensitive subpopulations in risk assessments under Chapter 6.8 (HSC §25300 et seq.). Accordingly, Section 69020(b) has been revised to add the phrase “consistent with HSC §25356.1.5” to acknowledge DTSC’s statutory obligation to consider sensitive California subpopulations that may be present in higher numbers here than elsewhere in the country.

Regarding the claim of insufficient studies, DTSC disagrees. The ISOR explains the justification for selecting toxicity criteria for inclusion in Appendix I. The supporting documentation discussing the studies used to derive the selected toxicity criteria in Appendix I are provided at the bottom of the following DTSC website:

<http://dtsc.ca.gov/LawsRegsPolicies/Regs/Toxicity-Criteria-for-Human-Health-Risk-Assessment.cfm>.

Regarding the comment that federal guidance and CERCLA already require accounting for potential exposed subpopulations when evaluating risk to human health, DTSC acknowledges U.S. EPA's obligation to set a single, 50-state standard that establishes a nationwide floor of health protection. However, a single nationwide standard is, by definition, not tailored to the demographics or cultural differences unique to each state. For reference, DTSC includes below HSC §25356.1(b)(4) and (5):

(b) Any health or ecological risk assessment prepared in conjunction with a response action taken or approved pursuant to this chapter shall be based upon Subpart E of the National Oil and Hazardous Substances Pollution Contingency Plan (40 C.F.R. 300.400 et seq.), the policies, guidelines, and practices of the United States Environmental Protection Agency developed pursuant to the federal act, and the most current sound scientific methods, knowledge, and practices of public health and environmental professionals who are experienced practitioners in the fields of epidemiology, risk assessment, environmental contamination, ecological risk, fate and transport analysis, and toxicology. Risk assessment practices shall include the most current sound scientific methods for data evaluation, exposure assessment, toxicity assessment, and risk characterization, documentation of all assumptions, methods, models, and calculations used in the assessment, and any health risk assessment shall include all of the following:

....

(4) Consideration of the effect of hazardous substances upon subgroups that comprise a meaningful portion of the general population, including, but not limited to, infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations, that are identifiable as being at greater risk of adverse health effects due to exposure to hazardous substances than the general population.

(5) Consideration of exposure and body burden level that alter physiological function or structure in a manner that may significantly increase the risk of illness and of exposure to hazardous substances in all media, including, but not limited to, exposures in drinking water, food, ambient and indoor air, and soil.

According to the 2010 Census², a higher percentage of California's population is of Asian descent, than every state except Hawaii. Different ethnicities can also have different cultural practices that can lead to different exposure and body burdens because of differences in diet or sources and levels of pollution at various locations across the state. For example, the paper by Spearow et al. (2017) discussed in Attachment 1 to this RTC on PCE discusses genetic, ethnic, and other variations in a population leading to increased susceptibility for some groups of people. This paper details numerous studies showing variation in PCE metabolism through the glutathione (GSH) conjugation pathway due to genetic and ethnic variation, as well as age, gender, diet, and pharmaceutical exposures.

Therefore, DTSC is proposing the use of peer-reviewed OEHHA toxicity criteria in this rule because the selected OEHHA values are more appropriate for California residents and workers consistent with HSC §25356.1.5, and as discussed in the ISOR. In line with this, California, along with several of other states, develop their own toxicity criteria and apply them within their boundaries.

Please also see herein the comment category "Rule Not Needed." While DTSC acknowledges that federal guidance and CERCLA require accounting for potentially exposed populations when evaluating risk to human health, the IRIS values set a 50-state standard floor of protection that is not tailored to any one state. DTSC developed the rule to ensure the use of toxicity criteria that factor in more sensitive sub-populations relevant to California-specific considerations such as the diverse demographic composition of California population, as discussed in the ISOR and consistent with HSC §25356.1.5.

Requested Revisions to Appendix I

Comments: CBG-01, CBG-02, CBG-04, CBG-05, CBG-06, CBG-08, CBG-09, INTG-02, RWQCB-01, and TS-04

Comment Summary: This comment category addresses requested revisions to specific toxicity criteria listed in Appendix I, for various reasons. Commenters noted that DTSC has not justified the omission of more protective OEHHA toxicity criteria from the appendix. A commenter recommended that the proposed rule be revised to describe the process for the initial selection of toxicity criteria listed in Appendix I and that a footnote be added indicating the listing procedure for the Appendix I values. More specifically, one comment noted that the inhalation unit risk (IUR) for arsenic, the oral cancer slope factor for 1,3-dichloropropene (DCP), cis-, trans-1,3-DCP and vinyl chloride, and the reference exposure level (REL) for epichlorohydrin and manganese (non-diet) were less stringent than the IRIS value and questioned why these less stringent OEHHA values were included in the Appendix. Related to this, the commenter noted that "California is obligated to use criteria at least as stringent as the U.S. EPA." Another comment included tables containing a detailed side-by-side comparison of corresponding OEHHA and IRIS toxicity criteria for many contaminants, and pointed out

² <https://www.census.gov/prod/cen2010/briefs/c2010br-11.pdf> (Table 2 on page 7)

that for “many” of the listed contaminants, the OEHHA toxicity criteria provide less protection than the “national minimum standards” (presumably the corresponding IRIS value), and that the rule unacceptably “mandates the weaker rather than stronger toxicity criteria.” Another comment noted that the proposed rule conflicts with HSC §25356.1.5(c). Last, a commenter claimed a lack of transparency because DTSC did not provide a table comparing the OEHHA and corresponding IRIS toxicity criteria, and that DTSC selected the “weaker” criteria between the two sources.

Response: The commenter is correct that DTSC cannot apply less stringent standards than that required under federal law. DTSC has reviewed Appendix I and made corrections as appropriate to ensure that listed toxicity criteria accurately reflect the needed stringency and best available science requirements in HSC §25356.1.5. Regarding the IUR and REL discrepancies for the listed contaminants discussed above, the OEHHA toxicity criteria were initially provided in Appendix I and have since been removed. This addresses the comment that stated, “California is obligated to use criteria at least as stringent as the U.S. EPA.”

During the development of Appendix I, DTSC used the DTSC Human and Ecological Risk Office (HERO) Human Health Risk Assessment (HHRA) Note 3 as the starting point and evaluated the toxicity criteria recommended in Note 3 based on the requirements of HSC §25356.1.5(c). DTSC believes the toxicity criteria listed in Appendix I meet the requirement of HSC §25356.1.5(c). There are several OEHHA toxicity criteria that are more health protective than their U.S. EPA IRIS counterparts, but do not comply with HSC §25356.1.5(c), and therefore cannot be included in Appendix I. The oral cancer slope factor from the OEHHA public health goal for benzo(a)pyrene falls into this category. For further discussion, please also see the comment category “Basis for Toxicity Criteria” herein.

DTSC appreciates the detailed analysis that the commenter provided in the side-by-side comparison tables. In the tables, toxicity criteria thought to be the more protective value between OEHHA, IRIS, and values listed in HERO HHRA Note 3 are highlighted. Please note, HERO HHRA Note 3 should not be used for this comparison as it is not a source of toxicity criteria, but instead provides currently recommended toxicity criteria from the following original sources: Rank 1: OEHHA; Rank 2: IRIS; and Rank 3: U.S. EPA Provisional Peer-Reviewed Toxicity Values (PPRTVs), the Agency for Toxic Substances and Disease Registry, and route-to-route extrapolated value(s) from OEHHA and IRIS where appropriate. Furthermore, the comparison table incorrectly includes Rank 3 sources since they may have not undergone sufficient peer review to meet the HSC §57004 requirements for incorporation into a formal regulation. In contrast, the Appendix I and IRIS values do satisfy the statutory peer review requirement.

DTSC reviewed the commenter’s side-by-side comparison Tables and identified several fundamental inaccuracies. For some contaminants, the commenter highlighted the less protective, rather than the most protective, oral cancer slope factors and inhalation unit risk factors. Toxicity criteria addressing the cancer potency is the upper bound estimate on the slope of a line that relates exposure (dose) to the corresponding probability or risk of cancer (oral cancer slope factor), or the upper-bound estimate of the excess

lifetime cancer risk which may result from continuous exposure to a chemical at a concentration of 1 microgram per cubic meter ($\mu\text{g}/\text{m}^3$) in air (inhalation unit risk). The steeper the slope of the line, the more potent the chemical, which results in a cancer potency value that will be a larger number. Thus, a chemical with a larger number is a more potent carcinogen than one with a smaller number, and is the more protective toxicity criteria.

Regarding use of the more protective value between the OEHHA REL and the IRIS reference concentration (RfC) for carbon tetrachloride, the commenter's table has a mathematical error in converting the IRIS RfC from mg/m^3 to $\mu\text{g}/\text{m}^3$. The OEHHA REL is more protective than IRIS. The commenter is correct that there are several OEHHA toxicity criteria that are more protective than IRIS, and that these criteria were not included in Appendix I. This is consistent with the rule requirements for applying best available science. The toxicity criteria listed in Appendix I from OEHHA have gone through a transparent peer-review process according to HSC §57004 and §25356.1.5(c) to be included in the regulation. For further information, please see the response herein under comment categories "Best Available Science" and "Basis for Toxicity Criteria."

DTSC disagrees with the comment that the rule conflicts with HSC §25356.1.5(c) as DTSC has scrutinized the Appendix I values carefully. HSC §25356.1.5(c) specifies application of the best available science, which includes consideration of peer review, as does the proposed rule.

DTSC disagrees with the comment that DTSC did not provide a rationale for not consistently applying the more protective OEHHA criteria for each contaminant. As explained in the ISOR and further herein, the proposed regulation specifies the selection of toxicity criteria based on best available science factoring in California-specific requirements set forth in statute, and in accordance with federal and state guidance.

Concerning the comment that the rule lacks transparency because DTSC did not provide a table comparing OEHHA and IRIS criteria for all contaminants, the HERO HHRA Note 3, Appendices A, B, and C provide the comparison the commenter is requesting, and can be found at: <http://www.dtsc.ca.gov/assessingrisk/humanrisk2.cfm>. Last, the rule does not select the "weaker" of the OEHHA and IRIS toxicity criteria; instead, the rule applies best available science methodology in determining the appropriate toxicity criteria.

Basis for Toxicity Criteria

Comments: CCEEB-07, CMTA-12, CMTA-12.1, CMTA-12.2, CMTA-12.3, CMTA-12.4, CMTA-12.5, CMTA-12.6, CMTA-16, CMTA-17, DOD-01, DOD-07.4, DOD-16, and INTG-07

Comment Summary: This comment category addresses concerns raised regarding the scientific basis for the OEHHA toxicity criteria listed in Appendix I. Those concerns included the following: that particular OEHHA toxicity criteria listed in Appendix I are simply the more protective value and do not reflect the most recent science, that there is inconsistency in selecting which OEHHA toxicity criteria are listed, and that OEHHA

toxicity criteria do not go through the same rigorous, or open and transparent, review process as the U.S. EPA values. The specific concerns are:

1. A commenter expressed concern that some of the OEHHA values listed in Appendix I are more stringent than the federal IRIS values, and, unlike the federal values, are not necessarily based on the most recent science.
2. A commenter stated that Appendix I appears to select the more stringent of the OEHHA and IRIS toxicity criteria, which contradicts the ISOR's stated goals of applying best available science, factoring in California-specific considerations. The commenter questioned why the less protective OEHHA criteria for formaldehyde and trichloroethylene (TCE), and the non-cancer toxicity criteria for hexavalent chromium are not provided in Appendix I. The commenter also questioned listing the benzo(a)pyrene OEHHA values in Appendix I, considering that in the August 28, 2017 rulemaking public workshop, DTSC stated its intent to use the recently released IRIS values. Last, the commenter disagreed with the inclusion of the OEHHA value for 1,3-butadiene in Appendix I.
3. Similar to the issue in item 1, a commenter noted that Appendix I contains OEHHA's inhalation unit risk (toxicity criteria) for 1,4-dioxane even though the corresponding IRIS value is more recent.
4. A commenter pointed out that Appendix I incorrectly characterizes the toxicity value for lead as an incremental value of 1 microgram per deciliter ($\mu\text{g}/\text{dL}$), rather than a benchmark incremental change in blood lead concentrations. The concern is that the proposed use of the value combined with OEHHA's decision that the soil lead concentration should correspond to a 90th percentile estimate of the increase in blood lead of 1 $\mu\text{g}/\text{dL}$ would restrict the use of site specific factors in evaluating risk and establishing remediation goals. Further, the commenter believes this approach would be inconsistent with federal and state law.
5. A commenter expressed concern that DTSC has a policy of always requiring the lowest available toxicity criteria regardless of whether the criteria are based on the best available science or consideration for site-specific circumstances that may warrant a different approach. The comment stems from text in HERO HHRA Note 3.
6. A commenter suggests that the OEHHA toxicity criteria are not subject to the same level of external scientific peer review and public input as the federal IRIS toxicity criteria. The commenter believes the ISOR needs to describe OEHHA's toxicity criteria determination process. The commenter then described several of OEHHA's programs for which toxicity criteria are developed and noted that unlike MCL development, OEHHA values are not promulgated through a formal rulemaking process, and suggested that this is required for toxicity criteria to be considered an applicable or relevant and appropriate requirement (ARAR). The commenter used the September 2016 OEHHA inhalation PCE toxicity criteria as an example that the OEHHA toxicity criteria are not subject to the same level of external scientific peer review as IRIS criteria undergo, and as a result, OEHHA adopted a more conservative criterion that included the GSH conjugation pathway when U.S. EPA

rejected this pathway in their analysis. Finally, the commenter claimed a lack of transparency in the selection of the criteria in Appendix I.

7. A commenter contends that rather than applying best available science, DTSC is mandating the use of the most stringent toxicity criteria. To support this, the commenter noted that OEHHA's IUR and oral cancer slope factor for TCE are not included in Appendix I.
8. A commenter stated that the proposed rule focuses on using the "most protective" criteria, which could be interpreted as the "lowest" value of the toxicity criteria sources and proposed adding the following as a definition of "most protective":
"...which focuses on using toxicity criteria that are the most scientifically valid for the exposure scenario and route being examined."
9. Finally, a commenter requested that the rule include text reinforcing the long-standing practice recommended in U.S. EPA's Risk Assessment Guidance for Superfund (RAGS) that toxicity criteria match the exposure duration of concern.

Response: DTSC reiterates that the proposed rule identifies the appropriate toxicity criteria developed using best available science factoring in California specific considerations, consistent with its mandate under HSC §25356.1.5. The specific concerns of the commenters are addressed below.

1. The commenter did not provide examples of OEHHA toxicity criteria listed in Appendix I that are not based on the most recent science compared to the federal counterpart. However, in response to this and other comments questioning selected toxicity criteria listed in Appendix I, DTSC conducted a review of the toxicity criteria listed in Appendix I to ensure the values accurately reflect the proposed rule requirements. Based on this review, DTSC removed from Appendix I the following toxicity criteria: the oral slope factor (CSFo) and IUR for carbon tetrachloride, the CSFo and IUR for chlordane, and the IUR for 1,4-dioxane.
2. Toxicity criteria for formaldehyde, TCE, and hexavalent chromium are not included in Appendix I since by state statute DTSC can be "no less stringent than" federal requirements (HSC §25356.1.5). Including these criteria in Appendix I would violate these statutes. Regarding the toxicity criteria for benzo(a)pyrene, consistent with DTSC's statements in the August 28, 2017 public workshop, DTSC uses the new U.S. EPA IRIS oral cancer slope factor. With respect to 1,3-butadiene, the U.S. EPA IRIS IUR is based on an epidemiological study (Delzell et al. 1995), and while the OEHHA value maybe an older value, there are inherent issues and uncertainties that come with basing values on epidemiological data. Furthermore, when developing the IRIS value, the U.S. EPA assessment noted concerns raised about the accuracy of the exposure estimates and in 2000, "Delzell et al. completed a re-assessment and concluded that the earlier a priori estimates were too low." The revised estimates still need to be evaluated by U.S. EPA, but if the "revised exposure estimates are valid, the leukemia portion of the cancer risk estimate would decrease somewhat" (U.S. EPA IRIS 2002). Other uncertainties associated with using epidemiological data include the appropriate dose metric for dose-response

analysis, which mathematical model to use to fit the epidemiological data, which modifying or confounding factors to include in the model, which parameter estimates to use in the model, and how to extend the relative rate models from the epidemiology study to derive lifetime excess leukemia incidence unit risk estimates for the population. Additionally, the precise model for low-dose extrapolation is unknown. The IRIS assessment also raised concerns that by only using the epidemiological data, risk could be underestimated since 1,3-butadiene may affect other sites in the human body that are not accounted for when using epidemiological data but can be accounted for when using rodent data. Based on all these issues, DTSC believes the OEHHA value for 1,3-butadiene represents best available science and has included this value in Appendix I.

3. DTSC re-evaluated the OEHHA and U.S. EPA IRIS 1,4-dioxane IUR toxicity criteria and agrees with the commenter. The IUR for 1,4-dioxane has been deleted from Appendix I. Please also see response to specific item 1 above and specific item 6 under the comment category “Best Available Science – General” herein.
4. DTSC agrees and has corrected Appendix I to reflect that the lead toxicity value is a benchmark incremental change in blood lead concentrations. To make this more apparent, DTSC has created Table B for the lead toxicity criterion alone. Accordingly, there are now two tables in Appendix I, Table A and Table B.
5. DTSC does not require the lowest available toxicity criteria regardless of whether the toxicity criteria are based on the best available science. Instead, DTSC applies best available science as an overarching determination in selecting toxicity criteria that are no less stringent than federal standards. In general, DTSC uses the more health protective toxicity criteria between OEHHA and U.S. EPA IRIS values factoring in best available science. But, as discussed above under specific items 2 and 3 and in the comment categories, “Basis for Toxicity Criteria,” and “Best Available Science – General,” DTSC does not always recommend the more health-protective OEHHA toxicity criteria.
6. OEHHA toxicity criteria listed in Appendix I must undergo a transparent peer-review process as required by HSC §57004 and §25356.1.5(c). Regarding the commenter’s request that the ISOR describe OEHHA’s process for determining toxicity criteria, please see the response to item 2 under the comment category “Best Available Science – General.” Since the proposed rule was noticed, DTSC has confirmed with OEHHA the peer-review status for contaminants listed in Appendix I, and updated Appendix I accordingly. Due to lack of peer-review the bromoform oral cancer slope factor, chlordane oral cancer slope factor and inhalation unit risk, and 1,3-dichloropropene, cis-and trans-1,3-dichloropropene oral cancer slope factor and inhalation unit risk factor have been removed from Appendix I. While OEHHA does not set toxicity criteria via a formal rulemaking process, the proposed rule will do so and require use of only those OEHHA toxicity criteria that satisfy the HSC §57004 peer review requirements. Further information regarding

this matter may be found herein in the General Comment Categories: Best Available Science” and “Definitions.” Regarding OEHHA’s September 2016 PCE inhalation toxicity criteria and the decision to include the GSH conjugation pathway when U.S. EPA did not, a more detailed discussion on this topic can be found herein the comment categories “Best Available Science – General,” “DTSC Tetrachloroethylene (PCE) Published Paper” and “Attachment 1 of the RTCs.”

7. DTSC omitted the OEHHA TCE toxicity criteria from Appendix I because these criteria are not based on the best available science and are less stringent than the more recently issued IRIS value. The 2011 U.S. EPA IRIS TCE toxicity criteria are based on more recent scientific studies, use multiple endpoints to derive the toxicity values, use updated physiologically based pharmacokinetic modeling, and represent the current scientific knowledge on the toxicity of TCE, compared to the 1990 OEHHA values.
8. The term “most protective” is not defined because it is no longer used in the proposed rule. DTSC’s “pre-rulemaking” version, publicly noticed in November 2016, did use the term “most protective.” However, this was deemed to be an inaccurate expression of the state’s past and current practice for selecting toxicity criteria. DTSC’s present practice is more accurately described as a multi-step process that employs the best available science and peer review, as well as California-specific protections and policies which comply with the requirements of HSC §25356.1.6 and §57004. These issues are discussed further in the “Basis for Toxicity Criteria” and “Best Available Science - General” comment categories.
9. The word “chronic” has been inserted in front of the words “reference exposure levels (RELs)” to §69021(a) and in Table A of Appendix I to the column header “Reference Exposure Level (REL)” to clarify the criteria listed and intended for use. The proposed rule does not address the use of non-chronic toxicity criteria such as the OEHHA acute 8-hour RELs.

DTSC Tetrachloroethylene (PCE) Published Paper

Comment: CMTA-18

Comment Summary: The comment focuses on the recently published review paper by DTSC staff entitled “*Review: Risk assessment Implications of Variation in Susceptibility to Perchloroethylene Due to Genetic Diversity, Ethnicity, Age, Gender, Diet and Pharmaceuticals*” (Spearow et. al. 2017). The commenter expressed concern with the paper’s position that a more conservative evaluation of PCE that considers the GSH conjugation pathway is necessary given the unique population diversity in California, and that the Asian population lacks the pathways for metabolizing PCE and removing toxic chemical species that can lead to increased cancer risk from the body. The commenter stated that no clear evidence is provided by the paper’s authors that additional protections are needed for these populations. Instead, the authors simply imply that because of reduced GSH metabolism in individuals of Asian descent, these individuals would produce other toxic metabolites not addressed in U.S. EPA’s analysis.

The commenter further claims that the authors provide no evidence in humans that additional toxic metabolites are in fact detected in this population. Last, the commenter questioned whether DTSC has conducted similar analyses for other chemicals, and concluded that there is no indication that this analysis is needed for PCE.

Response: DTSC disagrees with several statements in the comment, and does not believe the regulation should change based on this comment. The Spearow et al. paper (2017) is a literature review paper, and does not present original research. The paper details the available peer-reviewed published scientific research describing and documenting the variation in the GSH conjugation pathway of PCE metabolism, not just due to genetic and ethnic variation, but also due to age, gender, diet, and pharmaceutical exposures.

DTSC disagrees that the paper does not provide clear evidence of genetic and ethnic variation in the PCE metabolism pathway and refers the commenter to Table 2 and Figure 2 of the Spearow et al. paper (2017). Table 2 shows gene frequency of single nucleotide polymorphisms for candidate genes that are known to code for enzymes responsible for GSH conjugation. That table shows the wide variation in gene expression across different ethnic groups and further discussion of this issue is on page 17 of the paper. Figure 2 shows the PCE metabolism pathway and the enzymes involved in activation and detoxification of PCE. The paper discusses the various enzymes and the variation seen in the scientific literature on pages 15, 17, 19, and 31. Additionally, the paper discusses reported differences in rates of PCE metabolism, or activity of enzymes involved in PCE metabolism, measured in original experimental studies on human kidneys and rodents from key researchers in the field (see pages 15, 18, 19, and 26 -- human kidney; pages 24, 26 33, and 35 -- rodent). For a more detailed technical explanation regarding the concerns stated in the comment, please see Attachment 1 at the end of the Response to Comments.

Total Petroleum Hydrocarbons

Comments: DAAC-02, HB-02, HB-03, and RWQCB-02

Comment Summary: Commenters requested the rationale for excluding U.S. EPA PPRTVs for TPH from the proposed rule. One commenter expressed concern that the proposed rule precludes the use of any of the U.S. EPA PPRTVs for TPH toxicity criteria regardless of best available science practice, and recommended replacement language for §69021(c). Another general concern expressed in the comments was that the rule implies TPH mixtures have no toxicity and thus would not be accounted for when assessing a site with TPH contamination. To alleviate this concern, one commenter proposed TPH-criteria replacement language for the ISOR.

Response: The ISOR explained the rationale for excluding U.S. EPA's PPRTVs for TPH toxicity criteria in the rule. Please note that the proposed rule does not specifically prohibit use of non-cancer TPH U.S. EPA PPRTVs toxicity criteria, other state toxicity criteria, the forthcoming Interstate Technology & Regulatory Council Total Petroleum Hydrocarbon guidance document, or DTSC's forthcoming HHRA Note on TPH mixtures, if the criteria are specific to a laboratory analysis method. DTSC considers each of

these to be subdivision (c) sources that the project management team may determine is appropriate to use depending upon the site-specific circumstances. To address the concerns discussed above, the regulation text under §69021(c) has been revised to remove the words “(excluding TPH PPRTVs)” and a sentence was added that states, “However, use of the TPH PPRTVs is not required, but may be determined to be appropriate based on site-specific circumstances.”

Furthermore, to address the commenter’s concern on how TPH is addressed, the rulemaking package Final Statement of Reasons (FSOR) will provide a more thorough rationale based, in part, on the information provided herein under the comment category “Definition for Total Petroleum Hydrocarbons” and the following discussion.

The source for TPH mixtures toxicity criteria depends on the analytical method used to analyze the samples for TPH. TPH toxicity criteria may be available from other sources as defined in the proposed rule under §69021(c). Note that §69021(c) of the proposed rule neither provides a comprehensive list of alternate reference sources nor does it establish a hierarchy for sources within the subdivision. Until OEHHA or U.S. EPA IRIS develops 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.

Changing Existing Practice

Comments: CMTA-08, CMTA-09, CMTA-10, CMTA-22, CMTA-25, CMTA-28, and CMTA-30

Comment Summary: This category addresses comments expressing concern that the proposed rule changes the current process for selecting toxicity criteria and significantly affect the process for site assessment, remediation action selection, and establishing remediation goals for a site.

Specifically, commenters were concerned that (1) the discretion of the lead agency concerning which toxicity values to use in developing preliminary remediation goals (PRGs) would be largely eliminated; (2) the remediation goals derived from toxicity values would automatically become ARARs; and (3) the remediation goals derived from toxicity values would be set at a 10^{-6} risk level instead of in the 10^{-4} to 10^{-6} risk range. Moreover, the commenters believe these changes would result in more stringent cleanup standards than currently applied under existing procedures and hence, more expensive remedies, the generation of larger waste quantities requiring treatment or disposal, and would have an overall negative impact on Brownfields redevelopment sites. Finally, a commenter believes DTSC is required to perform an economic impact analysis of the above listed changes.

Response: As further described in the ISOR and herein under the comment category “Basis for Toxicity Criteria,” the rule does not change the process for selecting toxicity criteria. Consistent with its statutory mandates and federal guidance, DTSC has always sought to apply best available science which includes incorporating current sound scientific knowledge and practices (HSC §25356.1.5) when developing and selecting

toxicity criteria. In developing the rule, DTSC used its working guidance, HERO HHRA Note 3 as a starting point. As part of the rule development, DTSC conducted a thorough review of HERO HHRA Note 3 values and discovered some that had not been peer reviewed or considered best available science. Toxicity criteria that presently do not meet the requirements of HSC §25356.1.5 and §57004 were then excluded from Appendix I in deference to corresponding IRIS values. It appears from the comments on this issue that these differences looked like a change in practice, when instead, work on this rule functioned as a review and update of the HERO HHRA Note 3 values. Thus, where DTSC discovered that the criteria listed in HERO HHRA Note 3 did not meet best available science requirements, those values were excluded from Appendix I, causing the rule's values to differ from the values in HERO HHRA Note 3.

As described in the "Flexibility in Selecting Toxicity Criteria and Setting Site-Specific Remediation Goals" comment category, the rule does not affect the risk management process or how site-specific conditions will factor in to the selection of remediation goals. Because the rule reflects DTSC's present practice and obligation to use best available science, this rule will not result in more stringent cleanup standards, more expensive remedies, generation of larger waste quantities requiring treatment or disposal, or a negative impact to Brownfields redevelopment projects. Regarding the commenter's ARARs concern, the rule will promulgate toxicity criteria that are one of several factors used to develop remediation goals but do not set remediation goals at any particular level of risk. While toxicity criteria contained in the rule may ultimately be adopted as ARARs, they will remain one of many factors in the development of remediation goals for California cleanup projects. DTSC seeks to apply the Appendix I criteria to all sites undergoing cleanup in California, when remediation goal decision making is based on human health risk. This was the case before the rule was proposed as well.

Please see herein the comment category "Economic Impact (Form 399)" for information an explanation of the Economic Impact Analyses for the proposed rule.

Changing Present Practice – OEHHA Values Not Required

Comment: CMTA-07

Comment Summary: The commenter states, "Contrary to the Department's [DTSC] assertions in the ISOR, the proposed regulations do not simply codify existing policy and procedure with respect to selection of toxicity criteria. Nor do they appear to be limited just to this one aspect of the risk assessment and remedy selection process. OEHHA values are not currently ARARs and the stated purpose of the proposed regulations is to qualify them as ARARs. A proposed remedy must satisfy ARARs to be selected as the remedial action. While DTSC may generally use OEHHA toxicity values to establish clean up criteria at a given site, it is not legally required to do so."

Response: DTSC is promulgating this regulation to assure that toxicity criteria used for calculating risk-based screening numbers and remediation levels at both state and federal sites in California will meet a uniform best available scientific standard, be applied consistently, and be more readily enforceable. DTSC acknowledges that one

goal is for the Appendix I values to apply to sites statewide, including federally owned and overseen Superfund sites, and that with promulgation of the rule, toxicity criteria that are used will be consistently based on the best available science. Further discussion on this is provided herein under the comment category “Changing Existing Practice.”

Pre-Rule Making Versus Proposed Regulation Versions

Comment: CBG-07

Comment Summary: The comment is that the draft pre-rulemaking version of the regulation publicly noticed on November 11, 2016, and discussed at DTSCs December 12, 2016 public workshop differs from the proposed rule, noting that the draft, pre-rulemaking version required use of the most protective toxicity criteria from three sources: OEHHA, U.S. EPA IRIS, and U.S. EPA PPRTVs. The commenter suggests that DTSC has “backed down” from the draft pre-rulemaking version and that the proposed rule mandates use of less protective standards than the previous version.

Response: While the two versions of the proposed rule do differ, the current version more accurately reflects DTSC’s practice for the last two decades and complies with the statutory requirements to be no less stringent than federal regulations and to use best available science under HSC §25356.1.5 and HSC §57004. In addition, the proposed rule still specifies the more protective toxicity criteria from OEHHA as the first preferred source, U.S. EPA IRIS as the second or default source, and then lists multiple potential third choice sources consistent with the best available science requirement of HSC §25356.1.5. This ensures that the toxicity criteria used in the human health risk assessments, deriving risk-based screening levels, and setting risk-based remediation goals apply the best available science and are health-protective. DTSC acknowledges that several OEHHA toxicity criteria exist that are more protective than IRIS and are not included in Appendix I; however, these did not go through sufficient peer-review to satisfy the HSC §57004 requirement and thereby do not qualify for listing in Appendix I.

GENERAL COMMENT CATEGORY: SITE EVALUATION

Flexibility in Selecting Toxicity Criteria and Setting Site-Specific Remediation Goals

Comments: CCEEB-01, CCEEB-11, CMTA-01, CMTA-03, CMTA-05, CMTA-14, CMTA- 30, INTG-04, LCC-01, LCC-02, LCC-03, and LCC-04

Comment Summary: This category relates to concerns that the rule eliminates flexibility in selecting toxicity criteria and site-specific remediation goals and eliminates the discretion of risk managers (e.g., those responsible for identifying, developing or approving remedial actions based on evaluation of human health and ecological risk at hazardous substance release sites) to consider the best available science and site-specific circumstances in evaluating a site and determining remediation goals. Commenters were concerned that there will be a concomitant increase in remediation

costs, generate more waste that will need to be disposed of, and negatively impact property redevelopment. A commenter felt that the rule will not allow risk managers to apply the risk management approach specified in the NCP.

Specific issues raised by commenters include the following:

1. The inclusion of a remediation goal definition in the rule (in §69022(c)) would “anchor cleanup levels to the low end of the NCP risk range.”
2. Specifying the toxicity criteria as the rule requires “runs contrary to the purported goal of tailoring remedies to site-specific circumstances, including but not limited to potential variability among sensitive populations.”
3. During the August 28, 2017 workshop, DTSC staff said it was DTSC’s intent to “anchor the chemical hazard assessment component of the risk-based remedy selection process at the low end of the NCP risk range” thereby removing risk manager’s ability to use “discretion to consider all relevant site-specific factors in health risk assessments” and cited the ISOR’s discussion that some metals may be present at a given site in a form different than that for which the toxicity criteria for that metal was derived.
4. The rule should include a statement “...that allows for consideration of alternate toxicity values based on site-specific considerations, the confidence and/or certainty in the toxicity value, or the availability of new toxicity information and/or data evaluation techniques to avoid delays in decision-making on sites or moving forward with decisions without use of the best science.”

Response: DTSC is required to apply best available science for selecting toxicity criteria, and also apply criteria no less stringent than federal values; and as such, DTSC’s project (risk) managers do not have “flexibility” in choosing toxicity criteria for risk assessments in part given the requirements of HSC §25356.1.5. Rather, based on suspected and known contaminants of concern, DTSC’s toxicologists evaluate available toxicity criteria and identify those that represent best available science for use in risk assessments and to develop risk-based screening levels and remediation goals. This process is discussed in more detail in the Comment Categories “Basis for Toxicity Criteria” and “Best Available Science – General.”

Pursuant to the NCP, risk managers use the results of the human health risk assessment and other site-specific factors to determine if a remedy is warranted, and if so, design the remedy and set remediation goals accordingly. Examples of other factors (e.g., site-specific considerations) include the reliability of sampling results, contaminant background concentrations, confidence in the conceptual site model (CSM) and the data used to support the CSM, exposure pathways, potential receptors, projected land use, public input, and the technical feasibility of the remedy. Under certain circumstances, the NCP provides for remediation goals that lie within the risk management range of 1×10^{-4} to 1×10^{-6} in consideration of mitigating site-specific factors such as those identified above. The process of evaluating the above-listed site-specific factors when determining site remediation goals provides the necessary “flexibility” in selecting remediation goals. Issue-specific responses are provided below:

1. The commenter expressed concern that the remediation goals definition in the rule would “anchor” final cleanup numbers to the low end of the risk range. The definition does not “anchor” final cleanup numbers to any specific risk level because the rule specifies the selection of toxicity criteria which are only one of several factors that are used to select remediation goals.
2. DTSC reiterates that the rule does not eliminate the risk management process for remedy selection as described above. Toxicity criteria are not site-specific values and the same toxicity criteria would be selected regardless of the site use/reuse and receptors.
3. At the August 28, 2017 public workshop, DTSC indicated that a more protective toxicity criterion would anchor the risk range at lower levels than a less protective toxicity criteria. This rule does not default to or anchor the remediation goal at the low end of the NCP risk range. DTSC’s intent then and now is that toxicity criteria are one of many factors in the risk assessment whose results aid in determining the need for a remedy and the appropriate remediation goals for a site if a remedy is needed. Regarding the concern about metals, if the form of a metal onsite differs from the form of the metal on which the toxicity criteria are based, then as discussed in the ISOR, the toxicity criteria in Appendix I may not be the most appropriate for the site. Risk assessors are to consider this when developing the risk assessment. Accordingly, the rule will not change how risk assessments evaluate metals or how risk assessments are used in selecting remediation goals.
4. As explained above, toxicity criteria are developed generically, and not specific to a site. More recently issued toxicity criteria and site-specific considerations (such as land use) are considered in the risk assessment and the site evaluation to determine whether or not a remedy is needed and what the remedy should be. Additionally, as discussed in the “General Comment Category: Best Available Science,” the proposed rule identifies the appropriate toxicity criteria based on best available science and practice. Confidence in the value as well as new relevant information were taken into account in determining which toxicity criteria to incorporate into Appendix I.

Screening Numbers

Comment: CMTA-19

Comment Summary: The ISOR discusses how OEHHA previously developed screening levels pursuant to HSC §57008, and that these screening levels were never promulgated and are only an advisory number that have no regulatory effect. The commenter quoted the following from the ISOR: “The ISOR then states that the proposed regulation continues the Department’s [DTSC] *‘past practice by adopting and mandating the use’* of OEHHA’s screening levels” [emphasis in original], and then states that with the proposed rule, DTSC is changing past practice by formally adopting OEHHA screening levels that were previously not promulgated screening levels.

Response: The proposed rule does not promulgate screening levels. Instead, it does two things with respect to screening levels: 1) sets the toxicity criteria to be used; and

2) sets individual chemical cancer screening levels at 1×10^{-6} and individual chemical non-cancer hazard at 1. The actual sentence in the ISOR reads: “*past practice by adopting and mandating the use of OEHHA’s scientifically supported, peer-reviewed toxicity criteria (listed in Appendix I)*” [emphasis added], and does not mention the OEHHA screening levels. DTSC also notes that the ISOR reference to the OEHHA screening levels should have been removed. DTSC will clarify this in the FSOR.

Screening Levels Versus Remediation Goals

Comments: CCEEB-09 and TS-03

Comment Summary: To ensure flexibility in determining the need for a remedy and selecting site-specific remediation goals (see “Flexibility in Selecting Toxicity Criteria” comment category above), one commenter requested that the rule include language specifying screening levels as: “An incremental excess lifetime cancer risk to an individual of 1×10^{-4} to 1×10^{-6} , and as outlined in the NCP” while another commenter requested, to ensure clarity on application, that the rule specify that it is not intended to require that remediation goals be set at 1×10^{-6} incremental risk or a hazard quotient of 1.

Response: It is not appropriate to revise the regulation to include the proposed definitions of screening levels and remediation goals, as suggested by two comments, because both proposed definitions are inconsistent with the NCP. Consequently, DTSC’s statutory obligation to avoid being inconsistent with federal law and guidance bars the adoption of such definitions. Moreover, the NCP does not actually set screening levels at the range indicated in the comment. The NCP directs site managers to evaluate cleanup remedies if cumulative cancer risk falls within or above the risk management range noted by the commenter, and to use this same range to determine if a site needs a remedy.

Government agencies (such as U.S. EPA and DTSC) have developed generic contaminant-specific screening levels to aid site managers in determining if contamination may be present at unsafe levels for unrestricted use and may warrant further action (e.g., investigation or remedy evaluation). For this reason, screening levels are intentionally set at a conservative 1×10^{-6} individual contaminant cancer risk. Site-specific factors do not apply when setting screening levels. Screening levels are not intended to be remediation goals although some responsible parties have adopted a generic screening level as a site-specific remediation goal.

Regarding the request to have the rule state that it is not intended to require remediation goals to be set at 1×10^{-6} incremental risk or a hazard quotient (HQ) of 1, the rule only requires that (risk-based) remediation goals be based on the toxicity criteria in accordance with §69021. The rule does not set remediation goals at any particular point in the risk management range, and is intentionally silent on that issue to defer to the regular NCP risk-management process and the flexibility provided within that process. The rule neither requires nor prohibits risk managers from setting remediation goals at 1×10^{-6} incremental risk (or HQ of 1), or at any other point within the risk

management range. The remediation goal-setting decision is made for each individual site based on site-specific facts and conditions.

Background Levels

Comment: CMTA-21

Comment Summary: The commenter raises a concern that the proposed rule will eliminate consideration of background concentrations in determining the need for a remedy determination and in setting remediation goals. This in turn would exacerbate the problem with diminishing landfill capacity of the Legislature's mandate in the Integrated Waste Management Act (Public Resources Code §40000 et seq.).

Response: DTSC disagrees with the comment and declines to revise the rule. The scope of the proposed rule is limited to selecting the appropriate toxicity criteria for risk assessments, human health risk-based screening levels, and human health risk-based remediation goals. Background levels will still factor into the risk assessment and the selection of remediation goals. HERO HHRA Note 4 (October 26, 2016) recommends that all detected hazardous compounds initially be identified as contaminants of potential concern (COPCs) and included in the quantitative risk assessment, including screening level risk assessments. HERO HHRA Note 4 also recommends that the assessment include calculation of both the site-related risk and hazard index, and the total risk and hazard index on a site-specific basis. HERO HHRA Note 4 also states that in some cases, HERO may agree with eliminating specific COPCs from full consideration in a human health risk assessment due to specific factors, such as comparison to background levels for naturally occurring compounds.

DTSC's Preliminary Endangerment Assessment Guidance Manual (DTSC, October 2015) states that COPCs present at levels equivalent to background concentrations can be eliminated from the screening evaluation. However, it also states that if background risk might be of concern, it should be calculated separately from site-related risk.

Most importantly, DTSC does not generally require responsible parties to cleanup below ambient background levels. Consistent with state practice under HSC §25356.1.5 and federal guidance, when evaluating the site's hazard, risk managers consider and factor background levels into the decision for remedy need and remediation goals. The proposed regulation will not change current practice for handling background levels at sites. An additional discussion will be added to the FSOR to address background levels and current DTSC practice.

Risk Assessment (Co-Exposure)

Comment: DAAC-03

Comment Summary: The commenter proposes that the regulation be amended to address co-mingled contamination from multiple contaminants found in soil, soil gas, and groundwater. To accomplish this the commenter recommends the following:

1. Identify and incorporate variability in human exposure and vulnerability into health risk assessments;
2. Use science based default assumptions that protect people when

information is missing; 3. Incorporate information about potential impacts of exposure to multiple chemicals and look at social conditions; and 4. Assume that even low levels of exposure are associated with some level of risk, unless there is sufficient data to contradict the assumption.

Response: In general, this comment is about cumulative impact from exposure to multiple contaminants and appears to also be related to the “precautionary principle.” The precautionary principle generally holds that protective measures should be taken when some cause and effect relationships are not fully established. However, these issues are beyond the scope of the proposed regulation.

Note that, where possible, these concerns and the commenter’s recommendations are factored into the human health risk assessment process. Recommendations 1 and 2 are incorporated as much as possible into the toxicity criteria derivation according to DTSC’s and U.S. EPA’s respective guidance documents and DTSC’s statutory requirements. The default assumptions used in human health risk assessments are based on statistical data on various factors such as drinking water consumption; soil ingestion; dermal factors; consumption of fruits and vegetables, fish, meats, dairy products, and homegrown foods; human milk intake; human activity factors; consumer produce use; and building characteristics. For recommendations 3 and 4, the current state of risk assessment does not provide a mechanism to address the issue of co-exposures to toxic chemical mixtures with respect to the potential synergistic or antagonistic effects, but risk managers routinely consider this possibility when making remediation decisions based on human health risk. DTSC uses the best available and most current risk assessment procedures when assessing risk at a site.

Assessment of Multiple Contaminants

Comment: DAAC-04

Comment Summary: The comment discusses the importance of site characterization at a site with multiple contaminants that have differing detection and monitoring methods. The comment emphasizes the need for clarity in application of the rule in characterization of contaminated sites with multiple contaminants.

Response: DTSC agrees that site characterization is very important, and notes that the rule applies to toxicity criteria used in risk assessments and not directly to sampling plans or methods used to characterize contaminated sites. The rule is intended to identify appropriate toxicity criteria for risk assessments, and to calculate human health risk-based screening levels and risk-based remediation goals. DTSC has crafted the rule to be as clear as possible in selecting appropriate toxicity criteria for evaluating a site.

Please note the rule does not specify requirements for site characterization or, among other things, monitoring methods and detection levels. Analytical detection limits are considered when developing the workplan and efforts are made to ensure that detection limits meet promulgated standards and screening levels. Detection limits are also taken into consideration in the risk assessment and by risk managers when evaluating the site. Based on other portions of the comment letter, DTSC understands the commenter

is also concerned about toxicological effects resulting from simultaneous exposure to multiple contaminants; this issue is discussed further herein in comment category “Risk Assessment (Co-Exposure).” HSC §25356.1.5(b)(3) and DTSC’s present practice include “[c]onsideration of possible synergistic effects resulting from exposure to, or interaction with, two or more hazardous substances” present at a site.

Variance Language Request

Comment: CCEEB-05

Comment Summary: The commenter recommended addition of a variance procedure to allow DTSC flexibility in selecting toxicity criteria that would be most appropriate and based on site-specific considerations.

Response: Toxicity criteria are contaminant-specific measures of potential health risk used in risk assessment calculations. Toxicity criteria relate the magnitude of adverse health effects from exposure to a chemical and are not specific to a given site. As discussed in the comment category “Flexibility in Selecting Toxicity Criteria and Setting Site-Specific Remediation Goals,” site-specific considerations are factored into the risk assessment for each site, and do not affect the choice of toxicity criteria. Since the risk assessment considers site-specific considerations, there is no need for a variance procedure in the regulation. Further discussion of this issue is included herein under the “General Comment Category: Best Available Science.”

Five-Year Reviews and Changes to Existing Decisions

Comments: CMTA-27, INTG-08, INTG-10, L&W-04, and L&W-05

Comment Summary: Commenters expressed concern that the rule sets more stringent cleanup standards than those used in prior decision documents. This, in turn, would result in the “reopening of remedial decisions” and additional cleanup for sites where a remedy has already been determined. In particular, commenters expressed concern that “rule-mandated more stringent toxicity criteria” would have to be applied to a site undergoing a Five-Year Review, and that the rule would lead interested parties petitioning DTSC to reopen closed sites. One commenter requested language in the rule that the rule will only be applied prospectively and not retroactively to prior decisions. Another commenter requested that “the proposed rule...state that it does not apply to sites for which a Record of Decision or equivalent document selecting a remedy has already been issued.” Two commenters requested that the rule clearly state that it is not intended to be an ARAR in the Five-Year Review process.

Response: As discussed in the ISOR, the rule does not set remediation goals for hazardous waste and hazardous substance release sites. It selects toxicity criteria which are one of many factors that are applied in the risk assessment and determining remediation goals. Accordingly, the rule neither requires “more stringent standards” than those applied in prior decision documents, nor does the rule “open up” prior decision documents. This rule will apply to all future decision documents in accordance with applicable state and federal law. With respect to decision documents undergoing Five-Year Reviews, the primary issue being evaluated is the continued protectiveness

of the remedy. Toxicity criteria for constituents of concern are routinely reevaluated during the Five-Year Reviews to ensure that any assumptions made at the time of the original risk assessment continue to provide for a protective remedy.

Under the NCP and federal guidance, sites contaminated with hazardous substances must undergo review every five years during and after remedy implementation to assess whether the remedy selected still achieves the desired level(s) of protection. In that Five-Year Review, the lead agency must determine if 1) toxicity criteria have changed for any site contaminant, and 2) new toxicity criteria have been developed for any site contaminant that previously lacked toxicity criteria. The rule changes nothing in the Five-Year Review process but ensures consistency in the toxicity criteria DTSC would have otherwise put forward. New or updated toxicity criteria already require consideration in the Five-Year Review process. For these reasons, and because HSC §25356.1.5 favors consistency with federal law and guidance, DTSC does not believe the commenters' proposed Five-Year Review language is necessary.

With respect to "re-opening" closed sites, consistent with applicable law and guidance, DTSC typically will re-examine a "closed" site if there is evidence or substantial community concern that the remedy is not protective. However, of greatest significance, the rule does not apply more stringent standards than in the past for development of screening levels, remediation goals, or for Five Year Reviews. Furthermore, there is no provision in the rule that automatically triggers re-evaluation of a site's remedial status.

GENERAL CATEGORY: RULE PROCESS

Updating the Rule

Comments: CMTA-23, DOD-05, DOD-06, DOD-09, DOD-13, DOD-16, DOD-17, INTG-01, L&W-01, STO-02, and TS-01

Comment Summary: The primary theme of this comment category is the questioning of how toxicity criteria in the rule will be updated when new (appropriate) toxicity criteria are developed, and the frequency of amending the rule to update toxicity criteria. Specific concerns were:

1. That the rule results in "static" or fixed criteria that may become outdated potentially resulting in inappropriate risk assessments, screening levels, remediation goals, and actions at a site;
2. How "dated" criteria would be removed and how responsible parties would proceed if a chemical is not listed in any of the listed sources;
3. That Appendix I criteria may be modified or removed, or new criteria added following an "internal peer review process" without public input;
4. That action at sites could be delayed (with resulting deleterious impacts) "until these issues are resolved" or at least until the rule is amended with current appropriate toxicity criteria;

5. That the rule did not provide clarity on what triggers updates or the process for updating the criteria in Appendix I;
6. There was a lack of clarity on whether the criteria will be routinely reviewed and revised as new scientific information becomes available, and that the rule is unclear as to how new peer-reviewed scientific studies would be entered into the selection hierarchy; and
7. Finally, rather than DTSC periodically amending the rule (to reflect current toxicity criteria), one commenter suggested the rule instead reference the OEHHA and IRIS databases to ensure the promulgated criteria are fully current with the OEHHA/IRIS published values.

Response: 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. To address the concern that the Appendix I values are “dated,” additional text has been added to §69020(c)(3) and §69021(a) stating that the toxicity criteria listed in Appendix I shall be used so long as these values remain no less stringent than the IRIS toxicity criteria. DTSC originally wanted to refer readers to the OEHHA and IRIS databases as suggested, but not all OEHHA criteria are included in Appendix I, so a simple reference to the OEHHA database will not work.

DTSC has determined that over the past ten years, IRIS generally releases from two to four new or updated toxicity criteria annually. To the extent that IRIS issues a value more stringent than an Appendix I value, that IRIS value will be the proper value to use according to HSC §25356.1.5 and the “no less stringent” language now added to the revised rule. To incorporate future new or updated OEHHA values or delete an OEHHA value to reflect availability of a more stringent IRIS criteria, DTSC will amend the rule as needed, probably on an annual basis. When OEHHA is developing a new value, 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 regularly monitors such developments, and receives those notices. Note that rule amendments are done in accordance with the California Administrative Procedures Act (APA), which is an open and transparent process that includes public input. In regard to the comment that rule updates will undergo only an internal DTSC internal “peer review,” please note that OEHHA and IRIS perform the “peer review” when developing toxicity criteria; this is not done by DTSC. As has always been done, DTSC will review new or updated OEHHA and IRIS criteria and determine if they meet the HSC §25356.1.5 and §57004 requirements for inclusion in the rule, and, if so, will incorporate them.

Although the rule will be amended regularly, there may be a “lag time” when some criteria in the rule do not reflect the newest peer reviewed OEHHA and IRIS values. To address this complication, as is currently done, DTSC recommends site toxicologists and project managers monitor these updates and consider these updated criteria in current work, knowing that the criteria will be included in the next rule amendment. For example, for a given site, if a Record of Decision (ROD) is being developed, the site managers should ensure that the ROD consider pending new or updated toxicity

criteria. This approach is already current practice without the rule. For these reasons, the lag time in updating the rule should have rather limited impact on site cleanup programs.

In response to the query on whether criteria in the rule will be routinely reviewed and revised as new scientific information becomes available as mentioned above, DTSC intends to amend the rule on a regular basis. As is currently practiced, DTSC will monitor OEHHA and U.S. EPA activities on toxicity criteria development/updates and identify those that qualify as peer-reviewed OEHHA and IRIS criteria that will then be adopted by rule amendment as described herein.

Toxicity Criteria Approval - §69021(c)

Comments: INTG-05, L&W-02, and L&W-03

Comment Summary: The comment theme is that the proposed rule offers little guidance as to how the HERO Supervising Toxicologist would approve toxicity criteria under proposed §69021(c). There is concern that a more stringent value based on older or less certain science would be selected. Two commenters recommend revising the rule to provide guidelines for evaluating and selecting toxicity criteria among the listed sources. Additionally, one commenter recommended that DTSC consider specifying the use of ECOS (2007), or EPA guidance, or other applicable guidance to ensure consistent selection of toxicity criteria and decision making.

Response: DTSC concurs with the recommendation to provide more detailed guidance as to how the HERO Supervising Toxicologist will approve toxicity criteria under §69021(c). DTSC will provide a general explanation in the FSOR and will provide detailed guidance in a future HHRA Note that will be published on DTSC's public website. DTSC's practice has and will continue to follow relevant U.S. EPA guidance documents, and consider the recommendations in the white paper, *ECOS-DoD Sustainability Work Group, Identification and Selection of Toxicity Values/Criteria for CERCLA and Hazardous Waste Site Risk Assessments in Absence of IRIS Values* (April 23, 2007). Please note that when selecting toxicity criteria from a subdivision (c) source, there is frequently only one value (among the sources) available for a given contaminant. Current practice is that when selecting a subdivision (c) source, HERO recommends using the values listed in the HERO HHRA Note 3 in conjunction with the toxicity criteria in the U.S. EPA RSL table. The future approach, to be detailed in a forthcoming HERO HHRA Note, will be done similar to current practice. The forthcoming HERO HHRA Note will have a table that lists the HERO Supervising Toxicologist approved "other" toxicity criteria, and will be updated semiannually. For a given site, use of any value not in the table will require approval by the HERO Supervising Toxicologist, who is the second level supervisor or branch chief, and will be documented in a memorandum.

To ensure consistency, please note that HERO toxicologists already submit their memoranda for 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. Further

discussion on these subdivision (c) toxicity criteria not being ARARs is included in the comment category “ARARs (Applicable or Relevant and Appropriate Requirements) Determination” herein.

GENERAL COMMENT CATEGORY: LEGAL CONSIDERATIONS

Rule Not Needed

Comments: CMTA-06, CMTA-26, DOD-15, and DOD-18

Comment Summary: One commenter states that the DTSC’s stated goal is to qualify OEHHA toxicity criteria as ARARs, requiring their use at federally-owned and-operated Superfund sites. The commenter further states this rule appears to be “an over-reaction to a breakdown in negotiations with the federal government at a single site” and, “The Department’s [DTSC] proposed remedy is disproportionate to the scope of the problem it seeks to solve.” The commenter requested DTSC to “abandon this proposal and instead resume negotiations with the Department of Defense to establish appropriate toxicity criteria for risk assessments at federally owned and operated Superfund sites.”

The other commenter stated that the rule “leaves silent the relationship between the requirements of this regulation and other federal or State requirements” and “is unnecessary as the OSWER Directives allow for and directs the use of best available science, and thus the use of toxicity values protective of human health.” The commenter further noted how OSWER Directives 9285.7-53 and 9285.7-16 apply the “best available science” rule for selecting toxicity criteria, and the rule contradicts this approach by instead requiring “an unjustifiable and unnecessary “most stringent” methodology.”

Response: DTSC is promulgating this rule in part to provide clarity and ensure consistency in use of toxicity criteria at hazardous waste and substance release sites in California which qualifies the rule (or portions thereof) to be applied as an ARAR for federally owned and operated Superfund sites. DTSC and the Air Force have been in informal and formal dispute on this issue for at least 10 years. The ongoing disagreement with the Air Force has resulted in a number of concerns, including cleanup delays and expenditure of significant resources. One effect of the proposed rule is to reduce the time and expense required to resolve toxicity criteria disputes at federal sites and to assure consistent health protection across property boundaries throughout California while using the best available science. Given the long-standing debate, and continued challenges to DTSC’s need for toxicity criteria values based on compliance with HSC §25356.1.5, DTSC disagrees with the commenter’s views on the lack of need for this rule.

The U.S. EPA is the final arbiter of the dispute between DTSC and the Air Force. DTSC seeks to maintain existing human health protections utilizing the best science to determine remediation goals at federal Superfund sites in California. Although IRIS provides toxicity criteria that set a single minimum floor of health protection nationally (i.e., a single 50-state level), DTSC believes the toxicity criteria provided in Appendix I

provide greater protection and meet California's specific statutory protectiveness requirements. DTSC also believes that a rule that does not specify the toxicity criteria based on the best available science may result in the different risk-based remediation goals for federal Superfund sites than for all other hazardous substance release sites in California. Accordingly, DTSC is promulgating the rule to ensure consistent cleanup requirements and health protection for California citizens and workers, including its sensitive and disproportionately burdened subpopulations.

Regarding the issues raised by the second commenter, while DTSC and DOD both appear to agree that the referenced OSWER Directives apply the "best available science" for selecting toxicity criteria, as explained in the ISOR, the Air Force interprets the directives as mandating the use of IRIS toxicity criteria irrespective of corresponding OEHHA values. This is the genesis of the previously referenced formal dispute for Edwards Air Force Base. In contrast to the Air Force's dispute position, DTSC does not believe the directives require the use of the IRIS values and has developed the rule to clarify the requirement to use toxicity criteria that factor in California-specific considerations that account for California's diverse demographic and more sensitive sub-populations. This is further discussed in the ISOR and herein under comment categories "Basis for Toxicity Criteria," "Changing Existing Practice," and "Consistency with Federal/State Laws and Guidance." Also, the ISOR explained why DTSC believes the selected OEHHA values are more appropriate for California residents and workers. The rule does not require a "most stringent methodology"; instead, it applies a scientifically sound methodology which uses best available science consistent with California's diverse population.

Consistency with Federal/State Laws and Guidance

Comments: CMTA-11, CMTA-15, CMTA-19, CMTA-20, DOD-04, DOD-08, DOD-11, and DOD-15

Comment Summary: In this category, commenters expressed concern that the proposed rule is inconsistent with other federal and state laws and guidance; specifically the NCP, U.S. EPA RAGS, OSWER Directives 9285.7-53 and 9285.7-16, and HSC §57008. Concerns raised include:

1. How the proposed regulations fit with the NCP for purposes of selection of final remediation goals is unclear.
2. Slide 6 in the August 28, 2017 DTSC rulemaking workshop indicated that the federal hierarchy for toxicity criteria selection is discretionary, with the notable exception that it specifically requires consideration of best available science. It is unclear how the proposed selection hierarchy complies with federal law and guidance.
3. HSC §57008 states that OEHHA's screening levels are advisory only, have no legal effect and are published solely as reference values. The proposed regulations appear to be an attempt to overturn the intent of a statute through a regulation.
4. The proposed regulation conflicts with HSC §25356.1.5(c), which specifies that human health risk assessments "include the most current sound scientific methods,

knowledge, and practices of public health and environmental professionals.” The proposed hierarchy for selecting toxicity criteria, presented in §69021, does not allow for “best available science” to be considered until the third hierarchy tier is reached. This rigidity would result in the potential use of toxicity criteria that are not based on best available science, even when more current and scientifically based studies are available. This is not in compliance with the HSC.

5. It is unclear how the specific NCP provisions that are relevant to establishing remediation goals would incorporate the requirements of this rule, and what legal effect the proposed regulation will have on the CERCLA and NCP process.
6. The rule conflicts with the application of the nine NCP feasibility study evaluation criteria in several ways. Inclusion of specific toxicity criteria in a regulation seems to blur the lines between the two threshold NCP criteria, which are (1) overall protection of human health and the environment, and (2) compliance with (or waiver of) ARARs. One commenter states that DTSC is attempting to insert the proposed regulation into both the CERCLA risk assessment and ARAR process and this does not appear to be consistent with the NCP. The commenter also stated that it is unclear if the DTSC regulation, if finalized, would qualify as an ARAR.

Response: As described in the ISOR, the proposed regulation complies with federal law and guidance, including the NCP, RAGS, OSWER directives, and state regulations, including those identified in the comments. Responses to the above comments are below:

1. The NCP directs the lead agency to evaluate site risk (via a baseline risk assessment) and determine if a remedial action is warranted, and if so develop remediation goals (standards). The proposed rule identifies the toxicity criteria to be used in the risk assessment. Risk managers (e.g., site managers with the responsibility for evaluating site risks and making risk management decisions) evaluate the risk assessment and site-specific factors (e.g., property use, potential and actual receptors, background concentrations, public input, quality of site characterization data, confidence in the data and the conceptual site model) to determine if a remedy is needed and, if so, to establish the remediation goals. DTSC has also revised the title of the articles to clarify that the rule applies to screening levels and remediation goals based on human health risk rather than the broader category of remediation decision making.
2. Slide 6 in the August 2017 public workshop highlights specific points made in OSWER Directive 9285.7-53. The commenter may have interpreted the highlights as indicating that selection of toxicity criteria is discretionary when it is not. The directive states that best available science should be a primary factor in determining appropriate toxicity criteria. The proposed rule does this, consistent with HSC §25356.1.5. Appendix I criteria are certain OEHHA values that meet scientific quality and rigor requirements, and account for California-specific risk factors. Toxicity criteria under §69021(b) are IRIS criteria that meet U.S. EPA requirements. Toxicity criteria under §69021(c) are deemed by DTSC to represent the best, and often the only, available value in the absence of Appendix I or IRIS criteria. As

- explained in greater detail in the ISOR, the rule is consistent with federal statutes and guidance and the language in the rule is appropriate.
3. DTSC disagrees with the comment about conflict with state law. The proposed rule does not conflict with HSC §57008, because the rule does not include “OEHHA’s screening levels” (also known as California Human Health Screening Levels or “CHHSLs”). Instead, the rule adopts only select OEHHA toxicity criteria that have been further examined for scientific quality and rigor according to statutory requirements, and may change in the future. Moreover, toxicity criteria promulgated by the rule are contaminant specific values used for calculating risk at any level including the risk management range 1×10^{-6} or 1×10^{-4} . The rule is not “an attempt to overturn and intent of a statute through a regulation.”
 4. DTSC disagrees with the comment that the proposed rule conflicts with state law. The proposed rule does not conflict with HSC §25356.1.5(c). In fact, the proposed rule specifically applies the best available science requirement in HSC §25356. The Appendix I and IRIS criteria presented in the rule are considered the best available toxicity criteria for use in human health risk assessments, screening levels and remediation goals. To the extent that the commenter is referring to published values in the rule becoming “outdated” as new and better toxicity criteria are developed over time, DTSC is incorporating clarifying text in §69021(a) as noted above. This concern is also addressed in comment category “Updating the Rule.”
 5. DTSC disagrees with the comment and maintains that the rule is consistent with CERCLA, the NCP, and related guidance. The rule clarifies and standardizes the source of toxicity criteria used for development of screening levels and risk assessments. The intent of the rule is to use the best available and most relevant scientific information for that purpose.
 6. This rule does not alter or affect the Feasibility Study process or the NCP criteria for evaluating remedial alternatives. Ultimately, the U.S. EPA will determine whether the final rule is an ARAR.

Inconsistencies with Other State Agencies

Comment: CMTA-24

Comment Summary: The commenter asserts that the proposed rule will create inconsistencies with other statewide programs and, as an example, identified the California Air Resource Board’s (ARB) “promulgated” consolidated table of OEHHA and ARB-approved health risk assessment values for air toxics, which can be found at: <https://www.arb.ca.gov/toxics/healthval/contable.pdf>. The commenter noted that some of the toxicity factors in the ARB table are inconsistent with those listed in Appendix I of the proposed rule.

Response: Different environmental programs have different purposes and objectives under different laws and policies. Consequently, administering agencies have different obligations, and can use toxicity criteria differently. In this instance, the ARB table is used for stationary source risk assessments that air districts use in their permitting

decisions that govern ongoing, allowable air contaminant discharges. ARB's table is also based on laws requiring different assumptions for risk assessment than DTSC's remediation work. The health risk assessments performed under ARB's guidelines are generally used for industrial or commercial facilities that release air emissions into the air as part of their operation and may be subject to the use of Best Available Control Technologies (BACT), Best Available Retrofit Control Technologies (BARCT) for air toxics, or are subject to the California State Air Toxics Hot Spots Information and Assessment Act (Assembly Bill 2588) and subject to reporting air toxics emissions inventory, preparation of health risk assessments, public notification of the health risks from the facility to the surrounding community under public's right to know and potential control of air toxics for risk reduction, all resulting in emissions of air toxics into the air. By contrast, DTSC's use of toxicity criteria specified in this rule results in human health risk-based cleanup levels for contaminants that remain in the environment after all remediation work concludes.

DTSC notes incidentally that ARB's consolidated table is published, but not promulgated within its regulation. Also, as discussed in the August 28, 2017 public workshop and in the ISOR, DTSC and other state agencies are obliged to work together on shared issues, including use of toxicity criteria for environmental cleanup work. For instance, DTSC provides toxicological services for some sites under Water Board oversight, and will collaborate directly with Water Board staff on risk-based screening and remediation goals to assure that all site cleanups based on human health risk use the rule's toxicity criteria as appropriate. Also, under 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 risk-based cleanups under Chapter 6.5.

Applicable or Relevant and Appropriate Requirements Determination

Comments: CMTA-13 and DAAC-05

Comment Summary: Under this category, commenters want to know how proposed §69021(c) of the rule will qualify as an ARAR for federal Superfund sites. The second commenter requested clarity on the "application of this rule in determining ARARs for hazardous substance releases at properties" under federal oversight, because without this, "responsible parties might be reluctant to do adequate site characterization due to the costs."

Response: DTSC expects that both the requirement to use the toxicity criteria set forth in Appendix I of the proposed regulation and the narrative cleanup standards in §68400.5 and §69022(a) will qualify as ARARs. Because the values in Appendix I are already applied in California, DTSC anticipates no change to the toxicity criteria used in cleanups in California. Identifying ARARs is a collaborative process involving both the responsible party and the regulatory agencies, and this rule will be added to DTSC's default list of proposed ARARs. The lead regulatory agency has final authority to assess, approve and waive ARARs. DTSC agrees with the second commenter that adequate site characterization is essential; however, site characterization is beyond the

scope of this proposed regulation. For more on this, please see the response to DAAC-04 herein in the comment category “Assessment of Multiple Contaminants.”

Application at Non-DTSC Lead Sites

Comment: INTG-06

Comment Summary: The commenter requested clarification on how the rule will apply to sites where DTSC (the State) is not the lead agency (such as those under Superfund). Specifically, it claims “...the stated goal of this rule, which, as stated in the ISOR, is to create an applicable or relevant and appropriate requirement (ARAR) to be applied to all future cleanups, regardless of the lead agency, thereby removing the decision-making authority from non-DTSC lead agencies.” Furthermore, it states “The rule should be revised to clarify the role of both responsible parties and non-DTSC lead agencies in establishing cleanup goals, especially under the final tier in the hierarchy. Specifically, the toxicity criteria selected pursuant to 69021(c) should not be applied at an EPA or other agency led site without the consent of the EPA or another lead agency.”

Response: DTSC notes that the commenter’s quote does not accurately reflect the ISOR’s text, but is likely referring to the following: “The overarching reasons for drafting this rule, as proposed, are to: 1) enhance the clarity, predictability, and enforceability of these requirements; 2) to cover all hazardous substance release sites as CERCLA does; 3) to be at least as protective as federal law; and 4) by doing all of the above, to *qualify these requirements as ARARs for application to hazardous substance release sites that are federally owned or subject to federal oversight* (italics added for emphasis).”

As discussed in the ISOR, DTSC has the legal jurisdiction for cleanup decisions under HSC chapters 6.5, 6.8, and 6.82. DTSC will seek to apply the Appendix I values regardless of the lead agency assigned to a site within California’s boundaries. Furthermore, DTSC is expecting that the U.S. EPA will determine that the final rule, or any appropriate portion of the final rule, is an ARAR and applicable to federal sites in California including federal-lead sites. Last, HSC §69021(c) describes the process for selecting toxicity criteria when criteria do not exist under Appendix I or in IRIS and does not establish remediation goals. The described process is consistent with how DTSC and U.S. EPA have been selecting this category of toxicity criteria for at least two decades.

California Environmental Quality Act Considerations

Comments: CMTA-22, CMTA-28, CMTA-29, and CMTA-30

Comment Summary: This comment category reflects assertions that the proposed rule is not exempt from the California Environmental Quality Act (CEQA) as specified in the rulemaking Environmental Impact Report (EIR) and DTSC must prepare a comprehensive EIR to report the resulting environmental impacts (including landfill capacity and marketability of contaminated and formerly contaminated properties) due to increased waste generation from site cleanup, costs associated with additional site

cleanup (particularly for Brownfields and Orphan sites) and economic impact to properties near and adjacent to sites impacted by the proposed rule. Also as part of the EIR, cost effective alternatives should be evaluated. The commenter believes the EIR should evaluate impacts resulting from the rule implementing lower (more stringent or protective) cleanup standards at environmental sites. Last, the commenter states that the alternatives described in the ISOR should be considered in the CEQA analysis and evaluated in a CEQA EIR.

Response: As discussed under the general comment category “Best Available Science - General,” and comment categories “Consistency with Federal/State Laws and Guidance,” and “Changing Existing Policy,” the proposed rule does not modify existing policy or practice regarding toxicity criteria in California. The rule does not set remediation goals at any particular risk level as discussed under comment categories “Basis for Toxicity Criteria” and “Best Available Science.” One reason the CEQA environmental baseline does not change is that the proposed rule does not change regulatory thresholds, which means the rule would not change the number of properties or volume of contaminated media requiring remediation, and therefore should not affect property marketability. Implementation of the proposed rule will also not result in increased landfill use relative to current regulatory conditions. Therefore, since the existing setting does not change with adoption of the proposed rule, no significant direct or indirect (adverse) environmental effect should occur.

The commenter expressed concern about the economic impact of the proposed regulation; however, social and economic impacts are only considered under CEQA where these impacts affect the physical environment (CEQA Guidelines §15064 and §15382). As noted above, because this rule merely adopts toxicity criteria presently used, consistent with HSC §25356.1.5, the proposed rule does not require lower remediation goals or result in increased volumes of contaminated media needing remediation at sites. Thus, this rule should not result in a significant adverse environmental impact, or change in property values or cleanup costs relative to present practice without the rule; and no CEQA EIR is required.

The commenter states that the alternatives described in the ISOR should be considered in the CEQA analysis and evaluated in a CEQA EIR. As stated above, the proposed Toxicity Criteria rulemaking codifies current practice for selecting toxicity criteria that apply to contaminated sites undergoing remediation. DTSC disagrees with the commenter’s assertion that the proposed rulemaking would indirectly increase demand for landfill capacity, and believes this assertion is speculative (CEQA Guidelines §15064(d)(3)) and not supported by the evidence provided. Based on these facts, DTSC concludes that because the proposed action will not have a significant (adverse) effect on the environment, the activity is exempt from CEQA (CEQA Guidelines §15061(b)(3)). To document this conclusion, DTSC prepared a CEQA General Rule exemption. DTSC reaffirms its position that the project would not adversely affect any element of the environment and that a General Rule Exemption is the appropriate environmental documentation. DTSC also believes that the comment letter from the California Manufacturing and Technology Association does not meet the CEQA “fair

argument” standard (Public Resources Code §21080(d)) and that an EIR is not necessary.

CEQA requires that an EIR consider in detail a reasonable range of alternatives to avoid or minimize potential environmental impacts. However, DTSC has determined that a General Rule Exemption is appropriate for the proposed regulations, because DTSC believes that, with certainty, there is no possibility that the activity may have a significant effect on the environment and is not subject to CEQA (CEQA Guidelines section 15061(b)). Thus a detailed assessment of potentially significant (adverse) impacts to be avoided or minimized, including an alternatives analysis, is not required under CEQA.

Maximum Contaminant Levels

Comment: STO-01

Comment Summary: The commenter asked for clarification on whether the rule will result in remediation goals lower than those based on drinking water maximum contaminant levels (MCLs), and if so, whether the responsible party will be required to demonstrate feasibility of achieving these lower remediation goals.

Response: To ensure consistency with federal and state law under HSC §25356.1.5, the proposed rule specifically states “This Chapter does not replace applicable MCLs established under HSC §116365 or Title 42 United States Code §300(g) as remediation goals.” Accordingly, the rule will not result in remediation goals for groundwater at levels less than MCLs for those chemicals with either a state or federal MCL.

Set Cleanup Standards to Non-Detect Background Levels

Comment: SSIM-02

Comment Summary: The commenter recommends that DTSC withdraw the proposed rule in favor of a revised rule that requires cleanup of water and soil to reduce any remaining concentrations of a) metals to “natural background” levels and b) other hazardous substances to non-detect levels, unless a court of “appropriate jurisdiction” allows levels above non-detect. Cleanups would be paid by any one or combination of four proposed mechanisms not presently in place.

Response: The commenter is proposing cleanup standards that require an entirely different statutory framework than is currently in place. The commenter’s approach also renders various provisions of state and federal law and guidance irrelevant to cleanup decision making, and prevents remedial decision-making based on human health risk and site-specific use considerations.

Both state and federal law mandate that DTSC evaluate risk of exposure to hazardous substances as part of the cleanup process. HSC §25356.1.5(b)(1) and (2) read:

(b) Any health or ecological risk assessment prepared in conjunction with a response action taken or approved pursuant to this chapter shall be based upon Subpart E of the National Oil and Hazardous Substances Pollution Contingency Plan (40 C.F.R. 300.400 et seq.), the policies, guidelines, and practices of the

United States Environmental Protection Agency developed pursuant to the federal act, and the most current sound scientific methods, knowledge, and practices of public health and environmental professionals who are experienced practitioners in the fields of epidemiology, risk assessment, environmental contamination, ecological risk, fate and transport analysis, and toxicology. Risk assessment practices shall include the most current sound scientific methods for data evaluation, exposure assessment, toxicity assessment, and risk characterization, documentation of all assumptions, methods, models, and calculations used in the assessment, and any health risk assessment shall include all of the following:

- (1) Evaluation of risks posed by acutely toxic hazardous substances based on levels at which no known or anticipated adverse effects on health will occur, with an adequate margin of safety.
- (2) Evaluation of risks posed by carcinogens or other hazardous substances that may cause chronic disease based on a level that does not pose any significant risk to health.

Toxicity criteria for chemicals of concern based on best available science are an essential component of risk calculation regardless of the cleanup levels that are ultimately selected. Moreover, given the statutory authority noted above, and in the authority and reference lines under each proposed regulation section, DTSC does not have authority to do the recommended revision. Accordingly, without any regulatory authority or mandate, the rule may not be revised to set cleanup standards at non-detect and natural background levels, and will not eliminate use of toxicity criteria.

Both CERCLA and DTSC's existing cleanup program authorities clearly anticipate that some concentrations of hazardous substances at health protective levels may be left in place, and some at levels that could require other controls such as engineered encapsulation or use restrictions (HSC §25245, HSC §25356.1.5, 22 CCR §67391.1). These outcomes are also consistent with federal guidance regarding institutional controls (see <https://www.epa.gov/superfund/superfund-institutional-controls-guidance-and-policy> for various U.S. EPA guidance documents on this topic).

Since DTSC's work under Chapter 6.82 (§25395.60 et seq.) must be consistent with its work under the state cleanup laws (Chapter 6.8), risk assessment work must also meet the requirements of HSC §25356.1.5. Such strict cleanup levels without regard to human or environmental health impacts goes well beyond the statutory standards referenced above, and would likely impact DTSC's ability to conduct cleanup activities in a manner consistent with the NCP to the maximum extent possible as contemplated under HSC §25350. This commenter's recommended revision is therefore contrary to both state and federal law and guidance expressly allowing hazardous substances to remain in place so long as public health, safety, and the environment are protected.

As the commenter notes, additional funding would be required if DTSC were to require cleanup to non-detect or background. The proposed funding options are, however, also beyond DTSC's existing authority, and would therefore require significant legislative

changes. DTSC does not have the present statutory authority to adopt this commenter's recommendations, and therefore declines to change the rule.

GENERAL COMMENT CATEGORY: INSUFFICIENT REVIEW TIME

Insufficient Review Time

Comment: DOD-10

Comment Summary: The commenter claimed DTSC gave reviewers insufficient time (e.g., 45 days) to review the scientific basis for the 67 analytes in Appendix I.

Response: The commenter stated more time should be provided to the public to review and comment on the toxicological papers provided as references on DTSC's toxicity criteria rule public website. The Appendix I toxicity criteria were developed by OEHHA and used as reference documents in setting the Appendix I toxicity criteria. The opportunity for reviewing and providing input on these papers was given when OEHHA was developing the individual toxicity criteria provided in Appendix I. Accordingly, public review and input for these papers is not being solicited as part of this rule-making effort.

GENERAL COMMENT CATEGORY: FINANCIAL CONSIDERATIONS

Economic Impact (Form 399)

Comments: CMTA-25 and CMTA-26

Comment Summary: DTSC's Economic and Fiscal Impact Statement (Department of Finance Form 399) indicates the proposed rule will have no private sector cost impacts, no effect on the ability of California businesses to compete with other states, and no fiscal impact on local government. The Commenter notes instead that the proposed rule is likely to result in more stringent cleanup standards that will apply to California businesses but will not apply to businesses in other states; and that this should be noted in the filed Department of Finance Form 399.

The commenter also recommends that Department of Finance Form 399 Item B(5) "Are there comparable Federal regulations" and "Explain the need for State regulation given the existence or absence of Federal regulations"-be completed as leaving these blank does not adequately acknowledge federal Superfund and related guidance.

Response: The proposed rule applies DTSC's best available science requirement from HSC §25356.1.5 in selecting toxicity criteria consistent with current and past practice as discussed herein under the comment category "Changes to Existing Practice." Because of this, DTSC selected box A(1)(h) "None of the above"- as the rule will not impact businesses, employees, jobs, occupations California's business competitiveness, or individuals, and does not impose new reporting or prescriptive reporting requirements. Because of this, Item B(5) on Form 399 was left blank as instructed under Section A(1), which states "*If any box in Items 1 a through g is checked, complete this Economic*

Impact Statement. If box in Item 1.h. is checked, complete the Fiscal Impact Statement as appropriate.”

In direct response to the concern that Item B(5) should be checked, note that there are no “comparable federal regulations” because federal guidance describes the selection of toxicity criteria (e.g., Risk Assessments Guidance for Superfund, OSWER Directives 9285.7-53 and 9285.7-16). As discussed in the ISOR, DTSC believes the proposed rule is consistent with these guidance documents. OSWER Directive 9285.7-53 is the most closely related federal guidance to the proposed rule, as it describes a specific approach for selecting toxicity criteria for baseline risk assessments under Superfund. As discussed in the ISOR, this rule is consistent with the Directive, which doesn’t mandate the use of IRIS toxicity criteria and gives risk managers discretion in selecting the appropriate toxicity criteria for a given site. The rule is consistent with CERCLA Section 121, which authorizes the state to apply more stringent standards than federal levels, and with state law as explained in the ISOR; in particular, HSC §25356.1.5(a)(1) and §25356.1.5(c). Those state law sections also require the state to apply levels no less stringent than federal law, and specify certain requirements for risk assessments. Accordingly, DTSC believes the proposed rule is consistent with federal and state law (and guidance).

Finally, also in response to the commenter’s direct concern that, under Item B(5), DTSC should “Explain the need for State regulation given the existence or absence of Federal regulations,” the ISOR explains the need for the rule. DTSC believes that risk-based cleanups should be based on the same toxicity criteria regardless of who owns the land. DTSC believes that implementing the rule will result in more clear and consistent approaches for risk assessors in selecting toxicity criteria as compared to that done prior to rule promulgation. For example, where previously risk assessors would identify appropriate toxicity criteria via various sources, with the rule, risk assessors will now follow the steps described in the rule. These differences are discussed in the revised Economic and Fiscal Impact Analysis in the rulemaking package.

Staff Resources

Comments: CMTA-02, CMTA-04, CMTA-23, and DOD-12

Comment Summary: The primary theme of this category is that “unnecessary” staff resources will be expended to amend the rule as needed to ensure toxicity criteria in the rule are current. Updates to the rule would be needed to ensure toxicity criteria remain current, and new appropriate criteria from the various sources are incorporated into the rule. A commenter raised a concern that the rule would result in the creation of a “prescriptive program that itself will require more DTSC staff resources to manage.” In addition, the rule would “drive up costs to the regulated community and state taxpayers by saddling DTSC with additional costs at orphan sites.” Last, related to staff resources, another commenter noted that the proposed rule conflicts with the “nine criteria” in the NCP, which will cause extensive debate and consume staff time.

Response: Amendments will be done consistent with DTSC’s existing regulatory program and should not require significant additional staff resources. Regardless,

DTSC recognizes that amending the rule will require some staff time and has updated the attachment to the Economic Impact Statement (Form 399) and will discuss this in the FSOR.

Regarding the comment about the rule resulting in a “prescriptive program,” the rule will not result in the creation of a “prescriptive program.” As a reminder, the rule’s direction on selecting toxicity criteria is consistent with current practice that has been done for approximately 24 years, with the application of best available science factoring in California-specific conditions and policy. In fact, the rule simplifies work performed by risk assessors by providing the appropriate OEHHA toxicity criteria in Appendix I, and directing users to the IRIS database for any not listed. For contaminants not listed in either Appendix I or IRIS, criteria from the identified subdivision (c) sources may be applied consistent with current/past practice. The simplification will require less time to be expended by risk assessors in identifying the appropriate toxicity criteria for use in risk assessments to calculate and determine remediation goals based on human health risk.

Finally, the commenter is correct that the rulemaking is currently consuming staff time. The rule is an effort to provide upfront clarity and consistency regarding application of best available science for selecting toxicity criteria. In so doing, DTSC expects the rule will eliminate future formal disputes where responsible parties wish to reduce existing human health protection at California hazardous substance release sites. The rulemaking is one part of the extraordinary amount of staff resources being consumed by existing and ongoing formal dispute(s). The disputes have not settled the toxicity criteria issue and DTSC believes that promulgating the rule will assist the parties in moving toward resolution, and expect that the proposed rule will be deemed an ARAR for CERCLA sites. This in turn, will result in significant cost savings for DTSC, the Air Force, as well as the U.S. EPA and the Water Board, all of which are signatories to the various Federal Facility Agreements governing Air Force bases in California.

Cleanup Costs

Comment: SSIM-03

Comment Summary: The comment discussed the high costs of cleaning up hazardous substance release sites and proposes new fees, taxes, or crowdfunding to pay for the cleanup costs.

Response: Discussion of these proposals are beyond the scope of DTSC’s statutory authority for risk assessment, risk-based screening levels, risk-based remediation goals, and this toxicity criteria rulemaking.

GENERAL COMMENT CATEGORY: DEFINITIONS

Define “Screening Levels, Action Levels, and Remediation Goals”

Comments: CCEEB-02 and DOD-03

Comment Summary: One commenter requested the rule define “screening levels,” “action levels,” and “remediation goals.” Another commenter stated that the definition of “remediation goal” should include a description of how remediation goals are selected or else the rule could be interpreted as setting remediation goals at 1×10^{-6} . The commenter also requested that “land-use” be factored into the definition of remediation goal.

Response: Screening levels and remediation goals are defined in the rule in §69020. The term “action levels” is not used in the proposed rule so a definition is unnecessary.

Regarding the requested change to the remediation goal definition, DTSC disagrees that the definition should include an explanation of how remediation goals are set under federal and state jurisdiction. DTSC defers to CERCLA, the NCP or other relevant federal guidance. Furthermore, as discussed above under the “Flexibility in Selecting Toxicity Criteria and Setting Site-Specific Remediation Goals” comment category herein, 1×10^{-6} level is the screening level; it is not the default remediation goal, and specifying the toxicity criteria for setting remediation goals does not limit the flexibility for risk managers in setting remediation goals within the risk management range as occurs under current (and continuing) practice. Accordingly, the definition of remediation goal will not be revised to describe the remediation goal selection process.

Finally, DTSC agrees to incorporate the use of “land-use” in the definition of remediation goals. The definition has been changed to: “Remediation Goal is a contaminant concentration that is: (i) media-specific (e.g., for the air, groundwater, surface water, or soil affected by a release); (ii) site-specific (factoring in, for example, potential receptors, exposure pathways, contaminant background concentrations and reasonably anticipated future land uses); (iii) protective of human health and the environment; and (iv) serves as a final cleanup goal for the response or corrective action.”

Define “Peer-Reviewed”

Comments: CCEEB-03 and CCEEB-04

Comment Summary: The commenter requested the addition of a definition for the term “peer-reviewed” and for that definition to identify “peer-reviewed” as “generally accepted and evidence-based research not refuted by subsequent experiment or evidence” and be consistent with 3 CCR 1301(r). A second request was for DTSC to “make transparent their systematic review principles that the agency incorporates into a determination for any best available toxicity value for use.”

Response: The term “peer-review” will not be defined in the rule as the requirement is already addressed in HSC §57004. Consistent with HSC §25356.1.5 and §57004, DTSC has included in Appendix I only values that OEHHA has developed through its transparent and well-established peer-review process, which is similar to that of U.S. EPA’s IRIS program. OEHHA, not DTSC, is the state agency tasked with developing toxicity criteria for California. OEHHA’s methodology is consistent with 3 CCR 1301(r), which will be addressed further in the FSOR. DTSC supports the use of credible scientific research, which by its nature is evidence-based, and uses the expertise of our

state toxicologists to assess the science to ensure that DTSC's decisions are scientifically credible, defensible, and protective of human health and the environment.

Definition for "Total Petroleum Hydrocarbons"

Comment: HB-01

Comment Summary: The commenter proposed replacing the TPH definition in the ISOR.

Response: DTSC concurs. The following language will be added to the FSOR: "Total petroleum hydrocarbons (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."

GENERAL CATEGORY: EDITORIAL REQUESTS

Specify Rule's Purpose in §69020

Comment: CPEO-01

Comment Summary: The commenter requested that the rule include a "Purpose."

Response: DTSC has made clarifying edits at the beginning of §69020(b) to explicitly state the rule's purpose. The revised text follows: "The purpose of this Chapter is to adopt toxicity criteria, consistent with Health and Safety Code section 25356.1.5, for all human health risk assessments....".

Reference Additional Health and Safety Code Chapters

Comment: CCEEB-10

Comment Summary: The commenter recommended certain additions to §69022(c) which are identified in italics as follows: "All human health risk-based remediation goals for response actions conducted under Health and Safety Code, Division 20, Chapter 5, 6.5, 6.8, and 6.82 shall comply with HSC §25356.1.5(a)(1) and (d)" [*emphasis added in italics*].

Response: The proposed (Division 20) Chapter 5 (HSC §24600, et seq.) will not be added to §69022(c) because it is not related to cleanup of hazardous substance release sites. Toxicity criteria appear to have no relation or application to that Chapter 5. Chapter 5 also appears to be beyond DTSC's rulemaking authority. Regarding the proposed addition of Chapter 6.5 and Chapter 6.82 to this subdivision, DTSC notes that cleanups under Chapter 6.5 do not have to comply with the NCP which is referenced in

HSC §25356.1.5(a)(1). The rule clearly addresses use of the rule's toxicity criteria for corrective action under Chapter 6.5 in proposed §68400.5, so the additional, proposed reference in §69022(c) is unnecessary. Similarly, Chapter 6.82 risk assessments must be prepared in accordance with subdivisions (b), (c), and (d) of Section 25356.1.5, but not with subdivision (a), according to HSC §25395.94(a)(2). Therefore, DTSC disagrees and declines to add references to Chapters 6.5 and 6.82 to §69022(c).

Based on further review in response to these comments, §69022(c) has been changed to remove the reference to subdivision (a)(1) of HSC §25356.1.5. By removing the specific reference to subsection (a)(1) and not referencing subdivision (d), we avoid implying that the rest of subsection (a) and the other subsections may not apply to Chapter 6.8 risk assessments or the development of remediation goals. As revised, this section of the proposed rule clarifies that risk-based remediation goals for response actions under Chapter 6.8 must comply with the requirements HSC §25356.1.5 that governs risk assessment and the response actions under that Chapter. With this revision, it is still less clear or a conflict with the statute to add reference here to Chapters 6.5 and 6.82 as noted above.

Requests for Changes to the Issue Memo

Comments: RWQCB-03 and RWQCB-04

Comment Summary: The commenter proposes corrections to the Issue Memo, a preliminary DTSC briefing document discussing selected issues relative to the proposed rule. The commenter pointed out that the Water Board has toxicological expertise and that the Board and DTSC both oversee and have statutory obligations for Brownfields sites in California. No change to the rule was requested based on these corrections.

Response: DTSC acknowledges the recommended corrections and will discuss this in the FSOR.

Revise Problem Statement

Comment: SSIM-01

Comment Summary: The commenter proposes restating in the ISOR "the objective" or "problem statement" and suggests a more ambitious regulation that would abandon the process outlined in the NCP and U.S. EPA's risk assessment guidance, and instead require removal of residual contamination to non-detect without consideration of the qualitative threat a hazardous substance release would impose.

Response: The commenter's requests are beyond the scope of the proposed rule. The comments regarding applicable law and related policies do not accurately reflect DTSC's existing statutes and regulations. DTSC pursues this rule to promulgate certain OEHHA toxicity criteria values for use in risk assessments as governed by HSC §25356.1.5. The values listed in the rule must be peer reviewed under HSC §57004. DTSC conducts such risk assessments to develop appropriate cleanup levels for use

under the Hazardous Waste Control Law and DTSCs Cleanup Program, and does so consistent with federal guidance regarding risk assessment under CERCLA.

DTSC's existing cleanup laws anticipate that certain health-protective levels of hazardous substances may be left in place, and at levels that could require other controls such as engineered encapsulation and/or use restrictions (HSC §25245, HSC §25356.1.5, and 22 CCR 67391.1). This is consistent with various federal guidance regarding institutional controls. Since DTSC's work under Chapter 6.82 (§25395.60 et seq.) is to be consistent with its work under the state Superfund laws, risk assessment work there must also meet the requirements of HSC §25356.1.5.

Note that the proposed rule will improve U.S. EPA's well-established risk assessment process by ensuring that chemical specific toxicity criteria are consistently used, scientifically based and are uniformly health protective of California's diverse population.

Add "Evidence Based" To Rule

Comment: CCEEB-08

Comment Summary: The commenter requested that the term "evidence based" follow the term "peer-reviewed" in §69021(a) and §69021(b) and the term "peer-reviewed, evidence based" be inserted following "Toxicity criteria from another" and also between "Other" and "sources include" in §69021(c).

Response: The commenter does not specifically identify what is meant by "evidence based." A Google search defines the term as "*Integrating individual clinical expertise with the best available external clinical evidence from systematic research,*" while California Evidence Code section 140 defines evidence as follows:

"Evidence" means testimony, writings, material objects, or other things presented to the senses that are offered to prove the existence or nonexistence of a fact.

The commenter's recommended revision is not necessary as the HSC §25356.1.5 requirement to employ best available science would not allow use of mere assertion or suspicion in selecting toxicity criteria. And DTSC could not satisfy the requirement to use best available science if it did act to promulgate toxicity criteria based on mere assertion or bias. Furthermore, DTSC does not develop the OEHHA and IRIS toxicity criteria. Accordingly, DTSC disagrees and declines to add "evidence-based" to the proposed rule. Last, the requested insertion of the terms "peer-reviewed" into the process for selecting the third-tier toxicity criteria is not feasible. Not all of the toxicity criteria under §69021(c) have undergone a formal peer reviewed process that satisfied HSC §57004 as have the OEHHA and IRIS values, but they may, nonetheless, constitute the best available science contemplated under HSC §25356.1.5. Accordingly, "peer-reviewed" will not added to the rule.

ISOR and Rule Differ

Comments: INTG-09 and INTG-10

Comment Summary: The commenter noted discrepancies between selected ISOR statements and the rule.

Response: The commenter correctly identified specific discrepancies between the ISOR and the rule. DTSC will include information in the FSOR that will be consistent with the rule.

Expand the Alternatives Assessment Discussion

Comment: CMTA-29

Comment Summary: The commenter requested “a clear articulation of Alternative 2” (which is discussed in the ISOR and NOPA) and further requested that DTSC solicit public input into the Alternatives assessment. Last, the commenter stated that “because the potential impact on risk assessments used to establish action levels, points of departure, screening levels, and remediation goals and resulting determination of the need for and actual cleanup at hazardous waste sites in California, a full CEQA analyses of the three Alternatives is required.”

Response: All three alternatives were described in the ISOR and the rulemaking package public notice. Alternative 1 was the “pre-APA” draft noticed on November 11, 2016, and discussed in a public workshop on December 12, 2016. DTSC solicited comments and in response developed Alternative 2, which included the following changes from Alternative 1:

- Out of public concern that toxicity criteria listed may be for a metallic form different than present at a given site, and therefore not reflective of the hazard at the site, DTSC add a provision excluding metallic elements that are not inorganic soluble salts and not oxides of common oxidation states. For example, metallic elements may exist in multiple oxidation states, form various organic and inorganic compounds, or be alloyed together with other metal or non-metallic elements resulting in different toxicity than the elemental metals on which the toxicity criteria are based. However, DTSC subsequently omitted this provision from the proposed rule after finding it unnecessary because the listed toxicity criteria value is for a different form of the metal.
- Out of public concern that listed toxicity criteria in the rule could become outdated if a new or revised toxicity criteria was established by OEHHA and/or U.S. EPA (in their IRIS database), a “variance” provision to allow new IRIS or OEHHA values to be used in place of values in the regulation’s repository after the effective date of this rule, but before it could be amended. This provision was discarded in the proposed rule (Alternative 3) because the variance process was complicated, would be difficult and costly to implement (e.g., DTSC anticipated repeated petitions for variances), and potentially be deemed a procedural component that could prevent the rule from applying to federal facility cleanups.
- Out of public concern that the rule implied DTSC was setting (fixing) remediation goals at an incremental excess lifetime cancer risk of an individual at 1×10^{-6} and a cumulative hazard index of 1, this section of the rule was removed.

As described in the ISOR, upon detailed internal assessment, DTSC found some of the components of Alternative 2 unworkable or unnecessary; thus, they were modified or discarded. The result was Alternative 3, which was distributed as the proposed rule on August 4, 2017, for public comment. In summary, public input was solicited in three separate workshops, the September 20, 2017 public hearing, and via comments on the “pre-APA” and proposed rule.

DTSC has determined that the requested CEQA analysis is not necessary, see comment category “California Environmental Quality Act Considerations” for a more thorough discussion of this matter.

Lack of Clarity in Selecting Toxicity Criteria

Comment: DOD-14

Comment Summary: One commenter claimed the proposed rule was unclear regarding the use of toxicity criteria; specifically, how to proceed if a chemical is not listed in any of the “three sources listed.”

Response: DTSC believes the proposed rule is clear on how to identify the appropriate toxicity criteria for each contaminant present at a site. The proposed rule directs the reader first to the toxicity criteria in described in subdivision (a) and listed in Appendix I. Then, as described in subdivision (b), if the criteria are not listed in Appendix I, to look in the U.S. EPA IRIS database. Finally, if the criteria are also not listed in U.S. EPA IRIS database, then as described in subdivision (c) to select toxicity criteria from a list of suggested sources that include but are not limited to other OEHHA toxicity criteria not listed in Appendix I, U.S. EPA PPRTVs, Agency for Toxic Substances and Disease Registry Minimal Risk Levels, U.S. PPRTV Appendix Screening values, and U.S. EPA Superfund Health Effects Assessment Summary Table values. The proposed rule explicitly includes the following statements:

In subdivision (a): “If Appendix I does not list toxicity criteria for a specific COPC then the toxicity criteria listed under §69021, subdivision (b) shall be used.”

In subdivision (b): “If IRIS does not list toxicity criteria for a specific COPC then the toxicity criteria listed under §69021, subdivision (c) shall be used.”

DTSC suspects that the request for clarification is a holdover from the earlier “pre-APA” draft rule that was publicly noticed in November 2016 that did not include the specific language quoted above.

Attachment 1: Detailed Response to Comments on the Spearow et al. Paper

DTSC disagrees with several statements made in CMTA-18, and therefore declines to change the regulation to accommodate this comment.

The commenter raised a concern that: “The authors provide no evidence in humans that additional toxic metabolites are in fact detected in this population. As described in the EPA Toxicological Assessment for Tetrachloroethylene, the most toxic chemical metabolites were evaluated and, therefore, the IRIS toxicity values are protective of all ethnicities.” While the IRIS PCE assessment (EPA 2012) recognizes that the reactive metabolites dichlorothioketene (DCTK), 1,2,2-trichlorovinyl-L-cysteine (TCVC) sulfoxide, and N-acetyl-S-(1,2,2-trichlorovinyl)-L-cysteine (NAcTCVC) sulfoxide are the most toxic metabolites of the GSH conjugation pathway of PCE metabolism, DTSC does not agree that the most toxic chemical metabolites were adequately evaluated in the IRIS assessment for the following reasons:

1. U.S. EPA initially considered GSH conjugation pathway estimates in humans modeled by Chui and Ginsberg (2011). This toxicokinetic model of PCE metabolism considered trichloroethane (for oxidative pathway metabolism), dichloroethane (DCA) and NAcTCVC (for GSH conjugation pathway metabolism), but did not evaluate the reactive, toxic metabolites of the GSH conjugation pathway including, DCTK, TCVC sulfoxide, or NAcTCVC sulfoxide (Chiu and Ginsberg 2011; Lash and Parker 2001; Spearow et al. 2017).
2. Measuring DCA is not sufficient to estimate the production of these reactive metabolites because:
 - a) The DCA produced is unlikely to include the DCTK that formed covalent DNA and protein adducts.
 - b) The DCA produced is even less likely to include the reactive TCVC sulfoxide and NAcTCVC sulfoxide. These are trichloro- compounds that are unlikely to be broken down to DCA.
 - c) The rate of degradation and fate of the dichloro- and trichloro-DNA and protein adducts is unknown.
 - d) Thus, for the reasons described above, these other toxic metabolites were not adequately addressed in U.S. EPA’s analysis.
3. Additionally, measuring NAcTCVC does provide an estimate of how much PCE was detoxified by the GSH conjugation pathway since depending on an individual’s genotype, the NAcTCVC that remains in tissues may still be activated by cytochrome P450 (CYP)3A to NAcTCVC or reactivated by acylase (ACY3) to TCVC, where it could potentially be activated to form the toxic reactive metabolites discussed above (Lash and Parker 2001) (see Figure 2 of Spearow et al. 2017). Until the NAcTCVC is excreted in the urine, it may potentially be re-activated.

4. Finally, the toxicokinetic model of Chui and Ginsberg (2011) used by U.S. EPA to estimate flux through the GSH conjugation pathway did not address the research on human kidneys showing that β -lyase catalyzed metabolism to toxic reactive products is variable and heavily favored over N-acetylation to the non-toxic mercapturate (Altuntas and Kharasch 2002; Spearow et al. 2017). Specifically, studies by Altuntas and Kharasch (2002) on 20 human kidneys using a similar cysteine-S-halogen alkene substrate showed 7.4-fold differences between individuals in rates of deacylation. The ratio of deacylation to N-acetylation ranged from a low of 2-fold to a maximum of 54-fold, depending on the individual (Altuntas and Kharasch 2002). Analysis of enzyme activities in kidneys from 20 humans also showed that β -lyase catalyzed metabolism to toxic reactive products is heavily favored over N-acetylation to the non-toxic mercapturate. The ratio of β -lyase catalyzed metabolism to N-Acetylation metabolism of cysteine S-halogen alkene substrate ranged from 3-fold to 146-fold between individuals and averaged 32-fold (Altuntas and Kharasch 2002; Spearow et al. 2017). These data show that measurements of NAcTCVC production likely greatly underestimate production of activated reactive toxic metabolites of the GSH conjugation pathway of PCE metabolism in humans.

The following addresses the commenter's claim that "the authors provide no evidence in humans that additional toxic metabolites are in fact detected in this population." It is difficult to quantitate the production of the toxic reactive metabolites, including DCTK, TCVC sulfoxide, or NAcTCVC sulfoxide since they are reactive or unstable and form DNA and protein adducts in tissues where they are formed. Because the toxic reactive metabolites of the GSH conjugation pathway cannot be accurately measured, Chiu and Ginsberg (2011) proposed estimating the toxicity of this pathway by measuring other surrogates, including NAcTCVC and DCA. Nevertheless, immunological and other approaches have shown very good evidence for adducts formed by these PCE GSH conjugation pathway metabolites (Barshteyn and Elfarra 2009; Pahler et al. 1999). Rats exposed to PCE show that the concentration of protein adducts formed by DCTK was 5 to 10-fold higher in kidney mitochondria than in blood (Pahler et al. 1999), suggesting that most DCTK adducts are formed within the tissues producing the DCTK. However, as discussed below considering DCA production in the method proposed by Chiu and Ginsberg, (2011) and used by U.S. EPA (2012) to derive toxicity criteria for PCE is unlikely to address the DCTK that forms DNA or protein adducts, as well as the TCVC sulfoxide and NAcTCVC sulfoxide that is formed (regardless of whether these sulfoxides crosslinks proteins). These approaches likely underestimate the toxicity of PCE.

Another of the commenter's concerns was that "the authors claim that the Asian population lacks the pathways for metabolizing PCE and removing toxic chemical species that can lead to increased cancer risk from the body. Despite these claims, no clear evidence is provided by the authors that additional protections are needed for these populations. Instead, the authors simply imply that because of reduced GSH metabolism in individuals of Asian descent, these individuals would produce other toxic metabolites not addressed in EPA's analysis."

1. The DTSC authors do not claim “that the Asian population lacks the pathways for metabolizing PCE and removing the toxic chemical species that can lead to increased cancer risk from the body.” In general, the Spearow et al. paper (2017) raises the following points: 1) a lower percentage of Asians are likely to be susceptible to PCE-induced Renal Cell Cancer (RCC); 2) the gene frequency data for GSTT1 and cysteine conjugate β -lyase (CCBL1) shows that a lower percentage of Asians are likely to be susceptible to PCE; and 3) Asians with functional glutathione-S-transferases (GSTs), have a relatively high frequency of two particular higher risk alleles that may lead to a higher susceptibility to PCE. A more detailed discussion on these points is provided below. Also, to understand the role the GSH conjugation pathway for activation versus detoxification of PCE and TCE, DTSC refers the commenter to the publications by Bruckner et al. 2013; Lash et al. 1998a; Lash and Parker 2001; Lash et al. 2007; Spearow et al. 2017 as well as to Cristofori et al. 2015; Parkinson et al. 2013.

Individuals lacking GST activity, i.e., the first steps in the GSH conjugation pathway, are likely to produce very low levels of trichlorovinyl glutathione (TCVG) or TCVC. Thus, very low levels of activated metabolites or detoxified metabolites at the later steps in the pathway.

Asians show a lower frequency of individuals with functional (active) alleles at GSTT1 (55-60%) than other ethnic populations, including Caucasians (89%) with functional GSTT1 (Table 2 of Spearow et al. 2017). Asians also show a lower frequency of individuals with functional (active) alleles at both GSTT1 and GSTM1 (26 to 30%) than other ethnic populations, including Caucasians (36%), Africans (48 to 54%), Gujarati Indians (55%), and African Americans (62%) (Table 2 of Spearow et al. 2017). Since active alleles at GSTT1 and GSTM1 have been associated with increased RCC risk in TCE exposed workers, (Bruning et al. 1997; Moore et al. 2010), a lower percentage of Asians are likely to be susceptible to PCE induced RCC. However, for individuals that have GST activity and produce moderate or large amounts of TCVC, the toxicity depends on how much of the TCVC is activated rather than detoxified and excreted into the urine. For these individuals, the toxicity of this pathway is ultimately determined by the activity of enzymes in later steps in this pathway that then activate TCVC to toxic reactive metabolites, versus other enzymes and transporters that convert the TCVC into NAcTCVC and excrete it in the urine (see Figure 2, Spearow et al. 2017). As discussed in Spearow et al. (2017), “Any variation or factors that increase GST activity and increase either [β -lyase] CCBL activity, [alanine-glyoxylate amino transferase] AGAT/AGXT2 activity, [flavin-containing monooxygenase] FMO3 activity and/or CYP3A activity could increase production of highly toxic and mutagenic reactive metabolites (Lash et al. 2007).”

Data from Moore et al. (2010) show that certain alleles at *CCBL1* (β -lyase) are associated with high risk of RCC in TCE exposed workers in eastern/central Europe. International HapMap data show that the frequency of individuals with at least one high RCC risk allele at *CCBL1* was lowest in Caucasians, Japanese, Mexican American and Han Chinese (38 to 42%), somewhat higher in Tuscan Italians and Chinese in Denver (51 to 52%), higher in Gujarati Indians (69%), higher in African

Americans (79%) and highest in Africans (85 to 96%) (Table 1 of Spearow et. al. 2017). The percentage of individuals with high TCE-induced RCC risk alleles at *GSTT1* and *CCBL1*, i.e., a complete *GSTT1* and β -lyase activation pathway, the HapMap data show lowest frequency in Han Chinese (23%) and Japanese (24%), slightly higher in Chinese in Denver (31%), Mexicans (32%) and Caucasians (34%), and higher in other ethnic populations, including up to 63% in African Americans and 64% in Yorban Nigerians (Table 1 of Spearow et. al. 2017). Thus, the gene frequency data for *GSTT1* and *CCBL1* show that a lower percentage of Asians are likely to be susceptible to PCE, in terms of the production of the reactive DCTK.

However, for those individuals with GST activity that produce TCVC, their susceptibility to PCE also depends on the relative activity subsequent enzymes that activate or detoxify and excrete these metabolites. Susceptibility will be relatively greater for individuals with elevated *CCBL1*, *FMO3* and/or *CYP3A* activity that activate TCVC to reactive metabolites. Susceptibility will be greater for individuals with lower cysteine conjugate N-acetyltransferase (*CCNAT*) activity and higher acylase activity. Susceptibility will be relatively greater for individuals with low *MRP2/OAT1/3* or poor renal function that cannot transport NAcTCVC into the urine (see Figure 2 of Spearow et al. 2017). The poorer an individual's ability to excrete NAcTCVC into the urine, the greater the chance for activation by *CYP3A* to NAcTCVC sulfoxide, or reactivation by acylase to TCVC (see Figure 2 of Spearow et al. 2017).

As shown in Table 2 of Spearow et al., (2017), the frequency of likely high risk alleles at *NAT8* was lowest in ethnic groups of African origin (12 to 32%), moderately high in Asians (65 to 68%), and highest in Gujarati Indians and Mexican Americans (70 to 71%). The frequency of likely high activity/risk alleles at *ACY3* was lowest in populations of African descent (40 to 53%), moderately high in Asians (72 to 80%), and highest in Mexican Americans (92%) and Gujarati Indians (95%). These likely high risk *ACY3* alleles likely to increase reactivation by converting NAcTCVC back to TCVC. Thus, for individuals that have functional GSTs, including *GSTT1* and produce TCVC, the frequency of high risk genes at *NAT8*, *ACY3*, *MRP2* and *OAT1/3* are likely to increase the levels of metabolite available to be activated. Thus, for Asians that do have functional GSTs, the relatively high frequency of higher risk alleles at N-acetyltransferase (*NAT8*) and *ACY3* indicates that these individuals will like have relatively chances of activation and thus higher susceptibility to PCE.

Ethnic populations also differ in gene frequency and enzyme activity at other loci involved in the activation of GSH conjugation pathway intermediates to reactive sulfoxides, including *CYP3A4* and *CYP3A5* (Lamba et al. 2002; Stevens et al. 2003).

The percentage of individuals with an active GST at *GSTT1*, in Asians (55 to 60%) is slightly lower than that of other ethnic groups including Caucasians (89%). Nevertheless, of the Asians with a functional *GSTT1* that likely conjugates PCE to produces TCVG, about 72 to 80% are likely to have a *ACY3* allele that increases TCVC reactivation, resulting in greater potential for activation and thus greater susceptibility to PCE.

Nevertheless, the variability in susceptibility to PCE within each ethnic group is likely to be greater than the variability in susceptibility to PCE between ethnic groups. In other words, individuals with high risk alleles at many enzymatic steps in the GSH conjugation pathway of PCE metabolism (see Figure 2 of Spearow et al. 2017) are likely to be much more susceptible than those with few or no high risk alleles in this pathway.

To address the commenter's "question whether DTSC has conducted similar analyses for other chemicals, and there is no indication that this analysis is needed for PCE." One of the biggest gaps in risk assessment, as identified by the National Research Council, is that inter-individual variability is not being addressed at all (in animals), or incompletely (in epidemiological studies) (Zeise et al. 2013). DTSC conducted a literature review to determine if the 3000-fold difference in human predicted rates of PCE metabolism by the GSH conjugation pathway from the Chui and Ginsberg (2001) model was due to uncertainty or human variability. U.S. EPA (2012) did not include the GSH conjugation pathway in their derivation of PCE toxicity criteria since they were uncertain if this 3000-fold variability in metabolism of PCE by the GSH conjugation pathway was due to uncertainty or human variability. While, OEHHA did include the GSH conjugation pathway in estimating toxicity criteria for PCE (OEHHA 2016). The literature review showed evidence for a large amount of variation in the GSH conjugation pathway of PCE metabolism in humans due to genetic diversity, ethnicity, age, gender, diet and pharmaceuticals (Spearow et al. 2017). These findings support the use of OEHHA toxicity criteria for PCE. Since it is important to protect sensitive populations, DTSC may also investigate the genetic and other sources of variability in susceptibility to other contaminants, as it did for PCE.

Overall, the Spearow et al. 2017 paper describes and documents variation in the GSH conjugation pathway of PCE metabolism, not just due to genetic and ethnic variation, but also due to age, gender, diet and pharmaceutical exposures. Thus, DTSC respectfully disagrees that the paper does not provide clear evidence as to why the GSH conjugation pathway should be included when developing the inhalation unit risk factor for PCE.

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